



Health Policy Briefing

May 15, 2017

Senate Republicans Weigh Health Care Options

The Senate has begun work on its own bill to repeal and replace the Affordable Care Act (ACA) after the House of Representatives narrowly passed H.R. 1628, the American Health Care Act (AHCA), earlier this month. Majority Leader Mitch McConnell (R-Ky.) has acknowledged that the process in the Senate will be neither simple nor quick, but pledged to continue work on a repeal and replace measure without outlining a timeframe for the bill.

Senate Democrats have been critical of the Republican strategy for writing the legislation, characterizing it as taking place behind closed doors. They have also criticized the fact that the Senate GOP health care working group consists of only male Republican senators. Majority Leader McConnell has countered that negotiations are open to his entire caucus – he can only afford to lose two members of his own party in order to secure Senate passage. The bill, however, is not expected to go the route of the hearing and markup committee process, despite a request from the ranking members of the committees of jurisdiction.

Members of the Republican working group have begun revealing policies they are considering for inclusion in their version of repeal and replace. Sen. John Cornyn (R-Texas) has said that Republicans are looking into how to repeal the ACA's insurance regulations, such as the essential health benefit coverage requirements and community rating. Another option touted by Sen. Rob Portman (R-Ohio) is a new tax credit to assist those who are recently coming out of the Medicaid program with purchasing health insurance. Sen. Portman hopes the Senate bill will be better than AHCA in targeting the population close to the poverty line. Along with Sen. Pat Toomey (R-Pa.), Sen. Portman has been tasked by the Majority Leader with determining how to deal with Obamacare's expansion of Medicaid. Both senators come from states that accepted expansion of the program. The senators will need to determine how to wind down expansion, how quickly the cap on Medicaid payments should grow, and where additional flexibility should be provided to states in the administration of the program. Republicans in the upper chamber are far more divided than their House colleagues about how to handle the Medicaid program. Members like Sen. Portman are concerned about the effects of scaling back funding for the program due to the possible effects on enrollees as well

Inside

- [FDA Commissioner Confirmed.....](#)2
- [HELP Advances FDA User Fee Reauthorization Bill.....](#)2
- [HELP to Schedule Hearing on Drug Pricing.....](#)2
- [Senators Back ONDCP Funding.....](#)3
- [Lawmakers Request Clarification on HHS Whistleblower Memo.....](#)3
- [Upcoming Congressional Hearings/Meetings.....](#)3
- [Recently Introduced Health Legislation.....](#)4

as public health priorities like combatting the opioid epidemic.

The entire Senate Democratic caucus sent Majority Leader McConnell, Senate Finance Committee Chairman Orrin Hatch (R-Utah), and Senate HELP Committee Chairman Lamar Alexander (R-Tenn.) a letter asking Republicans to stop their work on Obamacare repeal and instead work together to fix the current health care system. They believe that Republican plans to repeal and replace the ACA will result in an increase in the cost of insurance for the patients who most need it, while also lowering the quality of coverage. The lawmakers express a willingness to work on decreasing drug costs and insurance premiums, and making it more affordable for small business to provide health insurance, without cutting coverage benefits. Majority Leader McConnell, however, responded that the status quo is unsustainable and requires more drastic action by Congress.

Secretary of the U.S. Department of Health and Human Services (HHS) Tom Price committed to working with the Senate and expects the upper chamber to vote on its health bill before August recess. Speaker of the House Paul Ryan (R-Wis.) made a similar prediction, stating that Congress would complete health-care legislation by the end of the summer, while allowing several years for implementation of the bill. Sen. John Cornyn (R-Texas) has also pledged that the Senate will pass a bill repealing and replacing Obamacare this year. A cost estimate of the House-passed AHCA by the Congressional Budget Office (CBO) is expected to be released next week.

FDA Commissioner Confirmed

The Senate confirmed Scott Gottlieb, MD as Commissioner of Food and Drugs by a vote of 57 to 42 last week. The following Democrats joined Republicans in supporting the nomination: Sens. Michael Bennet (D-Colo.), Tom Carper (Del.), Chris Coons (Del.), Heidi Heitkamp (N.D.), Angus King (I-Maine), and Bill Nelson (Fla.). Lawmakers commented on the timeliness of the confirmation, and expressed confidence that Dr. Gottlieb would begin work to address the opioid crisis, reauthorization of the user fee programs, and implementation of the 21st Century Cures Act.

