



## H&K Health Dose: May 21, 2024

A weekly dose of healthcare policy news

### LEGISLATIVE UPDATES

#### FY 2025 Spending Bills Begin to Take Shape; Budget Hearings Continue

U.S. House of Representative Republicans' proposed topline spending levels for fiscal year (FY) 2025 were released on May 1, 2024, by House Committee on Appropriations Chair Tom Cole (R-Okla.). In a press release announcing the interim subcommittee allocations, Rep. Cole indicated that some of the appropriations bills, including the House's version of the FY 2025 Labor, Health and Human Services, Education (Labor-HHS) bill, year-over-year funding "will receive significant cuts of 10-11 percent," while also noting that the topline are subject to change. The press release also indicates that the topline align with the Fiscal Responsibility Act of 2023 – last year's debt-limit agreement between the White House and former House Speaker Kevin McCarthy (R-Calif.)

The President's Budget Request included \$130.7 billion in discretionary funding and \$1.7 trillion in mandatory funding for the U.S. Department of Health and Human Services (HHS) for FY 2025. The House Appropriations Committee's Subcommittee on Labor-HHS will hold a markup on the FY 2025 Labor-HHS bill on June 27, 2024, with a full committee markup scheduled for July 10, 2024. The full schedule of announced FY 2025 markups is [available online](#).

On the U.S. Senate side, the Senate Committee on Appropriations will convene May 23, 2024, to examine the proposed [National Institutes of Health \(NIH\) budget for FY 2025](#). NIH Director Monica Bertagnoli is set to appear before the committee at the hearing.

#### FAA Reauthorization

President Joe Biden signed into law the [Federal Aviation Administration \(FAA\) Reauthorization Act of 2024 \(H.R. 3935\)](#) on May 16, 2024. This legislation reauthorizes the agency and its related revenue authorities for five years through Sept. 30, 2028. The measure was approved by the House on May 15, 2024, in a 387-26 vote. Previously, it was advanced by the Senate in a 88-4 vote. The bill includes a provision to create a working group to identify best practices for the transportation of organs via the nation's commercial airline system. The aviation industry plays a vital role in organ transplants. Organs, particularly kidneys, travel by commercial airlines to transplant teams and recipients. Since the Sept. 11 attacks, federal regulations required that organs be classified as cargo, flying under the plane with checked baggage instead of in the main cabin and under aircrew supervision. The law also includes multiple provisions that make it safer and easier for disabled passengers to travel by air, including new requirements related to the availability of onboard wheelchairs.

#### House BIOSECURE Bill Advances Out of Committee

The House Committee on Oversight and Accountability advanced the BIOSECURE Act (H.R. 8333) with overwhelming bipartisan support last week. The legislation would prohibit Chinese biotechnology companies of concern from receiving federal contracts, grants or loans and is aimed at blocking foreign governments from accessing Americans' health and genomic data. The Senate version of the bill (S. 3558) was advanced out of the Committee on Homeland Security & Governmental Affairs earlier this year. House Oversight Chair James Comer (R-Ky.) stated that he expects a floor vote on the bill in the next 30 days, while Senate Homeland Security Chair Gary Peters (D-Mich.) has discussed the possibility of attaching the legislation to the annual must-pass National Defense Authorization Act (NDAA).

#### Bipartisan Senate Group Releases Draft Electronic Prior Authorization Legislation

Sens. Roger Marshall (R-Kan.), Ben Ray Lujan (D-N.M.), Roger Wicker (R-Miss.), Sheldon Whitehouse (D-R.I.) and Joe Manchin (D-W.Va.) released the text of [draft legislation](#) on May 20, 2024, that, if enacted, would broadly require private health insurers to implement electronic prior authorization processes for prescription drugs.



Additionally, Sens. Roger Marshall, M.D. (R-Kan.), Kyrsten Sinema (I-Ariz.), John Thune (R-S.D.) and Sherrod Brown (D-Ohio), along with Reps. Mike Kelly (R-Pa.), Suzan DelBene (D-Wash.), Ami Bera, M.D. (D-Calif.) and Larry Bucshon, M.D. (R-Ind.), will reintroduce the Improving Seniors' Timely Access to Care Act, a bipartisan bill to streamline Medicare Advantage prior authorization. It [unanimously passed the House last Congress](#). However, the \$16 billion Congressional Budget Office (CBO) score prevented further advancement. The Senate and House co-leads [led efforts to reduce the score](#) by calling on Centers for Medicare & Medicaid Services (CMS) to implement the legislation through final rules, which advanced earlier this year. The bill was further modified to reduce cost-scoring implications and will be reintroduced on June 5, 2024.

