# HHS

## Hart Health Strategies Inc.



# Policy Bri

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### GOP Sets Ambitious Timeline for Reconciliation Bill

Republican leadership of the House of Representatives is aiming for all committees to hold markups of their respective components of the forthcoming reconciliation package within the first two weeks after the chamber returns from recess on April 28. The joint budget resolution adopted by Congress earlier this month sets a nonbinding deadline of May 9 for committees to deliver their respective sections of the bill. Senate and House Budget Committee leadership are targeting Memorial Day for sending the bill to President Donald Trump for his signature. House leadership encouraged committees to work over the recess in order to meet this ambitious timeline. The GOP aims to use the reconciliation package to advance the President's domestic policy agenda, including tax cuts, energy policy, and border security, while trimming the budget deficit by at least \$1.5 trillion. This includes \$880 billion in savings over the next decade from the House Energy and Commerce Committee, which is expected to necessitate cuts to the Medicaid program.

Twelve House Republicans signed on to a <u>letter</u> to GOP leadership stating that they will not support any final bill that includes cuts to Medicaid enrollees' benefits. "We must reform Medicaid so that it is a strong and long-lasting program for years to come," the lawmakers wrote in the letter, "However, we cannot and will not support a final reconciliation bill that includes any reduction in Medicaid coverage for vulnerable populations." The letter, which was signed by Reps. David Valadao (Calif.), Don Bacon (Neb.), Jeff Van Drew (N.J.), Rob Bresnahan (Pa.), Juan Ciscomani (Ariz.), Jen Kiggans (Va.), Young Kim (Calif.), Rob Wittman (Va.), Nicole Malliotakis (N.Y.), Nick LaLota (N.Y.), Andrew

Garbarino (N.Y.), and Jeff Hurd (Colo.), expresses openness to targeted reforms that "improve program integrity, reduce improper payments, and modernize delivery systems to fix flaws in the program that divert resources away from children, seniors, individuals with disabilities and pregnant women — those who the program was intended to help."

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### Internal Document Shows Deep Budget Cuts for HHS

The Trump administration is considering deep cuts to the U.S. Department of Health and Human Services (HHS) according to an internal budget proposal from the Office of Management and Budget (OMB). The 'pre-decisional' proposal would cut one-third of the department's budget, reducing discretionary funding from \$116.8 billion in fiscal year (FY) 2025 to approximately \$80.4 billion. The document proposes to cut funding for both the National Institutes of Health and the Centers for Disease Control and Prevention by more than 40%. Funding for the Substance Abuse and Mental Health Services Administration, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Administration for Community Living would be eliminated. The new Administration for a Healthy America, under which many of the eliminated programs would be consolidated, would receive roughly \$14 billion in budget authority. The proposal is still subject to change, given that the White House has not yet sent its formal FY 2026 budget proposal to Congress. Spokespeople for OMB have also confirmed that no final funding decisions have been made.

### Bipartisan Probe MA Compliance with MLR Requirements

Roffice (GAO) requesting that the agency investigate the growth of Medicare Advantage (MA) insurers, and specifically whether the insurers meet the federal requirement to spend at least 85% of their revenue on beneficiary health care. The letter suggests that insurer acquisition of related businesses like health care providers could undermine the effectiveness of medical loss ratio (MLR) requirements, noting that payments to a related business are considered medical expenses for purposes of calculating the MLR, even though a portion of these payments may ultimately be profits for the insurer. The lawmakers request that GAO examine the ownership structures of MA insurers, trends in spending on medical services and supplemental benefits, and the Centers for Medicare and Medicaid Services' (CMS) oversight of MA reporting requirements.

### Ways and Means RFI on OPOs

The House Ways and Means Committee issued a request for information (RFI) on the nation's 55 organ procurement organizations (OPOs) on Wednesday. The panel seeks information from the public about whether the groups, which qualify as tax-exempt organizations, are abiding by federal laws and regulations. The RFI provides background on the laws and regulations governing OPOs as 501(c)(3) entities, and also details recent reports suggesting that certain OPOs have billed Medicare for costs that may not be appropriate or allowable under law. Responses should be submitted to waysandmeansRFI@mail.house.gov by May 16, 2025.

