



Health Policy Briefing

June 12, 2017

Senate Pushes Forward on Health Care Bill, Though Skepticism Remains

Majority Leader Mitch McConnell (R-Ky.) has officially fast-tracked Affordable Care Act (ACA) repeal and replace legislation, allowing it to skip over the committee process. The move will allow him to bring the bill to the floor quickly once Republicans are ready to vote. Aides spent the week-long Memorial Day recess negotiating a draft of the Senate health care legislation, and early proposals possibly contained in the draft began circulating last week. The Majority Leader also presented the blueprint of the legislation to his colleagues during a closed-door GOP meeting last week. According to some sources, McConnell may propose to keep protections in place that would prevent people with pre-existing conditions from being charged higher premiums for health insurance coverage. Sen. Bill Cassidy (R-La.), a moderate whose vote is considered pivotal for passage of the legislation, said that he was encouraged that recent discussions have been geared toward addressing the needs of vulnerable patients.

Senators are still sending mixed messages about when the legislation will be ready for introduction, and are expressing various levels of optimism on whether or not it will successfully pass. Divisions remain about how to phase out Obamacare's Medicaid expansion, and how to reform the Medicaid program in general. The Senate bill is expected to include a lengthy off-ramp for ending Medicaid expansion. The Senate is also weighing the possibility of keeping some of the ACA's taxes in place, at least temporarily, in order to stabilize the insurance market in the short term. Several senators have also posed the possibility of a short-term legislative fix to stabilize insurance markets.

White House officials continue to state that the Senate will vote on Obamacare repeal and replacement by the end of July. Republican leadership is pushing for an even earlier vote, hoping to finish health care by the July 4th recess so they can move on to other items on the GOP agenda.

In order to meet this deadline, however, the bill would have to be sent to the Congressional Budget Office (CBO) for a score approximately two weeks in advance. The chamber is required to produce \$133 billion in savings. If the Senate is able to pass legislation, Republicans would still have to spend time merging the bill with

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the House-passed Affordable Health Care Act (AHCA). Major differences are expected, with the Senate bill being more modest in repeal of the ACA than its House counterpart.

Energy and Commerce Advances FDARA, Additional Public Health Bills

The House Energy and Commerce Committee advanced the Food and Drug Administration Reauthorization Act (FDARA), along with several other public health bills, during a markup last week. FDARA would reauthorize the agency's user fee programs, set to expire on September 30. Lawmakers approved five amendments to the bill, including a resolution offered by Rep. Jan Schakowsky (D-Ill.) directing Congress to work to lower prescription drug prices. She also offered an amendment to create a pilot program to gather post-market safety data on medical devices. Reps. Scott Peters (D-Calif.) and Ryan Costello (R-Pa.) offered two amendments. The first would create a regulatory pathway for imaging devices intended for use with contrast agents. The second aims to address concerns about the safety of medical devices serviced by third parties. Rep. Mimi Walters (R-Calif.) offered an amendment that would require medical device accessories to be classified according to the accessories' own risk rather than the risk of the parent device. The panel also debated several controversial amendments dealing with issues such as off-label communication and drug re-importation, which were ultimately withdrawn by the sponsors. The Committee voted 54-0 to advance FDARA to the House floor for consideration. Many members stressed the importance of passing the bill in a timely and bipartisan fashion during their opening statements. A number of Democratic members of the Committee also used the opportunity to request a hearing on drug pricing. The Senate version of the user fee legislation has already been passed out of committee and awaits action by the full chamber. During the markup, the Energy and Commerce Committee also advanced H.R. 1222, the Congenital Heart Futures Reauthorization Act, H.R. 2410, the Sickle Cell Disease Research, Surveillance, Prevention, and Treatment Act, and H.R. 1492, the Medical Controlled Substances Transportation Act, all by voice vote.

HELP Hearing to Examine Rx Prices

The Senate Health, Education, Labor, and Pensions (HELP) Committee will hold a hearing on the prescription drug delivery system on Tuesday. According to a statement from the Committee, the hearing will focus on "the process of moving prescription drugs from the manufacturer to patients -- and how that system affects what patients pay when picking up their prescriptions." This hearing will feature testimony from academic experts, while a second hearing yet to be scheduled is expected to hear from industry witnesses. The hearing was requested by Sen. Al Franken (D-Minn.) and nine other bipartisan HELP Committee members last month.

Collins to Stay at NIH

The White House has decided to keep Francis Collins in his position as director of the National Institutes of Health (NIH). Dr. Collins, a physician-geneticist, was unanimously confirmed by the Senate to lead the agency in 2009. He is on track to be one of the longest serving NIH directors since World War II.

