



HK Health Dose: Feb. 19, 2025

A weekly dose of healthcare policy news

The U.S. House of Representatives is in recess, while the U.S. Senate remained in session following the Presidents' Day holiday. The Senate is expected to continue confirming cabinet secretaries and will also consider the budget resolution advanced by the Senate Committee on the Budget. Additionally, the Senate Committee on Homeland Security and Governmental Affairs will hold a nomination hearing for Dan Bishop, the nominee for deputy director of the Office of Management and Budget (OMB). Meanwhile, the Senate Committee on the Judiciary will mark up the HALT Fentanyl Act, which passed the House earlier in February 2025. The act would make the temporary class-wide scheduling order for fentanyl-related substances permanent.

LEGISLATIVE UPDATES

Senate Confirms Robert F. Kennedy Jr. as HHS Secretary

In a 52-48 Senate vote, Robert F. Kennedy Jr. was confirmed as the next U.S. Department of Health and Human Services (HHS) Secretary. The Senate will now move forward on the confirmation processes for Mehmet Oz, M.D., to be administrator of the Centers for Medicare & Medicaid Services (CMS), Jay Bhattacharya, M.D., Ph.D., to serve as director of the National Institutes of Health (NIH) and Marty Makary, M.D., MPH, FACS, to serve as the U.S. Food and Drug Administration (FDA) commissioner. Confirmation hearings in the Senate Finance Committee could be scheduled as early as March 2025.

Congressional Budget Process/Markup of the Fiscal Year (FY) 2025 Budget Resolutions

Major budget legislation is pending before U.S. Congress, and current political dynamics are creating challenges for these bills.

First, although the FY started Oct. 1, 2024, the government is still operating under a temporary spending measure that expires March 14, 2025. Agreement on how to resolve the 12 unfinished bills that fund the government remains elusive, and time is quickly running out. It is unclear if the impasse can be resolved by agreeing to funding levels for the programs in each bill, enacting a full-year formulaic funding measure (a "continuing resolution"), or possibly stumbling into a government shutdown. As the FY 2025 process plays out, the Trump Administration will need to propose a FY 2026 budget. This is usually delayed in the case of a newly installed president, as budget proposals are typically released by the president in February or March each year. Extensive cuts to social programs are widely expected to be part of this budget proposal.

The second major budgetary item is known as a "budget reconciliation" bill, which is a package of changes to spending and revenues that, if properly crafted, can be passed in the Senate with only 51 votes. Both the House and Senate have advanced their iterations of a budget resolution, with the Senate voting to advance its budget resolution on Feb. 18, 2025, and additional action expected over the course of the next several days, including the 'vote-a-rama' which is a period when an unlimited number of amendments may be offered and teed up for votes. The Senate Committee on the Budget advanced its blueprint for a reconciliation bill focused on border security, the military and domestic energy production. To fully offset the \$85.5 billion package, the resolution outlines minimum savings to be achieved by each congressional committee. The resolution requires that both 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. The House's budget resolution calls for \$880 billion in savings over the next decade to come from the House Committee on Energy and Commerce.

Notably, the House and Senate have had difficulty agreeing on how to proceed with this legislation. Regardless of the process, the House and Senate have instructed their respective authorizing committees to cut Medicaid spending significantly to offset the cost of making the tax cuts from the Tax Cuts and Jobs Act permanent. The Medicaid target floors remain fluid at this point, and it is unclear how the Congressional Budget Office (CBO) will score a specific proposal, or which proposals might be considered extraneous in the Senate. The resolutions' final numbers are



merely a starting point or floor. Based on all reports, spending reductions are expected to go far deeper. Accordingly, it will be crucial to monitor which funding cuts Republicans may propose to support their policy priorities. Potential measures under consideration include, but are not limited to Medicaid work requirements, Medicaid per capita caps, consolidating and reducing Medicare payments for Graduate Medical Education at teaching hospitals, Medicare site-neutral payment reforms and limiting state taxes on healthcare providers.

