



HK Health Dose: Feb. 25, 2025

A weekly dose of healthcare policy news

Looking Ahead

This week, the U.S. House of Representatives will vote on the budget resolution advanced by the House Budget Committee two weeks ago. The House budget resolution allows for \$4.5 trillion in tax cuts, which will be offset by \$2 trillion in funding reductions to federal programs such as Medicaid. The vote comes one week after President Donald Trump offered his support for House Speaker Mike Johnson's (R-La.) plan to pass a single, all-encompassing reconciliation package, instead of the two reconciliation bills preferred by U.S. Senate leaders.

Congressional appropriations leaders have yet to agree on topline funding numbers for Fiscal Year (FY) 2025, with Democratic leaders insisting any agreement include requirements that President Trump distribute money appropriated by Congress in light of controversy around a Jan. 29, 2025 memorandum order freezing distributions of federal assistance. Republican leaders are not amenable to those restrictions, noting that they don't want to tie President Trump's hands. A continuing resolution (CR) is likely. Government funding will run out on March 14, 2025.

Hearings/Meetings This Week

The House Committee on Energy and Commerce Subcommittee on Health will [hold a hearing](#) on Feb. 26, 2025 at 10 a.m. entitled, "An Examination of How Reining in PBMs (Pharmacy Benefit Managers) Will Drive Competition and Lower Costs for Patients." Witnesses include experts from nonprofit public policy organizations and a pharmacy owner.

The Senate Special Committee on Aging will hold a [hold a hearing](#) on Feb. 26, 2025 at 3:30 p.m. entitled, "Combating the Opioid Epidemic."

The Medicaid and CHIP Payment and Access Committee (MACPAC) is set to meet this week to discuss key topics, including state supplemental and directed payments, substance use disorder treatment and the prior authorization process. [Registration for this meeting](#) is available online.

Week in Review

The Senate passed a budget resolution on Feb. 21, 2025 that would allow for more than \$340 billion in new spending on defense, immigration and energy policies fully offset by reductions in spending on other programs. Passage of the budget resolution moves the Senate one step closer toward advancing the first reconciliation package. However, the fate of the Senate-passed budget resolution is dependent on the actions of the House. The two chambers must pass the same resolution in order for committees to begin drafting the legislative text for the final reconciliation package.

ADMINISTRATIVE UPDATES

Executive Order Updates

The Trump Administration has continued to release wide-ranging Executive Orders (EOs). For real time updates, see our ["Trump's 2025 Executive Orders: Updates and Summaries"](#) landing page online.

Recent EOs issued by President Trump with healthcare impacts include:

- Feb. 14, 2025 EO entitled, ["Keeping Education Accessible and Ending COVID-19 Vaccine Mandates in Schools."](#) The EO seeks to limit federal funding for educational institutions that require students to receive vaccinations as a condition of their attendance. The EO directs the secretary of education and the secretary of the U.S. Health and Human Services (HHS) to provide plans to end required vaccinations by schools within 90 days.



- Feb. 18, 2025 EO entitled, "[Expanding Access to In Vitro Fertilization](#)." The EO directs the assistant to the president for domestic policy to provide a list of recommendations to protect access to and lower the costs of in vitro fertilization (IVF) within 90 days but makes no immediate changes to the availability or cost of IVF services. President Trump previously said his administration would require health insurance companies to cover all costs associated with IVF.
- Feb. 19, 2025 EO entitled "[Commencing the Reduction of the Federal Bureaucracy](#)." The EO directs agency and department heads to "terminate" the HHS Secretary's Advisory Committee on Long Covid and the Centers for Medicare & Medicaid Services' (CMS) Health Equity Advisory Committee.

The White House Announces Request for Information (RFI) on Artificial Intelligence (AI)

The White House announced a RFI on Feb. 25, 2025, seeking public comment from interested parties on actions that should be included in a [new action plan on AI](#). Interested parties are invited to submit public comments through 11:59 p.m. on March 15, 2025. Responses will inform efforts being led by the Office of Science and Technology Policy (OSTP) to establish policies for sustaining and enhancing U.S. efforts on AI. President Trump previously rescinded EO 14110 entitled, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," which was issued by the previous administration.

HHS Rescinds Previous Administration's Guidance from the Office of Civil Rights (OCR)

On Feb. 19, 2025, HHS [announced the rescission](#) of a 2022 guidance document issued by the previous administration entitled, "HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy." The [2022 guidance](#) stated that prohibitions against discrimination outlined in Section 1557 of the Affordable Care Act (ACA) includes a prohibition on discrimination on the basis of gender identity by entities receiving federal healthcare funding. The rescission follows the issuance of EO 14187 on Jan. 28, 2025 related to gender-affirming care for children.