Burgess Weighs in on CHIP

During a media briefing last week, Chairman of the House Energy and Commerce Health Subcommittee Michael Burgess (R-Texas) expressed support for a two year funding extension for the Children's Health Insurance Program (CHIP). Funding for the program expires on September 30, and the Medicaid and CHIP Payment and Access Commission (MACPAC) recommended renewing funding for the program for five years, through 2022. Rep. Burgess stated that he would prefer aligning CHIP funding with the program's authorization. The Energy and Commerce Health Subcommittee will hold a hearing on CHIP on June 14.

Cybersecurity Report Released

The Health Care Industry Cybersecurity Task Force released a **report** last week asserting that improved cybersecurity protections are needed for medical devices and health information technology. The public-private task force includes representatives from both the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Homeland Security, and was created by the Cybersecurity Act of 2015. The report recommends increased information sharing between the public and private sector on cyber-risks. The Task Force also supports the creation of exceptions to health care anti-fraud laws to allow health care organizations aid physicians in the purchase of cybersecurity software.

Puerto Rico Declares End of Zika Epidemic

The Puerto Rico Department of Health has officially declared that the 2016 Zika epidemic is over. Only approximately 10 cases have been reported in each four-week period since April 2017, down from the more than 8,000 cases reported during the same time period around August 2016. The Centers for Disease Control and Prevention (CDC) will continue to collaborate with Puerto Rico to report Zika virus cases going forward.

Trump Administration Update

The President has nominated **Robert Charrow** as general counsel for the U.S. Department of Health and Human Services (HHS). Charrow served as deputy general counsel and later principal deputy general counsel for HHS during the Reagan administration. He is currently with the Greenberg Taurig law firm. **Bruce Greenstein** has been tapped as the chief technology officer for HHS. He has previously worked as secretary of Louisiana's Department of Health and Hospitals. **Valerie Huber** was named as chief of staff for the Office of the Assistant Secretary for Health (OASH). She has been the leader of the National Abstinence Education Association, now known as Ascend, since 2007. The Senate Judiciary Committee has approved the nomination of **Makan Delrahim** to be the Justice Department antitrust chief by a vote of 19-1. If he is confirmed, Delrahim will take the lead in overseeing an investigation into generic drug price fixing.

Upcoming Congressional Hearings and Meetings

House Energy and Commerce Subcommittee on Communications and Technology hearing titled “Promoting Security in Wireless Technology;” 10:00 a.m., 2322 Rayburn Bldg.; June 13

Senate Foreign Relations Committee hearing on “President’s proposed budget request for fiscal year 2018 for the Department of State;” 10:00 a.m., 419 Dirksen Bldg.; June 13

Senate Health, Education, Labor, and Pensions (HELP) Committee hearing titled “The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay;” 10:00 a.m., 430 Dirksen Bldg.; June 13

House Foreign Affairs Committee hearing titled “FY 2018 Foreign Affairs Budget;” 9:00 a.m., 2172 Rayburn Bldg.; June 14

House Energy and Commerce Health Subcommittee hearing “Examining the Extension of Safety Net Health Programs;” 10:15 a.m., 2322 Rayburn Bldg.; June 14

Senate Veterans’ Affairs Committee to “Examine the President’s proposed budget request for fiscal year 2018 for veterans’ programs and fiscal year 2019 advance appropriations requests;” 2:30 p.m., 428 Russell Bldg.; June 14

Senate Aging Committee hearing to “Examine military caregivers, focusing on families serving for the long run;” 2:30 p.m., 106 Dirksen Bldg.; June 14

House Science, Space, and Technology Subcommittee on Oversight and Subcommittee on Research and Technology Joint Hearing titled “Bolstering the Government’s Cybersecurity: Lessons Learned from WannaCry;” 10:00 a.m., 2318 Rayburn Bldg.; June 15

Senate Appropriations Subcommittee on Departments of Labor, Health and Human Services, and Education, and Related Agencies hearing to Examine proposed budget estimates and justification for fiscal year 2018 for the Department of Health and Human Services;” 10:00 a.m., 138 Dirksen Bldg.; June 15

Senate Veterans’ Affairs Committee hearing to examine a number of bills including S.758, to amend the Public Health Service Act with respect to the Agency for Toxic Substances and Disease Registry’s review and publication of illness and conditions relating to veterans stationed at Camp Lejeune, North Carolina, and their family members; 11:00 a.m., 418 Russell Bldg.; June 15

