



H&K Health Dose: February 27, 2024

A weekly dose of healthcare policy news

LEGISLATIVE UPDATES

The U.S. Senate is back in session, and the U.S. House of Representatives will return from recess on Feb. 28, 2024, just ahead of the first of two quickly approaching fiscal year (FY) 2024 appropriations deadlines. Current short-term funding measures are set to expire March 1, 2024, for some agencies, including the U.S. Food and Drug Administration (FDA), and on March 8, 2024, for the remainder, including the U.S. Department of Health and Human Services (HHS).

Attempts to reach a consensus agreement over the weekend were unsuccessful, and on Feb. 25, 2024, Senate Majority Leader Chuck Schumer (D-N.Y.) circulated a [Dear Colleague letter](#): "While we had hoped to have legislation ready this weekend that would give ample time for members to review the text, it is clear now that House Republicans need more time to sort themselves out." In response, House Speaker Mike Johnson (R-La.) [released a statement](#) referring to the letter as "counterproductive rhetoric" and alleging that "many of the points still being debated come from new Democrat demands that were not previously included in the Senate bills." Speaker Johnson has indicated that members will have at least 72 hours to review legislative text before a House floor vote.

According to the [weekly schedule](#) released by House Majority Leader Steve Scalise's (R-La.) office, floor votes are scheduled Feb. 28-March 1, 2024. Legislators plan to vote on a dozen measures, including an [extension of Federal Aviation Administration \(FAA\) authorities](#) through May 10, 2024, under suspension of the rules – a procedure that requires a two-thirds majority for passage. The schedule also notes that votes on "additional legislative items related to FY 2024 appropriations are expected."

While it appears increasingly unlikely that Congress will be able to pass all 12 regular FY 2024 appropriations bills by the current deadlines, legislators are considering several options to avert a partial or complete shutdown. Last week, members of the conservative House Freedom Caucus [published a letter](#) to Speaker Johnson in support of a full-year FY 2024 Continuing Resolution (CR) that would fund the government but trigger a 1 percent across-the-board spending cut for all agencies. This 1 percent cut will take effect if any department is operating under temporary funding on April 30, 2024. Another proposal under consideration would push back the current deadlines by 14 days to March 16, 2024, and March 22, 2024.

President Joe Biden is set to meet with House Speaker Johnson and Minority Leader Hakeem Jeffries (D-N.Y.), along with Senate Majority Leader Schumer and Minority Leader Mitch McConnell (R-Ky.), on Feb. 27, 2024, to discuss government funding bills, as well as a potential supplemental national security package that would provide aid to Ukraine, Israel and Taiwan. A \$95 billion Senate-passed measure that includes the FEND Off Fentanyl Act – legislation that would provide funding to curb fentanyl trafficking and allow for the sanctioning of fentanyl cartels – has stalled in the House. A bipartisan group of House members have introduced a \$66 billion compromise measure.

In the coming weeks, the Senate is expected to receive the two articles of impeachment against U.S. Department of Homeland Security (DHS) Secretary Alejandro Mayorkas that the House approved earlier this month. Speaker Johnson must sign the articles of impeachment before they can be formally transmitted and presented to the Senate. The Senate may then dismiss the articles by a simple majority vote, refer them to a committee or proceed to a trial. It is likely Senate Majority Leader Schumer will attempt to dispense with the articles quickly, as active impeachment trials are disruptive to regular legislative business.



This Week: Senate Hearings on Reproductive Health, TBI, House Hearing on Rare Diseases

The Senate Committee on the Budget will [host a hearing](#), "No Rights to Speak of: The Economic Harms of Restricting Reproductive Freedom," on Feb. 28, 2024. The same day, the Senate Committee on Armed Services' Subcommittee on Personnel will [host a hearing](#) to receive testimony on traumatic brain injury and blast exposure care.

The House Committee on Energy and Commerce's (E&C) Subcommittee on Health will hold a hearing, "[Legislative Proposals to Support Patients with Rare Diseases](#)," on Feb. 29, 2024, to examine 18 draft measures and introduced bills. Several of the measures under consideration specifically relate to pediatric rare diseases, including legislation to reauthorize the FDA's Pediatric Rare Disease Priority Review Voucher (PRV) Program, which expires on Sept. 30, 2024. A draft measure introduced by Rep. Brett Guthrie (R-Ky.), tentatively titled the Patient Access Act, would permit Cell and Gene Therapy (CGT) Access Model manufacturers to cover travel, lodging, meals and other related expenses for patients staying at treatment centers starting on Jan. 1, 2025. In addition, the Accelerating Kids Access to Care Act (H.R. 4758) would allow certain qualifying out-of-state pediatric providers to enroll in a patient's state Medicaid program as participating providers under certain circumstances. The [committee's website](#) includes a full list of legislation to be discussed.