### E&C Republicans Investigate 23andMe Bankruptcy

Republican leadership of the House Energy and Commerce Committee have launched an <u>investigation</u> into 23andMe and its handling of Americans' sensitive data following the company's decision to file for bankruptcy. 23andMe filed for bankruptcy last month, and announced that it intends to sell all of its assets to pay off debts. The company's most valuable asset is considered to be its genetic database of over 15 million customers. "With the lack of a federal comprehensive data privacy and security law, we write to express our great concern about the safety of Americans' most sensitive personal information," the letter states. The lawmakers specifically express concerns about reports of customers experiencing issues accessing and deleting their data from their 23andMe accounts. The lawmakers request a response to questions related to the practices 23andMe will implement with regard to customers' sensitive information by May 1.

### Democrats Urge Part D Coverage of GLP-1's

Agroup of five Democratic senators have sent a letter to HHS Secretary Robert F. Kennedy Jr. regarding access to GLP-1's in the Medicare and Medicaid programs. The letter, signed by Sens. Jeff Merkley (Ore.), Amy Klobuchar (Minn.), Cory Booker (N.J.), Ben Ray Luján (N.M.), and Gary Peters (Mich.), calls on the administration to reissue a Biden-administration proposed rule that would have allowed Medicare Part D to cover the anti-obesity drugs. The Trump administration recently decided not to finalize the proposal, with CMS providing no reason for the decision. The lawmakers argue that allowing Medicare and Medicaid to cover drugs used to treat obesity "will not only benefit the health of Americans, but is also a critical long-term investment to improve the costly treatment of health complications associated with obesity."

### NJ Congressman in Intensive Care

Rep. Donald Norcross (D-N.J.), 66, was admitted to an intensive care unit on Tuesday and faces an extended recovery that could require physical rehabilitation, according to a press release from his office. Norcross was diagnosed with a gallbladder infection that had progressed to sepsis. Norcross has served in Congress since 2014 and currently serves on the Armed Services and Education and the Workforce committees.

### President Signs Drug Price Executive Order

President Donald Trump signed an executive order (E.O.) on Tuesday aimed at lowering prescription drug prices. The E.O. touches upon several key policy issues, including: 340B, the Inflation Reduction Act's "pill penalty," and pharmacy benefit managers. Hart Health Strategies Inc. has prepared an analysis of the E.O. below, and an official fact sheet can be found here.

### **Pharmacy Benefit Managers (PBMs)**

- Directs several offices to provide recommendations on how to promote "a more competitive, efficient, transparent, and resilient pharmaceutical value chain." While the E.O. does not explicitly cite PBMs, the section is titled "Reevaluating the Role of Middlemen," which has typically been understood as the PBMs, but could include others in the drug supply chain.
- Directs the Secretary to improve "fiduciary transparency" of PBM compensation for employer health plans under ERISA.

### **Drug Administration**

• Directs the Secretary to propose regulations that ensure Medicare payments for administered medications do not encourage care in hospital outpatient departments over "physician office settings."

### **Insulin & Injectable Epinephrine**

• Directs the Secretary to ensure that federally qualified health centers (FQHCs) offer insulin and injectable epinephrine at or below the 340B price to patients with a high cost-sharing requirement for either insulin or injectable epinephrine, a high unmet deductible, or no health care insurance. Ensuring these discounts will be a condition for future grants made under Section 330(e).

