Holland & Knight

H&K Health Dose: May 7, 2024

A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session for a legislative work period currently scheduled through May 24, 2024. This week, activity is expected at both the floor and committee level.

A legislative package that would reauthorize the Federal Aviation Administration (FAA) for five years is the main priority for members in both chambers. This reauthorization is widely considered to be one of the few remaining "must-pass" measures ahead of the November 2024 election. See below for further details.

On the House side, Rep. Marjorie Taylor Greene (R-Ga.) recently indicated she would file for a vote on the motion to vacate that she introduced in March 2024. If approved by simple majority, this measure would remove House Speaker Mike Johnson (R-La.) from his leadership position. It is expected that, should a vote be triggered, the motion to vacate would not be successful.

LEGISLATIVE UPDATES

FAA Reauthorization

Legislators heading the committees of jurisdiction on April 29, 2024, reached a bicameral, bipartisan negotiated agreement to reauthorize the FAA through fiscal year (FY) 2028. Funding authorities for the agency that expired on Sept. 30, 2023, have been temporarily extended three times by Congress, most recently through May 10, 2024.

Initially, leadership in both chambers had hoped to advance the legislative vehicle for the negotiated package (H.R. 3935) through the Senate before the weekend and avoid a lengthy amendment process. The measure is currently stalled on the Senate floor with more than 100 amendments filed. While a number of these amendments are directly related to FAA-related policy disagreements, many contain controversial policy riders. This is in part due to the reauthorization's "must-pass" status – it is seen by some members as the last concrete opportunity to move legislation before the lame duck session.

Among the amendments filed are a sweeping House-passed tax package supported by Senate Committee on Finance Chair Ron Wyden (R-Ore.), legislation introduced by Sen. Josh Hawley (R-Mo.) to expand a compensation program for victims of radiation exposure and a variety of energy- and environment-related measures.

The Senate may vote to limit amendments to the reauthorization package in an effort to avoid another short-term FAA extension. This depends on the progress of negotiationsin the coming hours and days.. The House floor schedule released by Majority Leader Steve Scalise (R-La.) indicates a vote on a Senate-passed measure this week is "expected."

House Passes Congressional Budget Office Data Sharing Act; Other Measures Related to Agencies' Practices for Rules and Guidance

The House passed legislation last week that will speed the rate at which data is shared between federal agencies, including the U.S. Department of Health and Human Services (HHS) and the Congressional Budget Office (CBO). The bipartisan CBO Data Sharing Act (H.R. 7032), which passed by voice vote, clarifies and expands the CBO director's authority to request and receive data from executive branch agencies and would require CBO to maintain the same level of confidentiality protections as the agency providing the data.

The House passed an additional measure related to federal agency oversight, transparency and communication on May 6, 2024. The Information Quality Assurance Act (H.R. 7219) would require the Office of Management and Budget (OMB) and other federal agencies to update guidelines related to the use of reliable information for developing rules and guidance and for disseminating information to the public.

Senate Committee on Finance Releases Discussion Draft on Drug Shortages

The initial focus of the draft legislation is on Medicare-furnished generics and targets drugs at the highest risk of shortage, starting with generic sterile injectables (GSIs) and infused medications such as chemotherapy treatments. The proposed draft would also make changes to the Medicaid Drug Rebate Program (MDRP) to address single-source, low-profit margin generic drugs that are dispensed at retail pharmacies by adjusting the generic drug inflation rebate. Through both the new Medicare program and the altered MDRP, the draft legislation includes a pathway for potential expansion to include multiple-source drugs in the future.

The Medicare provisions of this discussion draft would establish a new, voluntary Medicare Drug Shortage Prevention and Mitigation Program that would provide bonus payments to certain healthcare providers and other eligible "participants" – manufacturers, group purchasing organizations (GPOs) and wholesalers. These bonus payments are intended to incentivize certain activities aimed to prevent and mitigate shortages. Payment amount and eligibility would be linked to specific standards and measures outlined in the discussion draft (e.g., measures reflecting a hospital's buffer inventory maintenance, specific standards for purchaser contracting terms related to contract length, volume commitment, etc.). To be eligible for the program and to receive bonus payments, providers and other program participants would be required to apply for and enter into an agreement with HHS. All participating entities would be required to meet a number of reporting, attestation and compliance requirements.

A summary and section-by-section review of the legislation is available online. The committee is accepting feedback on the proposed legislation through June 6, 2024.

