



Health Policy Briefing

July 16, 2018

Kavanaugh Nominated to Serve as 114th Supreme Court Justice

President Trump announced his decision last week to nominate Brett Kavanaugh to fill the Supreme Court seat being vacated by Justice Anthony Kennedy. Kavanaugh is a judge on the U.S. Court of Appeals for the District of Columbia Circuit.

Kavanaugh has significant health-law experience. While serving on the U.S. Court of Appeals, he has dealt with provider-payer issues, access to contraception, the constitutionality of the Affordable Care Act (ACA), and questions surrounding abortion for an illegal immigrant in federal custody. He has written recent two opinions dealing with the Food and Drug Administration (FDA) and substantial equivalence. Kavanaugh has also been involved with cases regarding generic drug approvals and drug exclusivity. The President's announcement commences a confirmation battle that could potentially shape the ideology of the nation's highest court for the next several decades.

Without any defections, Republicans have the votes to confirm Kavanaugh. Senate Democratic leader Chuck Schumer (D-N.Y.) plans to oppose the nomination, warning that the President's choice will put reproductive rights and health care protections "on the judicial chopping block." Schumer has also suggested the President's nominee has an obligation to share his personal views on legal issues.

Kavanaugh began meeting with senators last week. Sens. Joe Manchin (D-W.V.), Heidi Heitkamp (D-N.D.), and Joe Donnelly (D-Ind.) were the only Democrats to vote in support of Trump's 2017 Supreme Court nominee. All are grappling with difficult reelection races in November. Sen. Manchin stated that he is evaluating Kavanaugh's record, particularly in regard to health care. Meanwhile, Sens. Susan Collins (R-Maine) and Lisa Murkowski (R-Alaska) are facing pressure from the left to protect reproductive rights and vote against the nomination. Sen. Rand Paul (R-Ky.) has also expressed reservations about Kavanaugh. Only four Democrats supported

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Kavanaugh's confirmation to the D.C. Circuit during the Bush administration. Sen. Tom Carper (D-Del.) is the only one still serving in the Senate.

The Supreme Court is expected to hear a number of fraud and patent cases involving drug and device manufacturers in its 2018 term, which begins in October.

House Appropriators Advance HHS Spending Bill

The House Appropriations Committee advanced a \$177.1 billion spending bill to fund the departments of Labor, Education, and Health and Human Services (HHS) for fiscal year (FY) 2019 last week. The legislation keeps overall funding levels in line with current spending. HHS would receive a total of \$12.1 billion, an \$89 million decrease compared to FY 2018. The National Institutes of Health (NIH) would receive a \$1.25 billion increase for a total of \$37.1 billion in funding. The Centers for Disease Control and Prevention (CDC) would receive \$6.9 billion in funding and the Substance Abuse and Mental Health Services Administration (SAMHSA) would receive \$5.7 billion. The increases in funding for CDC and SAMHSA would help support programs to promote maternal and infant health and enhanced neurological disease surveillance. The appropriations bill would also establish a \$325 million infectious disease rapid response fund within the CDC. Lawmakers narrowly adopted an amendment that would require HHS to report the most frequently used and most expensive drugs in the Medicare and Medicaid programs and which products received significant government research subsidies.

The markup, which had previously been postponed twice, lasted for 13 hours and included lengthy debates on over 50 amendments related to contentious issues such as abortion, the ACA, and immigration.

The panel rejected a Democratic amendment to reinstate Title X funding for family planning and preventive health services as well as an amendment to remove language from the legislation that would effectively defund Planned Parenthood. The Senate appropriations bill maintains funding for both Title X and Planned Parenthood. Republicans also blocked an amendment that would have funded gun violence research through the CDC. Members considered 16 amendments related to the issue of family separation, adopting many of them by voice vote. The Committee unanimously agreed upon a proposal to cut \$100,000 per day from HHS' budget if the department fails to explain to Congress how HHS is reunifying families separated at the border by August. Appropriators also endorsed language that prohibits the separation of immigrant siblings as well as the forced medication of children housed by the agency.

The House Appropriations Committee has now approved 11 of 12 FY 2019 spending bills. It is unclear when the Labor-Education-HHS bill will be brought to the floor for a vote. Senate appropriators have voiced support for combining its Labor-Education-HHS bill with funding for the Department of Defense to garner support for the measure. The House has already passed its Defense appropriations bill; if the Senate passes a combined bill and sends it to the House, the chamber could decide to skip a floor vote altogether in favor of a conference committee.

E&C, W&M Advance Health-Related Legislation

The House Committee on Energy and Commerce (E&C) unanimously advanced four health care workforce bills last week: the *Title VIII Nursing Workforce Reauthorization Act of 2017* (H.R. 959), the *Palliative Care and Hospice Education and Training Act* (H.R. 1676), the *Educating Medical Professionals and Optimizing Workforce Efficiency Readiness (EMPOWER) Act of 2017* (H.R. 3728), and the *Children's Hospital GME Support Reauthorization Act of 2018* (H.R. 5385). The panel also approved the *National Suicide Hotline Improvement Act* (H.R. 2345) by voice vote. The bill would require a study and report on the feasibility of designating a dialing code to be used for a national suicide prevention and mental health crisis hotline system.

