



## H&K Health Dose: April 30, 2024

A weekly dose of healthcare policy news

### THE WEEK AHEAD

The U.S. Senate and U.S. House of Representatives are back for a four-week work period, with healthcare activity at the committee level. The House will have a shortened legislative week: The chamber is set to adjourn on May 1, 2024, so that members may attend the funeral of late Rep. Donald M. Payne, Jr. (D-N.J.). When the House returns, Congress will remain in session until the Memorial Day recess.

Internal deadlines for members to communicate their fiscal year (FY) 2025 funding priorities to the Senate and House Appropriations Committees are just days away. Legislators are also prioritizing the passage of a compromise bill to reauthorize the Federal Aviation Administration (FAA) in the coming weeks (see below for further details). In addition to these timely items, key health legislators are continuing to discuss and flesh out policy concepts for potential inclusion in an expected year-end package.

On the regulatory front, the proposed rules for the Medicare Physician Fee Schedule (PFS) and Hospital Outpatient Prospective Payment System (OPPS) have also made their way to review by the Office of Management and Budget (OMB).

### LEGISLATIVE UPDATES

#### Rep. Cole Announces FY 2025 Earmark Eligibility Changes for Nonprofits; CPF Deadlines

Rep. Tom Cole (R-Okla.), House Appropriations Committee Chair, has made a significant change impacting community project funding (CPF) – earmarks – eligibility for FY 2025. In a [Dear Colleague letter and guidance](#) published April 25, 2024, Rep. Cole announced a new policy restricting House members from earmarking funds for nonprofits, including healthcare facilities, in the FY 2025 Transportation, Housing and Urban Development (T-HUD) appropriations bill.

Former chair of the House Appropriations Committee, Rep. Kay Granger (R-Texas), had previously banned House-originating earmarks in the FY 2024 Labor, Health and Human Services and Education (Labor-HHS); Defense; and Financial Services and General Government (FSGG) appropriations bills. Those restrictions remain in place for the FY 2025 spending bills.

The deadline for members to submit their earmark requests to the House Appropriations Committee is May 3, 2024, at 6 p.m. ET. The House deadline for programmatic and language requests is May 1, 2024, at 6 p.m. ET.

#### FAA Reauthorization

Senate Committee on Commerce, Science and Transportation Chair Maria Cantwell (D-Wash.) and Ranking Member Ted Cruz (R-Texas), as well as House Committee on Transportation and Infrastructure Chair Sam Graves (R-Mo.) and Ranking Member Rick Larsen (D-Wash.), released a joint statement on April 29, 2024, announcing a long-awaited agreement on bipartisan, bicameral legislation to reauthorize FAA through FY 2028.

FAA funding authorities that expired on Sept. 30, 2023, have been temporarily extended three times by Congress. The most recent extension pushed the reauthorization deadline to May 10, 2024. This leaves legislators with less than two weeks to either pass the negotiated reauthorization measure or come to an agreement on yet another stopgap measure.



Senate Majority Leader Chuck Schumer (D-N.Y.) has filed cloture on the compromise legislation using H.R. 3935 – an FAA reauthorization bill passed by the House in July 2023 – as a [legislative vehicle](#). A Senate vote is expected as early as May 1, 2024. Bill text and a section-by-section of the compromise measure are [available online](#).

## **House Budget GOP Calls for Updated GAO Report on CMMI; Senate Budget Chair Whitehouse Pushes for APM Provider Participation Incentives**

House Budget Committee Chair Jodey Arrington (R-Texas) and Budget Committee Health Care Task Force Chair Michael Burgess (R-Texas) are requesting that the U.S. Government Accountability Office (GAO) issue an updated report examining the Center for Medicare and Medicaid Innovation's (CMMI) use of federal funding and assessing its performance.

