



Health Policy Briefing

July 10, 2023

White House Announces New ‘Bidenomics’ Initiatives

President Joe Biden [announced](#) a series of new administration initiatives aimed at lowering health care costs and strengthening patient protections on Friday. The announcements were the latest in a series of actions by the administration to push the President’s “Bidenomics” agenda and eliminate hidden junk fees. Friday’s releases included new proposed rules to reverse the Trump administration’s expansion of short-term, limited duration health plans. Democrats argue that such “junk” plans undermine the patient protections put in place by the *Affordable Care Act*. The new regulations would limit these plans to four months, instead of the current three-year maximum, and would require more disclosure around coverage limitations. The administration also released guidance intended to prevent health care providers from gaming the *No Surprises Act’s* regulations around surprise medical billing. The guidance would specifically limit the ability of insurers that contract with hospitals to claim provided care was not in network. It would also require insurers to disclose facility fees that are charged to patients. Finally, the administration announced a new effort being undertaken by the Consumer Financial Protection Bureau, the U.S. Department of Health and Human Services, and the Treasury Department to examine whether health care provider and third-party efforts to encourage consumers to sign up for medical credit cards and loans are operating outside of existing consumer protections and breaking the law.

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Schumer Sends Dear Colleague on July Work Period

In a Dear Colleague [letter](#) on Sunday, Senate Majority Leader Chuck Schumer (D-N.Y.) previewed his agenda for the chamber's upcoming work period following lawmakers' return from the July 4th recess on Monday. In addition to considering bipartisan appropriations bills through regular order, Schumer hopes to advance bipartisan legislation to lower the cost of insulin and prescription drugs, combat the fentanyl crisis, and promote community health. He also announced his intention to build on his SAFE Innovation Framework for Artificial Intelligence (AI), which outlines how the Senate can advance American leadership in AI and harness its potential while protecting against potential harms. The Senate's summer recess is currently scheduled to begin on July 31.

HELP Releases Bipartisan PAHPA Discussion Draft

Chair and Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee Bernie Sanders (I-Vt.) and Bill Cassidy (R-La.) [released](#) a staff-level agreement on a package to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA) last week. While the lawmakers were able to reach a deal on much of the discussion draft to extend PAHPA authorities for five years, differences remain on several prescription drug pricing and drug development voucher provisions. Democrats are pushing to cap the cost of any product developed with the support of the Centers for Disease Control and Prevention or the Biomedical Advanced Research and Development Authority at the lowest price among G7 countries – U.S., U.K, Canada, France, Germany, Italy, and Japan. Republicans are seeking the reauthorization and expansion of the priority review voucher program at the Food and Drug Administration. The GOP proposal aims to incentivize the development of more medical countermeasures (MCMs) by providing a new, non-transferrable priority review voucher to companies that develop new MCMs on top of the transferrable voucher they currently receive, and by including threats to the Armed Forces within the program. HELP leadership sought feedback on their plan and the policies still under negotiation by July 10. Authorization for PAHPA's public health programs expires on September 30.

CMS Proposes 340B Remedy Following Supreme Court Decision

The Centers for Medicare and Medicaid Services (CMS) is [proposing](#) to provide hospitals participating in the 340B drug program with \$9 billion as compensation for \$10.5 billion in payment cuts dating back to 2018. CMS states that the higher payment rate for 340B hospitals that has been in place since 2022 will cover the remaining \$1.5 billion. The Supreme Court ruled last year that cuts made to the 340B program by the U.S. Department of Health and Human Services – aimed at increasing payment accuracy and addressing hospital overspending – were unlawful because CMS did not fully survey the impacted hospitals' costs for acquiring 340B-eligible drugs. The proposed rule released last week outlines a plan to distribute the money to the approximately 1,600 hospitals that were paid less due to the now-invalidated policy. The proposed lump sum approach would involve Medicare administrative contractors calculating how much each hospital will receive within 60 days, along with a 0.5% cut to non-drug items and services for all hospitals to keep the resolution budget neutral.

