



Health Policy Briefing

October 21, 2019

Key Committees Advance Democratic Drug Pricing Package

Members of Congress returned to Washington last week following a two-week recess. The three House committees of jurisdiction continued to debate Democratic leadership’s drug pricing plan (H.R. 3) in the hopes of bringing the measure for a vote on the floor the week of October 28. Several revisions to the **Lower Drug Costs Now Act** were unveiled early in the week. The changes would increase the minimum number of drugs for which the U.S. Department of Health and Human Services (HHS) Secretary must negotiate lower prices, from 25 to 35. The latest measure would also require negotiation on some newly-launched drugs if their wholesale acquisition cost (WAC) is greater than or equal to the median national household income. The changes were successful in securing the support of several additional progressive Democrats for the package.

The legislation was advanced by the House Education and Labor and Energy and Commerce committees along party-line votes. The Education and Labor Committee adopted four amendments to the bill. A measure from Rep. Pramila Jayapal (D-Wash.) would require the Department of Labor to examine the provision of rebates to group health plans when drug prices increase above inflation. Other adopted amendments would require that a drug’s copayment not exceed a health plan’s negotiated price, call for a Government Accountability Office (GAO) report on government price negotiations by 2025, and ensure that the data collection requirements included in H.R. 3 are coordinated with other similar collection efforts.

Only one amendment was adopted by the Energy and Commerce panel. The measure, which was offered by Rep. Kurt Schrader (D-Ore.), would increase Part B reimbursement for biosimilars for five years. During its markup of H.R. 3, Energy and Commerce also advanced legislation that would direct savings from government drug

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pricing negotiations to create dental (H.R. 4650), vision (H.R. 4665), and hearing (H.R. 4618) coverage in Medicare and to make program improvements for low-income program beneficiaries (H.R. 4671).

The Ways and Means Committee held its hearing on H.R. 3 last week and is expected to markup the bill this week. In a letter to his colleagues, Progressive Caucus Co-Chair Lloyd Doggett (D-Texas) stated that he would be seeking changes to the legislation during the markup, and if necessary, during consideration of the bill on the floor. He proposes to expand the number of drugs subject to negotiation, increase assistance for uninsured individuals with their drug costs, and further address the high launch prices of new drugs.

Elijah Cummings, Powerful Chairman and Civil Rights Leader, Passes Away at Age 68

Rep. Elijah Cummings (D-Md.) passed away last week due to complications from underlying health issues. He was 68 years old. Cummings had served 12 terms in Congress and held the position of top Democrat on the House Oversight and Reform Committee since 2011. Chairman Cummings' district includes several important health care institutions, including the Centers for Medicare and Medicaid Services' (CMS) headquarters and Johns Hopkins Hospital. During his time in Congress, Cummings was a strong supporter of medical research, the Affordable Care Act (ACA), and improving health care access and quality for underserved populations. In his capacity as Oversight and Reform Committee chairman, Cummings launched an investigation into the prescription drug industry's pricing practices. House Speaker Nancy Pelosi (D-Calif.) plans to rename her drug pricing package in his honor. Chairman Cummings will lie in state in National Statuary Hall on October 24. A memorial services is also scheduled for Thursday. Rep. Carolyn Maloney (D-N.Y.) will assume the position of acting chairwoman on Oversight and Reform. The Democratic Steering Committee is expected to meet soon to recommend Cummings' permanent replacement to the full caucus. Maryland Gov. Larry Hogan (R) will announce when a special election and general election will be held.

Ways and Means Republicans Reject Surprise Billing Negotiated Rulemaking

Ranking Member of the House Ways and Means Committee Kevin Brady (R-Texas) has rejected a proposal from panel Democrats to protect patients from surprise insurance gaps using a negotiated rulemaking process. Chairman Richard Neal (D-Mass.) was hopeful that the Ranking Member would support the use of a committee of stakeholder groups and administrative agencies to determine how to resolve billing disputes between providers and payers. Rep. Brady, however, suggested that lawmakers should go "back to the drawing board" rather than pursue this negotiated rulemaking process. Brady has instead made comments in support of a policy similar to the one advanced by the Energy and Commerce Committee, which would use an independent dispute resolution (IDR) process as a backstop in certain circumstances for providers to appeal a benchmark payment rate set by legislation. In response to Rep. Brady's comments, Chairman Neal's office stated that they continue to work in a bipartisan manner to explore all options available to address surprise medical bills.