### Inflation Reduction Act (IRA)

- While Republicans have long discussed the possibility of repealing the IRA, the E.O. commits to the Medicare Drug Price Negotiation Program (MDPNP) and directs the U.S. Department of Health and Human Services to continue seeking guidance and comments for future rounds of drug negotiations.
- Directs several offices to provide recommendation on how to "stabilize and reduce" Medicare Part D premiums.
- Directs Congress to end the "pill penalty," which currently allows for the MDPNP to review small molecule drugs (i.e. pills) four years earlier than it permits review of biologic products. The E.O. instructs Congress to address this discrepancy, which is understood to exempt all drugs from MDPNP eligibility for 13 years.

### **Generics & Biosimilars**

Directs the Secretary to provide administrative and legislative recommendations that increase generic, biosimilar, and
other select drug approvals. It also directs the Secretary to make recommendations on opportunities to reclassify

prescription drugs to over-the-counter medications.

### **International Importation**

• Directs the Secretary to streamline State application and approval of drug wholesale importation programs. While Florida's program has been approved, Colorado, Maine, New Hampshire, New Mexico, Texas, and Vermont have not received program approval to date.

### Medicare

• Instructs the Secretary to develop and implement a payment model to secure "better value" for high-cost prescription drugs that are not subject to the MDPNP. "Better value" is not defined within the E.O.

### **Site Neutrality**

• Instructs the Secretary to conduct a survey and subsequently propose adjustments that would achieve Medicare site neutrality for outpatient drugs. Site neutrality within the E.O. aims to remove additional payments made by Medicare for drugs provided at hospital outpatient departments. The E.O. does not comment on services nor does it mention physician offices.

### Medicaid

• Directs several offices to provide recommendations to improve the Medicaid drug rebate program with manufacturers, identify new drug payment methods, implement value-based care for drugs, and "support" Medicaid drug spending.

### **Pharmaceutical Manufacturers**

 Directs the Department of Justice, the Department of Commerce, and the Federal Trade Commission to conduct listening sessions and issue a report with recommendations to reduce "anti-competitive behavior" by pharmaceutical manufacturers.

### Dr. Oz Sworn-in as CMS Administrator

Mehmet Oz, MD was officially sworn in as administrator of CMS on Friday. Dr. Oz, a cardiothoracic surgeon, was confirmed by the Senate along party lines earlier this month. During his remarks at the swearing in ceremony, Oz identified several areas of focus for his work going forward – noting that Medicaid often crowds out other social programs in state budgets and highlighting how much the U.S. spends on health care per person compared to other countries, the prevalence of medical errors, and the decline in the nation's life expectancy since the start of the COVID-19 pandemic. Oz also aligned himself with the administration's Make America Healthy Again vision, stating "Together, we're going to make the care better. We're going to make … the outcomes improve, and we're going to make sure that America can actually be the healthiest country it could ever possibly be."

### DOJ Contacts Medical Journals About Competing Viewpoints

The Department of Justice has sent letters to at least three medical journals requesting information about how the publications handle scientific debates and competing viewpoints. The <u>letter</u> to the editor-in-chief of *CHEST* from Edward R. Martin Jr., U.S. Attorney for the District of Columbia, states that "more and more journals and publications like *CHEST* Journal are conceding that they are partisans in various scientific debates." Martin poses the following questions:

- How do you assess your responsibilities to protect the public from misinformation?
- How do you clearly articulate to the public when you have certain viewpoints that are influenced by your ongoing relations with supporters, funders, advertisers, and others?
- Do you accept articles or essays from competing viewpoints?
- How do you assess the role played by government officials and funding organizations like the National Institutes of Health in the development of submitted articles?
- How do you handle allegations that authors of works in your journals may have misled their readers? The letter requests a response by May 2.

### HHS Opens Tip Line on Gender Affirming Care

HS has launched a new whistleblower tip line to report physicians offering gender-affirming care to children. The page offers multiple options for submitting complaints "related to the chemical and surgical mutilation of children." President Donald Trump signed an executive order in January characterizing puberty blockers and hormones for people under 19 as forms of chemical and surgical mutilation. Enforcement of the order is currently on hold following a preliminary injunction by a U.S. district court judge, who ruled that the order unconstitutionally treated people differently based on their sex or transgender status in violation of the equal protection guarantee of the U.S. Constitution's Fifth Amendment.

