



Health Policy Briefing

July 23, 2018

House to Consider Package of Health Care Bills This Week

The House of Representatives plans to vote on several health care related bills this week. According to Majority Leader Kevin McCarthy (R-Calif.), the legislation is aimed at increasing the number of affordable health care choices available to Americans. The chamber will vote on the *Protect Medical Innovation Act*, a bill to permanently repeal the Affordable Care Act's (ACA) tax on medical devices. The House will consider the *Increasing Access to Lower Premium Plans and Expanding Health Savings Accounts Act*, legislation that would delay for two years the ACA's Cadillac tax on high cost health plans. The House will also vote on the *Restoring Access to Medication and Modernizing Health Savings Accounts Act*, which would expand the use of health savings accounts (HSAs). In addition to these bills, the *National Suicide Hotline Improvement Act of 2018*, the *Title VIII Nursing Workforce Reauthorization Act of 2018*, the *Palliative Care and Hospice Education and Training Act (PCHETA)*, the *EMPOWER Act of 2018*, the *Dr. Benjy Frances Brooks Children's Hospital GME Support Reauthorization Act of 2018* and several veterans' health care bills are also on the suspension calendar.

House Passes OTC and Animal Drug User Fee Legislation

The House of Representatives passed two bipartisan pieces of legislation relating to user fee programs at the Food and Drug Administration (FDA). The *Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018* (H.R. 5333) would modernize regulation of over-the-counter (OTC) products and establish a \$134 million, five-year user fee program to help ensure patients have timely access to new therapies. The bill would also shorten OTC products' market exclusivity and increase the FDA's ability to remove products with ingredients it deems unsafe. The *Animal Drug and Animal Generic Drug User Fee Amendments of 2018* (H.R. 5554) would reauthorize the new animal drugs and new generic animal drugs user fee programs, which expire in October. Both bills passed the House by voice vote.

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Senate Clears Bill to Delay Medicaid Rate Reduction

The Senate passed legislation (H.R. 6042) by unanimous consent to delay by one year a reduction in the Medicaid federal matching rate for states that fail to require an electronic visit verification system for personal care services. The reduction is scheduled to take effect January 1, 2019.

E&C Advances PAHPA Reauthorization

The House Energy and Commerce Committee advanced the *Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018* by voice vote last week. H.R. 6378 would reauthorize preparedness and response programs for five years. It also includes resources for the development of medical countermeasures for pandemic influenza and emerging infectious diseases as a part of the Biomedical Advanced Research and Development Authority (BARDA). The Pandemic and All-Hazards Preparedness Act (PAHPA) faces a September deadline for reauthorization and may be considered by the House this week.

FDA to Establish Drug Importation Working Group

U.S. Department of Health and Human Services (HHS) Secretary Alex Azar has requested that the FDA establish a working group to study how to safely import prescription drugs from other countries. More specifically, the working group will be responsible for examining the potential for importation to promote competition for drugs that are off-patent, not protected by exclusivities, produced by one manufacturer, and have experienced a supply disruption or whose price has dramatically increased. The Department stressed that the FDA's gold standard for safety and effectiveness will guide the working group's effort, while Azar reiterated that he is open to all potential solutions to lower the cost of drugs, as long as they are "effective, safe for patients, and respect choice, innovation, and access." Republican leadership on the House Energy and Commerce Committee praised the administration's move for leaving "no stone unturned" in its attempt to curb increasing drug prices, while emphasizing the complexity of the drug importation issue. Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) also said that he supports the FDA's work.

Brady Considers Legislative Solution to Risk-Adjustment Payments

House Ways and Means Committee Chairman Kevin Brady (R-Texas) told reporters last week that he is in talks with the Trump Administration about how to restart risk-adjustment payments under the ACA. The White House announced plans to suspend the \$10.4 billion in payments to insurers earlier this month, following a court ruling against the formula used for dispensing the funds. Insurers warn that the elimination of the risk-adjustment payments will result in increased premiums. Brady appeared open to finding a legislative solution to address the situation. As reported earlier, the House of Representatives plans to vote this week on several health care bills that would expand health savings accounts (HSAs) and delay or repeal a number of ACA taxes. Brady was unsure whether legislation impacting risk-adjustment payments could be added to the agenda.

Senate, WH at Odds on VA Mission Funding

Chairmen of the congressional Budget committees have called on appropriators to fund the *VA Mission Act* through cuts to other spending bills. Sen. Mike Enzi (R-Wyo.) and Rep. Steve Womack (R-Ark.) sent a letter to leadership on the Appropriations committees arguing that an additional \$1 to \$2 billion is needed to fund the legislation, which would increase flexibility for veterans to seek care outside of Department of Veterans Affairs (VA) facilities. Appropriators in the House cut funds from the Homeland Security spending bill to increase VA funding. Senate Appropriations Chairman Richard Shelby (R-Ala.), however, has expressed support for increasing spending caps by \$1.7 billion to fund the law instead of making cuts to other programs, which the White House opposes. While they do not explicitly threaten a veto, Office of Management and Budget (OMB) Director Mick Mulvaney and Acting VA Secretary Peter O'Rourke also wrote to appropriators last week calling on Congress to fund the *VA Mission Act* without expanding spending caps. House and Senate appropriators are currently working to reconcile the differences between their fiscal year (FY) 2019 Military Construction-VA spending bills.