Recently Introduced Health Legislation

H.R.2769 (introduced by Rep. David Loebsack): To prevent the application of the provisions of the individual mandate to individuals residing in rating areas with no qualified health plans offered on the Exchange; Ways and Means

H.R.2770 (introduced by Rep. David Loebsack): To allow individuals living in areas without qualified health plans offered through an Exchange to have similar access to health insurance coverage as members of Congress and congressional staff; Energy and Commerce, Ways and Means

S.1291 (introduced by Rep. Bill Nelson): A bill to amend title XVIII of the Social Security Act to establish rules for payment for graduate medical education (GME) costs for hospitals that establish a new medical residency training program after hosting resident rotators for short durations; Finance

H.R.2779 (introduced by Rep. Jeff Denham): To amend title XI of the Social Security Act to provide through the Center for Medicare and Medicaid Innovation (CMMI) for a Medicaid payment model demonstration project on Medicaid reimbursement for physicians’ services in counties with a disproportionately high proportion of Medicaid enrollees; Energy and Commerce

H.R.2785 (introduced by Rep. Clay Higgins): To amend title 38, United States Code, to require the Secretary of Veterans Affairs to pay the reasonable costs of urgent care provided to certain veterans, to establish cost-sharing amounts for veterans receiving care at an emergency room of the Department of Veterans Affairs, and for other purposes; Veterans' Affairs

H.R.2787 (introduced by Rep. Marcy Kaptur): To establish in the Department of Veterans Affairs a pilot program instituting a clinical observation program for pre-med students preparing to attend medical school; Veterans' Affairs

H.R.2788 (introduced by Rep. Michelle Lujan Grisham): To expand access to health care services, including sexual, reproductive, and maternal health services, for immigrant women, men, and families by removing legal barriers to health insurance coverage, and for other purposes; Energy and Commerce, Ways and Means

H.R.2790 (introduced by Rep. Martha McSally): To phase out cosmetic animal testing and the sale of cosmetics tested on animals, and for other purposes; Energy and Commerce

H.R.2797 (introduced by Rep. Earl Blumenauer): To amend title XVIII of the Social Security Act to provide for advanced illness care coordination services for Medicare beneficiaries, and for other purposes; Energy and Commerce, Ways and Means

S.1299 (introduced by Sen. Gary C. Peters): A bill to amend title XVIII of the Social Security Act to reduce the occurrence of diabetes in Medicare beneficiaries by extending coverage under Medicare for medical nutrition therapy services to such beneficiaries with pre-diabetes or with risk factors for developing type 2 diabetes; Finance

S.1301 (introduced by Sen. Bill Nelson): A bill to amend title XVIII of the Social Security Act to provide for the distribution of additional residency positions, and for other purposes; Finance

S.1304 (introduced by Sen. Pat Roberts): A bill to amend part B of title XVIII of the Social Security Act to exclude customary prompt pay discounts from manufacturers to wholesalers from the average sales price for drugs and biologicals under Medicare, and for other purposes; Finance

S.1307 (introduced by Sen. Dianne Feinstein): A bill to amend the Internal Revenue Code of 1986 to expand eligibility to receive refundable tax credits for coverage under a qualified health plan; Finance

H.R.2834 (introduced by Rep. Danny K. Davis): To improve the well-being of, and improve permanency outcomes for, children and families affected by heroin, opioids, and other substance abuse; Ways and Means

H.R.2843 (introduced by Rep. Diana DeGette): To amend titles XI and XIX of the Social Security Act to establish a comprehensive and nationwide system to evaluate the quality of care provided to beneficiaries of Medicaid and the Children's Health Insurance Program and to provide incentives for voluntary quality improvement; Energy and Commerce

H.R.2851 (introduced by Rep. John Katko): To amend the Controlled Substances Act to clarify how controlled substance analogues are to be regulated, and for other purposes; Energy and Commerce, Judiciary

S.1317 (introduced by Sen. Sherrod Brown): A bill to amend titles XI and XIX of the Social Security Act to establish a comprehensive and nationwide system to evaluate the quality of care provided to beneficiaries of Medicaid and the Children's Health Insurance Program and to provide incentives for voluntary quality improvement; Finance

S.1319 (introduced by Sen. Sherrod Brown): A bill to require the Secretary of Veterans Affairs to establish a continuing medical education program for non-Department of Veterans Affairs medical professionals who treat veterans to increase knowledge and recognition of medical conditions common to veterans, and for other purposes; Veterans' Affairs

S.1327 (introduced by Sen. Chuck Grassley): A bill to amend the Controlled Substances Act to clarify how controlled substance analogues are to be regulated, and for other purposes; Judiciary