The House Ways and Means Committee also held a markup of health-related legislation last week. The panel reviewed 11 bills previously advanced by the health subcommittee largely aimed at expanding the value and use of health savings accounts (HSAs), including five bipartisan pieces of legislation. The committee favorably reported H.R. 6199, a bill to allow reimbursement for over-the-counter (OTC) drugs without a prescription. During the markup, however, many Democratic members were critical of the agenda for adding to the national debt and argued that the bills would largely benefit wealthy Americans and had little chance of passing the Senate.

Ways and Means also considered Republican legislation making changes to the ACA. H.R. 4616 would provide retroactive relief from Obamacare's employer mandate. The *Employer Relief Act of 2018* would also delay the Cadillac tax on high-cost health insurance plans until 2023. The bill was approved by a vote of 22-15. H.R. 6311 would allow the use of ACA tax credits for plans outside of the individual market exchanges. The Committee passed the bill 23-16.

VA Secretary Nomination Advanced

The Senate Veterans Affairs Committee voted to advance the nomination of Robert Wilkie to serve as Secretary of the Department of Veterans Affairs last week. Sen. Bernie Sanders (I-Vt.) voted against the nomination, marking the first time in the panel's history that a member has voted against a nomination for secretary. Sanders has stated his suspicions that any appointee of President Trump is likely to advance the administration's push for privatization of the VA. Wilkie's nomination now advances to the full Senate for confirmation.

Pallone Requests Hearing on REMS

House E&C Ranking Member Frank Pallone (D-N.J.) has **written** to the panel's Republican leadership requesting a hearing to examine anti-competitive practices used by the pharmaceutical industry to delay generic competition. Pallone urges the committee to explore how the misuse of Risk Evaluation and Mitigation Strategies (REMS) blocks, impedes, or delays competition, and what potential legislative solutions are available. He specifically asks Chairman Greg Walden (R-Ore.) and Health Subcommittee Chairman Michael Burgess (R-Texas) to consider H.R. 2212, the *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017*, and H.R. 2051, the *Fair Access for Safe and Timely (FAST) Generics Act of 2017*.

White House Reduces Patient Navigator Funding

The Trump administration announced its decision to reduce the funding available to the navigator program, which works to help people enroll in the ACA individual health insurance market. The U.S. Department of Health and Human Services (HHS) will award up to \$10 million for such purposes in 2019. Navigators received \$36 million in federal grants last year, and \$63 million in grants two years ago. The administration argues that the public is made aware of the annual open enrollment period through means other than the navigator program, and that navigators do not enroll a meaningful number of people to justify additional money being spent on the program.

FDA Announces New Drug Shortages Task Force

Commissioner of Food and Drugs Scott Gottlieb announced the formation of a new drug shortages task force. The task force will examine the reasons why some shortages remain a persistent challenge as well as possible solutions to address the underlying causes of the shortages. The task force will be led by Keagan Lenihan, FDA Associate Commissioner for Strategic Initiatives.

Opioid Related News Update

Attorney General Jeff Sessions will target areas of the country that have been hit hardest by fentanyl overdose deaths. Additional prosecutors have been sent to Ohio, Tennessee, Kentucky, West Virginia, Maine, California, Pennsylvania, and New Hampshire. Sessions has instructed prosecutors to bring charges against anyone suspected of dealing the opioid, regardless of the quantity.

The Department of Justice also announced that it has finalized a proposal to slow the diversion of opioids and limit the number of opioids produced annually in the U.S. The Drug Enforcement Administration (DEA) can now issue stricter production limits on certain opioids if the agency believes a particular company's products are being diverted for misuse.

FDA Approves Freeze-Dried Plasma for Combat Troops

The Food and Drug Administration (FDA) announced an emergency use authorization that will allow the Department of Defense to provide freeze-dried plasma for the treatment of soldiers with combat injuries. The announcement settles a dispute between the two agencies over access to the product, which has not been formally approved by the FDA. The Pentagon had originally attempted to establish its own process for approving drugs and devices.

Upcoming Congressional Hearings and Markups

Senate Health, Education, Labor, and Pensions Committee hearing "Reducing Health Care Costs: Eliminating Excess Health Care Spending and Improving Quality and Value for Patients;" 10:00 a.m., 430 Dirksen Bldg.; July 17

House Energy and Commerce Oversight and Investigations Subcommittee hearing "Examining State Efforts to Improve Transparency of Health Care Costs for Consumers;" 10:15 a.m., 2322 Rayburn Bldg.; July 17

House Ways and Means Oversight Subcommittee hearing "Combating Fraud in Medicare: A Strategy for Success;" 10:00 a.m., 1100 Longworth Bldg.; July 17

House Ways and Means Health Subcommittee hearing "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program;" 2:00 p.m., 1100 Longworth Bldg.; July 17

