HHS

Hart Health Strategies Inc.



ealth Policy Briefing

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Senate Appropriations Timing Announced, Murray Pushes for Increase in Nondefense Spending

Senate appropriators will begin the process of marking up fiscal year 2025 government funding bills the week of July 8, according to an announcement from Appropriations Chair Patty Murray (D-Wash.) last week. Murray delivered a floor speech on Tuesday calling for an increase in nondefense discretionary funding beyond the 1% increase agreed upon in the 2023 debt limit deal. Murray specifically discussed the impact of a 1% increase on medical research, arguing that "One percent means we are blunting momentum for lifesaving biomedical breakthroughs. The National Institutes of Health (NIH) is looking at a \$280 million shortfall as *Cures Act* funding tapers off. That absolutely cannot be filled with a 1% bump. And that's on top of the \$678 million in NIH *Cures Act* funding that already expired last year—that we couldn't make up for because of the caps. There are countless patients who would be devastated to hear that totally arbitrary spending caps are stifling research that could save their life."

Drug Patent Bill Receives Favorable CBO Score

The Affordable Prescriptions for Patients Act (S. 150) which would reform the drug patent system and increase generic competition is estimated to save \$3 billion over the next decade, according to the bill's new score from the Congressional Budget Office (CBO). Supporters of the bipartisan legislation, introduced by Sen. John Cornyn (R-Texas) and Richard Blumenthal (D-Conn.), are pushing for its inclusion in a year-end health care package. The bill specifically aims to curtail the use of product hopping and patent thickets. The latest CBO savings projection is three times higher than the agency's 2022 estimate. The legislation was advanced by the Senate Judiciary Committee in a bipartisan vote last year.

Wyden, Senate Dems Release Bill to Address Labor & Delivery Unit Closures

Cenate Finance Committee Chairman Ron Wyden (D-Ore.) released draft

legislation last week that aims to prevent additional closures of hospital labor and delivery units in rural and underserved areas. The *Keep Obstetrics Local Act* would increase Medicaid payments for labor and delivery care, provide standby payments to support low-volume hospitals, and require Medicaid coverage

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of 12 months of postpartum care nationwide. Wyden was joined by fifteen Senate Democrats in releasing the proposal. A summary and section by section of the draft bill can be found <u>here</u>. Legislative text can be found <u>here</u>.

Democrats Push Administration to Improve Transparency of ERISA Plan Benefit Denials

Labor, and Pensions Subcommittee Ranking Member Mark DeSaulnier (D-Calif.) have sent a <u>letter</u> to the Department of Labor raising concerns about benefit denials by employer-based health plans. The letter highlights recent media investigations into systemic denials of health benefits by insurers and third-party administrators that prevent workers and their families from accessing needed health care services. Health plans subject to the *Employee Retirement Income Security Act* (ERISA), which cover more than 130 million Americans, are required to submit an annual report known as Form 5500 to the Department of Labor with information about their financial status and operations. Scott and DeSaulnier urge the Department to improve Form 5500 to ensure that necessary data regarding benefit denials is collected and to close loopholes that currently exempt millions of ERISA-covered plans from compliance with disclosure requirements.

CBO Releases Updated Data on 340B Spending

The Congressional Budget Office (CBO) has released new <u>data</u> on 340B drug discount program spending. CBO's analysis found that spending on cancer treatments, immunosuppressants, and anti-infective agents comprised 70% of total program spending in 2021, up from 58% in 2010. The analysis also found that 88% of the growth in program spending stems from drugs prescribed by hospitals and their affiliated clinics. CBO notes that only a portion of the growth in 340B spending can be explained by market wide trends or by disproportionate growth in spending on certain classes of drugs; other factors that may have contributed to the growth in 340B spending include integration of hospitals and clinics, expanded facility participation due to the *Affordable Care Act*; and expanded use of contract pharmacies.

CMS to Discontinue Change Accelerated Payment Program

The Centers for Medicare and Medicaid Services (CMS) has announced that it will discontinue the Change Healthcare/ Optum Payment Disruption program on July 12. The program was initiated following the February cyberattack on Change Healthcare to support providers experiencing cash flow disruptions. CMS has ultimately issued more than \$2.55 billion in accelerated payments to more than 4,200 Medicare Part A providers, and more than \$717.18 million in accelerated payments to 4,722 Part B suppliers. More than 96% of the payments made through the program have already been recovered.

FDA Releases Draft Interchangeability Guidance

The Food and Drug Administration (FDA) released a <u>draft guidance</u> on Friday that proposes to eliminate study requirements for demonstrating that biosimilar drugs are interchangeable with their FDA-licensed reference product. The agency asserts that since the publication of their 2019 interchangeability guidance, experience has demonstrated that the safety or diminished efficacy risk following a switch between a reference product and biosimilar is insignificant. "Health care professionals and patients can be confident in the safety and effectiveness of a biosimilar product, whether or not it has also been approved as an interchangeable biosimilar, just as they would be for an originator biologic," the FDA said in a statement. Comments on the draft guidance are due August 20.