In a [letter to GAO](#) requesting the investigation, Reps. Arrington and Burgess reference findings from a September 2023 [CBO report](#) suggesting that CMMI activities increased net federal spending by \$5.4 billion over its first decade, in contrast to initial projections. The report also projects that CMMI will increase spending by \$1.3 billion by 2030, while only six of the more than 50 models it has tested have resulted in statistically significant savings.

Senate Budget Committee Chair Sheldon Whitehouse (D-R.I.) recently highlighted a separate CBO publication, "[Medicare Accountable Care Organizations \(ACOs\): Past Performance and Future Directions](#)," released on April 16, 2024. Sen. Whitehouse noted that CBO did not include ACOs within the Medicare Shared Savings Program (MSSP) in its September 2023 analysis. Sen. Whitehouse pointed to the [Value in Health Care Act \(S. 3503\)](#), his legislation with Sen. John Barrasso (R-Wyo.) that would extend advanced Alternative Payment Model (APM) incentive payments for participating providers at the 5 percent level. It would also authorize Centers for Medicare & Medicaid Services (CMS) to make certain adjustments to qualifying participant thresholds, among other provisions.

## **HELP Committee Launches Investigation into Weight-Loss Drug Pricing**

Senate Committee on Health, Education, Labor and Pensions (HELP) Committee Chair Sen. Bernie Sanders (I-Vt.) initiated an investigation into the pricing of select diabetes, chronic weight management and obesity drugs on April 24, 2024.

In a press release, Sen. Sanders stated, "As important as these drugs are, they will not do any good for the millions of patients who cannot afford them. Further, if the prices for these products are not substantially reduced, they have the potential to bankrupt Medicare, Medicaid and our entire health care system. The United States Congress and the federal government cannot allow that to happen." In an accompanying letter, Sen. Sanders addressed the impacted manufacturers of the investigation and outlined his concerns.

## **E&C Health Subcommittee Considers Proposed Medicaid Legislation**

The House Committee on Energy and Commerce (E&C) Subcommittee on Health convened for a legislative hearing, "[Legislative Proposals to Increase Medicaid Access and Improve Program Integrity](#)," on April 30, 2024.

Measures considered by the subcommittee build upon policies previously discussed in an Oct. 25, 2023, House E&C Committee Subcommittee on Health hearing, "[Supporting Access to Long-Term Services and Supports \(LTSS\): An Examination of the Impacts of Proposed Regulations on Workforce and Access to Care](#)," as well as in a House E&C Committee Subcommittee on Oversight and Investigations hearing, "[Examining How Improper Payments Cost Taxpayers Billions and Weaken Medicare and Medicaid](#)," held April 16, 2024.



Several of the 18 proposals relate to long-term services and supports (LTSS) and home and community-based services (HCBS) workforce issues. This hearing comes on the heels of the Biden Administration's release of the Ensuring Access to Medicaid final rule. Legislation introduced by Rep. Kat Cammack (R-Fla.), [H.R. 8114](#), would prevent the secretary of the U.S. Department of Health and Human Services (HHS) from implementing regulations that impose pass-through payment requirements for HCBS. Such requirements were finalized in the Ensuring Access to Medicaid rule.

Other bills considered include Rep. John Sarbanes' (D-Md.) [H.R. 8115](#), which would allow for the deferral or disallowance of portions of payments for certain managed care violations under Medicaid; [H.R. 3227](#), the Ensuring Seniors' Access to Quality Care Act, introduced by Reps. Ron Estes (R-Kan.) and Gerald Connolly (D-Va.); and [H.R. 7513](#), the Protecting America's Seniors Access to Care Act, introduced by Reps. Michelle Fischbach (R-Minn.) and Greg Pence (R-Ind.).

A [full list of bills noticed for the hearing](#), as well as a background memo prepared by the E&C Committee Subcommittee on Health majority, is available online.

