HHS

Hart Health Strategies Inc.



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Government Shutdown Update

The path to reopening the federal government remains unclear as the shutdown extends into its fourth week. Senate Democrats have so far rejected the stopgap spending bill, which would extend government funding through November 21, 12 times. Democrats also blocked legislation last week that would have paid those federal employees who have worked since October 1 without pay. Most government employees missed their first full paycheck of the shutdown on Friday. Democrats are refusing to support any spending measure that does not extend the Affordable Care Act (ACA) advanced premium tax credits that are set to expire on December 31, while Republican leadership insists that the government be reopened before lawmakers debate the extension of the subsidies.

The next ACA marketplace enrollment period will open on November 1st, and is expected to be accompanied by significant premium hikes without extension of the enhanced subsidies beyond this calendar year. The President has reportedly expressed an interest in broader health care reform efforts, but has not provided guidance to congressional Republicans about whether or how to protect Americans from projected premium increases. Informal conversations are taking place amongst GOP leadership on Capitol Hill about pairing an extension of the credits with Republican health policy priorities, and using a future funding bill as a vehicle for passage. Reforming the structure of the tax credits and strengthening program integrity are also under discussion. A group of 13 moderate Republicans sent a <u>letter</u> last week urging House Speaker Mike Johnson (R-La.) to immediately turn his focus to extension of the subsidies once the government reopens. The lawmakers, led by Reps. Jen Kiggans (R-Va.) and Jeff Van Drew (R-N.J.), argue that "allowing these tax credits to lapse without a clear path forward would risk real harm to those we represent," while also acknowledging that reforms are needed to make the tax credits "more fiscally responsible."

The Centers for Medicare and Medicaid Services (CMS) will recall approximately 3,000 furloughed staff on Monday. The agency will use fees it charges outside researchers to access its data to pay the individuals, with plans to repay the user

fee fund when the government reopens. Approximately 47% of CMS staff were furloughed at the start of the government shutdown. A CMS spokesperson said that the move will allow CMS "to best serve the American people amid the Medicare and ACA open enrollment seasons."

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Scott, Gillibrand Release Report on Generic Supply Chain

Bipartisan leadership of the Senate Special Committee on Aging released a new investigative report last week regarding the nation's overreliance on foreign-made generic drugs. The report, *Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain*, from Chairman Rick Scott (R-Fla.) and Ranking Member Kirsten Gillibrand (D-N.Y.) highlights the decline in domestically manufactured pharmaceuticals consumed in the U.S. from 83% in 2002 to 37% in 2024, and makes recommendations for addressing generic drug supply chain vulnerabilities. The lawmakers suggest:

- Establishing a federal buyer's market for essential medicines;
- Mapping generic drug supply chains;
- Requiring companies to disclose country of origin for finished pharmaceuticals;
- Utilizing trade levers like the administration's 232 investigation authority;
- Passing clarifying language to close loopholes that allow foreign-made products to be categorized as 'Made in America';
 and
- Supporting U.S. biotechnology.

Lawmakers Comment on Medicaid Cuts, Changes

Sens. Ron Wyden (D-Ore.) and Jeff Merkley (D-Ore.) have sent a letter calling for the Trump administration to provide clarity about changes to the Medicaid program instituted by the GOP budget reconciliation bill earlier this year. The legislation placed a moratorium on three rules finalized under the Biden administration to improve Medicaid enrollment, reduce Medicare costs for low-income seniors, and ensure adequate staffing in nursing homes. The lawmakers attest that state leaders are unclear about which provisions within the final rules remain in effect, and whether they have the authority to implement certain policies as a state option, even if they are no longer required to implement the rules in their entirety. "This confusion is a precursor to the broader operational challenges states will face in implementing Trumpcare's many Medicaid cuts and federal mandates," the letter states. "The lack of clarity will result in eligible people losing or being unable to access Medicaid coverage, and less effective tools to assess the number of staff needed to safely staff nursing homes."

Sen. Chuck Grassley (R-Iowa) also sent several letters to the administration last week regarding states' use of taxpayer funding to provide Medicaid coverage for undocumented immigrants. Sen. Grassley details how certain states use provider taxes as an indirect mechanism to subsidize Medicaid coverage for immigrants. Federal law prohibits states from using federal Medicaid funds to cover undocumented individuals. His letter to the U.S. Department of Health and Human Services inspector general requests a nationwide investigation into this practice, and he asks CMS to review what guardrails are in place to prevent it. The One Big Beautiful Bill Act contained restrictions on how high states can set provider tax rates.

Democrat Committee Leaders Raise Concerns About TrumpRx

Congressional Democrats are demanding answers about the recently announced TrumpRx direct-to-consumer platform for pharmaceutical sales. Senate Finance Committee Ranking Member Ron Wyden (D-Ore.), House Energy and Commerce Committee Ranking Member Frank Pallone (D-N.J.), and House Ways and Means Committee Ranking Member Richard Neal (D-Mass.) are raising concerns about the initiative's association with companies, donors, and individuals with ties to the President. "Without more transparency, we cannot properly oversee the development and effectiveness of a new government prescription drug purchasing platform and the alleged price reductions," the lawmakers state in one Letter. "We are disappointed that the Administration has, once again, not been forthcoming about its plans with Congress or the public about a major announcement that claims to affect the affordability of health care for the American people." The Democratic committee leaders sent a separate Letter specifically related to Donald Trump Jr.'s position on BlinkRx's Board of Directors.