## Senate White Paper, Discussion Draft and RFI on Proposed Medicare Payment Reforms

Senate Committee on Finance Chair Ron Wyden (D-Ore.) and Ranking Member Mike Crapo (R-Idaho) released a [white paper](#) on May 17, 2024, outlining potential Medicare payment reforms. The white paper, "Bolstering Chronic Care through Physician Payment: Current Challenges and Policy Options in Medicare Part B," is primarily focused on issues related to Medicare Part B clinician payment policy, alternative payment models and telehealth. It builds upon some of the policies discussed by the committee during an April 11, 2024, hearing. Questions and potential policy concepts under consideration by the committee, as outlined in the white paper, include:

- inflationary updates to the Medicare Physician Fee Schedule (PFS) Conversion Factor (CF)
- various incentives for participation in advanced alternative payment models (A-APMs)
- "structural refinements" to statutory PFS budget-neutrality requirements
- bonus payments to clinicians through a new, hybrid payment model under Medicare Fee For Service (FFS)
- changes to Merit-based Incentive Payment System (MIPS) reporting requirements
- extending telehealth flexibilities under Medicare FFS

The white paper specifies that the committee will continue to conduct outreach to stakeholders and experts in an effort that will "ideally culminate in bipartisan legislation."

Complementary legislation, the [Pay PCPs Act \(S. 4338\)](#), was released on May 15, 2024, by Sens. Sheldon Whitehouse (D-R.I.) and Bill Cassidy, M.D. (R-La.). Sens. Cassidy and Whitehouse have indicated that the legislation was intended to serve as a marker bill "for future primary care legislation." Along with the draft legislation, the senators released a [Request for Information \(RFI\)](#) soliciting feedback from stakeholders. Feedback may be submitted via email through July 2024.

## Bipartisan Senate Workgroup Releases AI Roadmap

The Bipartisan Senate Artificial Intelligence (AI) Working Group, led by Senate Majority Leader Chuck Schumer (D-N.Y.), released "[Driving U.S. Innovation in Artificial Intelligence: A Roadmap for Artificial Intelligence Policy in the United States Senate](#)" on May 15, 2024. This road map is intended to serve as a high-level blueprint for Senate committees of jurisdiction as they continue to develop and advance bipartisan legislative proposals and includes recommendations for the following healthcare activity:

- Consider legislation that both supports further deployment of AI in healthcare and implements appropriate guardrails and safety measures to protect patients. This includes consumer protection, preventing fraud and abuse, and promoting the usage of accurate and representative data.
- Ensure that HHS has the proper tools to weigh the benefits and risks of AI-enabled products so that it can provide a predictable regulatory structure for product developers.
- Consider legislation that would provide transparency for providers and the public about the use of AI in medical products and clinical support services, including the data used to train the AI models.
- Consider policies to promote innovation of AI systems that meaningfully improve health outcomes and efficiencies in healthcare delivery. This should include examining the reimbursement mechanisms of the CMS and instituting guardrails to ensure accountability, appropriate use and broad application of AI across all populations.

A House AI working group is developing a similar policy paper related to AI, though the House effort is not as far along. For additional analysis, see Holland & Knight's alert, "[Senate Releases Bipartisan AI Roadmap](#)," May 20, 2024.



## House E&C Subcommittee on Health Marks Up 23 Bills, Including Telehealth Extender Bill

The House Committee on Energy and Commerce (E&C) Subcommittee on Health [marked up](#) a slate of healthcare proposals on May 16, 2024, including legislation to extend, for two years, pandemic-era telehealth flexibilities currently set to expire in December 2024.

The telehealth measure approved by the committee includes a modifier for telehealth services for claims that are provided through a telehealth virtual platform or billed incident to a physician's or practitioner's professional service. Although similar to the telehealth extension bill advanced by the House Committee on Ways and Means (W&M) last week, the bills are not identical, necessitating further work before a telehealth extension bill will reach the House floor for a vote.

Twenty other bills advanced, including the [Accelerating Kids' Access to Care Act \(H.R. 4758\)](#). More information on amendments and vote outcomes can be found on the [House E&C Committee website](#).

## Senate HELP Committee to Hold Public Health Reauthorization Markup

The Senate Committee on Health, Education, Labor and Pensions (HELP) will convene on May 23, 2024, for a markup of several public health reauthorization bills and one nomination. Among the measures under consideration is a manager's amendment to the Dr. Lorna Breen Health Care Provider Protection Reauthorization Act (S. 3679). A full list of legislation under consideration is available on the [committee website](#).

