



Health Policy Briefing

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Senate Faction Optimistic on Bipartisan Health Care Reform

Sens. Bill Cassidy (R-La.) and Susan Collins (R-Maine) have begun work on health care reform apart from the GOP working group backed by Republican leadership. Sens. Cassidy and Collins are pushing for bipartisan negotiations, and are attempting to find Senate Democrats willing to come to the table. Their plan would allow states to keep the Affordable Care Act (ACA) in place if they wish, and would also leave the ACA's taxes and fees intact. They convened a meeting of six Republicans and three Democrats to discuss a possible bipartisan path forward. Attendance included Republican Sens. Dean Heller (Nev.), Lindsey Graham (S.C.), Dan Sullivan (Alaska) and Shelley Moore Capito (W.V.) and Democrats Joe Manchin (W.V.), Joe Donnelly (Ind.) and Heidi Heitkamp (N.D.). Sen. Cassidy noted that additional lawmakers had expressed interest in attending, and that more meetings are planned for the future.

Republicans in the upper chamber have yet to reach a compromise on what to do about the Medicaid program. GOP members from Medicaid expansion states are reluctant to repeal the expansion in its entirety, but acknowledge the need to limit program spending. Sen. Rob Portman (R-Ohio) has proposed to phase out expansion funding over five years beginning in 2020. Sen. Patrick Toomey (R-Pa.) would cap new spending at the rate of inflation. The most conservative senators wish to repeal the ACA in its totality, even if it means abandoning or changing the rules surrounding reconciliation.

Chairman of the Senate Finance Committee Orrin Hatch (R-Utah) has creached out to industry trade groups and other officials requesting feedback on the Senate's ACA repeal process by May 23. Stakeholders were asked to weigh in on issues under Finance Committee jurisdiction, including Obamacare taxes, expansion of health savings accounts (HSAs), the Medicaid program, health insurance tax credits, and stabilization of the individual market.

The Congressional Budget Office (CBO) announced that it would release a cost estimate of the House-passed American Health Care Act (AHCA)

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the afternoon of May 24. The score will also include an estimate of the effects of the legislation. Sen. John Thune (R-S.D.) is working on a proposal that would increase the tax credits to assist in the purchase of health insurance included in AHCA, but better target the credits to those with low incomes and the elderly. He is waiting on the score of the House-bill to better understand how to adjust the tax credits.

The possibility of a second House vote on AHCA was reported last week, but House Majority Leader Kevin McCarthy (R-Calif.) blamed the confusion on a technical issue, saying that he is confident that the bill will move to the Senate after the CBO score is released. Speaker of the House Paul Ryan (R-Wis.) explained that the bill has been held in the House for the sake of caution, and to ensure that the legislation conforms with the Senate's rules for reconciliation.

Congress, Administration Continue Focus on Drug Pricing

A bipartisan group of senators have **written** to Office of Management and Budget (OMB) Director Mick Mulvaney requesting his help in lowering the cost of prescription drugs. The lawmakers believe that the OMB can use existing authority to lower drug prices. The senators also ask Director Mulvaney to work with U.S. Department of Health and Human Services (HHS) Secretary Tom Price to certify importation of prescription drugs from Canada in cases when the drug is off patent or no longer marketed in the U.S. by the innovator company that developed it, when there are significant and unexplained increases in price, when there is no competitor drug that would benefit the market, or when the drug is produced in another country by a manufacturer that commonly sells pharmaceutical products in the U.S. The letter was sent by Sens. Amy Klobuchar (D-Minn.), John McCain (R-Ariz.), and Chuck Grassley (R-Iowa). Also last week, a bipartisan group of senators reintroduced legislation that would require companies to notify HHS before raising the price of certain drugs. The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act would require drug manufacturers to submit a report 30 days in advance of increasing the price of certain products that cost at least \$100 by 10 percent or greater in one year or 25 percent or greater over three years. It would also require the company to disclose manufacturing, R&D, and marketing costs, in addition to the profits associated with the drug. The bill is sponsored by Sens. Tammy Baldwin (D-Wis.) and John McCain (R-Ariz.) in the Senate (S. 1131), and Rep. Jan Schakowsky (D-Ill.) in the House (H.R. 2439). The Trump Administration is also in the process of holding listening sessions on ways to combat rising drug prices. The White House has invited industry groups and advocates to meet with Secretary Price, who requested feedback from attendees once the Administration decides on a proposal.

