# HHS

## Hart Health Strategies Inc.



# Ith Policy Briefing

August 4, 2025

### Appropriations Update

The Senate passed the fiscal year (FY) 2026 Agriculture-Food and Drug Administration (FDA) spending bill on Friday in an 87-9 vote as a part of a minibus package with the Military Construction-Veterans Affairs spending bill for FY 2026. Under the legislation, the FDA would receive \$7.1 billion in funding, roughly in line with FY 2025 spending levels. The FY 2026 Labor-Health and Human Services (LHHS) spending bill was advanced by the Senate Appropriations Committee last week in a bipartisan 26-3 vote. The legislation totals \$116.6 billion, a \$446 million increase in discretionary funding over the current fiscal year. The bill increases funding for the National Institutes of Health by \$400 million and maintains funding for the Centers for Disease Control and Prevention at current levels. The panel also advanced the FY 2026 Defense spending bill. Together, Defense and LHHS account for approximately two-thirds of federal discretionary spending. The LHHS bill text can be found here, a bill summary here, and the committee-report here.

The House of Representatives adjourned for August recess before releasing its FY 2026 LHHS appropriations proposal. House appropriators are currently expected to consider the LHHS bill the first week after reconvening on September 2. Lawmakers will return from their August recess next month with about four weeks to pass legislation to avoid a government shutdown. Without a broader government funding deal, there is a strong likelihood that Congress passes a short-term continuing resolution to extend funding for the federal government beyond September 30.

### Susan Monarez Confirmed as CDC Director

The Senate confirmed Susan Monarez as Director of the Centers for Disease Control and Prevention (CDC) on Tuesday in a 51-47 vote. Monarez has worked in the federal government for two decades, most recently serving as the acting director of the CDC after working as the deputy director of the Advanced Research Projects Agency for Health. During the first Trump administration, she served as deputy assistant secretary for strategy and analysis at the

Department of Homeland Security. Monarez, who has a PhD in microbiology, is the first person without a medical degree to lead the CDC since 1953. She is also the first Senate-confirmed CDC director, following a statutory change made in 2022 requiring approval of the CDC director by the upper chamber.

### Inside

HELP Marks Up Health, Reauthorization Bills2
HSGAC Advances Gain of Function Research
Oversight Bill2
Administration Launches Health Tech Ecosystem
Initiative2
President Urges Implementation of Most Favored
Nation Pricing3
External Experts Cut from ACIP Working Groups
Decently Introduced Health Logislation

### HELP Marks Up Health, Reauthorization Bills

The Senate Health, Education, Labor, and Pensions (HELP) Committee held a markup of several health-related bills on Wednesday. The panel advanced the following bills unanimously via an en bloc vote:

- The Over-the-Counter (OTC) Monograph Drug User Fee Amendments (S. 2292), to reauthorize the Food and Drug Administration's authority to collect industry fees and review OTC drugs through October 1, 2030.
- The Improving Care in Rural America Reauthorization Act (S. 2301), to reauthorize three grant programs for preventive screenings, telehealth services, and chronic disease management for underserved populations through 2030.
- The Kay Hagan Tick Reauthorization Act (S. 2398), to reauthorize programs to combat tick- and vector-borne diseases.
- The Uniformed Services Leave Parity Act (S. 1440), to expand leave for U.S. Public Health Service Commission Corps to be on par with other uniformed services.

### HSGAC Advances Gain of Function Research Oversight Bill

The Senate Homeland Security and Governmental Affairs Committee (HSGAC) advanced legislation last week to establish a Life Sciences Research Security Board to provide oversight of gain-of-function research. The bipartisan Risky Research Review Act (S. 854) was approved in an 11-2 vote, with Democratic Sens. Andy Kim (N.J.) and Ruben Gallego (Ariz.) voting no. The oversight panel established by the bill would include nine members appointed by the president who serve terms up to eight years in duration. It would be responsible for reviewing research proposals involving enhanced pathogens with pandemic potential. The legislation, which was reintroduced by committee chair Rand Paul (R-Ky.) and ranking member Gary Peters (D-Mich.), was previously advanced by HSGAC last Congress but did not receive a Senate floor vote.

