



## Health Policy Briefing

May 1, 2017

### Republicans Release Text of Amendment to AHCA

House Republicans unveiled a new, amended version of the American Health Care Act (AHCA) last week. The latest draft was negotiated between centrist Rep. Tom MacArthur (R-N.J.) and conservative Rep. Mark Meadows (R-N.C.). The bill now includes an amendment from Rep. MacArthur, which would give states the ability to waive certain Obamacare insurance regulations, including the ability to charge people with pre-existing conditions more for coverage, as long as an alternative like high-risk pool coverage was offered. The amendment would also allow states to waive the essential health benefit requirements, as well as restrictions on how much more insurers can charge older people than younger people. In order to receive a waiver, states would have to meet one of a list of possible criteria, including reducing premiums, increasing coverage, increasing choice of plans, stabilizing the market, or stabilizing premiums. Waivers would be approved by default unless rejected by the Secretary of the U.S. Department of Health and Human Services (HHS) within 60 days. The revised bill earned the support of the conservative House Freedom Caucus, who believe that the Affordable Care Act's (ACA) insurance regulations are responsible for rising premiums. But in gaining the support of conservative Republicans, the changes may have caused additional defections among moderates who supported the earlier version of the bill. A vote on the legislation has not yet been scheduled. President Trump expressed disappointment in the proceedings, having pushed for a vote on the bill before Saturday, which marked his 100th day in office. The President later indicated that a vote could take place as early as this week. House leadership has stated that they will schedule a vote on AHCA when they are confident the bill has enough support to pass. Republicans can only afford to lose 22 votes from their own caucus for guaranteed passage. A number of lawmakers, including House Rules Committee Chairman Pete Sessions (R-Texas), have expressed doubts that the MacArthur amendment would secure enough votes for passage in the House. At least 21 Republicans have expressed opposition to the revised measure, with many more still undecided. Rep. MacArthur has said that he is open to making changes to the bill to gain the support of more moderates, but it is unclear what those changes might entail. The Government Accountability Office (GAO) has said that a score of the bill including the MacArthur amendment will not be ready either this week or next. Moderate Republicans are likely to be hesitant to vote on the legislation without an updated analysis of the bill's

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cost and impact on enrollees. It remains unclear whether the revised bill could pass the Senate's rules for reconciliation, and members from both chambers and both sides of the aisle have questioned whether passage in the upper chamber would be possible given its lukewarm reception by Senate Republicans. The latest legislation has been formally opposed by the American Medical Association (AMA), due to concerns that the proposed changes could result in the loss of coverage for millions of Americans while making coverage unaffordable for patients with preexisting conditions. The modified AHCA has also been opposed by the AARP, in part because it would allow insurers to charge older Americans up to five times more than younger Americans.

### ***Congress Passes One-Week CR and Reaches Agreement for Longer-Term Funding***

In order to avoid a partial government shutdown at midnight on April 28, Congress passed a one-week continuing resolution (CR) to provide additional time to finalize negotiations on a fiscal year (FY) 2017 spending bill. The short-term funding bill was introduced and passed in the House of Representatives by a vote of 382-30 early on Friday. Sixteen Republicans and 14 Democrats voted against the bill. The Senate passed the stopgap-spending bill by voice vote shortly thereafter. The seven-day spending measure expires at midnight on May 5. The White House has assured Democrats that the Administration will continue funding Obamacare cost sharing subsidies. The payments were one obstacle that threatened to lead to a government shutdown. Democrats had said that they would oppose any spending bill that did not ensure the continuation of the cost sharing reduction payments, a demand that was rejected by GOP leadership. It is still unclear, however, how long the Administration will continue the payments. The White House also backed away from its demand for border wall funding, which had been categorized as a poison pill and deal breaker by Democrats. Congressional leaders were able to reach a broad government funding agreement over the weekend, which includes \$2 billion in new spending for the National Institutes of Health (NIH). The deal would fund the government through the conclusion of the fiscal year on September 30.

### ***HELP Advances FDA Nominee***

The Senate Health, Education, Labor, and Pensions (HELP) Committee has advanced the nomination of Scott Gottlieb to be Commissioner of Food and Drugs. He was approved by a 14-9 vote. Two Democrats, Michael Bennet (D-Colo.) and Sheldon Whitehouse (D-R.I.), joined Republican committee members in voting in favor of Dr. Gottlieb's nomination. The vote had been postponed in order to allow panel members to review the nominee's answers to member queries, largely regarding his potential conflicts of interest. Dr. Gottlieb's answers to a letter from Ranking Member Patty Murray (D-Wash.) were provided the same morning of the initially scheduled vote. In his letter, Dr. Gottlieb outlines his support for the phasing out of certain antibiotics in the agricultural industry in order to further advance antibiotic stewardship. On the topic of right-to-try, Dr. Gottlieb said that he understood both the importance of patient access as well as the benefits of clinical trials for experimental medicines. No date has been set for a confirmation vote on the Senate floor.