FDA Fully Approves Leqembi

The Food and Drug Administration (FDA) has granted full approval to the Alzheimer's treatment Leqembi. The drug has been shown to modestly slow cognitive decline in the early stages of Alzheimer's disease, but also comes with potentially life-threatening side effects. It is the first drug for slowing the progression of Alzheimer's – and not just targeting its symptoms - to be granted full FDA approval. In its phase three clinical trial of 1,795 patients with mild cognitive impairment or early-stage Alzheimer's, disease progression was slowed by 27% over an 18-month period. The FDA's approval includes a boxed warning about the potential for brain swelling and hemorrhage, which can lead to seizures and death. Approximately 12.6 % of patients who received Leqembi in the clinical trial developed brain swelling, compared with 1.7% of those in the placebo group, and around 17% of the Leqembi group experienced brain bleeds, versus 9% in the placebo group. Three deaths have been linked to the drug. Leqembi is administered intravenously every two weeks and will carry a list price of \$26,500 per year. Following the FDA's approval of the drug, the Centers for Medicare and Medicaid Services (CMS) confirmed that it would provide coverage of Leqembi under the Medicare program. In keeping with its previously announced policy, CMS will mandate that physicians collect real-world evidence on the performance of the treatment through participation in a qualifying CMS-facilitated registry.

U.S. Maternal Mortality Rates Continue to Rise

U.S. maternal mortality rates have doubled over the last decade according to a new [study](#) published in the Journal of the American Medical Association last week. The estimated number of deaths per 100,000 live births increased from 12.7 deaths in 1999 to 32.2 deaths in 2019. States in the south saw the highest maternal death rates across all race and ethnicity groups, and black women had the highest median maternal death rate.

Upcoming Congressional Hearings and Markups

Senate HELP Subcommittee on Primary Health & Retirement Security hearing “Superbugs: The Impact of Antimicrobial Resistance on Modern Medicine;” 10:00 a.m.; July 11

House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic hearing “Investigating the Proximal Origin of a Cover Up;” 10:00 a.m.; July 11

Senate Appropriations Committee hearing “Accelerating Breakthroughs: How the Special Diabetes Program Is Creating Hope for those Living with Type 1 Diabetes;” 10:00 a.m.; July 11

Senate Judiciary Subcommittee on Intellectual Property hearing “Artificial Intelligence and Intellectual Property – Part II: Copyright;” 3:00 p.m.; July 12

House Small Business Subcommittee on Oversight, Investigations, and Regulations hearing “Burdensome Red Tape: Overregulation in Health Care and the Impact on Small Businesses;” 10:00 a.m.; July 19

H.Res.564 — Supporting the goals and ideals of Alzheimer’s and Brain Awareness Month. Sponsor: Barragan, Nanette Diaz [Rep.-D-CA-44]; Committees: House - Energy and Commerce

H.Res.572 — Expressing support for the designation of the month of June 2023 as “National Post-Traumatic Stress Injury Awareness Month” and June 27, 2023, as “National Post-Traumatic Stress Injury Awareness Day”. Sponsor: Peters, Scott H. [Rep.-D-CA-50]; Committees: House - Armed Services; Veterans’ Affairs

H.R.4395 — To amend the Energy Policy and Conservation Act to modify standards for water heaters, furnaces, boilers, and kitchen cooktops, ranges, and ovens, and for other purposes. Sponsor: Bice, Stephanie I. [Rep.-R-OK-5]; Committees: House - Energy and Commerce

H.R.4400 — To direct the Secretary of Veterans Affairs to conduct an independent review of the deaths of certain veterans by suicide, and for other purposes. Sponsor: Buchanan, Vern [Rep.-R-FL-16]; Committees: House - Veterans’ Affairs

H.R.4402 — To amend title XI of the Social Security Act to clarify manufacturer transparency reporting requirements for certain transfers used for educational purposes. Sponsor: Burgess, Michael C. [Rep.-R-TX-26]; Committees: House - Energy and Commerce; Ways and Means

H.R.4408 — To amend the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes. Sponsor: Gallagher, Mike [Rep.-R-WI-8]; Committees: House - Energy and Commerce

H.R.4410 — To amend title XVIII of the Social Security Act to make the Medicare Savings Program available in all jurisdictions. Sponsor: González-Colón, Jenniffer [Resident Commissioner-R-PR-At Large]; Committees: House - Energy and Commerce

H.R.4411 — To amend title XVIII of the Social Security Act to establish a floor in Medicare Advantage benchmark rates for regions with low Medicare fee-for-service penetration. Sponsor: González-Colón, Jenniffer [Resident Commissioner-R-PR-At Large]; Committees: House - Ways and Means; Energy and Commerce

H.R.4412 — To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, to award grants to States to implement a tick identification pilot program. Sponsor: Gottheimer, Josh [Rep.-D-NJ-5]; Committees: House - Energy and Commerce