HHS also [released new guidance](#) outlining the imposition of new, more narrow definitions for words including "sex," "female," "male" and other gender-related definitions.

Secretary Kennedy Plans to Revamp HHS Advisory Committees

Despite making assurances to members prior to his confirmation that he would leave unchanged the membership of various vaccine-related HHS advisory committees, Secretary Robert F. Kennedy said he intends to remove members of certain advisory committees with ties to the pharmaceutical industry, which he stated are 'conflicts of interest.' Major committees such as the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) may be impacted. Any change to federal advisory committees may have an impact on the vaccines recommended to the public or their availability.

Potential Tariffs on Pharmaceutical Products by April 2, 2025

President Trump indicated he plans to impose 25 percent tariffs "or higher" on pharmaceutical products as soon as April 2, 2025. He did not say whether exceptions would be considered but stated that companies should consider shifting their manufacturing facilities to the U.S. if they want to avoid tariffs being levied on their products. The 25 percent tariffs will be in addition to the 10 percent tariffs President Trump imposed on China for failure to stop flows of illicit fentanyl into the U.S. While Canada and Mexico worked with the Trump Administration to delay tariffs from being imposed on their respective nations earlier this year, President Trump indicated he plans to move ahead with tariffs on both nations. While there is still time for the nations to reach another agreement with the administration to further delay the tariffs, it seems unlikely President Trump is willing to make similar agreements with China before the April 2, 2025 deadline. China did not receive a delay in the imposition of tariffs earlier this year.

Personnel Updates

- John Squires is expected to be nominated as director of the U.S. Patent and Trademark Office (USPTO). The USPTO plays a critical role in protecting intellectual property and exclusivity, particularly for pharmaceutical products. Mr.



Squires previously worked at several investment firms and law firms, with his practice focused on emerging technologies.

- Kyle Diamantas is expected to be announced as the U.S. Food and Drug Administration's (FDA) new deputy commissioner for human foods. He is currently a special assistant in the FDA commissioner's office. The previous deputy commissioner for human foods resigned earlier in February 2025, following the firings of employees across the FDA.

LEGISLATIVE UPDATES

Reconciliation

The Senate took the first step toward passing a budget reconciliation package by passing Senate Budget Committee Chairman Lindsey Graham's (R-S.C.) budget resolution on Feb. 21, 2025. The budget resolution is an outline of increases and decreases in spending that will be included in the final package. Chairman Graham's budget resolution requires that the Senate Committee on Finance and the Senate Committee on Health, Education, Labor and Pensions (HELP) report changes in law that reduce the deficit by at least \$1 billion over the next 10 years and directs \$340 million in new spending for defense, immigration and energy policies. The budget resolution, however, must also pass the House before additional action may be taken at the committee level to begin drafting legislative language for the reconciliation package.

In the House, Speaker Johnson's reconciliation plan continues to focus on passage of a single, all-encompassing reconciliation package, including \$4.5 trillion in tax cuts, immigration changes, energy policies and defense enhancements offset by spending reductions. The House's budget resolution calls for \$880 billion in spending reductions over the next decade to come from the House Committee on Energy and Commerce. This indicates a significant amount of savings are expected to come from changes to healthcare programs such as Medicaid. The vote on the House floor this week will be instructive, as members of the Republican conference appear to remain far apart on what a final reconciliation package should include. Moderate Republicans, including those with home to large populations of beneficiaries who depend upon Medicaid for their health coverage and those facing potentially challenging re-election races, have shared concerns about passing a budget reconciliation package that dramatically reduces benefits for beneficiaries, while other parts of the conference are concerned the budget resolution does not reduce spending by enough.

In addition to the House considering its budget resolution on the floor, House Majority Leader Steve Scalise (R-La.) highlighted [several potential rules](#) related to energy, financial services and environmental policies that Republicans may seek to roll-back using the Congressional Review Act (CRA).

The House will also need to quickly turn its attention to the status of government funding. Discussions among top appropriators have reportedly not progressed, with discussions around passing a short-term or longer, six-month CR gaining steam.

Retirements

On Feb. 20, 2025, Sen. Mitch McConnell (R-Ky.) announced he will not seek re-election in 2026. By the end of his tenure, Sen. McConnell will have served 42 years, with 16 years as Senate Majority Leader, making him the longest-serving Senate leader in American history. In his announcement, Sen. McConnell noted that he has "some unfinished business to attend to," signaling his investment in getting several Republican priorities across the finish line before he leaves office. Following the announcement, Sen. McConnell's former legal counsel and former Kentucky Attorney General Daniel Cameron positioned himself to run in the race to replace Sen. McConnell as an "America First" and Trump-allied contender. Although Cameron is the only one to officially announce his bid so far, U.S. Rep. Andy Barr (R-Ky.) has said he's considering entering the race.