Senate to Consider FY 2020 Appropriations This Week

Senate Majority Leader Mitch McConnell (R-Ky.) announced his plans for the chamber to try and consider two packages of appropriations legislation for fiscal year (FY) 2020 this week. The first would encompass domestic spending across the departments of Commerce, Justice, Agriculture, Interior, Transportation, and Veterans Affairs. If the Senate succeeds in passing that package, the chamber would then begin consideration of a spending bill for the Defense, Labor, Health and Human Services, Education, State, and Energy departments. The legislative details are still being negotiated by Appropriations Chairman Richard Shelby (R-Ala.) and Ranking Member Patrick Leahy (D-Vt.). Cloture has already been filed on the House bills that will serve as the vehicles for the Senate's appropriations work. House Democratic leadership and Senate Republican leadership, however, have yet to reach an agreement on top line spending levels. The current continuing resolution (CR) funding the federal government will expire on November 21.

Lawmakers Raise Questions on Reimbursement for Non-Opioid Treatments

Sens. Jeanne Shaheen (D-N.H.) and Shelley Moore Capito (R-W.Va.) have sent a [letter](#) to U.S. Department of Health and Human Services (HHS) leadership regarding the impact of Medicare reimbursement policy on the use of opioid-based pain management treatments. The lawmakers ask HHS and CMS to ensure that payment policies do not incentivize the use of opioids over non-opioid alternatives, and express concern about the cost disparity between opioid-based medications and non-opioid drugs in the treatment of post-surgical pain.

Grassley Investigates GME Financing, Tax-Exempt Hospital's Billing Practices

Senate Finance Committee Chairman Chuck Grassley (R-Iowa) has [written](#) to HHS Secretary Alex Azar requesting information on graduate medical education (GME), program financing, and what processes are in place to prevent GME fraud and abuse. His letter cites three separate reports which raise concerns about potential waste in GME program funding.

Chairman Grassley is also [examining](#) a recent report that the University of Virginia (UVA) Health System is failing to meet its legal obligations as a tax-exempt organization. In a letter to UVA Medical Center, Grassley notes that “relentless debt-collection efforts by tax-exempt hospitals” appear to be at odds with requirements that such hospitals serve community health needs, provide financial assistance, limit amounts charged for medically-necessary care, and refrain from extraordinary collection actions against patients eligible for financial assistance. He asks for additional information on UVA’s debt-collections history and processes, charity care and financial assistance offered, patients’ rights and transparency guidelines, potential overcharging, and its process for determining prices.

Lawmakers Consider Further Restrictions on E-Cigarette, Vaping Products

Vaping and the use of e-cigarette products among young adults continues to be an issue of strong bipartisan interest among lawmakers on Capitol Hill. The House Judiciary Committee advanced legislation (H.R. 3942, the ***Preventing Online Sales of E-Cigarettes to Children Act***) that would require age verification for both the purchase and delivery of e-cigarette products. The House Energy and Commerce Committee convened a hearing on H.R. 2339, the ***Reversing the Youth Tobacco Epidemic Act of 2019*** which would extend federal rules for tobacco sales and advertising to e-cigarettes. The bill would also increase the age to buy tobacco products to 21 and ban all flavored e-cigarettes. Principal Deputy Director of the Centers for Disease Control and Prevention (CDC) Anne Schuchat also appeared before the House Appropriations Subcommittee on Health last week to discuss vaping as a public health issue. The House Ways and Means Committee is reportedly planning to consider a federal tax on e-cigarettes.

Latest reports from the CDC estimate that the number of confirmed and probable lung injury cases resulting from the use of e-cigarette or vaping products has reached 1,479, with 33 deaths across 24 states. Approximately 16 percent of those who have become ill are under the age of 18.

FL Rep. Rooney to Retire

Florida Republican Rep. Francis Rooney announced that he will not seek reelection in 2020. Rooney was first elected to the House of Representatives in 2016 and currently serves on the Education and Workforce Subcommittee on Health, Employment, Labor, and Pensions. He is the 19th Republican lawmaker to announce his retirement from the House. Florida’s 19th congressional district is not considered a swing district.

BARDA Celebrates More than 50 FDA Products for Health Security

The HHS Assistant Secretary for Preparedness and Response (ASPR) announced that the Biomedical Applied Research and Development Authority (BARDA) achieved a major milestone this month when it realized the FDA approval, licensure or clearance for more than 50 health security products. BARDA, which was established in law to secure the nation from chemical, biological, radiological and nuclear threats, engages in public-private partnerships with industry to advance research, development, and manufacturing of medical countermeasures and products to address emerging threats, including pandemic influenza and emerging infectious diseases. BARDA Director Rick Bright, PhD, announced this achievement in the ASPR [Blog](#), further noting that BARDA and its private sector partners “achieved eight of these in the past year alone, substantially increasing the nation’s health security preparedness.”