## Senate Judiciary Committee to Examine Prescription Drug Costs

The Senate Committee on the Judiciary convened on May 21, 2024, for a hearing, "Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market." A press release from U.S. Senate Majority Whip and Judiciary Committee Chair Sen. Dick Durbin (D-III.) highlighted that the committee has "jurisdiction over competition issues and the intellectual property system, which play critical roles in incentivizing true innovation and protecting a healthy market that keeps prices for prescription drugs within reach of the patients that need them." A webcast of the hearing is available on [the committee website](#).

## House Hearings on Healthcare Consolidation

Two House committees will hold hearings this week on consolidation in healthcare systems and barriers to patient care. The House Committee on the Budget will convene on May 23, 2024, for a hearing, "[Breaking Up Health Care Monopolies: Examining the Budgetary Effects of Health Care Consolidation](#)." The House W&M Committee's Subcommittee on Health will hold a hearing on May 24, 2024, "[The Collapse of Private Practice: Examining the Challenges Facing Independent Medicine](#)."

## House E&C Committee to Hold Hearing Featuring CBER, CDER, CDRH Directors

The House E&C Committee Subcommittee on Health will convene on May 22, 2024, for a hearing, "[Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices](#)." Witnesses will include:

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

## Senate HELP Subcommittee Hearing on "Food in Medicine"

The Senate HELP Committee's Subcommittee on Primary Health and Retirement Security convened May 21, 2024, for a hearing, "Feeding a Healthier America: Current Efforts and Potential Opportunities for Food in Medicine." A webcast of the hearing is [available online](#).



## Upcoming Senate Finance Committee Hearing on Fentanyl

The Senate Committee on Finance will convene May 23, 2024, for a hearing, "[Front Lines of the Fentanyl Crisis: Supporting Communities and Combating Addiction through Prevention and Treatment](#)." Statements for the record will be accepted by the committee through June 6, 2024.

## REGULATORY UPDATES

### ARPA-H "Upgrade" Investment in Cybersecurity

The Biden Administration [announced in September 2023](#) \$50 million in funding for six contract awards through the Digital Health Security (DIGIHEALS) project. Since then, various cybersecurity attacks have targeted the healthcare system, leading to questions about the level of security safeguards in place in the industry. On May 20, 2024, Advanced Research Projects Agency for Health (ARPA-H) [announced a program to automate cybersecurity](#) for healthcare facilities. According to ARPA-H's director, "UPGRADE will speed the time from detecting a device vulnerability to safe, automated patch deployment down to a matter of days, providing confidence to hospital staff and peace of mind to the people in their care."

### FDA ICER Framework for Clinical Trial Diversity

In its May 2024 edition of *Journal of Clinical Epidemiology*, the Institute for Clinical and Economic Review (ICER) published "[A Framework for Evaluating the Diversity of Clinical Trials](#)," a review of 110 studies that examined clinical trial diversity. The research found that about 85 percent of studies evaluated clearly defined the benchmark used for evaluation, but less than half (48 percent) used disease prevalence as the benchmark. Only 64 percent of studies defined what would be considered adequate representation. ICER recommended using epidemiology of the condition being studied as the benchmark for assessing trial diversity. In April 2024, the FDA's [CDER launched](#) the CDER Center for Clinical Trial Innovation (C3TI) to promote innovation in clinical trials.

### CBER Statement on IRA Drug Negotiation Program

At the Food and Drug Law Institute's annual conference May 15-16, 2024, Julie Tierney, current deputy center director for strategy, policy and legislation for CBER and former FDA chief of staff, spoke on the relationship between the Biden Administration's Inflation Drug Act (IRA), the law's enforcing agency, CMS and drug company strategy. In her comments, Tierney said that the IRA's definition for orphan drug exclusion, including the year distinction between biologic and small molecule drugs, could impact the strategy of drug companies. In the guidance revised in June 2023, CMS clarified that a drug that is designated for more than one rare disease or condition will not qualify for the orphan drug exclusion, even if it is not approved for any indications for those additional diseases or conditions. Various interested parties have noted the rising tension between the two agencies, and Tierney's comments have bolstered such perceptions. [The Retaining Access and Restoring Exclusivity \(RARE\) Act](#), which would've clarified FDA's interpretation of the Orphan Drug Act (ODA) designation of orphan drug exclusivity to apply to approved uses or indications with only a single approved drug, rather than excluding cases in which multiple drugs may be approved for the same disease but for multiple uses or indications, was not advanced out of the House E&C Committee during its May 16, 2024, mark up.