



HK Health Dose: April 2, 2025

A weekly dose of healthcare policy news

Looking Ahead: A Budget Resolution and HHS Reorganization

The U.S. Senate is expected to advance a compromise budget resolution at the end of this week, with text being released imminently. The Senate and the U.S. House of Representatives must pass the same budget resolution to enable committees of jurisdiction to start writing the legislative text for the reconciliation package, making this week a critical juncture as the Republican Conference seeks to pass a reconciliation package by the end of the year.

Meanwhile, federal agencies and personnel await additional information following the reorganization of the U.S. Department of Health and Human Services (HHS), which was announced on March 27, 2025.

In addition, during the lead up to April 2, 2025, which President Donald Trump is calling "Liberation Day," details are expected on additional tariffs. Committees with healthcare jurisdiction are also expected to be active this week, with legislative hearings scheduled and the potential for markups of legislation.

Hearings This Week: Congressional Hearings on Health and Cybersecurity

The House Committee on Energy and Commerce Subcommittee on Health held a hearing entitled, "[Examining the FDA's Regulation of Over-the-Counter Monograph Drugs](#)" on April 1, 2025 at 10:15 a.m.

The House Committee on Energy and Commerce Subcommittee on Oversight and Investigations held a hearing entitled, "[Aging Technology, Emerging Threats: Examining Cybersecurity Vulnerabilities in Legacy Medical Devices](#)" on April 1, 2025 at 10:30 a.m.

The House Committee on Energy and Commerce will hold a full committee mark-up hearing on April 8, 2025 at 10:15 a.m. During this hearing, 26 bills will be considered, including six related to healthcare that were non-controversial and advanced on a bipartisan basis by the Committee last Congress:

- [H.R. 1442](#), Youth Poisoning Protection Act
- [H.R. 973](#), Setting Consumer Standards for Lithium-Ion Batteries Act
- [H.R. 633](#), Tools to Address Known Exploitation by Immobilizing Technological Deepfakes on Websites and Networks (TAKE IT DOWN) Act
- [H.R. 1664](#), Deploying American Blockchains Act of 2025
- [H.R. 2444](#), Promoting Resilient Supply Chains Act of 2025
- [H.R. 2480](#), Securing Semiconductor Supply Chains Act
- [H.R. 1402](#), Transparency in Charges for Key Events Ticketing (TICKET) Act
- [H.R. 1479](#), Hotel Fees Transparency Act of 2025
- [H.R. 859](#), Informing Consumers About Smart Devices Act
- [H.R. 2481](#), Romance Scam Prevention Act
- [H.R. 617](#), American Music Tourism Act of 2025
- [H. R. 2269](#), Wastewater Infrastructure Pollution Prevention and Environmental Safety (WIPPES) Act
- [H.R. 906](#), Foreign Adversary Communications Transparency (FACT) Act
- [H.R. 2449](#), Future Uses of Technology Upholding Reliable and Enhanced (FUTURE) Networks Act
- [H.R. 2458](#), Secure Space Act
- [H.R. 866](#), Removing Our Unsecure Technologies to Ensure Reliability and Security (ROUTERS) Act
- [H.R. 2482](#), National Telecommunications and Information Administration (NTIA) Reauthorization Act of 2025



- [H.R. 2399](#), Rural Broadband Protection Act of 2025
- [H.R. 2037](#), OpenRAN Outreach Act
- [H.R. 1717](#), Communications Security Act H.R. 2483, SUPPORT for Patients and Communities Reauthorization Act of 2025
- [H.R. 2483](#), SUPPORT for Patients and Communities Reauthorization Act of 2025
- [H.R. 1520](#), Charlotte Woodward Organ Transplant Discrimination Prevention Act
- [H.R. 2319](#), Women and Lung Cancer Research and Preventive Services Act of 2025
- [H.R. 1669](#), To amend the Public Health Service Act to reauthorize the Stop, Observe, Ask, and Respond to Health and Wellness Training Program
- [H.R. 1082](#), Shandra Eisenga Human Cell and Tissue Product Safety Act
- [H.R. 2484](#), Seniors' Access to Critical Medications Act

The House Committee on Education & the Workforce will hold a hearing entitled, "[A Healthy Workforce: Expanding Access and Affordability in Employer-Sponsored Health Care](#)" on April 2, 2025 at 2 p.m.

