HHS

Hart Health Strategies Inc.



May 12, 2025

Reconciliation Update

 ${f R}$ epublicans on Capitol Hill continue to work to advance a budget reconciliation package containing the spending and savings directives from the fiscal year 2025 budget resolution adopted in early April. The House Ways and Means Committee, and the House Energy and Commerce Committee are scheduled to mark up their portions of the bill beginning on Tuesday at 2:00 p.m. The Ways and Means <u>legislative proposal</u> released in advance of the markup includes a provision to limit Medicare coverage to citizens and aliens meeting specific conditions. Additional changes may be made to the text through the markup process. The Energy and Commerce Committee markup is expected to run continuously through the night and into Wednesday with no breaks. The panel has been instructed to produce approximately \$880 billion in savings over the next decade, which is expected to necessitate cuts to the Medicaid program. In an op-ed published on Sunday, Chair Brett Guthrie (R-Ky.) noted that the package will include a reduction in federal aid to states that allow illegal immigrants to enroll in Medicaid, Medicaid work requirements for capable adults, and a prohibition on Medicaid funding for 'gender reassignment' surgery for children.

The Congressional Budget Office (CBO) released new <u>estimates</u> last week related to the impact of several policies under consideration by the GOP. The projections, which were requested by Senate Finance Committee Ranking Member Ron Wyden (D-Ore.) and House Energy and Commerce Committee Ranking Member Frank Pallone (D-N.J.), indicate that reducing Medicaid expansion states' enhanced federal match rate could lead to 5.5 million people losing health care coverage. Capping federal spending in expansion states could lead to 3.3 million people losing coverage, according to CBO's estimates. The agency's letter also considers the potential impact of limiting state taxes on health care providers, establishing caps on federal spending for the entire Medicaid

population, and repealing Medicaid's eligibility and enrollment rule.

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President Signs Biological Research, Pharmaceutical Manufacturing Orders

President Donald Trump signed an <u>executive order</u> (E.O.) last week to limit federal funding for gain of function research. The order halts U.S. funding of such research in countries deemed to have "insufficient research oversight" and empowers federal research entities to end funding of "other biological research that could pose a threat to American public health, public safety, or national security."

The <u>second</u> E.O. issued by the White House last week aims to restore a domestic manufacturing base for prescription drugs, in part by reducing the regulatory barriers to construction. The order directs the Food and Drug Administration (FDA) to reduce the amount of time it takes to approve domestic pharmaceutical manufacturing plants, and directs the Environmental Protection Agency to accelerate the construction of facilities designed to manufacture prescription drugs, active pharmaceutical ingredients, and other necessary raw materials. Federal agencies issuing permits for a domestic pharmaceutical manufacturing facility are instructed to designate a single point-of-contact to coordinate permit applications. The FDA is further charged with increasing the frequency of inspections on overseas manufacturers.

The President has indicated that further executive actions related to drug pricing and the pharmaceutical industry should be anticipated in the coming days. These are expected to include a decision on tariffs for pharmaceuticals made overseas, as well as an E.O. to be signed Monday morning directing agencies to pursue a most-favored-nation initiative linking the price paid by the U.S. government for certain pharmaceuticals to the lower prices paid abroad. The White House had recently been in talks with lawmakers to include such a policy in the reconciliation package, but the provision drew opposition from congressional Republicans.

Casey Means Tapped as New Nominee for Surgeon General

The Trump administration announced its decision last week to withdraw the nomination of Janette Nesheiwat to serve as U.S. Surgeon General last week, tapping Dr. Casey Means as the new nominee. Nesheiwat, a Fox News contributor, had faced scrutiny about both her medical education credentials and her support of the COVID-19 vaccine. President Trump stated that Nesheiwat will instead serve in another capacity at the U.S. Department of Health and Human Services (HHS). Casey Means is a medical doctor, wellness influencer, and co-founder of the bio wearables and health-tracking company Levels. Means graduated medical school but dropped out of her surgical residency in her fifth year, opting to open a functional medicine practice. She has written in support of reforms to allow lawsuits against vaccine manufacturers for vaccine related injuries, and has called for investigating the current vaccine schedule. She is also a vocal critic of direct-to-consumer pharmaceutical advertising. She is the sister to Calley Means, who currently serves as a White House adviser.

