Holland & Knight

H&K Health Dose: June 4, 2024

A weekly dose of healthcare policy news

The U.S. Senate and U.S. House of Representatives are in session, with floor and committee-level activity in both chambers expected. Notably, the House Committee on Energy and Commerce (E&C) Subcommittee on Oversight and Investigations held a hearing on June 4, 2024, on the 340B Drug Pricing Program.

LEGISLATIVE UPDATES

Senate Finance Committee Members Drafting Bipartisan GME Bill

A bipartisan group of Senate Committee on Finance members is preparing to introduce legislation to increase federally funded graduate medical education (GME) slots. The bill is a part of the committee's efforts to increase the number of primary care and psychiatry providers working in rural and underserved areas. The proposal would allocate 25 percent of the new slots to primary care physicians and 15 percent to psychiatry residents, and hospitals would be required to maintain the new GME slots for a decade. The U.S. Department of Health and Human Services (HHS) would be required to track where the residents train and eventually practice. The policymakers are still determining how many new GME slots to add and what budgetary offsets will be paid for the proposal. The full text of the policy outline can be found online. Comments are due June 24, 2024.

Legislation to Prohibit Biotechnology Contracting with Foreign Adversaries

Rep. Brad Wenstrup (R-Ohio) recently announced plans to introduce the BIOSECURE Act (H.R. 7085) as an amendment to the annual must-pass National Defense Authorization Act (NDAA). This legislation would bar American companies from doing business with biotechnology companies that are based in a foreign adversary nation. The Senate version of the bill (S. 3558) was advanced out of the Senate Committee on Homeland Security & Governmental Affairs earlier this year, and Senate Homeland Security Chair Gary Peters (D-Mich.) has similarly discussed the possibility of attaching the legislation to the NDAA.

Sen. Paul Files Resolution on Laboratory Developed Tests

On May 17, 2024, Sen. Rand Paul (R-Ky.) introduced a resolution under the Congressional Review Act (CRA) that, if approved, would overturn the U.S. Food and Drug Administration's (FDA) final rule on laboratory developed tests. However, this action will not likely gain traction, since the FDA's rule was finalized before the beginning of CRA's lookback period.

Congress Members Request Expanded Digital Therapeutics Coverage

In a recent letter to the Centers for Medicare & Medicaid Services (CMS), Reps. Kevin Hern (R-Okla.), Mike Thompson (D-Calif.), August Pfluger (R-Texas) and Doris Matsui (D-Calif.) encouraged the agency to "expand Medicare beneficiary access to evidence-based care by covering and paying for digital therapeutics under existing benefit categories." The representatives acknowledged the 2024 Medicare Physician Fee Schedule proposed rule request for information (RFI) on digital therapeutics as a first step, and they encouraged expanded coverage under existing authority granted by Congress through the Social Security Act.

Bipartisan Group of Legislators on E&C Health Subcommittee Introduce 340B Legislation

Reps. Larry Bucshon, MD (R-Ind.), Buddy Carter (R-Ga.) and Diana Harshbarger (R-Tenn.) – who serve on the House E&C Committee, the committee of jurisdiction – introduced the 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act (340B ACCESS Act) (H.R. 8574) on May 28, 2024. The legislation would define "patient" for 340B covered entities, make changes to child site eligibility and recognize contract pharmacies in statutes, among other changes.

On June 4, 2024, the House E&C Committee's Subcommittee on Oversight and Investigations held a hearing, "Oversight of the 340B Drug Pricing Program." A press release and hearing memo prepared by E&C Republicans is available on the committee website.

At Rep. Pallone's Request, GAO Releases Prior Authorization Report

House E&C Committee Ranking Member Frank Pallone, Jr. (D-N.J.) released a new report on May 29, 2024, which he requested from the U.S. Government Accountability Office (GAO), on Medicaid managed care plans' use of prior authorization for children's healthcare benefits. In a press release, Rep. Pallone stated, "This report underscores the need for heightened oversight of Medicaid managed care plans' use of prior authorization, especially when it comes to our children's health care. These findings will inform Democrats' ongoing investigation into the use of prior authorization and its impact on access to care." In the report, GAO recommended that CMS clarify whether managed care plans can require prior authorization for Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services when a state does not have such requirements, as this discrepancy often creates confusion.

