



Health Policy Briefing

July 2, 2018

Kennedy Announces Retirement from Supreme Court

Justice Anthony Kennedy announced his plans to retire from the Supreme Court effective July 31. Kennedy was first nominated to the court in 1987, and has been the court’s swing vote in a number of important 5-4 decisions. His exit from the nation’s high court provides President Trump and the Republican Senate with the opportunity to shape the judicial branch and shift it to the right for the next several decades. The confirmation process for the President’s nominee is likely to dominate the Senate schedule through the fall. President Trump said he has already narrowed down his list of potential nominees to five names, and will announce his pick on Monday, July 9. Senate Majority Leader Mitch McConnell (R-Ky.) said that the Senate will confirm a successor before the November midterm elections. Confirmation hearings will likely be held in August or September in order to hold a vote before the Supreme Court’s new session begins in October. Much of the focus has been on the implications of Kennedy’s retirement on *Roe v. Wade*. Sens. Susan Collins (R-Maine) and Lisa Murkowski (R-Alaska), both of whom support abortion rights, are likely to be at the center of the debate. Their support will be crucial in a Senate confirmation vote; Collins has already stated that she would prefer the next justice to uphold the *Roe v. Wade* decision. A Kaiser Family Foundation [poll](#) conducted prior to the announcement of Supreme Court Justice Anthony Kennedy’s retirement found that two-thirds of the public do not want to see the Supreme Court overturn *Roe v. Wade*, while three in ten (29 percent) would like to see the decision overturned.

Appropriations Update

The House Appropriations Committee postponed its markup of the fiscal year (FY) 2019 Labor-HHS-Education spending bill for the second time. The panel now plans to consider the bill after the July 4 recess. The markup was likely postponed due to the ongoing immigration debate about separating families at the border. The House panel has already approved 10 appropriations bills; Labor-HHS-Education and Homeland Security are the only two left to consider.

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The Senate Appropriations Committee completed its markup of all twelve FY 2019 spending bills last week with its approval of the \$179.3 billion Labor-HHS-Education funding bill by a vote of 30-1. The Senate's bill would provide \$39.1 billion for the National Institutes of Health (NIH) – a \$2 billion increase over current levels, and \$3.7 billion to combat the opioid epidemic -- a \$145 million increase. The spending legislation also includes \$3.5 billion in appropriations for public health preparedness and \$1.6 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA).

HELP, E&C Advance Health-Related Legislation

The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced three pieces of health-related legislation last week. The Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act of 2018 (S. 3029) continues research and education programs aimed at preventing preterm births to reduce infant deaths and improve infant health. The Maternal Health Accountability Act of 2017 (S. 1112) will support state efforts to track pregnancy-related deaths and explore ways to combat rising maternal mortality rates. Finally, the Sports Licensure Medical Clarity Act of 2017 (S. 808) clarifies that sports medicine professionals who travel outside the state in which they are licensed are still covered by their medical liability insurance provider.

The House Energy and Commerce Health Subcommittee approved five measures that will reauthorize important health-related programs. The panel advanced the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2018, the Children's Hospital GME Support Reauthorization Act of 2018 (H.R. 5385), the Title VIII Nursing Workforce Reauthorization Act of 2017 (H.R. 959), and the Educating Medical Professionals and Optimizing Workforce Efficiency Readiness (EMPOWER) Act of 2017 (H.R. 3728) by voice vote. The subcommittee also advanced the Palliative Care and Hospice Education and Training Act (PCHETA) (H.R. 1676), which would award grants to improve palliative care and hospice health professional training, increase education and awareness about palliative care, and enhance research on palliative care.

Bipartisan Support Emerges for Biennial Budgeting

House Speaker Paul Ryan (R-Wis.) and Minority Leader Nancy Pelosi (D-Calif.) both expressed support for moving from single-year budget resolutions to two-year budgets during a hearing at the Joint Select Committee on Budget and Appropriations Process Reform last week. Under Ryan's proposal, lawmakers would agree upon top-line funding levels every two years and pass six of the 12 appropriations bills each year. Pelosi agreed with the idea of a biennial budget but argued that Congress should continue to pass 12 single appropriations bills each year. The change to the congressional schedule would help avoid government shutdowns and reduce the use of continuing resolutions (CRs), while adding more long-term predictability to spending decisions. The Select Committee was created to propose changes to the current budget process, and is required to make recommendations that have bipartisan support from a majority of panel members by November 30.

Wyden, Finance Dems Release Drug Pricing Report

Senate Finance Committee Democrats released a **report** last week on Medicare drug prices and the pharmaceutical supply and payment chains. The report argues that every part of the drug supply chain stands to benefit from higher prices due to financial arrangements in the delivery system. The lawmakers believe that the current administration is underestimating the challenges in the way of reducing drug prices and argue that real reform will require exposing the profit motives within the industry. The report was released ahead of the Committee's hearing titled "Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market," in which panel members heard from U.S. Department of Health and Human Services (HHS) Secretary Alex Azar.