White House Budget Proposal Expected This Week

The Trump Administration plans to release its full proposed fiscal year (FY) 2018 budget on Tuesday, May 23. The budget is expected to balance within the next decade, largely due to predicted cuts to mandatory spending. It is likely that the plan will face opposition from lawmakers of both parties. The Trump skinny budget, which outlines discretionary spending levels and was released earlier this year, included \$15 billion in cuts to the U.S. Department of Health and Human Services (HHS), with \$6 billion coming from the National Institutes of Health (NIH). Sen. Patty Murray (D-Wash.) spearheaded a **letter** to HHS Secretary Tom Price warning against cuts to public health, and outlining possible implications on the implementation of the 21st Century Cures Act. Chairman of the House Appropriations HHS Subcommittee Tom Cole (R-Okla.) has also expressed concerns about the proposed cuts to medical research. The President's budget request will be used as a starting point for lawmakers to begin crafting their own budget resolution. House Budget Chairwoman Diane Black (R-Tenn.) has expressed interested in the inclusion of changes to Medicaid payments in the budget, and Speaker of the House Paul Ryan (R-Wis.) would like to tackle some Medicare reforms through the appropriations process. House Appropriations Committee member Mike Simpson (R-Idaho), however, predicted that Congress would be forced to pass a continuing resolution (CR) for FY 2018, due to disagreements among Republicans on the appropriate spending level. Office of Management and Budget (OMB) Director Mick Mulvaney will testify at the House Budget Committee's hearing on the President's budget on May 24. The 2018 fiscal year begins on October 1st.

CHRONIC Care Act Advanced through Finance Committee

The Senate Finance Committee has advanced legislation to expand home health care and telehealth reimbursement by Medicare. S. 870, the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 aims to help health care providers better coordinate care for the chronically ill. It would expand a home care program known as Independence at Home, and would allow beneficiaries receiving home dialysis to receive assessments through telehealth services. It would also allow doctors participating in Medicare Advantage (MA) and accountable care organizations (ACOs) to offer telehealth visits. Additionally, the bill expands ACOs ability to use prospective assignment to enroll beneficiaries. The bill is a product of the Finance Committee's chronic care working group, spearheaded by Sens. Johnny Isakson (R-Ga.) and Mark Warner (D-Va.). The CHRONIC Care Act would be paid for between 2018-2022 through funding from the Medicare Improvement Fund and the Medicaid Improvement Fund. During the markup, the Committee approved one amendment that would allow Part D drug plan sponsors to obtain Part A and B data in order to advance care coordination and improve medication use. There is no immediate schedule to consider the legislation on the floor of the Senate.

User Fee Reauthorization Sent To Full Energy and Commerce Committee

The House Energy and Commerce Health Subcommittee advanced the Food and Drug Administration Reauthorization Act (FDARA) last week. H.R. 2430 will reauthorize the FDA's user fee programs through 2022. Four amendments were added to the bill during the committee markup. Reps. Joe Kennedy (D-Mass.) and Marsha Blackburn (R-Tenn.) offered an amendment to allow the purchase of over-the-counter (OTC) hearing aids. An amendment from Reps. Kurt Schrader (D-Ore.) and Gus Bilirakis (R-Fla.) would provide incentives for the development of generic drugs when there is no competition for the brand-name product. The third amendment, authored by Reps. Larry Bucshon (R-Ind.) and G.K. Butterfield (D-N.C.), would establish a risk-based medical device inspection process. Finally, the Committee approved an amendment from Chairman Michael Burgess (R-Texas) and Ranking Member Gene Green (D-Texas) that would protect the drug supply chain from diversion and counterfeiting by addressing statutory gaps in penalties. The Senate version of the bill has already been approved by the Health, Education, Labor, and Pensions (HELP) Committee. Current authorization for the user fee programs expires on September 30.

Administration Pushes for Increase in User Fees

U.S. Secretary of Health and Human Services (HHS) Tom Price has **recommended** that lawmakers increase the Food and Drug Administration's (FDA) reliance on industry user fees. Congress is currently working to reauthorize the user fee programs, and has already come to an agreement with name-brand, generic, biosimilar, and device manufacturers. Under Secretary Price's proposal, user fees would fund 100 percent of the FDA's review of medical products, with no requirement of budget authority financing. Secretary Price's request was not well received by the lawmakers who are attempting to advance reauthorization legislation as quickly as possible. Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) said that the request has come too late in the negotiation process, but could be considered in the future. Congress must send legislation to the President's desk before the end of July in order to avoid triggering the FDA process to terminate the employment of 5,000 individuals.