## **House and Senate Hearings on Change Healthcare Cyber Attack**

The CEO of the payer impacted by the Change Healthcare cyberattack will appear before the House E&C Committee Subcommittee on Oversight and Investigations and the Senate Committee on Finance on May 1, 2024. Due to the payer's noticeable absence at the prior congressional hearing on the cyberattack, the CEO is expected to receive significant scrutiny on the payer's role in long-lasting industry impacts.

## **Appropriations Subcommittees Review FY 2025 President's Budget Request; House Labor-HHS Member Day**

The Senate Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (L-HHS) convened on April 30, 2024, [for a hearing](#) to review the president's FY 2025 budget request for the U.S. Department of Education. Education Secretary Miguel Cardona appeared before the subcommittee.

The House Committee on Appropriations Subcommittee on L-HHS held a [member day hearing](#), "Labor, Health And Human Services, Education, And Related Agencies – Member Day," also on April 30, 2024.

## **Senate Committee on HELP to Hold Hearing on Health Workforce Diversity; Maternal Health**

The Senate HELP Committee will convene on May 2, 2024, for a hearing, "[What Can Congress Do to Address the Severe Shortage of Minority Health Care Professionals and the Maternal Health Crisis?](#)" Sen. Laphonza Butler (D-Calif.) and Rep. Michael Burgess (R-Texas) will appear as witnesses.

## **Senate Armed Services Hearing on Drug Safety**

The Senate Committee on Armed Services' Subcommittee on Personnel convened for a hearing, "[To Receive Testimony on the Department of Defense's \(DoD\) Efforts to Ensure Servicemembers' Access to Safe, High-Quality, Pharmaceuticals](#)," on April 30, 2024. At the hearing, members were expected to discuss issues related to foreign-based drug and active pharmaceutical ingredient (API) manufacturers – such as drug quality and safety and the U.S. Food and Drug Administration's (FDA) foreign inspection programs – as well as issues related to drug shortages and the medical supply chain.

Lester Martinez-López, the DoD's assistant defense secretary for health affairs, and David Smith, deputy assistant defense secretary for health readiness policy and oversight, were scheduled to testify.



## Dr. Fauci to Appear Before House Pandemic Panel

[Dr. Anthony Fauci](#) is scheduled to testify before the House Select Subcommittee on the Coronavirus Pandemic on June 3, 2024. This will be the first time the former director of the National Institute of Allergy and Infectious Diseases (NIAID) and former chief medical adviser to President Joe Biden has appeared before a congressional committee since retiring from his career as a public official.

## Rep. Payne Jr.'s Passing; Special Election to Fill Former Rep. Higgins' Seat

On April 24, 2024, Rep. Donald M. Payne Jr. (D-N.J.) died at the age of 65. Rep. Payne was first elected to Congress in 2012 and co-chaired the Men's Health, the Peripheral Artery Disease and the Colorectal Cancer caucuses. New Jersey Gov. Phil Murphy has not yet publicly announced whether a special primary to fill the solidly-blue seat will be held in July 2024. The special general election would take place in September 2024.

The vacancy left by Rep. Payne will leave the balance of power at 217 Republicans and 212 Democrats at the beginning of the week. In an April 30, 2024, special election to fill New York's 26th District seat left vacant by former Rep. Brian Higgins (D-N.Y.), it is expected that House Democrats will again reach 213 seats. Sen. Timothy Kennedy (D-N.Y.) is the frontrunner in that election.

## REGULATORY UPDATES

### CMS Released New Surprise Billing Progress Report

CMS released "[Progress Toward Advanced Explanation of Benefits \(AEOB\) Rulemaking and Implementation](#)," on April 23, 2024, which expresses the agency's plan to implement No Surprises Act requirements such as consumer communication, as well as interest in pilot testing standards for the electronic transfer of data that providers and payers will need to comply with.

### FTC Issues Controversial Breach Notification Rule Despite Internal Criticism

The Federal Trade Commission (FTC) extended the scope of its Health Breach Notification Rule on April 26, 2024, to include personal health information collected by health apps and other technology that fall outside the Health Insurance Portability and Accountability Act (HIPAA). Various stakeholders, including developers and two of its own commissioners, have expressed vehement disapproval of the extension, pointing toward insufficient FTC authority.