The Trump Administration has established a Department of Government Efficiency (DOGE) within what was formerly the White House Digital Services Office. The DOGE is staffed by Elon Musk and a number of his former employees. DOGE has extensively intervened in the affairs of the U.S. Office of Personnel Management (OPM) and General Services Administration (GSA). This weekend, the DOGE fired numerous personnel at several HHS sub-agencies, including the CMS, FDA, the Administration for Strategic Preparedness and Response (ASPR) and the Health Resources and Services Administration (HRSA). Last week, as many as 1,500 employees at the NIH and 1,300 employees at the CDC were laid off, targeting mostly "probationary employees," a broad category that includes both new hires and long-time staffers who have recently changed position or title within the past one to two years. Legal challenges are expected.

AI in Public Health Legislation Introduced

Sens. Ted Budd (R-N.C.) and Ed Markey (D-Mass.) [introduced a bill](#) requiring the HHS secretary to develop a public health preparedness strategy and response to artificial intelligence (AI) threats. It has been referred to the Senate Committee on HELP.

Hearings This Week

On Feb. 19, 2025, at 10:15 a.m., the Senate Committee on the Judiciary [held a hearing](#) titled, "Children's Safety in the Digital Era: Strengthening Protections and Addressing Legal Gaps." Additionally, the Judiciary Committee will [markup](#) the HALT Fentanyl Act on Feb. 20, 2025, to amend the Controlled Substances Act to make the temporary class-wide scheduling order for fentanyl-related substances permanent.

ADMINISTRATIVE UPDATES

Executive Order (EO) Update

President Donald Trump has signed more than 60 executive orders (EOs), several of which are set to impact healthcare significantly. More EOs are expected. For real time updates, please view our [Trump's 2025 Executive Orders: Updates and Summaries landing page](#).

Notably, lawsuits continue to be filed against actions taken by the Trump Administration, including EOs and other administrative actions. Some of the most recent legal actions include:

- In response to President Trump's EO titled "Protecting Children from Chemical and Surgical Mutilation," two judges have paused actions related to the EO. The latest legal challenge arose from a group of three states and three physicians who provide care for transgender patients. The challenge mirrors a temporary restraining order (TRO) by a federal judge in Maryland, which halted actions related to the EO for 14 days. The pause will remain in place until the legal proceedings are resolved.
- Regarding the NIH guidance on indirect cost rates for grants, lawsuits challenging the guidance were quickly filed. Two federal courts issued TROs, blocking its implementation on Feb. 10, 2025. The issue of indirect costs will likely become a matter for legislative discussion going forward.

Make America Healthy Again Commission Established

On the same day that the Senate confirmed Secretary Kennedy to lead HHS, President Trump issued an EO establishing the Make America Healthy Again (MAHA) Commission, with Secretary Kennedy to serve as chair. The Commission will advise and assist the president in addressing the prevalence of chronic disease among children. The EO tasks a group of federal agency leaders to complete an initial 'Make Our Children Healthy Again' assessment within 100 days, which assesses the potential consequences of different classes of drugs, including those for weight loss and depression, certain



food ingredients and chemicals. This assessment will also evaluate existing federal programs related to exercise and nutrition and enhance data transparency.

The commission selected heads of the FDA, CDC and NIH, but didn't include the incoming CMS administrator as a member.

Key Directives for the Commission:

- Health agencies' role: Members include the secretaries of additional agencies and HHS subagencies. The Commission may hold public hearings and expert meetings to solicit feedback. CMS is not listed as an initial member, though the EO allows for additional appointees to be added.
- Agencies must prioritize reversing chronic diseases, including mental health disorders, obesity and diabetes. The NIH is directed to focus on why Americans are getting sick, promote open-source research and collaborate with farmers to ensure access to healthy, affordable food.
- Expanded treatment options: Agencies are tasked with ensuring a wider range of treatments, including flexible health insurance coverage.
- Commission's first mission: Address childhood chronic diseases by studying causes, launching public education efforts and providing policy recommendations.

Timeline:

- Within 100 days: The Commission must submit a Make Our Children Healthy Again assessment, comparing U.S. childhood chronic disease rates with other countries and identifying best prevention practices.
- Within 180 days: A strategy to restructure the government's response to childhood chronic diseases must be developed.