HHS Secretary Robert F. Kennedy has been [invited](#) to testify before the Senate Committee on Health, Education, Labor and Pensions (HELP) on April 10, 2025, during a hearing titled "An Update on the Restructuring of the Department of Health and Human Services." The hearing will begin at 10:00 a.m. ET in room 430 of the Dirksen Senate Office Building. The letter sent by Chair Sen. Bill Cassidy (R-La.) and Ranking Member Sen. Bernie Sanders (I-Va.) refers to commitments then-nominee Kennedy made to come before the HELP Committee on a quarterly basis upon request from the chair. Secretary Kennedy has, at the time of writing, not publicly confirmed his attendance at the hearing.

It is expected that additional committee activity, including hearings and markups, will be announced for next week in the coming days.

Week in Review: Senate Confirms Key Healthcare Nominees

Key healthcare nominees were confirmed by the Senate, including Dr. Jayanta Bhattacharya to be director of the National Institutes of Health (NIH) and Dr. Martin Makary to be commissioner of the U.S. Food and Drug Administration (FDA). Dr. Mehmet Oz, who has been nominated to be administrator of the Centers for Medicare & Medicaid Services (CMS), is awaiting consideration of his nomination on the full Senate floor.

ADMINISTRATIVE UPDATES

Executive Order Updates

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

Personnel Updates

- Thomas M. Bell has been nominated to be HHS Inspector General (IG). He currently serves as General Counsel to the House Republican Conference and previously served as chief of staff for the former HHS Secretary Alex Azar.
- Dr. Brian Christine has been nominated to be assistant secretary for health. Dr. Christine is from Alabama and focuses his medical practice in urology.
- Alex Adams has been nominated to be assistant secretary for family support at the HHS. He currently serves as director of the Idaho Department of Health and Welfare. Dr. Peter Marks, director of the Center for Biologics Evaluation and Research (CBER) at the FDA, stated in a letter addressed to Acting FDA Commissioner Sara Brenner that effective April 5, 2025, he will resign and retire from federal service.



LEGISLATIVE UPDATES

Senate to Take Up Compromise Budget Resolution This Week

The Senate is expected to consider an updated budget resolution that bridges the gap in spending cut targets between the two different versions passed by each chamber. The House and Senate must pass the same budget resolution in order to unlock the budget reconciliation package, which allows committees of jurisdiction to begin drafting legislative language that determines how spending reductions or increases will be accomplished.

The compromise budget resolution currently under consideration will set two spending reduction floors. Rather than align Senate and House committees behind the same target spending reductions or increases, Senate committees will be directed to find a different, smaller spending reduction target than House committees. Senate committees are expected to be directed to find a minimum of \$1 billion in savings, while House committees will be directed to identify over \$1.5 trillion. The bifurcated spending targets for each chamber would allow the House Freedom Caucus and other Republicans who are supportive of finding a higher level of savings to pursue larger reductions to offset the cost of extending tax cuts from the Tax Cuts and Jobs Act (TCJA).

If passed, the compromise budget resolution will allow committees to begin drafting legislative language to achieve spending targets. Committees may identify higher levels of savings than they are directed to find by the budget resolution, indicating that the extent of potential changes to healthcare programs will largely be driven by the size of tax cuts pursued by House committees.

Further, a factor that may necessitate quick action by Congress is the debt limit. The debt limit is the maximum amount of debt the U.S. Department of the Treasury can issue to allow the federal government to pay bills it has already incurred. The debt limit is set by statute and was most recently suspended by Congress through Jan. 1, 2025. Since Jan. 1, 2025, the U.S. Treasury has undertaken certain measures to ensure the federal government continues payments and remains solvent. However, there is a date often referred to as the 'x-date' by which the government will no longer be able to take measures to avoid reaching the debt limit.

The Congressional Budget Office (CBO) released its estimate of when the x-date may occur on March 26, 2025, and found that the x-date will likely fall sometime in August or September of 2025. If the debt limit is not suspended or raised by the x-date, the government will be unable to meet its financial obligations. There is prevailing thought that the x-date may occur earlier, necessitating action sooner rather than later, pending funding the U.S. Treasury receives or outlays it makes following the April 15, 2025 tax deadline.