### Upcoming Congressional Hearings and Markups

House Energy and Commerce Committee markup to consider: 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 (SOAR) to Health and Wellness Training Program; H.R. 1082, Shandra Eisenga Human Cell and Tissue Product Safety Act; and H.R. 2484, Seniors' Access to Critical Medications Act; 10:15 a.m.; April 29

Senate Appropriations Committee hearing "Biomedical Research: Keeping America's Edge in Innovation;" 10:30 a.m.; April 30

### Recently Introduced Health Legislation

H.Res.332 — Supporting the designation of the week of April 11 through April 17, 2025, as the eighth annual "Black Maternal Health Week", founded by Black Mamas Matter Alliance, Inc. (BMMA), to bring national attention to the maternal and reproductive health crisis in the United States and the importance of reducing maternal mortality and morbidity among Black women and birthing people; Sponsor: Adams, Alma S. [Rep.-D-NC-12]; Committees: House - Energy and Commerce

H.R.2921 —To require the Secretary of Defense to provide to firefighters of the Department of Defense medical testing and related services to detect and prevent certain cancers; Sponsor: Bacon, Don [Rep.-R-NE-2]; Committees: House - Armed Services

H.R.2934 —To amend the Controlled Substances Act to provide for a new rule regarding the application of the Act to marijuana, and for other purposes; Sponsor: Joyce, David P. [Rep.-R-OH-14]; Committees: House - Energy and Commerce; Judiciary; Transportation and Infrastructure

H.R.2935 — To establish a Commission on the Federal Regulation of Cannabis to study a prompt and plausible pathway to the Federal regulation of cannabis, and for other purposes; Sponsor: Joyce, David P. [Rep.-R-OH-14]; Committees: House - Energy and Commerce; Judiciary; Ways and Means; Agriculture; Financial Services

H.R.2936 — To amend the Public Health Service Act to allow certain public health data modernization grants to be used to track hospital bed capacity, and for other purposes; Sponsor: Joyce, John [Rep.-R-PA-13]; Committees: House - Energy and Commerce; Ways and Means

H.R.2937 — To require the Secretary of Health and Human Services to improve the detection, prevention, and treatment of mental health issues among public safety telecommunicators; Sponsor: Kelly, Robin L. [Rep.-D-IL-2]; Committees: House - Energy and Commerce

H.R.2942 —To amend title 38, United States Code, to establish standard practices for a grant or pilot program

administered by the Secretary of Veterans Affairs through the Veterans Health Administration, and for other purposes; Sponsor: Landsman, Greg [Rep.-D-OH-1]; Committees: House - Veterans' Affairs

H.R.2943 — To direct the Comptroller General of the United States to conduct a study on insurance coverage of dyspraxia/developmental coordination disorder; Sponsor: Lawler, Michael [Rep.-R-NY-17]; Committees: House - Energy and Commerce; Ways and Means; Oversight and Government Reform

H.R.2957 —To amend the Public Health Service Act to support the development and implementation of programs using data analysis to identify and facilitate strategies to improve outcomes for children in geographic areas with a high prevalence of trauma from exposure to adverse childhood experiences, and for other purposes; Sponsor: Pressley, Ayanna [Rep.-D-MA-7]; Committees: House - Energy and Commerce

H.R.2960 — To amend title III of the Public Health Service Act to reauthorize the program of payments to children's hospitals that operate graduate medical education programs; Sponsor: Schrier, Kim [Rep.-D-WA-8]; Committees: House - Energy and Commerce

H.R.2970 — To amend title 38, United States Code, to make certain improvements to the laws relating to advocacy for veterans who receive health care and other benefits furnished by the Department of Veterans Affairs, and for other purposes; Sponsor: Yakym, Rudy [Rep.-R-IN-2]; Committees: House - Veterans' Affairs