Upcoming Congressional Hearings and Markups

House Ways and Means Committee markup of H.R. 3, The Lower Drug Costs Act Now Act of 2019; H.R. 3398, The Pathways to Health Careers Act of 2019; H.R. 4650, The Medicare Dental Act of 2019; HR. 4665, The Medicare Vision Act of 2019; and H.R. 4618, the Medicare Hearing Act of 2019; 9:30 a.m., 1100 Longworth Bldg., October 22

Senate Commerce, Science, and Transportation Subcommittee on Science, Oceans, Fisheries, and Weather hearing to “examine research and innovation, focusing on ensuring America’s economic and strategic leadership;” 2:15 p.m., 562 Dirksen Bldg.; October 22

House Energy and Commerce Oversight and Investigations Subcommittee hearing “Sabotage: The Trump Administration’s Attack on Health Care;” 10:00 a.m., 2123 Rayburn Bldg.; October 23

Senate Finance Committee hearing “Treating Substance Misuse in America: Scams, Shortfalls, and Solutions;” 10:30 a.m., 215 Dirksen Bldg.; October 24

Recently Introduced Health Legislation

H.R.4669 — To amend title XVIII of the Social Security Act to provide for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA-PD plans. Sponsor: Rep. Stevens, Haley M. [D-MI-11]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4667 — To amend the 21st Century Cures Act to reauthorize funding for NIH innovation projects, and for other purposes. Sponsor: Rep. Sherrill, Mikie [D-NJ-11]; Cosponsors: (2) Committees: House - Energy and Commerce

H.R.4666 — To amend title XVIII of the Social Security Act to provide certain low-income territorial residents with automatic eligibility for premium and cost-sharing subsidies under the Medicare program, and for other purposes. Sponsor: Rep. Shalala, Donna E. [D-FL-27]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4665 — To amend title XVIII of the Social Security Act to provide coverage for certain vision items and services under part B of the Medicare program. Sponsor: Rep. Schrier, Kim [D-WA-8]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4663 — To amend title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation. Sponsor: Rep. Porter, Katie [D-CA-45]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4661 — To amend title XVIII of the Social Security Act to provide for the automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program, and for other purposes. Sponsor: Rep. Pappas, Chris [D-NH-1]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4655 — To amend title XVIII of the Social Security Act to provide for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program, and for other purposes. Sponsor: Rep. Lee, Susie [D-NV-3]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4652 — To establish an Individual Market Reinsurance fund to provide funding for State individual market stabilization reinsurance programs. Sponsor: Rep. Langevin, James R. [D-RI-2]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4651 — To amend the Internal Revenue Code of 1986 to expand health savings accounts, and for other purposes. Sponsor: Rep. King, Steve [R-IA-4]; Cosponsors: (0) Committees: House - Ways and Means

H.R.4650 — To amend title XVIII of the Social Security Act to provide coverage for certain dental items and services under part B of the Medicare program. Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4649 — To amend title XVIII of the Social Security Act to provide for a cap on beneficiary liability under part D of the Medicare program, and for other purposes. Sponsor: Rep. Horsford, Steven [D-NV-4]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4640 — To require persons who undertake Federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services. Sponsor: Rep. DeFazio, Peter A. [D-OR-4]; Cosponsors: (0) Committees: House - Energy and Commerce

H.R.4633 — To amend the 21st Century Cures Act to reauthorize funding for FDA innovation projects, and for other purposes. Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Cosponsors: (1) Committees: House - Energy and Commerce

H.R.4632 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to disseminate to part D subsidy eligible individuals information comparing the premiums under LIS benchmark plans for such individuals. Sponsor: Rep. Kind, Ron [D-WI-3]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4631 — To amend the Internal Revenue Code to impose an excise tax on opioid manufacturers, to make the funds collected through such tax available for opioid (including heroin) abuse prevention and treatment programs, and for other purposes. Sponsor: Rep. Rose, Max [D-NY-11]; Cosponsors: (4) Committees: House - Ways and Means; Energy and Commerce; Budget

H.R.4678 — To amend the Public Health Service Act to authorize a public education campaign across all relevant programs of the Health Resources and Services Administration to increase oral health literacy and awareness. Sponsor: Rep. Cardenas, Tony [D-CA-29]; Cosponsors: (2) Committees: House - Energy and Commerce

H.R.4676 — To amend title XVIII of the Social Security Act to provide for the guaranteed issue of Medigap policies to all Medigap-eligible Medicare beneficiaries and Medicare Advantage enrollees, and for other purposes. Sponsor: Rep. Schneider, Bradley Scott [D-IL-10]; Cosponsors: (0) Committees: House - Ways and Means; Energy and Commerce

H.R.4675 — To amend title XVIII of the Social Security Act to provide for enhanced Medicare beneficiary information through access to annual Medicare notifications in multiple languages. Sponsor: Rep. Gomez, Jimmy [D-CA-34]; Cosponsors: (3) Committees: House - Ways and Means; Energy and Commerce

H.R.4671 — To amend titles XVIII and XIX of the Social Security Act to reduce cost-sharing, align income and resource eligibility tests, simplify enrollment, and provide for other program improvements for low-income Medicare beneficiaries. Sponsor: Rep. Kim, Andy [D-NJ-3]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