### ***Bipartisan Bill to Increase Access to Generics Reintroduced***

A group of bipartisan lawmakers have reintroduced legislation aimed at preventing brand-name pharmaceutical manufacturers from blocking the entry of generics on to the market. The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act creates a cause of action in federal court for generic manufacturers who are experiencing difficulties obtaining access to reference products subject to a Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use (REMS with ETASU) or a restricted distribution system self-imposed by the reference product manufacturer. The Congressional Budget Office (CBO) estimates that the bill would decrease the federal deficit by \$3.3 billion. S. 974 was sponsored by Sen. Patrick Leahy (D-Vt.), and is cosponsored by Sens. Chuck Grassley (R-Iowa), Dianne Feinstein (D-Calif.), Mike Lee (R-Utah), and Amy Klobuchar (D-Minn.). Companion legislation (H.R. 2212) has been introduced in the House by Reps. Tom Marino (R-Pa.) and David Cicilline (D-R.I.).

## Upcoming Congressional Hearings/Meetings

*House Energy and Commerce Subcommittee on Health hearing on “Examining Improvements to the Regulation of Medical Technologies;” 10:00 a.m.; 2123 Rayburn Bldg.; May 2*

*House Energy and Commerce Subcommittee on Oversight and Investigations hearing on “Combating Waste, Fraud, and Abuse in Medicaid’s Personal Care Services Program;” 10:15 a.m., 2322 Rayburn Bldg.; May 2*

*Senate Armed Services Subcommittee on Emerging Threats and Capabilities hearing on “Department of Defense Laboratories and Their Contributions to Military Operations and Readiness;” 10:00 a.m., 222 Russell Bldg.; May 3*

*Senate Appropriations Subcommittee on Defense hearing on “A review of Defense Innovation and Research Funding;” 10:30 a.m., 192 Dirksen Bldg.; May 3*

*House Small Business Subcommittee on Contracting and Workforce and House Science, Space, and Technology Subcommittee on Research and Technology joint hearing on “Improving the Small Business Innovation Research and Small Business Technology Transfer Programs;” 9:00 a.m., 2318 Rayburn Bldg.; May 4*

*Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies hearing on “Telemedicine in the VA: Leveraging Technology to Increase Access, Improve Health Outcomes, and Lower Costs;” 10:30 a.m., 124 Dirksen Bldg.; May 4*

## Recently Introduced Health Legislation

*H.R. 2086 (introduced by Rep. Marsha Blackburn): To amend the Internal Revenue Code of 1986 to waive the individual mandate in areas with no Exchange plans; Ways and Means*

*H.R. 2113 (introduced by Rep. Steve Stivers): To require the Food and Drug Administration to expedite review of pharmaceuticals that are approved for marketing in the European Union; Energy and Commerce*

*S.914 (introduced by Sen. Jeanne Shaheen): A bill to improve and coordinate interagency Federal actions and provide assistance to States for responding to public health challenges posed by emerging contaminants, and for other purposes; Environment and Public Works*

*S.916 (introduced by Sen. Bill Cassidy): A bill to amend the Controlled Substances Act with regard to the provision of emergency medical services; Health, Education, Labor, and Pensions*

*S.920 (introduced by Sen. Jeanne Shaheen): A bill to establish a National Clinical Care Commission; Health, Education, Labor, and Pensions*

*H.R.2118 (introduced by Rep. Ryan A. Costello): To amend the Federal Food, Drug, and Cosmetic Act to require the registration of establishments that service devices, and for other purposes; Energy and Commerce*

*H.R.2123 (introduced by Rep. Glen Thompson): To amend title 38, United States Code, to improve the ability of health care professionals to treat veterans through the use of telemedicine, and for other purposes; Veterans’ Affairs*

*H.R.2141 (introduced by Rep. Bradley Scott Schneider): To provide incentives to physicians to practice in rural and medically underserved communities and for other purposes; Judiciary*

*H.R.2144 (introduced by Rep. Mimi Walters): To amend the Federal Food, Drug, and Cosmetic Act to provide for the appropriate, risk-based classification of device accessories based on their intended uses.*

*S.925 (introduced by Sen. Joni Ernst): A bill to amend title 38, United States Code, to improve the ability of health care professionals to treat veterans through the use of telemedicine, and for other purposes; Veterans’ Affairs*

*S.934 (introduced by Sen. Lamar Alexander): A bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes; Health, Education, Labor, and Pensions*

*S.Res.140 (introduced by Sen. Johnny Isakson): A resolution supporting the designation of April 2017 as “Parkinson’s Awareness Month”; submitted, considered, and agreed to in the Senate.*

*H.R.2163 (introduced by Rep. Brian K. Fitzpatrick): To amend the Federal Food, Drug, and Cosmetic Act to require physicians and physician’s offices to be treated as covered device users required to report on certain adverse events involving medical devices, and for other purposes; Energy and Commerce*

*H.R.2164 (introduced by Rep. Brian K. Fitzpatrick): To amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices; Energy and Commerce*

*S.967: A bill to amend title XVIII of the Social Security Act to increase access to ambulance services under the Medicare program and to reform payments for such services under such program, and for other purposes; Finance*

*S.974; A bill to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products; Judiciary*

*S.977: A bill 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; Finance*

*S.980: A bill to amend title XVIII of the Social Security Act to provide for payments for certain rural health clinic and Federally qualified health center services furnished to hospice patients under the Medicare program; Finance*

*S.986: A bill to amend title XVIII of the Social Security Act to permit hospitals in all-urban States to be considered Medicare dependent hospitals, and for other purposes; Finance*