Potential Health Reauthorizations; Health Extenders in Spending Measures

While an agreement has not yet been announced and no legislative text has been made publicly available, Congress is finalizing the details of a healthcare package that may be included in the legislative vehicle for the FY 2024 U.S. Department of Labor (DOL), HHS, U.S. Department of Education and Related Agencies (Labor-HHS) appropriations bill or an upcoming stopgap measure.

Some legislators had hoped that a larger, more sweeping health package – one containing controversial site neutral payment policies, provider transparency measures and Pharmacy Benefit Manager (PBM) reforms – might gain traction, but it is likely that a consensus health extender package will be more limited. The more extensive provisions are likely to move when Congress must address telehealth extensions and other priorities at the end of the year.

At a minimum, the health package will likely include funding for essential programs – specifically, the Community Health Centers (CHC) program, National Health Services Corps (NHSC), Teaching Health Center Graduate Medical Education Program (THCGME) and Special Diabetes Programs (SDP) – that would otherwise run out of funding once the upcoming deadlines pass. Exact funding levels and whether such programs will see full reauthorizations or temporary extenders are still up in the air. For example, for CHCs, House-passed legislation would fund the program at \$4.4 billion through 2025, a 10 percent increase, while the Senate Committee on Health, Education, Labor and Pension's (HELP) legislation would fund CHC programs through 2026 at \$17.4 billion.

Other policies likely to be included in the health package include an extended delay to the implementation of \$8 billion in annual cuts to Medicaid Disproportionate Share Hospitals (DSHs), at least temporarily. Additionally, there may be a partial, temporary fix to the 3.37 percent cut to the Medicare Physician Fee Schedule (MPFS) conversion factor (CF) that took effect on Jan. 1, 2024. This fix would likely be prospective – applicable only to payment rates going forward – rather than a retroactive fix applicable to all claims paid at the lower rate since it took effect. A limited number of new provisions are also possible, such as reauthorization of the SUPPORT Act.



House Republicans Compete to Fill House E&C Committee Vacancy

Since former Rep. Bill Johnson (R-Ohio) stepped down in January 2024 to become president of Youngstown State University, his seat on the House E&C Committee has been vacant. Freshman Reps. Russell Fry (R-S.C.), Brandon Williams (R-N.Y.), John James (R-Mich.) and Nick Langworthy (R-N.Y.) are campaigning for the seat. There is no deadline to fill the vacancy.

Ranking Member Cassidy Releases Report on Health Data Privacy

Senate Committee on HELP Ranking Member Bill Cassidy (R-La.) released a report on Feb. 21, 2024, "[Strengthening Health Data Privacy for Americans: Addressing the Challenges of the Modern Era](#)," that explored policy options to reform existing health data and privacy laws, as well as proposals to implement new health privacy protections in response to new technologies. The report, which is based on feedback received from a September 2023 [request for information \(RFI\)](#), recommends Congress consider the following actions:

- require HHS to provide clear guidance on how the "minimum necessary" standard aligns with other regulatory requirements as mandated by the 21st Century Cures Act
- define which requests for copies of personal health information (PHI) are eligible for the "patient rate"
- ensure parity across specific types of health information (e.g., no unique standards for reproductive health records and substance use disorder treatment records)
- address gaps in privacy protections in the Health Insurance Portability and Accountability Act (HIPAA) "gray area" (e.g., for wearable devices and software applications), using a "federal floor" model similar to HIPAA
- implement more stringent protections for direct-to-consumer (DTC) companies that collect genetic data; expand research protections to genetic data collected by DTC genetic testing entities
- address risk of artificial intelligence (AI) technology re-identifying personal health information; consider requiring patient compensation for sharing their identifiable data
- create a robust, modernized framework to safeguard against unauthorized disclosure of health data with Office for Civil Rights (OCR) – not the Federal Trade Commission (FTC) – as the primary enforcement body

House Oversight Democrats Launch Investigation on Drug Shortages

Last week, Democrats on the House Committee on Oversight and Accountability, led by Ranking Member Jamie Raskin (D-Md.), launched an investigation into domestic drug shortages by sending letters to three drug manufacturers. The letters request that the companies provide by March 6, 2024, "a briefing and information prompted by ongoing shortages of a number of cancer drugs, including carboplatin, cisplatin, and methotrexate, the antibiotic amoxicillin, and stimulant medications." This investigation builds upon a previous investigation on drug pricing practices that was initiated by the committee in 2019.

House E&C Democrats Press FDA on Overdue Clinical Trial Diversity Guidance

The Food and Drug Omnibus Reform Act of 2022 (FDORA) requires drug and medical device manufacturers to submit diversity action plans to the FDA ahead of certain clinical trials. FDORA directed FDA to publish draft guidance on the format and content of such diversity action plans to implement this requirement, with a statutory deadline of Dec. 29, 2023. Despite this deadline, FDA has not yet issued the guidance.