Congressional Retirements and Resignations

 \mathbf{A} running list of members of Congress who are retiring or seeking other office can be found below.

SENATE		
Stabenow (D), MI	Braun (R), IN	
Cardin (D), MD	Romney (R), UT	
Carper (D), DE		
Butler (D), CA		
Manchin (D), WV		
Sinema (I), AZ		
HOUSE OF REPRESENTATIVES		
Porter (D), CA	Mooney (R), WV	
Lee (D), CA	Banks (R), IN	
Gallego (D), AZ	Bishop (R), NC	
Schiff (D), CA	Lesko (R), AZ	
Slotkin (D), MI	Granger (R), TX	
Allred (D), TX	Buck (R), CO (effective March 22, 2024)	
Trone (D), MD	Burgess, MD (R), TX	
Blunt Rochester (D), DE	Wenstrup, DPM (R), OH	
Napolitano (D), CA	McHenry (R), NC	
Wexton (D), VA	Johnson (R), OH (effective Jan. 21, 2024)	
Kim, Andy (D), NJ	Ferguson, IV, DMD, PC (R), GA	
Jackson, Jeff (D), NC	Curtis (R), UT	
Sarbanes (D), MD	Luetkemeyer (R), MO	
Blumenauer (D), OR	Lamborn (R), CO	
Kilmer (D), WA	Bucshon, MD (R), IN	
Spanberger (D), VA	Pence (R), IN	
Kildee (D), MI	Duncan (R), SC	
Phillips (D), MN	Armstrong (R), ND	
Cardenas (D), CA	McMorris Rodgers (R), WA	
Eshoo (D), CA	Gallagher (R), WI (effective April 19, 2024)	
Manning (D), NC	LaTurner (R), KS	
Nickel (D), NC	Graves (R), LA	
Ruppersberger (D), MD		
Sablan (D), MP		
Kuster (D), NH		

Hart Health Strategies Inc. Upcoming Congressional Hearings and Markups

House Judiciary Subcommittee on Administrative State, Regulatory Reform, and Antitrust hearing "Follow the Science?: Oversight of the Biden Covid-19 Administrative State Response;" 10:00 a.m.; June 26

House Veterans' Affairs Subcommittee on Health hearing "The Continuity of Care: Assessing the Structure of VA's Healthcare Network;" 2:15 p.m.; June 26

House Ways and Means Subcommittee on Health hearing "Improving Value-Based Care for Patients and Providers;" 3:00 p.m.; June 26

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies markup of FY 2025 Labor, Health and Human Services, Education, and Related Agencies bill; 8:00 a.m.; June 27

House Energy and Commerce markup of the American Privacy Rights Act; 10:00 a.m.; June 27

Recently Introduced Health Legislation

H.Res.1301 — Expressing support for the inaugural Heart Recovery Awareness Day on February 20, 2025; Sponsor: Moulton, Seth [Rep.-D-MA-6]; Committees: House - Energy and Commerce

H.R.8749 — To amend title XVIII of the Social Security Act to promote preparedness and Medicare beneficiary access to safer, more accurate sterile intravenous drug preparations through automated hospital infrastructure; Sponsor: Kelly, Mike [Rep.-R-PA-16]; Committees: House - Ways and Means

H.R.8756 — To establish the Chief Artificial Intelligence Officers Council, Chief Artificial Intelligence Officers, and Artificial Intelligence Coordination Boards, and for other purposes; Sponsor: Connolly, Gerald E. [Rep.-D-VA-11]; Committees: House - Oversight and Accountability; Science, Space, and Technology

H.R.8763 — To provide grants to States to encourage the implementation and maintenance of firearms licensing requirements, and for other purposes; Sponsor: Pressley, Ayanna [Rep.-D-MA-7]; Committees: House - Judiciary

H.R.8764 — To require the Attorney General to make publicly available a list of federally licensed firearms dealers with a high number of short time-to-crime firearm traces, and to prohibit Federal departments and agencies from contracting with such dealers; Sponsor: Raskin, Jamie [Rep.-D-MD-8]; Committees: House - Judiciary; Oversight and Accountability

H.R.8767 — To amend title XIX of the Social Security Act to remove the exclusion from medical assistance under the Medicaid program of items and services for patients in an institution for mental diseases; Sponsor: Thanedar, Shri [Rep.-D-MI-13]; Committees: House - Energy and Commerce

H.R.8768 — To authorize the Attorney General to make grants available to support State, Tribal, and local firearm destruction activities, and for other purposes; Sponsor: Tokuda, Jill N. [Rep.-D-HI-2]; Committees: House - Judiciary

H.R.8771 — Making appropriations for the Department of State, foreign operations, and related programs for the fiscal year ending September 30, 2025, and for other purposes; Sponsor: Diaz-Balart, Mario [Rep.-R-FL-26]; Committees: House – Appropriations