Senate Homeland Security and Governmental Affairs hearing to examine the Administration's government reorganization proposal; 10:00 a.m., 342 Dirksen Bldg.; July 18

House Energy and Commerce Health Subcommittee hearing "21st Century Cures Implementation: Examining Mental Health Initiatives;" 10:00 a.m., 2123 Rayburn Bldg.; July 19

Recently Introduced Health Legislation

H.R.6301 — To amend the Internal Revenue Code of 1986 to provide high deductible health plans with first dollar coverage flexibility; Sponsor: Rep. Roskam, Peter J. [R-IL-6]; Committees: House - Ways and Means

H.R.6305 — To amend the Internal Revenue Code of 1986 to improve access to health care through modernized health savings accounts; Sponsor: Rep. Kelly, Mike [R-PA-3]; Committees: House - Ways and Means

H.R.6306 — To amend the Internal Revenue Code of 1986 to increase the contribution limitation for health savings accounts, and for other purposes; Sponsor: Rep. Paulsen, Erik [R-MN-3]; Committees: House - Ways and Means

H.R.6309 — To amend the Internal Revenue Code of 1986 to allow individuals entitled to Medicare Part A by reason of being over age 65 to contribute to health savings accounts; Sponsor: Rep. Paulsen, Erik [R-MN-3]; Committees: House - Ways and Means

H.R.6310 — To amend the Internal Revenue Code of 1986 to provide that direct primary care service arrangements do not disqualify deductible health savings account contributions, and for other purposes; Sponsor: Rep. Paulsen, Erik [R-MN-3]; Committees: House - Ways and Means

H.R.6311 — To amend the Internal Revenue Code of 1986 and the Patient Protection and Affordable Care Act to modify the definition of qualified health plan for purposes of the health insurance premium tax credit and to allow individuals purchasing health insurance in the individual market to purchase a lower premium copper plan; Sponsor: Rep. Roskam, Peter J. [R-IL-6]; Committees: House - Energy and Commerce, Ways and Means

H.R.6312 — To amend the Internal Revenue Code of 1986 to treat certain amounts paid for physical activity, fitness, and exercise as amounts paid for medical care; Sponsor: Rep. Smith, Jason [R-MO-8]; Committees: House - Ways and Means

H.R.6313 — To amend the Internal Revenue Code of 1986 to allow the carryforward of health flexible spending arrangement account balances; Sponsor: Rep. Stivers, Steve [R-OH-15]; Committees: House - Ways and Means

H.R.6314 — To amend the Internal Revenue Code of 1986 to allow bronze and catastrophic plans in connection with health savings accounts; Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Ways and Means

H.R.6315 — To provide women with increased access to preventive and life-saving cancer screening; Sponsor: Rep. Gomez, Jimmy [D-CA-34]; Committees: House - Energy and Commerce

S.3184 — A bill to amend title 38, United States Code, to modify the requirements for applications for construction of State home facilities to increase the maximum percentage of nonveterans allowed to be treated at such facilities, and for other purposes; Sponsor: Sen. Bennet, Michael F. [D-CO]; Committees: Senate - Veterans' Affairs

H.R.6317 — To amend the Internal Revenue Code of 1986 to provide that direct primary care service arrangements do not disqualify deductible health savings account contributions, and for other purposes; Sponsor: Rep. Paulsen, Erik [R-MN-3]; Committees: House - Ways and Means

H.R. 6340 – To amend the Patient Protection and Affordable Care Act to cap prescription drug cost-sharing, and for other purposes; Sponsor: Rep. Rosen, Jacky [D-NV-3]; Committees: House - Energy and Commerce

H.R. 6341 – To amend title XVIII of the Social Security Act to provide for the extension or renewal of certain reasonable cost reimbursement contracts under the Medicare program through 2020; Sponsor: Walz, Timothy J. [D-MN-1]; Committees: House - Energy and Commerce, Ways and Means

S.3194 — A bill to amend the Patient Protection and Affordable Care Act to cap prescription drug cost-sharing, and for other purposes; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.6343 — To provide for a demonstration program and pilot project to expand choice for inpatient psychiatric services under Medicaid and Medicare; Sponsor: Rep. Huizenga, Bill [R-MI-2]; Committees: House - Energy and Commerce, Ways and Means

H.R.6357 — To direct the Comptroller General of the United States to assess and make recommendations related to disaster medical assistance teams, and for other purposes; Sponsor: Rep. Bilirakis, Gus M. [R-FL-12]; Committees: House - Energy and Commerce

S.3203 — A bill 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: Sen. Murray [D-WA]; Committees: Senate - Health, Education, Labor, and Pensions

S.3207 — A bill to amend the Higher Education Act of 1965 to allow for the deferment of certain student loans during a period in which a borrower is receiving treatment for cancer; Sponsor: Sen. Nelson [D-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.3212 — A bill to facilitate effective research on and treatment of neglected tropical diseases through coordinated domestic and international efforts; Sponsor: Sen. Brown [D-OH]; Committees: Senate - Health, Education, Labor, and Pensions