HELP Advances FDA User Fee Reauthorization Bill

The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced legislation to reauthorize the Food and Drug Administration's (FDA) user fee programs last week by a vote of 21-2. Sen. Bernie Sanders (I-Vt.) and Sen. Rand Paul (R-Ky.) voted against the measure. S. 934 would reauthorize the programs for fiscal years (FY) 2018 through 2022. The manager's amendment to the FDA Reauthorization Act (FDARA) adds a number of provisions beyond user fee program reauthorization related to pediatric drugs and devices, bioequivalence, device inspections and regulations, indications of contrast agents, and the availability of over-the-counter (OTC) hearing aids. Two additional amendments were added to the bill, one from Sens. Orrin Hatch (R-Utah), Michael Bennet (D-Colo.), Richard Burr (R-N.C.), and Bob Casey (D-Pa.) on expanded access to drugs and one from Sens. Susan Collins (R-Maine) and Al Franken (D-Minn.) on generic drugs and competition. Current authorization for the user fees expires on September 30. The bill now moves to the full Senate for consideration. The House Energy and Commerce Committee is expected to schedule consideration of FDA user fees legislation later this month.

HELP to Schedule Hearing on Drug Pricing

During the markup of legislation to reauthorize the Food and Drug Administration's (FDA) user fee programs, Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) announced plans to hold a hearing on U.S. prescription drug prices. The hearing comes at the bipartisan **request** of several committee members including Al Franken (D-Minn.), Bill Cassidy (R-La.), Tammy Baldwin (D-Wisc.), Susan Collins (R-Maine), Sheldon Whitehouse (D-R.I.), Lisa Murkowski (R-Alaska), Bernie Sanders (I-VT), Shelley Moore Capito (R-WV), Elizabeth Warren (D-Mass.) and Mike Enzi (R-Wyo.). The Chairman **responded** to the senators saying that the hearing will be scheduled in the near future.

Senators Back ONDCP Funding

A bipartisan group of senators have **written** to the Trump Administration requesting that they fully fund the Office of National Drug Control Policy (ONDCP) in the White House fiscal year (FY) 2018 budget. The letter to the Office of Management and Budget (OMB) Director Mick Mulvaney cites the success of the ONDCP in fighting drug abuse and addiction. The White House has proposed cutting nearly the entire budget of the ONDCP – reducing its funding by 95 percent. “Eliminating critical prevention and enforcement programs would endanger our efforts to confront the drug overdose epidemic that has gripped our nation,” the lawmakers write. The letter was led by Sen. Dianne Feinstein (D-Calif.) and Sen. Chuck Grassley (R-Iowa) and was signed by 11 other bipartisan senators.

Lawmakers Request Clarification on HHS Whistleblower Memo

Senate Judiciary Committee Chairman Chuck Grassley (R-Iowa) and House Oversight Committee Chairman Jason Chaffetz (R-Utah) have written to U.S. Department of Health and Human Services (HHS) Secretary Tom Price regarding HHS staff’s ability to speak to lawmakers. Agency employees received a memo telling them to contact the Office of the Assistant Secretary for Legislation prior to speaking with members of Congress. “Protecting whistleblowers who courageously speak out is not a partisan issue — it is critical to the functioning of our government,” the letter states. The lawmakers request that Secretary Price issue a clarification telling federal workers that they have a right to contact members of Congress.

Upcoming Congressional Hearings/Meetings

Senate Finance Committee hearing to examine bipartisan Medicare policies that improve care for patients with chronic conditions; 10:00 a.m., 215 Dirksen Bldg.; May 16

House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Oversight Hearing with NIH Director Dr. Francis Collins testifying entitled “Advances in Biomedical Research;” 10:00 a.m., 2358-C Rayburn; May 17

House Energy and Commerce Health Subcommittee hearing entitled “Examining Initiatives to Advance Public Health;” the Committee will consider H.R. 931, the Firefighter Cancer Registry Act; H.R. 1836, the Good Samaritan Health Professionals Act; H.R. 767, the SOAR to Health and Wellness Act; and the Action for Dental Health Act; 10:15 a.m., 2322 Rayburn Bldg.; May 17

Senate Veterans Affairs Committee hearing on pending health and benefits legislation including S. 23, the Biological Implant Tracking and Veteran Safety Act; 2:30 p.m., 418 Russell Bldg.; May 17

House Ways and Means Subcommittee on Health hearing entitled “The Current Status of the Medicare Program, Payment Systems, and Extenders;” 2:00 p.m., 1100 Longworth Bldg.; May 18

Recently Introduced Health Legislation

H.R.2351 (introduced by Rep. Maxine Waters): To amend the Public Health Service Act to authorize grants to provide treatment for diabetes in minority communities; Energy and Commerce

H.R.2360 (introduced by Rep. Joyce Beatty): To provide for systemic research, treatment, prevention, awareness, and dissemination of information with respect to sports-related and other concussions; Energy and Commerce

H.R.2368 (introduced by Rep. Brian K. Fitzpatrick): To authorize the use of experimental drugs, biological products, and devices by patients diagnosed with a terminal illness in accordance with State law, and for other purposes; Energy and Commerce, Judiciary

H.R.2373 (introduced by Rep. Mike Kelly): To amend title XVIII of the Social Security Act with respect to the accreditation of osteopathic residency training programs for purposes of graduate medical education payments under the Medicare program; Ways and Means, Energy and Commerce