Carter, Auchincloss Lead Bipartisan Letter on Impact of IRA on Pharmacies

Reduction Act's maximum fair price is unsustainable for pharmacies, as it requires the pharmacies to purchase medications subject to price negotiations at a high price and wait for reimbursement. "We have an opportunity to reduce Americans' out-of-pocket costs, and preserve health care access in rural America by preventing the pharmacy benefit managers' (PBM) current unfair treatment of pharmacies," the letter states. "The Centers for Medicare and Medicaid Services can help the PBM reform effort by using its existing statutory authority to ensure that reimbursement rates and other Part D contractual terms offered to all pharmacies are adequate to allow reasonable patient access to prescription drugs and pharmacy services." The letter was signed by a bipartisan group of 24 other lawmakers.

Carter, Kelly Launch Campaigns for Senate

Rep. Buddy Carter, BSPharm (R-Ga.) has launched a campaign for the GOP primary to challenge Senator Jon Ossoff (D-Ga.) for his seat in the Senate. Rep. Carter is a licensed pharmacist who has served in the House since 2015. He currently chairs the House Energy and Commerce Subcommittee on Health.

Rep. Robin Kelly (D-Ill.) announced her campaign to succeed retiring Sen. Dick Durbin (D-Ill.). Rep. Kelly stated that she is running for the Senate to "fight for health care that doesn't bankrupt families, for wages that lift people up, for housing that's affordable, for neighborhoods safe from gun violence." Kelly has served in the House since 2013 and is currently a member of the House Energy and Commerce Committee. She joins a growing Democratic primary that also includes Rep. Raja Krishnamoorthi (D-Ill.) and Lieutenant Governor Juliana Stratton.

GAO Report on VA Oversight of Behavioral Health Medical Records

The Government Accountability Office (GAO) has released a new <u>report</u> recommending that the Department of Veterans Affairs (VA) increase its oversight related to behavioral health medical records and provider training. When patients are referred to providers outside the VA for mental health care, those providers are supposed to send medical records back to the VA. GAO found that a significant portion of medical records were missing for the referrals reviewed, and that the VA does not monitor whether records are ever sent back to the department. Veterans received more than 350,000 referrals to receive behavioral health services from community providers in fiscal years 2021 through 2023.

Upcoming Congressional Hearings and Markups

Senate Judiciary Committee hearing "PBM Power Play: Examining Competition Issues in the Prescription Drug Supply Chain;" 10:15 a.m.; May 13

House Energy and Commerce Committee markup of legislative proposals to comply with the reconciliation directive of H.Con.Res. 14; 2:00 p.m.; May 13

House Ways and Means Committee markup of legislative proposals to comply with the reconciliation directive of H.Con. Res 14; 2:00 p.m.; May13

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Budget Hearing – U.S. Department of Health and Human Services; 9:30 a.m.; May 14

House Judiciary Subcommittee on Administrative State, Regulatory Reform, and Antitrust hearing "The MATCH Monopoly: Evaluating the Medical Residency Antitrust Exemption;" 10:00 a.m.; May 14

Senate Finance Committee hearing "Trade in Critical Supply Chains;" 10:00 a.m.; May 14

Senate HELP Committee hearing on Fiscal Year 2026 Department of Health and Human Services Budget (witness: The Honorable Robert F. Kennedy, Jr.); 1:30 p.m.; May 14

House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies Budget Hearing – U.S. Department of Veterans Affairs; 10:00 a.m.; May 15

House Homeland Security Committee hearing "In Defense of Defensive Measures: Reauthorizing Cybersecurity Information Sharing Activities that Underpin U.S. National Cyber Defense;" 2:00 p.m.; May 15