GAO Makes Recommendations on 340B

The Government Accountability Office (GAO) has released a new **report** making seven recommendations to the Health Resources and Services Administration (HRSA) on how to ensure compliance among contract pharmacies with the 340B Drug Pricing Program. GAO presents its findings on the prevalence of contract pharmacies within 340B, and the distance between covered entities and their contract pharmacies. Twenty five of the 55 covered entities reviewed did not report that they provided low-income, uninsured patients with discounts on 340B drugs at some or all of their contract pharmacies, which could result in these patients facing higher drug prices. GAO also found that HRSA has failed to ensure that discounted drugs are going to the right patients and that pharmaceutical companies are not subject to both the 340B discount and Medicaid rebates. HRSA also has incomplete data on the total number of pharmacy contract arrangements. The GAO report was requested by the House Energy and Commerce Committee.

CMS Releases Latest Open Payments Data

The Centers for Medicare and Medicaid Services (CMS) released the latest **data** on payments made from drug and device manufacturers to physicians and teaching hospitals in 2017. The Open Payments program was created by the Affordable Care Act (ACA) and requires industry to report all payments they make to providers. In 2017, companies spent a combined \$8.4 billion -- a reduction of 4.5 percent compared to 2016. This total includes 11.54 million records attributable to 628,214 physicians and 1,158 teaching hospitals. Payments to physicians for the purpose of conducting research accounted for \$4.66 billion of the total. Approximately \$2.8 billion was classified as 'general,' which accounts for items such as travel expenses and meals, and the remaining \$927 million was attributed as physician ownership interests in pharmaceutical and device companies.

CMS Announces New Medicaid Integrity Initiatives

CMS has announced new efforts to improve the oversight of the Medicaid program following the release of state Medicaid scorecards earlier this year. The changes are designed to preserve the sustainability of the safety net program and will focus on flexibility, accountability, and integrity. CMS will begin emphasizing program integrity in audits of state claims for federal match funds and medical loss ratios (MLRs). The agency will also conduct new audits of state beneficiary eligibility determinations. Finally, CMS plans to begin optimizing state-provided claims and provider data.

Opioid-Related News Update

The Department of Justice (DOJ) has announced charges against 601 individuals for their role in health care fraud that in some cases contributed to the nation's opioid epidemic. The arrests were announced as a part of the annual National Health Care Fraud Takedown. This year marks the largest health care fraud enforcement action in history. During the takedown, the DOJ filed charges against 76 doctors in 84 opioid cases that involved more than 13 million illicit doses. DOJ's actions also involved cases unrelated to opioids, including schemes to bill government health care programs for medically unnecessary prescription medications and compounded drugs.

FDA Approves First Cannabis-Derived Drug

The Food and Drug Administration (FDA) has approved the first drug derived from marijuana. Epidiolex is manufactured by GW Pharmaceuticals and is intended to treat seizures associated with Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS) -- two forms of severe, rare child-onset epilepsy resistant to most treatment. The FDA approved Epidiolex for patients aged two years and older. It is made of cannabidiol (CBD), which is a component of marijuana that does not give users a high. The Drug Enforcement Administration (DEA) currently classifies CBD as a Schedule 1 drug -- indicating that it has no medical value and a high potential of abuse due to being a chemical component of cannabis. The FDA is working to provide the DEA with medical and scientific information about CBD so that that it can be reclassified, and GW can begin to market Epidiolex. GW expects DEA reclassification to occur within 90 days.