House W&M to Mark Up Legislation to Extend Telehealth Waivers

With telehealth waivers currently set to expire at the end of the calendar year, legislators are honing in on specific proposals to extend those flexibilities. Discussions are ongoing regarding either a temporary or permanent extension of certain policies. The House Committee on Ways and Means (W&M) will mark up several measures on May 8, 2024, that would extend some telehealth flexibilities for two years. Legislation under consideration includes:

- H.R. ____, the Preserving Telehealth, Hospital, and Ambulance Access Act
- H.R. 7931, the PEAKS Act
- H.R. 8245, the Rural Hospital Stabilization Act
- H.R. 8244, the Ensuring Seniors' Access to Quality Care Act
- H.R. 8235, the Rural Physician Workforce Preservation Act
- H.R. 8246, the Second Chances for Rural Hospitals Act

FDA Officials to Appear Before E&C Subcommittee

The House Committee on Energy and Commerce (E&C) Subcommittee on Health announced it will convene for a hearing, "Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices," on May 22, 2024.

Witnesses will include:

- Dr. Patrizia Cavazzoni, Director of the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER)
- Dr. Peter Marks, Director of the FDA Center for Biologics Evaluation and Research (CBER)
- Dr. Jeffrey Shuren, Director of the FDA Center for Devices and Radiological Health (CDRH)

House and Senate Hearings on Administrative and Regulatory Burdens in Healthcare

The House Committee on Small Business is scheduled to convene for a hearing, "Stifling Innovation: Examining the Impacts of Regulatory Burdens on Small Businesses in Healthcare," on May 8, 2024. The Senate Committee on the Budget will also convene that day for a similarly focused hearing, "Reducing Paperwork, Cutting Costs: Alleviating Administrative Burdens in Health Care."

As outlined in a public memo prepared by House Republicans on the Small Business Committee, the House hearing will largely center on the impacts of FDA regulation on innovation in healthcare, with a particular focus on the FDA's approval process for drugs, biologics and other medical products. Members will also discuss concerns about the ability of small and independent healthcare providers to handle costs associated with regulatory compliance, as well as administrative burdens posed by utilization management protocols such as prior authorization. Witness testimony suggests that issues related to healthcare consolidation, pharmacy benefit manager (PBM) reform, the 340B drug pricing program and Medicare payment policies may be raised during the House hearing. The Senate hearing will likely have a greater focus on these topics.

Last Week: Hearings on Change Cyberattack; Medicaid and LTSS; Maternal Mortality and Workforce Diversity

Committees in both chambers held hearings on the Change Healthcare cyberattack last week, featuring the payor impacted by the cyberattack as a witness. At the Senate Committee on Finance, members asked pointed questions regarding the extent of the breach's impact. Senate Finance Committee Chair Ron Wyden (D-Ore.) has indicated his office is currently in the process of drafting legislation to address cybersecurity challenges by strengthening Health Insurance Portability and Accountability Act (HIPAA) privacy protections.

On the House side, some House E&C Committee members expressed general support for the concept of addressing cybersecurity by amending HIPAA. Others pointed to the potential for consolidation in the health sector to compound the damage caused by cyberattacks.

At a House E&C Committee Subcommittee on Health hearing, "Legislative Proposals to Increase Medicaid Access and Improve Program Integrity," on April 30, 2024, members considered 19 introduced bills and draft measures intended to improve Medicaid coverage of long-term services and supports (LTSS) and address improper payments under the Medicaid program. Daniel Tsai, deputy administrator and director of the Center for Medicaid and CHIP Service (CMCS), appeared as a witness. A summary of each measure considered is available in a public hearing memo prepared by House Republicans serving on the subcommittee.

Additionally, on May 2, 2024, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing, "What Can Congress Do to Address the Severe Shortage of Minority Health Care Professionals and the Maternal Health Crisis?"

REGULATORY UPDATES

Medicare and Social Security Trustees Release Annual Reports

The Medicare Trustees Report that was released on May 6, 2024, estimates that the Part A Trust Fund will be able to pay 100 percent of total scheduled benefits until 2036, five years later than reported last year. The trustees cited a better economy and lower-than-expected expenses from lower-than-expected inpatient hospital and home health agency costs and the exclusion of medical education expenses from costs used when developing Medicare Advantage (MA) spending.

The trend toward prolonging the insolvency date continues from last year where trustees predicted the fund would be depleted in 2031, adding three years to the 2022 projection of 2028. A bipartisan group of legislators in the Senate and the House, as well as some stakeholders, have been pushing to establish a fiscal commission that can rein in costs.

In the report, the trustees again state that Medicare Physician Payments are inadequate, saying that "While the physician payment system put in place by MACRA avoided the significant short-range physician payment issues resulting from the SGR system approach, it nevertheless raises important long-range concerns that will almost certainly need to be addressed by future legislation. … The specified rate updates could be an issue in years when inflation levels are high and would be problematic when the cumulative gap between the price updates and physician costs becomes large. Absent a change in the delivery system or level of update by subsequent legislation, the Trustees expect access to Medicare-participating physicians to become a significant issue in the long term."