Hart Health Strategies Inc. Recently Introduced Health Legislation

- S.1587 A bill to require that the retail list price for certain prescription drugs and biological products may not exceed the average retail list price for the drug or biological product among certain nations; Sponsor: Hawley, Josh [Sen.-R-MO]; Committees: Senate Health, Education, Labor, and Pensions
- S.1595 A bill to establish standards for trauma kits purchased using funds provided under the Edward Byrne Memorial Justice Assistance Grant Program; Sponsor: Cornyn, John [Sen.-R-TX]; Committees: Senate Judiciary
- S.1598 A bill to address maternity care shortages and promote optimal maternity outcomes by expanding access to birth centers and exploring more effective payment models for birth center care, and for other purposes; Sponsor: Lujan, Ben Ray [Sen.-D-NM]; Committees: Senate Finance
- S.1599 —A bill to address maternity care shortages and promote optimal maternity outcomes by expanding educational opportunities for midwives, and for other purposes; Sponsor: Lujan, Ben Ray [Sen.-D-NM]; Committees: Senate Health, Education, Labor, and Pensions
- S.1600 A bill to protect hospital personnel from violence, and for other purposes; Sponsor: Hyde-Smith, Cindy [Sen.-R-MS]; Committees: Senate Judiciary
- H.Res.382 Providing a point of order in the House of Representatives during the 119th Congress against reconciliation measures that reduce benefits under the Medicaid program or the supplemental nutrition assistance program; Sponsor: Nunn, Zachary [Rep.-R-IA-3]; Committees: House Rules
- H.Res.385 Expressing support for the designation of May 2, 2025, as "NKH Awareness Day"; Sponsor: Vindman, Eugene Simon [Rep.-D-VA-7]; Committees: House Energy and Commerce
- H.R.3178 —To protect hospital personnel from violence, and for other purposes; Sponsor: Dean, Madeleine [Rep.-D-PA-4]; Committees: House Judiciary
- H.R.3183 —To amend title 38, United States Code, to establish the Office of Falls Prevention of the Department of Veterans Affairs, and for other purposes; Sponsor: Budzinski, Nikki [Rep.-D-IL-13]; Committees: House Veterans' Affairs; Education and Workforce
- H.R.3205 To deny tax deductions and other Federal funding for the costs of gender transition procedures; Sponsor: Tenney, Claudia [Rep.-R-NY-24]; Committees: House Energy and Commerce; Ways and Means
- S.Res.206 A resolution supporting the goals and ideals of National Nurses Week, to be observed from May 6 through May 12, 2025; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate Health, Education, Labor, and Pensions
- S.1607 A bill to establish an Inspector General of the National Institutes of Health, an Inspector General of the Centers for Disease Control and Prevention, and an Inspector General for the Food and Drug Administration; Sponsor: Schmitt, Eric [Sen.-R-MO]; Committees: Senate Health, Education, Labor, and Pensions
- S.1609 A bill to provide for further comprehensive research at the National Institute of Neurological Disorders and Stroke on unruptured intracranial aneurysms; Sponsor: Blumenthal, Richard [Sen.-D-CT]; Committees: Senate Health, Education, Labor, and Pensions
- S.1611 A bill to promote public service announcement campaigns targeted at youth substance use prevention, and for other purposes; Sponsor: Kelly, Mark [Sen.-D-AZ]; Committees: Senate Judiciary
- S.1624 A bill to amend title XVIII of the Social Security Act to establish a floor on the work geographic index for

