Holland & Knight

H&K Health Dose: July 9, 2024

A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session, with votes scheduled and health-related activity at the committee level.

Both chambers' appropriations committees will convene this week to mark up a slew of fiscal year (FY) 2025 spending bills. In addition, the Senate Committee on Health, Education, Labor and Pensions (HELP) will hold a hearing on medical debt cancellation, and the House Committee on Ways & Means (W&M) will hold a field hearing on medical innovation.

While health-related floor votes are not expected this week, House Speaker Mike Johnson (R-La.) previewed some health-related legislation at an event on June 8, 2024, and is expected to be called up for a vote before the end of the year. Specifically, Speaker Johnson indicated that the BIOSECURE Act (H.R. 8333) – a measure aimed at blocking foreign governments from accessing Americans' health and genomic data – would be passed by the House as part of a China-focused legislative package by the end of the year.

The public is awaiting the release of proposed rules on the Physician Fee Schedule; the Hospital Outpatient Prospective Payment System; and Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability. These three rules have all cleared the U.S. Office of Management and Budget (OMB) review. Also, as shared June 8, 2024, the Spring 2024 Unified Agenda was released on July 5, 2024, and outlines the Biden Administration's outstanding regulations and target release dates.

LEGISLATIVE UPDATES

FY 2025 Appropriations Markups

The House Committee on Appropriations will mark up three FY 2025 spending measures on July 10, 2024, including its Labor, Health and Human Services, Education and Related Agencies (Labor-HHS) bill. The full committee mark up, full committee report and a summary of the Labor-HHS bill are available on the committee website. The Senate Committee on Appropriations will convene July 11, 2024, to mark up the first three of its FY 2025 spending measures and consider 302(b) subcommittee allocations for all 12 bills.

Senate Commerce Committee Hearing on Privacy Rights, Artificial Intelligence (AI)

Conversations in Congress regarding potential data privacy legislation are ongoing. The Senate Committee on Commerce will hold a hearing on July 11, 2024, to "explore how AI has accelerated the need for a federal comprehensive privacy law that protects individual privacy and sets clear guidelines for businesses as they develop and deploy AI systems." This hearing follows the last-minute cancellation of a House Committee on Energy and Commerce (E&C) markup of the American Privacy Rights Act (APRA) previously scheduled for June 27, 2024. The bill's scope is broader than healthcare but has significant healthcare implications.

Sen. Cassidy Sends Letters on *Chevron* Compliance; No Surprises Act Implementation

U.S. Senate Committee on HELP Ranking Member Sen. Bill Cassidy, M.D. (R-La.) has sent letters to federal agencies under his panel's jurisdiction regarding their plans for complying with the Supreme Court's overturning of the *Chevron* deference. Sen. Cassidy specifically highlights the U.S. Food and Drug Administration's (FDA) laboratory developed test (LDT) rule, the U.S. Department of Health and Human Services' (HHS) implementation of the No Surprises Act, and HHS' proposed march-in rights framework as deserving further scrutiny in light of the high court's recent decision. Sen. Cassidy's letter to HHS and his letter to the FDA can be found online. He has requested the agencies respond to his specific questions by July 19, 2024.

REGULATORY UPDATES

New Draft Guidance Around Diversity in Clinical Studies

In a joint effort from multiple centers and offices within the FDA, draft guidance was released that includes recommendations to assist sponsors of studies to meet requirements under certain statutes. The guidance is intended for sponsors conducting certain clinical studies involving drugs, biological products and devices. To improve enrollments of underrepresented participants in clinical studies, the guidance outlines potential Diversity Action Plan details such as format, content, timing and process. The guidance also outlines the criteria and process by which FDA will evaluate sponsor's waiver requests. Comments are due Sept. 26, 2024.

NOFO Application Period Open for the TMaH Model

The Notice of Funding Opportunity (NOFO) application for the Transforming Maternal Health (TMaH) Model is open through Sept. 20, 2024. The Centers for Medicare & Medicaid Services (CMS) anticipates announcing the recipients selected to participate in the model in Fall 2024. TMaH aims to improve health outcomes for mothers and infants dually enrolled in Medicaid and the Children's Health Insurance Program (CHIP). Interested parties outside of potential model participants (State Medicaid agencies) are encouraged to form partnerships and write to their state Medicaid agencies showing their interest in the program.

Calendar Year 2025 ESRD PPS Proposed Rule (CMS-1805-P) Released

CMS released its proposed rule on June 27, 2024 to update payment rates and policies and includes requests for information (RFIs) under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for services furnished to Medicare beneficiaries for dialysis on or after Jan. 1, 2025. The rule proposes several updates to payment rates for services performed, including the acute kidney injury (AKI) dialysis payment rate for calendar year (CY) 2025. The rule also proposes extended Medicare coverage of dialysis at home for patients with AKI. Updates to the ESRD Quality Incentive Program are also proposed. The rule aims to establish more equitable care for underserved populations by improving care coordination and removing known barriers to care (i.e., absence of reliable transportation).

CMS Releases State RFA for the CGT Access Model

CMS released the State Request for Applications (RFA) for the Cell and Gene Therapy (CGT) Access Model. The model is for Medicare beneficiaries living with rare and severe diseases, and it aims to improve access to treatment, improve health outcomes and reduce healthcare costs. The model will initially focus on gene therapies for sickle cell disease. According to CMS, the model will test whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies improves Medicaid beneficiaries' health outcomes, broadens access to innovative treatment and reduces healthcare expenditures.

The RFA is available online, and the application will be open from December 2024 through Feb. 28, 2025. The State RFA factsheet offers additional details. For more information about the model, see the model webpage and the CGT Access Model press release. For updates on the model, please register for the model listserv.

Judge Partially Blocks FTC's Ban on Noncompete Agreements

A U.S. district court judge has temporarily restricted the Federal Trade Commission (FTC) from implementing a ban on employment contracts containing noncompete clauses. The regulation was set to go into effect in September 2024 prior to the federal judge's decision that the agency lacks the appropriate authority for such a rule. The order only currently applies to the plaintiffs in the case – including tax services firm Ryan, the Business Roundtable, the U.S. Chamber of Commerce and two Texas business groups – but the judge has stated her plans to issue a broader ruling by the end of August 2024.