H.R.4413 — To provide for the issuance of a Lyme Disease Research Semipostal Stamp. Sponsor: Gottheimer, Josh [Rep.-D-NJ-5]; Committees: House - Oversight and Accountability; Energy and Commerce

H.R.4414 — To amend title X of the Public Health Service Act to prohibit requiring a recipient or subrecipient of funds to provide referrals for abortion, and for other purposes. Sponsor: Green, Mark E. [Rep.-R-TN-7]; Committees: House - Energy and Commerce

H.R.4418 — To amend title 10, United States Code, to repeal the restriction on the use of funds and facilities of the Department of Defense for abortion care. Sponsor: Houlihan, Chrissy [Rep.-D-PA-6]; Committees: House - Armed Services

H.R.4419 — To amend the Public Health Service Act with respect to the Public Health Emergency Medical Countermeasures Enterprise, and for other purposes. Sponsor: Hudson, Richard [Rep.-R-NC-9]; Committees: House - Energy and Commerce

H.R.4420 — To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response related to the Centers for Disease Control and Protection, and for other purposes. Sponsor: Hudson, Richard [Rep.-R-NC-9]; Committees: House - Energy and Commerce

H.R.4421 — To reauthorize certain programs under the Public Health Service Act with respect to public health security and all-hazards preparedness and response related to the Administration for Strategic Preparedness and Response, and for other purposes. Sponsor: Hudson, Richard [Rep.-R-NC-9]; Committees: House - Energy and Commerce

H.R.4424 — To direct the Secretary of Veterans Affairs to study and report on the prevalence of cholangiocarcinoma in veterans who served in the Vietnam theater of operations during the Vietnam era, and for other purposes. Sponsor: LaLota, Nick [Rep.-R-NY-1]; Committees: House - Veterans' Affairs

H.R.4431 — To amend the Omnibus Crime Control and Safe Streets Act of 1968 to provide for a pilot program under the Comprehensive Opioid Abuse Grant Program for local law enforcement agencies located in rural areas to purchase naloxone to prevent and reduce opioid overdose deaths, and for other purposes. Sponsor: Newhouse, Dan [Rep.-R-WA-4]; Committees: House - Judiciary

H.R.4438 — To amend title XVIII of the Social Security Act to provide for coverage and payment of Alpha-1 Antitrypsin Deficiency Disorder treatment under part B of such title, and for other purposes. Sponsor: Salazar, Maria Elvira [Rep.-R-FL-27]; Committees: House - Energy and Commerce; Ways and Means

H.R.4449 — To establish the Commission on Strengthening the Domestic Pharmaceutical Supply Chain, and for other purposes. Sponsor: Torres, Ritchie [Rep.-D-NY-15]; Committees: House - Energy and Commerce

H.R.4458 — To amend title III of the Public Health Service Act to provide for clarity with respect to the duration of contracts for procurement of supplies for the Strategic National Stockpile, and for other purposes. Sponsor: Griffith, H. Morgan [Rep.-R-VA-9]; Committees: House - Energy and Commerce

H.R.4459 — To amend title III of the Public Health Service Act to specify the duration of contracts, grants, cooperative agreements, or other transactions awarded or entered into with the Biomedical Advanced Research and Development Authority, and for other purposes. Sponsor: Griffith, H. Morgan [Rep.-R-VA-9]; Committees: House - Energy and Commerce

H.R.4473 — To amend title XVIII of the Social Security Act to provide for site neutral payment for cancer care services under part B of the Medicare program; Sponsor: Arrington, Jodey C. [Rep.-R-TX-19]; Committees: House - Energy and Commerce; Ways and Means

H.R.4489 — To amend the 21st Century Cures Act to clarify that grants for State and Tribal response to opioid use disorders may, at the discretion of the Secretary of Health and Human Services, also be used to address associated health conditions, and for other purposes; Sponsor: Guthrie, Brett [Rep.-R-KY-2]; Committees: House - Energy and Commerce

H.R.4490 — To amend the Controlled Substances Act to authorize pharmacies to deliver certain controlled substances to an administering practitioner in lieu of delivering such substances to the to the ultimate user, and for other purposes; Sponsor: Guthrie, Brett [Rep.-R-KY-2]; Committees: House - Energy and Commerce; Judiciary

H.R.4498 — To promote a 21st century artificial intelligence workforce; Sponsor: Soto, Darren [Rep.-D-FL-9]; Committees: House - Education and the Workforce; Science, Space, and Technology