- physicians' services furnished in Hawaii; Sponsor: Schatz, Brian [Sen.-D-HI]; Committees: Senate Finance
- S.1629 A bill to amend title XVIII of the Social Security Act to align Medicare fee-for-service payment rates across ambulatory settings; Sponsor: Kennedy, John [Sen.-R-LA]; Committees: Senate Finance
- S.1630 A bill to amend the Public Health Service Act to provide more opportunities for mothers to succeed, and for other purposes; Sponsor: Britt, Katie Boyd [Sen.-R-AL]; Committees: Senate Health, Education, Labor, and Pensions
- S.1631 A bill to require the Secretary of Health and Human Services to approve a risk evaluation and mitigation strategy for mifepristone that is identical to the strategy previously approved, and for other purposes; Sponsor: Hawley, Josh [Sen.-R-MO]; Committees: Senate Health, Education, Labor, and Pensions
- H.Res.387 Expressing support for the designation of May 2025 as "National Asthma and Allergy Awareness Month"; Sponsor: Dingell, Debbie [Rep.-D-MI-6]; Committees: House Oversight and Government Reform
- H.Res.388 Supporting the designation of the first week of April as "Adolescent Immunization Action Week" and recognizing the importance of encouraging vaccination for adolescents and young adults to protect against serious illness; Sponsor: Espaillat, Adriano [Rep.-D-NY-13]; Committees: House Energy and Commerce
- H.Res.389 Supporting the goals and ideals of National Nurses Week, to be observed from May 6 through May 12, 2025; Sponsor: Joyce, David P. [Rep.-R-OH-14]; Committees: House Energy and Commerce
- H.Res.392 Expressing support for the designation of May as "National Bladder Cancer Awareness Month"; Sponsor: Murphy, Gregory F. [Rep.-R-NC-3]; Committees: House Energy and Commerce
- H.Res.394 Expressing support for the designation of July 16, 2025, as "Glioblastoma Awareness Day"; Sponsor: Williams, Roger [Rep.-R-TX-25]; Committees: House Energy and Commerce
- H.R.3218 To amend title 18, United States Code, to ensure requests for data on individuals do not pertain to reproductive services; Sponsor: Lieu, Ted [Rep.-D-CA-36]; Committees: House Judiciary
- H.R.3222 To amend title XVIII of the Social Security Act to improve risk adjustment under Medicare Advantage, and for other purposes; Sponsor: Spartz, Victoria [Rep.-R-IN-5]; Committees: House Energy and Commerce; Ways and Means
- S.1637 —A bill to amend title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements, and for other purposes; Sponsor: Mullin, Markwayne [Sen.-R-OK]; Committees: Senate Finance
- S.1640 A bill to amend title XVIII of the Social Security Act to increase support for physicians and other practitioners in adjusting to Medicare payment changes; Sponsor: Marshall, Roger [Sen.-R-KS]; Committees: Senate Finance
- S.1643 A bill to amend title XVIII of the Social Security Act to protect patient access to ground ambulance services under the Medicare program; Sponsor: Cortez Masto, Catherine [Sen.-D-NV]; Committees: Senate Finance
- S.1644 A bill to amend title 38, United States Code, to modify the authority of the Secretary of Veterans Affairs to furnish improvements and structural alterations as part of home health services for disabled veterans; Sponsor: Cortez Masto, Catherine [Sen.-D-NV]; Committees: Senate Veterans' Affairs
- S.1650 A bill to amend title 38, United States Code, to modify authorities relating to the collective bargaining of employees in the Veterans Health Administration; Sponsor: Duckworth, Tammy [Sen.-D-IL]; Committees: Senate -

Veterans' Affairs

- S.1655 A bill to expand congressional oversight of the operation of the Veterans Crisis Line of the Department of Veterans Affairs, to improve workforce protections for all Veterans Crisis Line personnel, and to ensure robust performance standards that fulfill the Veterans Crisis Line mission and meet caller demand, and for other purposes; Sponsor: Duckworth, Tammy [Sen.-D-IL]; Committees: Senate Veterans' Affairs
- S.1657 A bill to amend title 38, United States Code, to limit the authority of the Secretary of Veterans Affairs to deny the claim of a veteran for benefits under the laws administered by such Secretary on the sole basis that such veteran failed to appear for a medical examination associated with such claim, and for other purposes; Sponsor: Banks, Jim [Sen.-R-IN]; Committees: Senate Veterans' Affairs
- H.Res.396 Expressing support for the designation of the week of May 4, 2025, through May 10, 2025, as "Tardive Dyskinesia Awareness Week"; Sponsor: Peters, Scott H. [Rep.-D-CA-50]; Committees: House Energy and Commerce
- H.R.3235 To amend the Public Health Service Act to provide more opportunities for mothers to succeed, and for other purposes; Sponsor: Fischbach, Michelle [Rep.-R-MN-7]; Committees: House Ways and Means; Energy and Commerce
- H.R.3257 To ensure affordable health insurance coverage for low-income individuals in States that have not expanded Medicaid; Sponsor: Sewell, Terri A. [Rep.-D-AL-7]; Committees: House Energy and Commerce; Ways and Means
- H.R.3260 To amend the Public Health Service Act to reauthorize mental and behavioral health education and training grants; Sponsor: Sykes, Emilia Strong [Rep.-D-OH-13]; Committees: House Energy and Commerce
- H.R.3261 To amend title 38, United States Code, to modify authorities relating to the collective bargaining of employees in the Veterans Health Administration; Sponsor: Takano, Mark [Rep.-D-CA-39]; Committees: House Veterans' Affairs
- H.R.3262 To make demonstration grants to eligible local educational agencies or consortia of eligible local educational agencies for the purpose of increasing the numbers of school nurses in public elementary schools and secondary schools; Sponsor: Titus, Dina [Rep.-D-NV-1]; Committees: House Education and Workforce; Energy and Commerce
- H.R.3263 To amend title XVIII of the Social Security Act to establish a floor on the work geographic index for physicians' services furnished in Hawaii; Sponsor: Tokuda, Jill N. [Rep.-D-HI-2]; Committees: House Energy and Commerce; Ways and Means
- S.Res.208 A resolution supporting the designation of May 10, 2025, as "National Asian American, Native Hawaiian, and Pacific Islander Mental Health Day"; Sponsor: Hirono, Mazie K. [Sen.-D-HI]; Committees: Senate Health, Education, Labor, and Pensions
- S.1673 A bill to authorize the Secretary of Health and Human Services to make loans and loan guarantees for planning, constructing, or renovating pediatric or adult mental health treatment facilities and pediatric or adult substance use disorder treatment facilities, and for other purposes; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate Health, Education, Labor, and Pensions
- S.1677 A bill to provide health insurance benefits for outpatient and inpatient items and services related to the diagnosis and treatment of a congenital anomaly or birth defect; Sponsor: Baldwin, Tammy [Sen.-D-WI]; Committees: Senate Health, Education, Labor, and Pensions
- S.1689 A bill to amend the Public Health Service Act to provide for a national outreach and education strategy and reach to improve behavioral health among the Asian American, Native Hawaiian, and Pacific Islander population, while addressing stigma against behavioral health treatment amongst such population; Sponsor: Hirono, Mazie K. [Sen.-D-HI];