### Administration Launches Health Tech Ecosystem Initiative

Last week, the Centers for Medicare and Medicaid Services (CMS) hosted a "Make Health Tech Great Again" event during which the Trump administration announced commitments by private sector health care and information technology firms – including Amazon, Anthropic, Apple, Google, and OpenAI – to support the creation of a patient-centric health care ecosystem through interoperability and user-friendly apps. The effort will focus on the promotion of a CMS Interoperability Framework to enable information sharing between patients and providers and increasing the availability of personalized health tools for patients. The event featured the unveiling of voluntary criteria for trusted, patient-centered, and practical data exchange for all network types. CMS also announced plans to add an app library to Medicare.gov to spotlight trusted, personalized digital health tools. A full list of companies who have currently pledged their support for the initiative can be found here. The event followed a May 2025 request for information from CMS and the Assistant Secretary for Technology Policy on ways to modernize the nation's digital health ecosystem which received nearly 1,400 stakeholder responses. It also coincided with the 60th anniversary of the July 30, 1965, establishment of the Medicare and Medicaid programs. Further information on CMS' Health Technology Ecosystem initiative can be found here.

### President Urges Implementation of Most Favored Nation Pricing

President Donald Trump has sent letters to the CEOs of 17 pharmaceutical companies urging them to lower drug prices and work with him to implement his executive order related to a most favored nation (MFN) drug pricing policy. The President requests the selected pharmaceutical companies to "bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations" within the next 60 days through the following steps:

- Extending MFN pricing to Medicaid for all drugs;
- Guaranteeing MFN pricing for newly launched drugs for Medicare, Medicaid and commercial payers;
- Utilizing U.S. trade policy to raise prices internationally for all "foreign freeloading nations" and reinvesting revenues directly into lowering prices for American patients; and
- Participating in direct-to-consumer and/or direct-to-business distribution models for high-volume, high-rebate prescription drugs to ensure MFN pricing.

The letters warn that if companies "refuse to step up" within this time frame, the administration "will deploy every tool in our arsenal to protect American families from continued abusive drug pricing practices." Merck, Novo Nordisk, Eli Lilly, AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Novartis, Gilead Sciences, EMD Serono, Pfizer, AstraZeneca, Amgen, Genentech, Johnson & Johnson, GSK, Regeneron Pharmaceuticals, and Sanofi received letters from the President.

### External Experts Cut from ACIP Working Groups

The CDC has informed outside experts that they will no longer be invited to help review vaccine data and develop recommendations for consideration by the Advisory Committee on Immunization Practices (ACIP). As a result, liaison organizations will not be allowed participate in the private deliberations of the ACIP working group process, though they will still be able to participate in the panel's open public meetings. Bloomberg Government has reported that the email informing the liaisons of the change characterized the outside groups as biased "based on their constituency and/or population that they represent."

# Hart Health Strategies Inc. Recently Introduced Health Legislation

- H.R.4773 To amend title XVIII of the Social Security Act to establish a SNF-at-home program under the Medicare program; Sponsor: Smith, Adrian [Rep.-R-NE-3]; Committees: House Ways and Means; Energy and Commerce
- H.R.4770 To amend chapter 6 of title 5, United States Code, to provide additional requirements for the periodic review of rules, and for other purposes; Sponsor: Schweikert, David [Rep.-R-AZ-1]; Committees: House Judiciary; Small Business
- H.R.4768 To amend title 10, United States Code, to improve dependent coverage under the TRICARE Young Adult Program; Sponsor: Ryan, Patrick [Rep.-D-NY-18]; Committees: House Armed Services
- H.R.4762 To prohibit the export of drugs and prosthetics to the Russian Federation; Sponsor: Luttrell, Morgan [Rep.-R-TX-8]; Committees: House Foreign Affairs
- H.Res.612 Sponsor: Mast, Brian J. [Rep.-R-FL-21]; Committees: House Armed Services
- H.Res.611 Expressing the importance of accurate information for medical professionals treating pregnant women and their unborn children in the emergency department, and for informing the general public, and for other purposes; Sponsor: Cammack, Kat [Rep.-R-FL-3]; Committees: House Energy and Commerce
- S.2483 A bill to provide that members of the Advisory Committee on Immunization Practices may not be terminated except for cause and to require the immediate reinstatement of the members of such advisory committee; Sponsor: Blunt Rochester, Lisa [Sen.-D-DE]; Committees: Senate Health, Education, Labor, and Pensions
- S.2482 TRICARE Travel Improvement Act A bill to amend title 10, United States Code, to reduce the distance required for the Secretary of Defense to reimburse travel expenses relating to specialty care, and for other purposes; Sponsor: Heinrich, Martin [Sen.-D-NM]; Committees: Senate Armed Services
- S.Res.343 A resolution recognizing the important work of the United States Preventive Services Task Force; Sponsor: King, Angus S., Jr. [Sen.-I-ME]; Committees: Senate Health, Education, Labor, and Pensions
- S.2524 A bill to amend Public Law 119-21 to repeal the prohibition on making payments under the Medicaid program to certain entities; Sponsor: Smith, Tina [Sen.-D-MN]; Committees: Senate Finance
- S.2521 A bill to allow participants in the National Health Service Corps to defer their obligated service in order to receive training in palliative care services; Sponsor: Rosen, Jacky [Sen.-D-NV]; Committees: Senate Health, Education, Labor, and Pensions
- S.2519 A bill to amend the Fair Credit Reporting Act to prohibit the inclusion of medical debt on a consumer report, and for other purposes; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate Banking, Housing, and Urban Affairs
- S.2518 A bill to amend title XVIII of the Social Security Act to revise payment for air ambulance services under the Medicare program; Sponsor: Bennet, Michael F. [Sen.-D-CO]; Committees: Senate Finance
- S.2514 A bill to authorize appropriation of funds to the Centers for Disease Control and Prevention for conducting or supporting research on firearms safety or gun violence prevention; Sponsor: Markey, Edward J. [Sen.-D-MA]; Committees: Senate Health, Education, Labor, and Pensions
- S.2513 A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to transparency and reporting regarding over-the-counter drug monograph activities, and for other purposes; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate Health, Education, Labor, and Pensions