In [a letter](#) sent to FDA Commissioner Robert M. Califf, MD, House E&C Committee Ranking Member Frank Pallone (D-N.J.), Subcommittee on Health Ranking Member Anna Eshoo (D-Calif.), and Subcommittee on Oversight and Investigations Ranking Member Kathy Castor (D-Fla.) called on the agency to "move forward with guidance to improve the diversity of populations represented in clinical trials."

Retirements

House Committee on Homeland Security Chair Mark Green (R-Tenn.) recently stated that he is "seriously reconsidering" his decision to retire, just weeks after making the announcement he would not seek reelection to Congress at the end of his 2024 term. Additionally, Rep.-elect Tom Suozzi (D-N.Y.) will be sworn in on Feb. 28, 2024 to fill the seat left vacant by former Rep. George Santos (R-N.Y.). Rep.-elect Suozzi previously held the seat for three terms, from 2017 to 2023. Rep.-elect Suozzi's victory will put the House balance of power at 219 Republicans to 213 Democrats, further narrowing the Republicans' already razor-thin majority.

REGULATORY UPDATES

Congress Responds to FDA FAQs on ACA Coverage of Preventive Services

On Jan. 22, 2024, the FDA released [FAQs](#) on Affordable Care Act (ACA) Implementation of certain provisions. Last week, several democratic members of Congress – including Sens. Elizabeth Warren (D-Mass.), Catherine Cortez Masto (D-Nev.) and Tina Smith (D-Minn.), along with Reps. Lois Frankel (D-Fla.), Ayanna Pressley (D-Mass.) and Kathy Manning (D-N.C.) – wrote a letter to several insurers urging compliance with the ACA's requirement to cover all FDA-approved contraceptives without cost-sharing, specifically urging the companies to immediately adopt the "therapeutic equivalent standard" the administration outlined in FAQs on Jan. 22, 2024. The policy requires that plans must cover without cost-sharing contraceptives with no generic equivalent, but, if generics exist, plans can choose to cover only one of those products if they've established an exceptions process.

CMS to Increase Baltimore Presence, Return to Work Updates

According to HHS staff, the Centers for Medicare & Medicaid Services (CMS) employees will be increasing their in-office presence starting in March 2024. Beginning on March 11, 2024, and contingent on employment type and location, CMS will ask employees to work in its Baltimore headquarters or regional offices more often, though specifics have not been named.

ARPA-H Funding for Women's Health Research and Development

First Lady Dr. Jill Biden [announced](#) that \$100 million in federal funding for research and development will go to a new women's health initiative. This funding will come from the Advanced Research Projects Agency for Health (ARPA-H) and is the first action of the Biden Administration's [Women's Health Research](#) initiative announced in November 2023. According to Dr. Biden, the initiative has a clear goal to "fundamentally change how [the] nation approaches and funds women's health research. Research on women's health has always been underfunded, many medical studies have focused on men and left women out, many of the medicine dosages, treatments, medical school textbooks, are based on men and their bodies – and that information doesn't always apply to women. There are big gaps in research on diseases and conditions that only affect women, that disproportionately affect women, or that affect women and men differently."



NIH Institute of Child Health and Human Development Webinar on Clinical Trial Diversity

As part of the Principles of Pediatric Clinical Pharmacology and Therapeutics lecture series, the National Institutes of Health (NIH) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) will hold a webinar, "Diversity in Clinical Trials: The Barriers and the Opportunities" on Feb. 28, 2024, from 12:00-1:00 p.m. ET. The webinar will cover topics, including "the role of representation in the evolution of health disparities, barriers associated with enrollment and retention, and the role of various disciplines to bridge the gaps of racial diversity in clinical trials." Visit the [webinar page](#) to learn more and register.

CMS to Hold Virtual Education Session on Interoperability and Prior Authorization Final Rule

As a follow-up to a January 2024 [final Prior Authorization rule](#) intended to enhance access to health information and streamline prior authorization processes, CMS' Office of Burden Reduction & Health Informatics will hold a virtual education session on March 26, 2024, on the rule. The education session is aimed at patients and clinicians, as well as administrative, health information technology and government affairs professionals. A [link to register](#) for the education session is available.

CMS Upcoming Webinar: Review of Best "Enrollee Advisory Committee (EAC)" Practices For Dual Eligibles

CMS will host [a webinar](#) on March 14, 2024, to discuss best practices for health plans serving dual eligible individuals, individuals who are enrolled in both Medicare and Medicaid. EACs are charged with improving access, coordination and equity of services for underserved populations. The webinar is intended for plans including Dual Eligible Special Needs Plans (D-SNPs), Medicare-Medicaid Plans (MMPs) and any other plan or provider organization wishing to better incorporate health equity into enrollee governance practices.