Committees: Senate - Health, Education, Labor, and Pensions

- S.1690 A bill to amend the Internal Revenue Code of 1986 to increase funding for Social Security and Medicare; Sponsor: Whitehouse, Sheldon [Sen.-D-RI]; Committees: Senate Finance
- S.1701 A bill to permit the use of health care workforce platforms during declared emergencies, and for other purposes; Sponsor: Budd, Ted [Sen.-R-NC]; Committees: Senate Homeland Security and Governmental Affairs
- S.1702 A bill to amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under such titles, and for other purposes; Sponsor: Capito, Shelley Moore [Sen.-R-WV]; Committees: Senate Finance
- H.R.3266 To authorize the Secretary of Health and Human Services to make loans and loan guarantees for planning, constructing, or renovating pediatric or adult mental health treatment facilities and pediatric or adult substance use disorder treatment facilities, and for other purposes; Sponsor: McClellan, Jennifer L. [Rep.-D-VA-4]; Committees: House Energy and Commerce
- H.R.3269 To address patent thickets; Sponsor: Arrington, Jodey C. [Rep.-R-TX-19]; Committees: House Judiciary
- H.R.3271 To amend the Internal Revenue Code of 1986 to increase funding for Social Security and Medicare; Sponsor: Boyle, Brendan F. [Rep.-D-PA-2]; Committees: House Ways and Means
- H.R.3277 To provide health insurance benefits for outpatient and inpatient items and services related to the diagnosis and treatment of a congenital anomaly or birth defect; Sponsor: Dunn, Neal P. [Rep.-R-FL-2]; Committees: House Energy and Commerce; Education and Workforce; Ways and Means
- H.R.3287 To require the Secretary of Health and Human Services to establish a clearinghouse of ZIP-Code based information to expecting mothers, and for other purposes; Sponsor: Harshbarger, Diana [Rep.-R-TN-1]; Committees: House Energy and Commerce
- H.R.3288 To amend titles XVIII and XIX of the Social Security Act to provide for coverage of prescription digital therapeutics under the Medicare and Medicaid programs, and for other purposes; Sponsor: Hern, Kevin [Rep.-R-OK-1]; Committees: House Energy and Commerce; Ways and Means
- H.R.3295 To amend the Public Health Service Act to improve the accuracy and transparency of animal use data collected by the National Institutes of Health from entities that conduct biomedical and behavioral research with funds provided under such Act; Sponsor: Malliotakis, Nicole [Rep.-R-NY-11]; Committees: House Energy and Commerce
- H.R.3302 To amend the Public Health Service Act to reauthorize the Healthy Start Initiative; Sponsor: Ocasio-Cortez, Alexandria [Rep.-D-NY-14]; Committees: House Energy and Commerce
- H.R.3309 To amend title 38, United States Code, to increase the amount paid by the Secretary of Veterans Affairs to veterans for improvements and structural alterations furnished as part of home health services; Sponsor: Sorensen, Eric [Rep.-D-IL-17]; Committees: House Veterans' Affairs