Senate HELP Committee Approves Six Measures

The Senate Committee on Health, Education, Labor and Pensions (HELP) approved six bills on May 23, 2024, which would reauthorize several healthcare programs aimed at addressing clinician mental health, increasing funding for health research and improving pediatric care. The six bills include the BOLD Infrastructure for Alzheimer's Act, the Dr. Lorna Breen Health Care Provider Protection Act, the Emergency Medical Services for Children Reauthorization Act and the Congenital Heart Futures Reauthorization Act of 2024, among other measures.

House Hearings on Healthcare Consolidation

Two House committees recently held hearings to examine consolidation in healthcare systems and barriers to patient care. The House Committee on the Budget convened on May 23, 2024, for a hearing, "Breaking Up Health Care Monopolies: Examining the Budgetary Effects of Health Care Consolidation." The House Committee on Ways and Means (W&M) Subcommittee on Health convened on May 24, 2024, for a hearing, "The Collapse of Private Practice: Examining the Challenges Facing Independent Medicine."

New Preventive Health Caucus

Rep. Vern Buchanan (R-Fla.), chair of the House W&M Committee's Subcommittee on Health, and Rep. Gwen Moore (D-Wis.) launched the Congressional Preventive Health and Wellness Caucus last week. The group will address the obesity epidemic through prevention, research, food as medicine, exercise and health disparities.

Congressional Retirements and Resignations

Rep. Maxine Dexter, MD (D-Ore.) has won the Democratic primary in the race to replace retiring Rep. Earl Blumenauer (D-Ore.). Dexter is a pulmonologist and critical care medicine specialist. She is expected to win November's general election to represent Oregon's heavily Democratic 3rd Congressional District in the House of Representatives.

REGULATORY UPDATES

FDA: AI Guidance to Address Data Quality, Transparency, Standard Definitions

At the U.S. Pharma and Biotech Summit on May 18, 2024, Tala Fakhouri, associate director for policy analysis at the FDA, said FDA plans to release guidance by the end of the year titled "Considerations For the Use of AI in Regulatory Decision-Making." The guidance will address data quality, transparency in artificial intelligence (AI) models and common definitions for AI-related terms as they relate to the use of AI in drug and device development.

NIH Releases Equitable and Affordable Access Proposal and RFI

The National Institutes of Health (NIH) published a policy proposal last week that suggests how the agency can improve its own licensing process to advance equitable and affordable access to drugs, vaccines, devices and treatments. The proposal applies to products developed from NIH-owned invention, which have, according to NIH, provided the foundation for new vaccines, drugs and medical devices. The proposal seeks feedback on the proposal by July 21, 2024.

OCR Guidance Reversal

HHS' Office for Civil Rights (OCR) reversed its breach notification guidance on May 31, 2024, for covered entities impacted by the Change Healthcare cyberattack, clarifying that impacted entities may delegate notification requirements to Change Healthcare. Under the Health Insurance Portability and Accountability Act (HIPAA), covered entities (providers, insurers, etc.) have up to 60 calendar days from discovering a breach of unsecured protected health information (PHI) to file breach reports to HHS. Covered entities that discover a breach also must notify affected individuals "without unreasonable delay." In the newly issued FAQs (FAQs 6 and 7), OCR states that UnitedHealth Group (UHG) has not yet declared an official breach notification. OCR also points to FAQs released by UHG that state that "to help ease reporting obligations on other stakeholders whose data may have been compromised as part of this cyberattack, UnitedHealth Group has offered to make notifications and undertake related administrative requirements on behalf of any provider or customer."

In related news, Sen. Ron Wyden (D-Ore.) is asking the Federal Trade Commission (FTC) and the U.S. Securities and Exchange Commission (SEC) to further investigate cybersecurity and technology failures by UHG to determine whether any laws were broken in the events leading up to the hack of Change Healthcare.

CMS Oncology Model Expansion

Capability Maturity Model Integration (CMMI) released a Request for Applications (RFA) to solicit applications for a second cohort of participants in the Enhancing Oncology Model (EOM). Additionally, the model has been extended by two years, will include a higher monthly payment for enhanced services and will establish a higher recoupment threshold, all effective Jan. 1, 2025. The second cohort will begin participation in EOM on July 1, 2025, and end on June 30, 2030, for a five-year model performance period. The first performance period began on July 1, 2023, and the model test will end on June 30, 2030, for all participants, which is a two-year extension from the original end date of June 30, 2028. Eligible participants are Medicare-enrolled oncology physician group practices identifiable by a unique federal taxpayer identification number. The application portal for interested applicants will be open from July 1, 2024, to Sept. 16, 2024.