340B Working Group Expansion

Sen. Jerry Moran (R-Kan.) [announced several new members](#) of the Senate 340B bipartisan working group on March 21, 2025, including Sens. Tim Kaine (D-Va.), Markwayne Mullin (R-Okla.) and John Hickenlooper (D-Colo.) Following the latest developments in the restructuring of the HHS, it is likely that administration of the 340B Program will go to CMS. Since the program was originally founded to address unintended consequences of the Omnibus Budget Reconciliation Act (OBRA) of 1990, it is feasible that the program will be placed under one of several sub-agencies in CMS.

Previously, with 340B under the Health Resources and Services Administration (HRSA), 340B has primarily been administered through guidance due to the agency's limited rulemaking authority, which has led to numerous court cases. However, if 340B is administered through CMS, there is potential for more enforceability through greater regulatory leeway.

In the calendar year (CY) 2018 Medicare hospital Outpatient Prospective Payment System (OPPS) and the Medicare ambulatory surgical center (ASC) Final Rule, CMS adjusted the payment rate for 340B drugs to ASP minus 22.5 percent.

However, due to the lack of a survey by HHS, the U.S. Supreme Court ruled this payment rule unconstitutional. If CMS gains full authority over the program, there may be an opportunity to revisit this rule and possibly rewrite it.



Senate Finance Committee Democratic Staff Release Investigation into Tax Practices of Major Pharma Co.

Democratic staff on the Senate Committee on Finance released an [eight-page report](#) on March 27, 2025, detailing their findings on how a major pharmaceutical company utilizes certain tax provisions to limit the amount of profits taxable in the United States. The committee staff refer to a tax process known as 'round-tripping,' which occurs when a U.S. company treats income from U.S. sales as foreign for tax purposes and therefore does not need to pay taxes on those profits to the Treasury. Staff reviewed tax return data for the major pharmaceutical company in 2019, two years after passage of the TCJA, which contained a provision that reduced the tax rate on foreign income to 10.5 percent.

Ranking Member Ron Wyden has long advocated for changes in the tax structure to ensure multinational corporations, particularly those in the pharmaceutical industry, pay a higher tax rate. The March 27, 2025 report follows several other Committee staff reports on the tax practices of other pharmaceutical companies. This report will likely be heavily referred to as conversations about extending the tax cuts from the TCJA continue, especially as the healthcare committees of jurisdiction look for ways to offset the costs of extending or including new tax cuts in the reconciliation package.

REGULATORY UPDATES

HHS Grants Terminated

Last week, [HHS canceled](#) over \$12 billion in grants to state and local healthcare departments. Over \$11 billion of those cuts will go back to the Centers for Disease Control and Prevention (CDC) from grants that were largely focused on vaccines, HIV prevention and programs deemed related to diversity, equity and inclusion (DEI). Substance abuse, mental health, genetic sequencing and reproductive health were among the awards cut. Also clawed back includes funding allocated during the COVID-19 pandemic as part of several relief packages.

HHS Announces Plan to Reduce Federal Healthcare Workforce by 10,000

Secretary Robert F. Kennedy Jr. announced a sweeping reorganization of the HHS on March 27, 2025, which will include the consolidation of multiple major divisions and the elimination of more than 10,000 full time federal employees.

According to [a statement issued by the HHS](#), the agency's workforce will be reduced in size from 82,000 to 62,000, which will be reached through a combination of eliminating full-time employee positions and staff departures due to retirements or buy-outs. The HHS' current 28 divisions will be consolidated into 15. More information on the consolidation and changes in force are below:

- HHS will have a new assistant secretary for enforcement to provide oversight of the Departmental Appeals Board (DAB), Office of Medicare Hearings and Appeal (OMHA) and the Office for Civil Rights (OCR) to combat waste, fraud and abuse. Five of the HHS' 10 regional offices will close.
- The programs within the Administration for Community Living (ACL) that support older adults and people of all ages with disabilities will be split across the Administration for Children and Families (ACF), Office of the Assistant Secretary for Planning and Evaluation (ASPE), and CMS.
- A new entity called the Administration for a Healthy America (AHA) will be created, which will aim to "more efficiently coordinate chronic care and disease prevention programs," and harmonize health resources to low-income Americans. Included in that new division will be:
 - Office of the Assistant Secretary for Health (OASH)
 - HRSA
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
 - Agency for Toxic Substances and Disease Registry (ATSDR)
 - National Institute for Occupational Safety and Health (NIOSH)