S.2600 — A bill to promote minimum State requirements for the prevention and treatment of concussions caused by participation in school sports, and for other purposes. Sponsor: Sen. Durbin, Richard J. [D-IL]; Cosponsors: (0) Committees: Senate - Health, Education, Labor, and Pensions

H.R.4704 — To direct the Director of the National Science Foundation to support multidisciplinary research on the science of suicide, and to advance the knowledge and understanding of issues that may be associated with several aspects of suicide including intrinsic and extrinsic factors related to areas such as wellbeing, resilience, and vulnerability. Sponsor: Rep. McAdams, Ben [D-UT-4], Cosponsors: (3) Committees: House - Science, Space, and Technology

H.R.4701 — To expand access to health care services, including sexual, reproductive, and maternal health services, for immigrants by removing legal and policy barriers to health insurance coverage, and for other purposes. Sponsor: Rep. Jayapal, Pramila [D-WA-7], Cosponsors: (22) Committees: House - Energy and Commerce

H.R.4699 — To amend title XIX of the Social Security Act to remove the matching requirement for a territory to use specially allocated Federal funds for Medicare covered part D drugs for low-income individuals. Sponsor: Rep. Gonzalez-Colon, Jennifer [R-PR-At Large], Cosponsors: (0) Committees: House - Energy and Commerce

H.R.4698 — To amend the HITECH Act to allow an individual to obtain a copy of such individual's protected health information at no cost unless certain circumstances apply. Sponsor: Rep. Foster, Bill [D-IL-11], Cosponsors: (3) Committees: House - Energy and Commerce

H.R.4693 — To amend title 38, United States Code, to establish an advisory committee on the implementation by the Department of Veterans Affairs of an electronic health record. Sponsor: Rep. Hudson, Richard [R-NC-8], Cosponsors: (1) Committees: House - Veterans' Affairs

S.Res.359 — A resolution authorizing the use of the atrium in the Philip A. Hart Senate Office Building for the National Prescription Drug Take Back Day, a semiannual event for the Drug Enforcement Administration. Sponsor: Sen. Klobuchar, Amy [D-MN], Cosponsors: (1), Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

H.R.4716 — To amend the Internal Revenue Code of 1986 to provide a safe harbor for high deductible health plans without a deductible for certain inhalers. Sponsor: Rep. Cox, TJ [D-CA-21]; Cosponsors: (1); Committees: House - Ways and Means

H.R.4712 — To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs. Sponsor: Rep. Dean, Madeleine [D-PA-4]; Cosponsors: (3); Committees: House - Energy and Commerce

H.R.4711 — To amend the Internal Revenue Code of 1986 to deny any deduction for advertising prescription drugs. Sponsor: Rep. Lipinski, Daniel [D-IL-3]; Cosponsors: (0); Committees: House - Ways and Means

H.R.4710 — To direct the Secretary of Defense to include in each national defense strategy steps to strengthen the United States industrial base and to assure an uninterrupted supply of medicines. Sponsor: Rep. Garamendi, John [D-CA-3]; Cosponsors: (1); Committees: House - Armed Services; Veterans' Affairs; Financial Services

H.Res.636 — Expressing support for the designation of October 17, 2019, as "National Vitiligo Awareness Day". Sponsor: Rep. Johnson, Henry C. "Hank," Jr. [D-GA-4]; Cosponsors: (33) Committees: House - Energy and Commerce

S.2633 — A bill to amend title XVIII of the Social Security Act to provide coverage for wigs as durable medical equipment under the Medicare program. Sponsor: Sen. Blumenthal, Richard [D-CT]; Cosponsors: (0); Committees: Senate - Finance

S.2629 — A bill to amend the Public Health Service Act with respect to the Public Health Service Corps. Sponsor: Sen. Rounds, Mike [R-SD]; Cosponsors: (1); Committees: Senate - Health, Education, Labor, and Pensions

S.2628 — A bill to amend title XIX of the Social Security Act to remove a limitation on an individual's eligibility for medical assistance under the State Medicaid plan while the individual is in custody pending disposition of charges. Sponsor: Sen. Markey, Edward J. [D-MA]; Cosponsors: (3); Committees: Senate - Finance

S.2626 — A bill to remove limitations on inmate eligibility for Medicare, the Children's Health Insurance Program, and veteran's health benefits. Sponsor: Sen. Merkley, Jeff [D-OR]; Cosponsors: (0); Committees: Senate - Finance

S.2619 — A bill to amend the Public Health Service Act to reauthorize the Healthy Start program. Sponsor: Sen. Brown, Sherrod [D-OH]; Cosponsors: (3); Committees: Senate - Health, Education, Labor, and Pensions