H.R.2376 (introduced by Rep. Leonard Lance): To amend the Federal Food, Drug, and Cosmetic Act to protect and strengthen the drug supply chain in the United States by closing several statutory gaps in the penalty provisions of such Act that apply to drug diversion and counterfeiting; Energy and Commerce

H.R.2392 (introduced by Rep. Janice D. Schakowsky): To amend the Public Health Service Act to establish direct care registered nurse-to-patient staffing ratio requirements in hospitals, and for other purposes; Energy and Commerce, Ways and Means

H.Res.315 (introduced by Rep. Eddie Bernice Johnson): Expressing support for the designation of the week of May 6 through May 12, 2017, as National Nurses Week; Energy and Commerce

S.1044 (introduced by Sen. Shelley Moore Capito): A bill to amend title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes; Finance

S.1045 (introduced by Sen. Patty Murray): A bill to guarantee coverage of certain women's preventive services under all health plans; Health, Education, Labor, and Pensions

S.1048 (introduced by Sen. Orrin G. Hatch): A bill to expand patient access to experimental treatments in clinical trials, and for other purposes; Health, Education, Labor, and Pensions

S.1049 (introduced by Sen. Margaret Woods Hassan): A bill to allow the Secretary of Health and Human Services to require that risk evaluation and mitigation strategies for certain drugs include communication plans that provide information about drug formulations or properties described in the drug labeling; Health, Education, Labor, and Pensions

S.1052 (introduced by Sen. Roger F. Wicker): A bill to strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs; Health, Education, Labor, and Pensions

S.1062 (introduced by Sen. Richard Burr): A bill to increase reporting transparency and accountability with respect to Food and Drug Administration user fees; Health, Education, Labor, and Pensions

S.1063 (introduced by Sen. Sherrod Brown): A bill to amend the Public Health Service Act to establish direct care registered nurse-to-patient staffing ratio requirements in hospitals, and for other purposes; Health, Education, Labor, and Pensions

S.1069 (introduced by Sen. Robert P. Casey, Jr.): A bill to establish pilot projects in order to provide timely and reliable information on the safety and effectiveness of cleared or approved devices; Health, Education, Labor, and Pensions

S.1070 (introduced by Sen. Pat Roberts): A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the appropriate, risk-based classification of device accessories based on intended use; Health, Education, Labor, and Pensions

H.R.2404 (introduced by Rep. Stacey E. Plaskett): To amend titles XVIII and XIX of the Social Security Act to make improvements to the treatment of the United States territories under the Medicare and Medicaid programs, and for other purposes; Energy and Commerce, Ways and Means

S. 1077 (introduced by Sen. Manchin): A bill to direct the Secretary of Health and Human Services to amend the mission statement of the Food and Drug Administration; Health, Education, Labor, and Pensions

S. 1078 (introduced by Sen. Manchin): A bill to establish procedures regarding the approval of opioid drugs by the Food and Drug Administration; Health, Education, Labor, and Pensions

S. 1079 (introduced by Sen. Manchin): A bill to require the Food and Drug Administration to revoke the approval of one opioid pain medication for each new opioid pain medication approved; Health, Education, Labor, and Pensions

S.1093 (introduced by Sen. Al Franken): A bill to amend the Federal Food, Drug, and Cosmetic Act to improve pediatric medical device application procedures; Health, Education, Labor, and Pensions

H.R.2410 (introduced by Rep. Danny K. Davis): To amend the Public Health Service Act to reauthorize a sickle cell disease prevention and treatment demonstration program and to provide for sickle cell disease research, surveillance, prevention, and treatment; Energy and Commerce

H.Res.320 (introduced by Rep. Tim Murphy): Expressing support for the designation of May 2017 as “Mental Health Month”; Energy and Commerce

S.1106 (introduced by Sen. Jeff Merkley): A bill to designate the same individual serving as the Chief Nurse Officer of the Public Health Service as the National Nurse for Public Health; Health, Education, Labor, and Pensions

S.1109 (introduced by Sen. Jeff Merkley): A bill to amend title VIII of the Public Health Service Act to extend advanced education nursing grants to support clinical nurse specialist programs, and for other purposes; Health, Education, Labor, and Pensions

S.1112 (introduced by Sen. Heidi Heitkamp): A bill to support States in their work to save and sustain the health of mothers during pregnancy, childbirth, and in the postpartum period, to eliminate disparities in maternal health outcomes for pregnancy-related and pregnancy-associated deaths, to identify solutions to improve health care quality and health outcomes for mothers, and for other purposes; Health, Education, Labor, and Pensions

S.1113 (introduced by Sen. Dianne Feinstein): A bill to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics; Health, Education, Labor, and Pensions

S.1115 (introduced by Sen. Susan M. Collins): A bill to improve access to prescription drugs; Health, Education, Labor, and Pensions