- Other Divisions of AHA will include Primary Care, Maternal and Child Health, Mental Health, Environmental Health, HIV/AIDS and Workforce, with support of the U.S. Surgeon General and Policy team.
- HHS will combine the ASPE and Agency for Healthcare Research and Quality (AHRQ) into the Office of Strategy to conduct research that informs the secretary's policies and evaluates the effectiveness of the department's programs for a healthier America.
- The FDA will decrease its workforce by approximately 3,500 full-time employees, with a focus on streamlining operations and centralizing administrative functions. This reduction will not affect drug, medical device or food reviewers, nor will it impact inspectors.
- The CDC will decrease its workforce by approximately 2,400 employees, with a focus on returning to its core mission of preparing for and responding to epidemics and outbreaks. ASPR will be moved under CDC to enhance coordination of response efforts.
- The NIH will decrease its workforce by approximately 1,200 employees by centralizing procurement, human resources and communications across its 27 institutes and centers.
- The CMS originally reported decreasing its workforce by approximately 300 employees, with a focus on reducing minor duplication across the agency. However, the number of staff reductions at CMS is significantly higher than the 300 initially reported. So far, staff have been let go from the following CMS offices:
 - Center for Program Integrity
 - Federal Coordination Health Care Office (also known as the Duals Office)
 - CMS Office of Minority Health
 - CMS Acquisitions and Grants Office
 - CMS Regional Offices (focused on compliance, outreach and beneficiary casework)

In addition, staff handling Freedom of Information Act (FOIA) requests at various HHS agencies, including CDC, NIH and FDA, have also been affected.

According to the HHS, no additional cuts are currently planned, but the department will continue to look for further ways to streamline its operations and agencies.

DOJ Launches Anticompetitive Regulations Task Force

The U.S. Department of Justice (DOJ) launched the Anticompetitive Regulations Task Force on March 27, 2025, to identify regulations it views as harmful and constraining free market competition. The Task Force will focus on several different industries, including the healthcare industry. Once a problematic regulation has been identified, the Task Force would help the DOJ's Antitrust Division take 'appropriate action,' which could include but not be limited to revising or eliminating existing regulations. In the DOJ's announcement, the DOJ notes that "[l]aws and regulations in healthcare markets too often discourage doctors and hospitals from providing low-cost, high-quality healthcare and instead encourage overbilling and consolidation. These kinds of unnecessary anticompetitive regulations put affordable healthcare out of reach for millions of American families."

The DOJ will accept public comments on the Task Force plan until May 26, 2025.

Medicare Payment Rules Anticipated in Coming Weeks

In early April 2025, it's anticipated that CMS will announce the following proposed and final rules:

- Medicare Inpatient Prospective Payment System (IPPS) Proposed Rule
- 2026 Final Rate Notice for Medicare Advantage and Part D plans



JUDICIAL UPDATES

Texas Court Strikes Down FDA's Rule on Laboratory-Developed Tests (LDTs)

On March 31, 2025 the U.S. District Court for the Eastern District of Texas struck down the FDA's May 6, 2024 final rule on LDTs. The final rule had sought to establish a regulatory framework for regulating LDTs as medical devices. The rule elicited significant pushback from stakeholders, including those in the clinical laboratory space. The ruling states that, "FDA's final rule exceeds its authority and is unlawful" and that "Congress has already considered the distinct issues raised by laboratory-developed test services in [the Clinical Laboratory Improvement Amendments or CLIA] and chose to address those issues by vesting regulatory authority in CMS, not in FDA. Through the final rule, it appears that FDA is attempting to circumvent that legislative decision. It has no authority to do so."

The case is now remanded to HHS Secretary Kennedy for further consideration and review, though it is not likely the Trump Administration will appeal the ruling. Congress previously considered legislation introduced by former Rep. Larry Bucshon (R-Ind.) and Rep. Diana DeGette (D-Colo.) that would provide a legislative solution to improve FDA's oversight of LDTs, but legislative efforts stalled last Congress. The court's ruling increases the likelihood that Congress may consider the legislation again this session.