New CBO Estimate of Reconciliation Bill's Orphan Drug Provision

The Congressional Budget Office (CBO) released an <u>analysis</u> last week responding to questions regarding an orphan drug provision contained in this year's budget reconciliation bill. The information came in response to a request from Senate Finance Committee Ranking Member Ron Wyden (D-Ore.), House Energy and Commerce Committee Ranking Member Frank Pallone (D-N.J.), and House Ways and Means Committee Ranking Member Richard Neal (D-Mass.). CBO originally estimated the cost of enacting section 71203, which delays or exempts certain drugs from selection for the Medicare Drug Price Negotiation Program, at \$4.9 billion. This estimate did not account for the orphan drugs Darzalex, Keytruda, and Opdivo during the 2025–2034 period. After incorporating those drugs into its analysis, CBO now estimates that the 10-year cost of this section of the bill will be \$8.8 billion.

Alicia Jackson Sworn in as ARPA-H Director

The Trump administration has selected Alicia Jackson to lead the Advanced Research Projects Agency for Health (ARPA-H). Jackson is a health technology entrepreneur. She previously served as the deputy director for the Defense Advanced Research Projects Agency's biology programs office, and most recently founded and served as the CEO of Evernow, a telehealth company for menopause care. Renee Wegrzyn, the inaugural ARPA-H director, was fired from her post in February. The position requires a presidential appointment but not confirmation by the Senate.

Upcoming Congressional Hearings and Markups

Senate Finance Committee hearing to consider the nomination of Thomas Bell, of Virginia, to be Inspector General, Department of Health and Human Services; 10:00 a.m.; October 29

Senate HELP Committee hearing "The Future of Biotech: Maintaining U.S. Competitiveness and Delivering Lifesaving Cures to Patients;" 10:00 a.m.; October 29

Senate Health, Education, Labor, and Pensions Committee hearing to consider the nomination of Casey Means to be Medical Director in the Regular Corps of the Public Health Service and Surgeon General of the Public Health Service; 11:00 a.m.; October 30

Hart Health Strategies Inc. Recently Introduced Health Legislation

H.R.5764 — To amend the Small Business Act to require small business development centers to assist small business concerns with the use of artificial intelligence, and for other purposes; Sponsor: Alford, Mark [Rep.-R-MO-4]; Committees: House - Small Business

H.R.5768 — Skin Substitute Access and Payment Reform Act – To amend title XVIII of the Social Security Act to adjust payment for skin substitute products under the Medicare program; Sponsor: Carter, Earl L. "Buddy" [Rep.-R-GA-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.5770 — To establish biotechnology workforce training programs for Department of Defense personnel, and for other purposes; Sponsor: Houlahan, Chrissy [Rep.-D-PA-6]; Committees: House - Armed Services

H.R.5784 — To amend the Small Business Act to help small business concerns critically evaluate artificial intelligence tools, and for other purposes; Sponsor: Scholten, Hillary J. [Rep.-D-MI-3]; Committees: House - Small Business

H.R.5791 — To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to establish an expedited process for the approval of certain biologics license application supplements for blood centers, and for other purposes; Sponsor: Wied, Tony [Rep.-R-WI-8]; Committees: House - Energy and Commerce

S.3019 — A bill to amend title XI of the Social Security Act to provide for the treatment of orphan drugs under the Medicare Drug Price Negotiation Program; Sponsor: Welch, Peter [Sen.-D-VT]; Committees: Senate – Finance

S.3033 — A bill to require the Secretary of Veterans Affairs to establish partnerships between medical facilities of the Department of Veterans Affairs and medical facilities in rural areas, and for other purposes; Sponsor: Duckworth, Tammy [Sen.-D-IL]; Committees: Senate - Veterans' Affairs

S.Res.464 — A resolution designating September 2025 as "National Cholesterol Education Month" and September 30, 2025, as "LDL-C Awareness Day"; Sponsor: Hyde-Smith, Cindy [Sen.-R-MS]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.Res.465 — A resolution designating September 2025 as "National Childhood Cancer Awareness Month"; Sponsor: Scott, Tim [Sen.-R-SC]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.3038 — A bill to establish a real-time data dashboard for graduate medical education training positions to improve health care workforce planning and distribution for the purposes of alleviating physician shortages in medically underserved communities; Sponsor: Blackburn, Marsha [Sen.-R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3042 — A bill to amend title 38, United States Code, to require the Secretary of Veterans Affairs to submit to Congress each year an annual report that contains data and information on the causes of deaths among veterans, and for other purposes; Sponsor: Hickenlooper, John W. [Sen.-D-CO]; Committees: Senate - Veterans' Affairs

S.3047 — A bill to provide for the treatment of certain critical access hospitals; Sponsor: Hyde-Smith, Cindy [Sen.-R-MS]; Committees: Senate – Finance

S.3048 — A bill to amend the Controlled Substances Act to allow for the use of telehealth in substance use disorder treatment, and for other purposes; Sponsor: Murkowski, Lisa [Sen.-R-AK]; Committees: Senate - Health, Education, Labor, and Pensions