- S.2497 A bill to amend title XVIII of the Social Security Act to require a separate identification number and an attestation for each off-campus outpatient department of a provider; Sponsor: Hassan, Margaret Wood [Sen.-D-NH]; Committees: Senate Finance
- S.2496 A bill to amend titles XIX and XXI of the Social Security Act to provide for continuous eligibility for certain children under the Medicaid program and the Children's Health Insurance Program; Sponsor: Bennet, Michael F. [Sen.-D-CO]; Committees: Senate Finance
- S.2493 A bill to amend title 38, United States Code, to improve matters relating to medical examinations for veterans disability compensation, and for other purposes; Sponsor: Blumenthal, Richard [Sen.-D-CT]; Committees: Senate Veterans' Affairs
- S.2491 A bill to amend the Federal Food, Drug, and Cosmetic Act to improve the regulatory review process to determine the safety and effectiveness of nonprescription drugs intended for topical administration, and for other purposes; Sponsor: Hassan, Margaret Wood [Sen.-D-NH]; Committees: Senate Health, Education, Labor, and Pensions
- S.2490 A bill to improve the Long-Term Care Ombudsman program; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate Health, Education, Labor, and Pensions
- H.Res.620 Celebrating the 60th anniversary of Medicaid; Sponsor: Evans, Gabe [Rep.-R-CO-8]; Committees: House Energy and Commerce
- H.Res.619 Supporting the goals and ideals of "Minority Mental Health Awareness Month" and recognizing the disproportionate impacts of mental health conditions and struggles on minority populations and communities; Sponsor: Crockett, Jasmine [Rep.-D-TX-30]; Committees: House Energy and Commerce
- H.Res.617 Supporting the goals and ideals of Fentanyl Prevention and Awareness Day; Sponsor: Carter, Earl L. "Buddy" [Rep.-R-GA-1]; Committees: House Energy and Commerce
- H.R.4827 To amend the Fair Credit Reporting Act to prohibit the inclusion of medical debt on a consumer report, and for other purposes; Sponsor: Williams, Nikema [Rep.-D-GA-5]; Committees: House Financial Services
- H.R.4821 To authorize the appropriation of funds to the Centers for Disease Control and Prevention for conducting or supporting research on firearms safety or gun violence prevention; Sponsor: Strickland, Marilyn [Rep.-D-WA-10]; Committees: House Energy and Commerce
- H.R.4807 To amend Public Law 119-21 to repeal certain changes to provider taxes under the Medicaid program; Sponsor: Landsman, Greg [Rep.-D-OH-1]; Committees: House Energy and Commerce
- H.R.4805 To direct the Secretary of Veterans Affairs to conduct a study on the long-term physiological and psychological effects of military aviation veterans who served as aviators in the Armed Forces, and for other purposes; Sponsor: Kiggans, Jennifer A. [Rep.-R-VA-2]; Committees: House Veterans' Affairs
- H.R.4796 To amend Public Law 119-21 to repeal the prohibition on making payments under the Medicaid program to certain entities; Sponsor: Friedman, Laura [Rep.-D-CA-30]; Committees: House Energy and Commerce
- H.R.4792 To amend title XVIII of the Social Security Act to revise payment for air ambulance services under the Medicare program; Sponsor: Estes, Ron [Rep.-R-KS-4]; Committees: House Energy and Commerce; Ways and Means