In related news, the Senate plans to vote today on the confirmation of Robert Wilkie as Veterans Affairs secretary.

AHA Loses 340B Case

The U.S. Court of Appeals for the D.C. Circuit has denied the American Hospital Association's (AHA) challenge to cuts to the 340B Drug Discount Program. The HHS proposed cuts of nearly 30 percent to 340B. The hospitals argued that the \$1.6 billion loss in reimbursements would impact care of underserved populations. The federal appeals court ruling will allow the Trump administration to begin making cuts to the drug discount program. The White House applauded the court's decision, reiterating its commitment to finding solutions to lessen the cost of prescription drugs. AHA stated plans to refile promptly in district court.

The Government Accountability Office (GAO) also released a [report](#) last week analyzing the differences between 340B hospital participants and other hospitals. The agency found that 95 percent of 2016 participants are either critical access hospitals (CAHs), sole community hospitals, or general acute care hospitals that treat a disproportionate share of low-income patients (many of which were teaching hospitals). The 340B hospitals generally provided similar amounts of charity care when compared with non-340B hospitals but higher amounts of uncompensated care. GAO also found that acute care hospital participation in 340B has increased in states that expanded their Medicaid programs.

Upcoming Congressional Hearings and Markups

House Energy and Commerce Oversight and Investigations Subcommittee hearing "Examining Advertising and Marketing Practices within the Substance Use Treatment Industry;" 10:00 a.m., 2123 Rayburn Bldg.; July 24

House Ways and Means Human Resources Subcommittee hearing "The Opioid Crisis: Implementation of the Family First Prevention Services Act (FFPSA);" 10:00 a.m., 1100 Longworth Bldg.; July 24

House Energy and Commerce Health Subcommittee hearing "21st Century Cures Implementation: Updates from FDA and NIH;" 9:00 a.m., 2123 Rayburn Bldg.; July 25

Senate Health, Education, Labor, and Pensions Committee executive session to consider S. 2554, Patient Right to Know Drug Prices Act; H.R. 1222, Congenital Heart Futures Reauthorization Act of 2017; S. 2465, Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act of 2018; and S. 3016, Action for Dental Health Act of 2018; 10:00 a.m., 430 Dirksen Bldg.; July 25

House Energy and Commerce Health Subcommittee hearing "MACRA and MIPS: An Update on the Merit-based Incentive Payment System;" 10:00 a.m., 2123 Rayburn Bldg.; July 26

Recently Introduced Health Legislation

H.R.6371 — To ensure that Medicaid beneficiaries have the opportunity to receive care in a home and community-based setting; Sponsor: Rep. Cartwright, Matt [D-PA-17]; Committees: House - Energy and Commerce

H.R.6372 — To require the Secretary of Health and Human Services issue regulations to ensure due process rights for physicians furnishing emergency medical services; Sponsor: Rep. Collins, Chris [R-NY-27]; Committees: House - Energy and Commerce

H.R.6378 — To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes; Sponsor: Rep. Brooks, Susan W. [R-IN-5]; Committees: House - Energy and Commerce, Judiciary, Veterans' Affairs, Homeland Security

H.R.6387 — To plan, develop, and make recommendations to increase access to sexual assault examinations for survivors by holding hospitals accountable and supporting the providers that serve them; Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Energy and Commerce, Ways and Means, Education and the Workforce

H.R.6398 — To authorize the Department of Energy to conduct collaborative research with the Department of Veterans Affairs in order to improve healthcare services for veterans in the United States, and for other purpose; Sponsor: Rep. Norman, Ralph [R-SC-5]; Committees: House - Science, Space, and Technology, Veterans' Affairs

H.R.6413 — To combat trafficking in human organs, and for other purposes; Sponsor: Rep. Trott, David A. [R-MI-11]; Committees: House - Foreign Affairs

H.R.6421 — To advance treatment and cures for blindness and other retinal conditions and to promote competitiveness in the United States through a pilot program to increase funding for translational research, and for other purposes; Sponsor: Rep. Sessions, Pete [R-TX-32]; Committees: House - Energy and Commerce

H.R.6431 — To amend title XVIII of the Social Security Act to provide for certain reforms with respect to medicare supplemental health insurance policies; Sponsor: Rep. Levin, Sander M. [D-MI-9]; Committees: House - Ways and Means, Energy and Commerce

S.Res.576 — A resolution designating September 4, 2018, as "National Polycystic Kidney Disease Awareness Day", and raising awareness and understanding of polycystic kidney disease; Sponsor: Sen. Blunt, Roy [R-MO]; Committees: Senate - Judiciary

H.Res.1004 — Supporting the goals and ideals of National Clinicians HIV/AIDS Testing and Awareness Day, and for other purposes; Sponsor: Rep. Waters, Maxine [D-CA-43]; Committees: House - Energy and Commerce

H.R.6448 — To amend the National Organ Transplant Act to clarify the definition of valuable consideration, to clarify that pilot programs that honor and reward organ donation do not violate that Act, and for other purposes; Sponsor: Rep. Cartwright, Matt [D-PA-17]; Committees: House - Energy and Commerce

H.R.6458 — To amend the Public Health Service Act to revise and extend the national organ transplantation procurement program; Sponsor: Rep. Rice, Tom [R-SC-7]; Committees: House - Energy and Commerce

S.3253 — A bill to amend the Internal Revenue Code of 1986 to provide authority to add additional vaccines to the list of taxable vaccines; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Finance