Secretary Kennedy: First Week at HHS

Secretary Kennedy's first days in office have focused on carrying out directives from The White House to reduce the federal workforce at healthcare agencies, including the CDC, FDA and NIH. On Feb. 13, 2025, the OPM sent a memorandum advising federal agencies to terminate employees in their first and second year of employment with the federal government. A few days later, this materialized through the termination of thousands of staff at federal healthcare agencies. Certain senior level officials, including deputy commissioner for human foods at the FDA, resigned.

Following his confirmation, Secretary Kennedy also noted that President Trump wants the HHS to conduct a study on the safety of mifepristone, medication that may be taken to reverse an abortion. President Trump previously said on the campaign trail that he also wanted his administration to complete a study on gender affirming care for children, including the provision of hormones. Both studies are possible with Secretary Kennedy now installed.

Personnel Updates

- Gary Andres has been nominated to serve as the HHS assistant secretary for legislation. Mr. Andres is currently Republican staff director for the House Budget Committee. He previously served in the George W. Bush and George H.W. Bush Administrations.
- Michael Stuart, a West Virginia state senator, has been nominated to be the HHS general counsel.
- Gustav Chiarello III was tapped to serve as HHS assistant secretary for financial resources.
- Dr. Brett Giroir, who previously served as assistant secretary of the HHS and was a member of The White House Coronavirus Task Force and The White House's coronavirus testing czar, has joined the HHS as an unpaid policy advisor. He will advise Secretary Kennedy on infectious diseases.
- Clark Minor is reportedly joining the HHS as chief information officer, where he will lead HHS efforts on information security, cybersecurity, privacy and records management. He joins the HHS from a leading technology consulting company.



- Terry Cole, the secretary of public safety and homeland security for the commonwealth of Virginia, has been nominated to be administrator of the U.S. Drug Enforcement Administration (DEA). President Trump's first pick, Sheriff Chad Chronister, withdrew from consideration in December 2024.
- Tom Engels will return to the HRSA, a role he held for two years in the first Trump Administration.
- Peter Nelson, formerly with the Center for American Experiment, will lead the Center for Consumer Information and Insurance Oversight, which has jurisdiction over the Affordable Care Act (ACA).

Also as discussed above, President Trump's nominees to lead the FDA and NIH are beginning to meet with key senators ahead of their confirmation hearings. Dr. Martin Makary, who has been nominated to be FDA commissioner, has begun meeting with members of the Senate Committee on HELP. Dr. Jayanta "Jay" Bhattacharya also met with Sen. Patty Murray (D-Wash.) to discuss how he would protect biomedical research if confirmed. Hearing dates for both nominees have not been announced but are expected within the coming weeks.

REGULATORY UPDATES

On Feb. 11, 2025, the Office of Information and Regulatory Affairs (OIRA) published a [proposed rule](#) 'under consideration' related to the ACA and program integrity. While few details about the proposed rule are available at this time, the proposed rule could have significant healthcare impacts on beneficiary care and future plans offered on the exchanges. The rule could provide a vehicle for limitations on access to gender-affirming care for beneficiaries who receive their health coverage through the marketplaces.

The proposed rule under consideration mirrors efforts announced on Feb. 14, 2025, to reduce federal funding for navigator programs, which help beneficiaries find and enroll in plans available under the ACA. The CMS announced it would reduce federal funding for navigator programs from \$98 million to \$10 million, stating that the reduction will result in savings for beneficiaries in the form of lower premiums.

The rule may also include similar limitations [like those finalized by President Trump in November 2017](#), which shortened the duration of and eligibility for special enrollment periods.

DEA and HHS Controlled Substance Prescribing Rules Delayed

On Jan. 17, 2025, the DEA and HHS published two final rules related to the practice of telemedicine titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients."

These final rules were scheduled to become final on Feb. 18, 2025. In accordance with the Presidential Memorandum of Jan. 20, 2025, titled "Regulatory Freeze Pending Review," the DEA and HHS are [delaying the effective dates](#) of these two final rules to March 21, 2025, and are soliciting public comments specifically regarding this delayed effective date. Comments on the new effective date are due on Feb. 28, 2025.