- S.2556 A bill to repeal the changes made by the health subtitle of the One Big Beautiful Bill Act, and for other purposes; Sponsor: Schumer, Charles E. [Sen.-D-NY]; Committees: Senate Finance
- S.2546 A bill to provide for an extension of the legislative authority of the National Emergency Medical Services Memorial Foundation to establish a commemorative work in the District of Columbia and its environs; Sponsor: Coons, Christopher A. [Sen.-D-DE]; Committees: Senate Energy and Natural Resources
- S.2540 A bill to amend the Omnibus Crime Control and Safe Streets Act of 1968 to reauthorize the Comprehensive Opioid Abuse Grant Program of the Department of Justice; Sponsor: Whitehouse, Sheldon [Sen.-D-RI]; Committees: Senate Judiciary
- S.2534 A bill to improve the reproductive assistance provided by the Department of Defense and the Department of Veterans Affairs to certain members of the Armed Forces, veterans, and their spouses or partners, and for other purposes; Sponsor: Murray, Patty [Sen.-D-WA]; Committees: Senate Veterans' Affairs
- S.2531 A bill to authorize the Secretary of Health and Human Services to award grants to increase early detection of and intervention for uterine fibroids, and for other purposes; Sponsor: Alsobrooks, Angela D. [Sen.-D-MD]; Committees: Senate Health, Education, Labor, and Pensions
- S.2529 A bill to increase the clarity and predictability of the process for developing applications for Rx-to-nonprescription switches; Sponsor: Husted, Jon [Sen.-R-OH]; Committees: Senate Health, Education, Labor, and Pensions
- S.Res.358 A resolution honoring the life of Dr. Paul Farmer by recognizing the duty of the Federal Government to adopt a 21st century global health solidarity strategy and take actions to address past and ongoing harms that undermine the health and well-being of people around the world; Sponsor: Markey, Edward J. [Sen.-D-MA]; Committees: Senate Foreign Relations
- S.2628 Catastrophic Specialty Hospital Act A bill to amend title XVIII of the Social Security Act to establish new payment rules for certain catastrophic specialty hospitals under the Medicare program; Sponsor: Warnock, Raphael G. [Sen.-D-GA]; Committees: Senate Finance
- S.2625 A bill to require the Secretary of Health and Human Services to carry out certain activities relating to the regulation of independent agents and brokers and third-party marketing organizations under parts C and D of the Medicare program, and for other purposes; Sponsor: Rounds, Mike [Sen.-R-SD]; Committees: Senate Finance
- S.2621 A bill to amend the Public Health Service Act to reauthorize support for State-based maternal mortality review committees, to direct the Secretary of Health and Human Services to disseminate best practices on maternal mortality prevention to hospitals, State-based professional societies, and perinatal quality collaboratives, and for other purposes; Sponsor: Capito, Shelley Moore [Sen.-R-WV]; Committees: Senate Health, Education, Labor, and Pensions
- S.2620 A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to approval of abbreviated new drug applications; Sponsor: Durbin, Richard J. [Sen.-D-IL]; Committees: Senate Health, Education, Labor, and Pensions
- S.2617 A bill to amend title XVIII of the Social Security Act to require that coinsurance for drugs under Medicare part D be based on the drug's net price and not the drug's list price; Sponsor: Rosen, Jacky [Sen.-D-NV]; Committees: Senate Finance
- S.2612 A bill to amend title XVIII of the Social Security Act to include physical therapists and occupational therapists as health professionals for purposes of the annual wellness visit under the Medicare program, and for other purposes; Sponsor: Justice, James C. [Sen.-R-WV]; Committees: Senate Finance

S.2587 — An original bill making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2026, and for other purposes; Sponsor: Capito, Shelley Moore [Sen.-R-WV]; Committees: Senate – Appropriations

S.2575 — A bill to amend title 10, United States Code, to eliminate certain health care charges for members of the Selected Reserve eligible for TRICARE Reserve Select, and for other purposes; Sponsor: Baldwin, Tammy [Sen.-D-WI]; Committees: Senate - Armed Services

S.2561 — A bill to amend title XVIII of the Social Security Act to reform the payment rules regarding skin substitute products; Sponsor: Cassidy, Bill [Sen.-R-LA]; Committees: Senate – Finance