### U.S. Preventive Services Task Force's Updated Guidelines on Breast Cancer Screening

The U.S. Preventive Services Task Force released final recommendations related to breast cancer screening on April 30, 2024. These [new recommendations](#), published in the medical journal *JAMA*, replace the task force's [2016 recommendations](#). In addition to recommending biennial breast cancer screening for women ages 40 to 74, the task force stuck with its draft recommendations from May 2023, reporting that it found insufficient evidence for screening women 75 and older. In addition, the U.S. Preventive Services Task Force (USPSTF) concluded that there was insufficient evidence to recommend supplemental screening with MRI or ultrasound in women, regardless of breast density.

### HIPAA 2 Privacy Rule

HHS' Office for Civil Rights (OCR) issued a final rule on April 26, 2024, to modify the Standards for Privacy of Individually Identifiable Health Information (2024 Privacy Rule) under HIPAA and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act).



The 2024 Privacy rule finalizes provisions that strengthen privacy protections for protected health information (PHI). OCR summarized in stating, "This final rule (2024 Privacy Rule) amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care. This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society in protecting individual privacy, thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided."

OCR finalized its "purpose-based prohibition" on certain uses and disclosures of PHI related to reproductive healthcare. This prohibits covered entities and business associates from using or disclosing PHI for certain activities.

Regarding attestation, OCR states in the preamble its intent to publish a model attestation form prior to the Final Rule's compliance date but clarified that an attestation that meets the Privacy Rule requirements, electronic or hard copy, is compliant even if it does not take the form promulgated by OCR.

## **CMS Publishes Update to National Quality Strategy**

CMS released "[Quality in Motion: Acting on the CMS National Quality Strategy](#)" on April 24, 2024. This succeeds its 2022 National Quality Strategy that was launched with a goal of improving the quality and safety of healthcare for everyone, with a focus on those from underserved and under-resourced communities.

CMS describes its four priority areas as the following:

- Outcomes and Alignment
- Equity and Engagement
- Safety and Resiliency
- Interoperability and Scientific Advancement

The new action plan recommends implementing the Universal Foundation, including the newly published hospital, maternity care and post-acute care/long-term care add-on sets.

## **HRSA Meeting: Advisory Committee on Heritable Disorders in Newborns and Children**

The Health Resources and Services Administration (HRSA) Advisory Committee on Heritable Disorders in Newborns and Children is holding a public meeting May 9-10, 2024. Registration is [required for attendance](#) and closes on May 8, 2024, at noon. The committee advises the secretary of HHS on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards, including:

- advice and recommendations concerning grants and projects authorized awarded or funded related to screening heritable disorders in newborns and children
- technical information to develop Heritable Disorders Program policies and priorities that will enhance the ability of the state and local health agencies to provide screening, counseling and healthcare services for newborns and children who have or are at risk for heritable disorders
- recommendations, advice and information to enhance, expand or improve the ability of the secretary to reduce mortality and morbidity from heritable disorders in newborns and children



## HHS Releases AI Plan

HHS released their "[Plan for Promoting Responsible Use of Artificial Intelligence in Automated and Algorithmic Systems by State, Local, Tribal, and Territorial Governments in Public Benefit Administration](#)," on April 29, 2024, per requirements of Executive Order (EO) 14110. The plan addresses the EO's charge of addressing the use of AI-enabled automated or algorithmic systems in the implementation by states and localities of public benefits and services funded by HHS such as to promote:

- assessment of access to benefits by qualified recipients
- notice to recipients about the presence of such systems
- regular evaluation to detect unjust denials
- processes to retain appropriate levels of discretion of expert agency staff
- processes to appeal denials to human reviewers
- analysis of whether algorithmic systems in use by benefit programs achieve equitable and just outcomes