HHS, DOL and Treasury Department Release Cost Sharing FAQs

HHS, the U.S. Department of Labor (DOL) and the U.S. Department of the Treasury issued a set of frequently asked questions announcing that they are extending their enforcement discretion with respect to how health plans calculate the qualifying payment amount (QPA) due to the Texas Medical Association (TMA) III decision. The QPA is the basis for determining individual cost sharing for items and services covered by the balance-billing protections in the No Surprises Act (NSA) under certain circumstances. Original enforcement discretion was supposed to end May 1, 2024, but is now being extended by six months to Nov. 1, 2024, giving insurers an extension on compliance.

In justification for their decision, the departments noted, "[D]espite taking reasonable steps to come into compliance, plans and issuers need additional time to complete the significant efforts associated with recalculating QPAs in a manner consistent with the statutes and regulations that remain in effect after the TMA III vacatur, as several of the changes to the QPA calculation methodology necessitate a manual process to locate data."

HHS Releases Draft Guidance for the Second Cycle of Medicare Drug Price Negotiation Program

The Centers for Medicare & Medicaid Services (CMS) released draft guidance on May 3, 2024, for public comment on the second cycle of negotiations under the Medicare Drug Price Negotiation Program (Negotiation Program). Negotiations have been initiated on the first set of 10 prescription drugs, and this second cycle of negotiations will include up to 15 additional drugs selected for negotiation. CMS will announce up to 15 additional drugs selected for potential negotiation for 2027 by Feb. 1, 2025. This second round of negotiations must occur during 2025, and any negotiated maximum fair prices will be effective for this second set of drugs starting Jan. 1, 2027.

Additionally, CMS is setting forth policies that outline how manufacturers ensure eligible Medicare beneficiaries

have access to the negotiated maximum fair prices for 2026 and 2027.

CMS is soliciting comment on options for the Medicare Transaction Facilitator (MTF) to support optional facilitation of retrospective payment from participating drug companies to participating dispensing entities to help effectuate access to the negotiated maximum fair price to people with Medicare prescription drug coverage.

FDA Releases Laboratory Developed Test Final Rule

The FDA has finalized a rule to regulate laboratory-developed tests (LDTs) as medical devices. (See Holland & Knight's client alert, "FDA Announces Final Regulation Governing Laboratory Developed Tests, May 1, 2024.) The regulation, which is aimed at ensuring the accuracy and reliability of LDTs, will be phased in over a four-year period. Notably, the final rule amends FDA regulations to make explicit that in vitro diagnostic (IVD) products are devices under the Federal Food, Drug and Cosmetic Act (FD&C), including when the manufacturer of the IVD is a laboratory. This is significant because the FDA has historically exercised enforcement discretion with respect to most of these tests and has not required the laboratories offering these tests to comply with FDA regulatory requirements for medical devices. Lawmakers in Congress, including House E&C Committee Chair Cathy McMorris Rodgers (R-Wash.), had previously called on the agency to rescind the proposed rule due to concerns about its impact on patient access to innovative diagnostics.

The FDA issued two draft guidances. The first provides the agency's perspective on an enforcement discretion policy for certain laboratories offering certain unauthorized IVDs for immediate response to an emergent situation. The second provides the FDA's perspective on the factors it intends to consider when developing a policy regarding enforcement discretion for certain IVDs during a public health emergency. The FDA shared a press release with more details and will host a webinar on the final rule on May 14, 2024.

DACA Health Coverage Rule Finalized

HHS, through CMS, finalized a rule which states that Deferred Action for Childhood Arrivals (DACA) recipients will no longer be excluded from eligibility to enroll in a Qualified Health Plan (QHP) through the Affordable Care Act (ACA) Health Insurance Marketplace or for coverage through a Basic Health Program (BHP). CMS estimates that this rule could lead to 100,000 previously uninsured DACA recipients enrolling in health coverage through Marketplaces or a BHP.

HHS Secretary Xavier Beccera praised the rule stating, "HHS is committed to making health coverage accessible for people. DACA recipients – Dreamers – who have worked hard to live the American Dream. Dreamers are our neighbors and friends; they are students, teachers, social workers, doctors, and nurses. More importantly, they are fellow Americans. More than one third of DACA recipients currently do not have health insurance, so making them eligible to enroll in coverage will improve their health and wellbeing, and help the overall economy."

MACPAC Appointments

U.S. Government Accountability Office (GAO) Comptroller General Gene L. Dodaro announced on May 2, 2024, the appointment of several new positions – including a new chair, two members, as well as the reappointment of four members – to the Medicaid and CHIP Payment and Access Commission (MACPAC).