Recently Introduced Health Legislation

- H.R.6196 — *To amend the Elementary and Secondary Education Act of 1965 to require local educational agencies to implement a policy on allergy bullying in schools; Sponsor: Rep. Cartwright, Matt [D-PA-17]; Committees: House - Education and the Workforce*
- H.R.6199 — *To amend the Internal Revenue Code of 1986 to include certain over-the-counter medical products as qualified medical expenses; Sponsor: Rep. Jenkins, Lynn [R-KS-2]; Committees: House - Ways and Means*
- H.R.6201 — *To require the Secretary of Health and Human Services to establish a National Advisory Committee on Individuals with Disabilities in All-Hazards Emergencies; Sponsor: Rep. Langevin, James R. [D-RI-2]; Committees: House - Energy and Commerce*
- H.R.6203 — *To amend the Public Health Service Act to expand research and education with respect to endometrial cancer, and for other purposes; Sponsor: Rep. Scott, David [D-GA-13]; Committees: House - Energy and Commerce*
- H.R.6205 — *To amend the Controlled Substances Act to authorize hospitals to dispose of controlled substances on behalf of patients who die at the hospital, and for other purposes; Sponsor: Rep. Young, Don [R-AK-At Large]; Committees: House - Energy and Commerce, Judiciary*
- H.Res.960 - *Expressing the sense of the House of Representatives in support of HIV pre-exposure prophylaxis research, education, and usage, and addressing the barriers to receiving this treatment, especially for communities of color, gay and bisexual men, and transgender people; Sponsor: Rep. Watson Coleman, Bonnie [D-NJ-12]; Committees: House - Energy and Commerce*
- S.3120 — *An original bill to amend titles XVIII and XIX of the Social Security Act to help end addictions and lessen substance abuse disorders, and for other purposes; Sponsor: Sen. Hatch, Orrin G. [R-UT]; Committees: Senate - Finance*
- H.R.6225 — *To permit occupational therapists to conduct the initial assessment visit and complete the comprehensive assessment under a Medicare home health plan of care for certain rehabilitation cases; Sponsor: Rep. Smith, Jason [R-MO-8]; Committees: House - Ways and Means, Energy and Commerce*
- H.R.6240 — *To amend the Public Health Service Act to provide for certain user fees under the 340B drug discount program; Sponsor: Rep. Collins, Chris [R-NY-27]; Committees: House - Energy and Commerce*
- H.Res.973 — *Expressing support for the designation of July 15, 2018, as “National Leiomyosarcoma Awareness Day” and the designation of July 2018, as “National Sarcoma Awareness Month”; Sponsor: Rep. Levin, Sander M. [D-MI-9]; Committees: House - Energy and Commerce*
- H.R.6261 — *To require short-term limited duration insurance issuers to renew or continue in force such coverage at the option of the enrollees; Sponsor: Rep. Budd, Ted [R-NC-13]; Committees: House - Energy and Commerce*
- H.R.6269 — *To amend title XVIII of the Social Security Act to restructure the payment adjustment for non-emergency ESRD ambulance transports under the Medicare program; Sponsor: Rep. LaHood, Darin [R-IL-18]; Committees: House - Energy and Commerce, Ways and Means*
- H.R.6273 — *To amend the Public Health Service Act to ensure appropriate care by certain 340B covered entities for victims of sexual assault, and for other purposes; Sponsor: Rep. Walters, Mimi [R-CA-45]; Committees: House - Energy and Commerce*
- H.R.6283 — *To amend the Internal Revenue Code of 1986 to allow individuals only enrolled in Medicare Part A to contribute to health savings accounts; Sponsor: Rep. Latta, Robert E. [R-OH-5]; Committees: House - Ways and Means*

H.R.6291 — To exempt from certain requirements of the Clean Air Act incinerator units owned and operated by a Federal, State, or local law enforcement agency when used for the sole purpose of destroying contraband or household pharmaceuticals, and for other purposes; Sponsor: Rep. Rice, Tom [R-SC-7]; Committees: House - Energy and Commerce

H.R.6294 — To amend the Federal Food, Drug, and Cosmetic Act to encourage the development of priority antimicrobial products through the award of a transferable exclusivity extension period, and for other purposes; Sponsor: Rep. Shimkus, John [R-IL-15]; Committees: House - Energy and Commerce

S.Res.561 — A resolution designating July 15, 2018, as “National Leiomyosarcoma Awareness Day” and the month of July 2018 as “National Sarcoma Awareness Month”; Sponsor: Sen. Stabenow, Debbie [D-MI]; Committees: Senate - Judiciary

S.3158 — 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, 2019, and for other purposes; Sponsor: Sen. Blunt, Roy [R-MO]; Committees: Senate - Appropriations

S.3160 — A bill to amend title XVIII of the Social Security Act to improve access to, and utilization of, bone mass measurement benefits under part B of the Medicare program by establishing a minimum payment amount under such part for bone mass measurement; Sponsor: Sen. Collins, Susan M. [R-ME]; Committees: Senate - Finance

S.3161 — A bill to establish the Centers for Disease Control and Prevention Emergency Response Fund to provide assistance with respect to a public health emergency, and for other purposes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions

S.3175 — A bill to amend title 38, United States Code, to provide health care, vocational training and rehabilitation, and monetary allowance to children suffering from spina bifida whose parents are veterans who served in Thailand and were exposed to herbicide agents, and for other purposes; Sponsor: Sen. McCaskill, Claire [D-MO]; Committees: Senate - Veterans' Affairs

S.3181 — A bill to direct the Secretary of Defense to include in periodic health assessments, separation history and physical examinations, and other assessments an evaluation of whether a member of the Armed Forces has been exposed to open burn pits or toxic airborne chemicals, and for other purposes; Sponsor: Sen. Klobuchar, Amy [D-MN]; Committees: Senate - Armed Services