Sen. Tina Smith (D-Minn.) announced earlier this month she would also not seek re-election when her current term ends. Sen. Smith has championed mental health parity, reducing prescription drug costs and improving access to reproductive care. Minnesota Lieutenant Gov. Peggy Flanagan announced that she would enter the race to replace Sen. Smith. Additional candidates may include Minnesota Gov. Tim Walz (D-Minn.) and Rep. Angie Craig (D-Minn.).



REGULATORY UPDATES

FDA Quietly Rehires Previously Fired Employees

Though the number is not yet confirmed, the FDA moved over the weekend to rehire a number of employees who were dismissed, following instructions from The White House to reduce the size of federal agencies, and instructions from the Department of Government Efficiency (DOGE), who visited several HHS offices over the past month in search of waste, fraud and abuse. The re-hirings seem in some cases to be broad. All 12 of the employees fired, who were tasked with reviewing surgical and infection control devices, were rehired. Further, two of the three individuals fired in FDA's digital health office were rehired, in addition to several individuals overseeing AI-enabled imaging devices. It is yet to be seen whether this indicates other agencies will follow suit. Many of the rehires were of employees whose work is funded wholly or in part by user fees paid by companies with products regulated by the FDA, including medical devices.

CMS Announces Public Engagement Events for the Second Cycle of Negotiations

CMS will host a series of public engagement events this spring as part of the [Medicare Drug Price Negotiation Program](#). The virtual public engagement events will provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, such as clinicians and researchers, to share input relevant to the drugs selected for the second cycle of negotiations.

FDA Update on Semaglutide Shortage

The FDA announced on Feb. 21, 2025 that semaglutide injection products, such as Wegovy and Ozempic, are no longer deemed to be in shortage. Semaglutide injection products may be used to treat cardiovascular disease, diabetes and certain other health conditions, but have been in short supply since 2022. While semaglutide injection products were deemed to be in shortage, many entities began legally producing similar products and selling them at lower prices, including compounding entities and direct-to-consumer companies. Brand name drug manufacturers have raised concerns about the quality and safety of these products. However, now that the semaglutide injection products are no longer deemed to be in shortage, many entities are no longer legally permitted to manufacture the products without following additional rules and regulations.

Other drug products similar to semaglutide injections remain in shortage, including dulaglutide injection and liraglutide injection products.

JUDICIAL UPDATES

Attorneys with the U.S. Department of Justice (DOJ) defended multiple lawsuits in courts across the U.S. that started during the Biden Administration. It is notable the DOJ is standing by these cases, which are outlined below, because the DOJ previously opted to withdraw from other cases brought by the previous administration, including a case regarding a Tennessee law related to gender affirming care.

- **Laboratory Developed Tests (LDTs):** On Feb. 20, 2025, the DOJ argued in favor of maintaining an FDA final rule to bring LDTs under FDA's authority. The final rule at issue was published in July 2024 following unsuccessful attempts over several congresses to pass comprehensive legislation to give the FDA the authority to regulate LDTs. Two organizations representing laboratories and laboratory staff challenged the legality of the final rule, arguing the FDA exceeded its statutory authority. A ruling in the case is expected soon.
- **Inflation Reduction Act (IRA):** The DOJ filed a brief in support of the Medicare Drug Price Negotiation Program, defending the program against a lawsuit brought by a major pharmaceutical company. Oral arguments in a separate, similar lawsuit brought by a different pharmaceutical company will be heard in April 2025.
- **National Institutes of Health (NIH) Indirect Cost Rates:** On Feb. 21, 2025, a federal judge extended the temporary pause on implementation of an order to reduce NIH indirect cost rates until the judge makes a permanent decision in the case.
- **U.S. Preventive Services Task Force (USPSTF) Braidwood Lawsuit:** The Trump Administration submitted its first brief in a U.S. Supreme Court case, which will determine the constitutionality of the USPSTF. The



case, set to be heard on April 21, 2025, stems from a lower court ruling that deemed the USPSTF unconstitutional, arguing that its members exercise legislative-like authority without presidential appointment or Senate confirmation. The Trump Administration has aligned with predecessors from the previous administration in defending the ACA preventive services mandate for no-cost access to certain services. However, the Trump Administration takes a step further in its legal arguments, particularly regarding the authority of the HHS secretary. Although the Biden Administration previously contended that the USPSTF's authority derives from the HHS secretary's supervisory role, the Trump Administration asserts that the HHS secretary holds full authority over the task force, including final decision-making power over its membership, recommendations and areas of study.