S.4554 — A bill to express support for protecting access to reproductive health care after the Dobbs v. Jackson decision on June 24, 2022; Sponsor: Murray, Patty [Sen.-D-WA]; Latest Action: Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time

S.4556 — A bill 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: King, Angus S., Jr. [Sen.-I-ME]; Committees: Senate - Veterans' Affairs

S.Res.738 — A resolution expressing support for the designation of June 19, 2024, as "World Sickle Cell Awareness Day" in order to increase public awareness across the United States and global community about sickle cell disease and the continued need for empirical research, early detection screenings, novel effective treatments leading to a cure, and preventative care programs with respect to complications from sickle cell anemia and conditions relating to sickle cell disease; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate - Foreign Relations

S.4575 — A bill to amend the Older Americans Act of 1965 to require the Assistant Secretary for Aging to make available to States, area agencies on aging, and service providers information and technical assistance to support the provision of evidence-informed practices that are likely to improve health outcomes, and for other purposes; Sponsor: Braun, Mike [Sen.-R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4577 — A bill to amend the Older Americans Act of 1965 to require the Assistant Secretary for Aging to publish on an online portal information on national resource centers authorized or supported under such Act, and for other purposes; Sponsor: Braun, Mike [Sen.-R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4578 — A bill to amend the Older Americans Act of 1965 to require reports to Congress on State Long-Term Care Ombudsman Programs, and for other purposes; Sponsor: Braun, Mike [Sen.-R-IN]; Committees: Senate - Health, Education, Labor, and Pensions

S.4581 — A bill to require the Secretary of State, in coordination with the Secretary of Health and Human Services, the Administrator of the United States Agency for International Development, and such other heads of departments and agencies as the Secretary of State considers appropriate, to formulate a strategy for the Federal Government to secure support from foreign countries, multilateral organizations, and other appropriate entities to facilitate the development and commercialization of qualified pandemic or epidemic products, and for other purposes; Sponsor: Kelly, Mark [Sen.-D-AZ]; Committees: Senate - Foreign Relations

S.4583 — A bill to amend the Federal Food, Drug, and Cosmetic Act to extend the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases; Sponsor: Casey, Robert P., Jr. [Sen.-D-PA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4587 — A bill to amend the Public Health Service Act to include rural emergency hospitals in the definition of a covered entity for purposes of the drug discount program under section 340B of such Act; Sponsor: Peters, Gary C. [Sen.-D-MI]; Committees: Senate - Health, Education, Labor, and Pensions

S.4592 — A bill to amend the Public Health Service Act to authorize the Secretary of Health and Human Services, acting through the Deputy Assistant Secretary for Minority Health, to award grants to faith- or community-based organizations to address persistent health inequities and chronic disease challenges; Sponsor: Gillibrand, Kirsten E. [Sen.-D-NY]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.1304 — Expressing support for the designation of June 19, 2024, as "World Sickle Cell Awareness Day" in order to increase public awareness across the United States and global community about sickle cell disease and the continued need for empirical research, early detection screenings, novel effective treatments leading to a cure, and preventative care programs with respect to complications from sickle cell anemia and conditions relating to sickle cell disease; Sponsor: Davis, Danny K. [Rep.-D-IL-7]; Committees: House - Energy and Commerce

H.Res.1306 — Expressing support for the designation of June 21, 2024, as National ASK (Asking Saves Kids) Day to promote children's health and safe storage of guns in the home; Sponsor: Crow, Jason [Rep.-D-CO-6]; Committees: House - Energy and Commerce

H.Res.1307 — Expressing support for the designation of June 20, 2024, as "World FSHD Day"; Sponsor: Dingell, Debbie [Rep.-D-MI-6]; Committees: House - Energy and Commerce

H.Res.1310 — Expressing support for the designation of the month of June 2024 as "National Post-Traumatic Stress Awareness Month" and June 27, 2024, as "National Post-Traumatic Stress Awareness Day"; Sponsor: Peters, Scott H. [Rep.-D-CA-50]; Committees: House - Armed Services; Veterans' Affairs

H.R.8776 — To amend the Internal Revenue Code of 1986 to treat membership in a health care sharing ministry as a medical expense, and for other purposes; Sponsor: Kelly, Mike [Rep.-R-PA-16]; Committees: House - Ways and Means S.4612 — A bill to ensure that the background check system used for firearms purchases denies a firearm to a person prohibited from possessing a firearm by a lawful court order governing the pretrial release of the person; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate – Judiciary

S.4614 — A bill to direct the Secretary of Health and Human Services and the Secretary of Education to coordinate and distribute educational materials and resources regarding artificial intelligence and social media platform impact, and for other purposes; Sponsor: Markey, Edward J. [Sen.-D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4616 — A bill to establish a public health plan; Sponsor: Bennet, Michael F. [Sen.-D-CO]; Committees: Senate – Finance