Lawmakers Circulate OTC Legislation

Sens. Johnny Isakson (R-Ga.) and Bob Casey (D-Pa.) are circulating a draft bill that would reform the way that the Food and Drug Administration (FDA) regulates over-the-counter (OTC) products. The senators are proposing to streamline product approvals by eliminating the requirement that the agency do rulemaking for each therapeutic class. Instead, the Secretary would establish standards for each OTC drug type.

Legislation Introduced to Increase Access to Addiction Treatment

Bipartisan legislation has been introduced in the Senate that would expand access to addiction treatment by easing federal restrictions on Medicaid reimbursement for substance abuse treatment centers. The Medicaid Coverage for Addiction Recovery Expansion (Medicaid CARE) Act (S. 1169) was introduced by Sens. Dick Durbin (D-Ill.), Rob Portman (R-Ohio), Sherrod Brown (D-Ohio), Shelley Moore Capito (R-W.V.), Angus King (I-Maine), and Susan Collins (R-Maine) – all of whom represent states significantly impacted by the opioid abuse epidemic. Substance abuse treatment centers with up to 40 beds would be allowed reimbursement by Medicaid for up to 60 consecutive days. The Medicaid program is currently prohibited from paying for substance abuse treatment at centers with more than 16 beds, in order to discourage institutionalization.

Lawmakers Request Better Oversight of Opioid Overprescribing

A group of Democratic lawmakers have **written** to the U.S. Drug Enforcement Agency (DEA), the Centers for Medicare and Medicaid Services (CMS), and commercial insurers requesting that they use data to improve oversight of opioid prescribing practices and to better hold prescribers accountable for overprescribing painkillers. “There are too many providers who are prescribing opioids at rates significantly higher than their peers, and there are too many regions of the country where opioid dispensing is far beyond sensible need,” the lawmakers write. They ask the agencies and insurers to examine the Part D Opioid Prescribing Mapping Tool for red flats, outliers, trends, or particular areas of concern about over-prescribing. The letters were signed by Sens. Dick Durbin (D-Ill.), Sherrod Brown (D-Ohio), Angus King (I-Maine), Amy Klobuchar (D-Minn.), and Tammy Duckworth (D-Ill.).

Upcoming Congressional Hearings/Meetings

House Energy and Commerce Oversight and Investigations Subcommittee hearing entitled “U.S. Public Health Response to the Zika Virus: Continuing Challenges;” 10:00 a.m., 2123 Rayburn Bldg.; May 23

House Budget Committee hearing entitled “The President’s Fiscal Year 2018 Budget;” 9:30 a.m., 1334 Longworth Bldg.; May 24

Senate Budget Committee hearing to examine the President’s fiscal year 2018 budget proposal; 9:45 a.m., 608 Dirksen Bldg.; May 25

Recently Introduced Health Legislation

H.R.2422 (introduced by Rep. Robin L. Kelly): To the Public Health Service Act to improve essential oral health care for low-income and other underserved individuals by breaking down barriers to care, and for other purposes; Energy and Commerce

S.1123 (introduced by Sen. Jeanne Shaheen): A bill to reauthorize the Office of National Drug Control Policy, and for other purposes; Judiciary

H.R.2430 (introduced by Rep. Greg Walden): 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; Energy and Commerce

H.R.2439 (introduced by Rep. Janice D. Schakowsky): To require reporting regarding certain drug price increases, and for other purposes.

H.R.2445 (introduced by Rep. Marsha Blackburn): To amend title XVIII of the Social Security Act to provide for a prior authorization process under the Medicare program for certain high cost durable medical equipment, prosthetics, orthotics, and supplies; Energy and Commerce, Ways and Means

H.R.2465 (introduced by Rep. Cathy McMorris Rodgers): To amend title XVIII of the Social Security Act to make permanent the removal of the rental cap for durable medical equipment under the Medicare program with respect to speech generating devices; Energy and Commerce, Ways and Means

H.R.2474 (introduced by Rep. Mimi Walters): To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative standard for substantial equivalence determinations for devices, and for other purposes; Energy and Commerce

H.Res.327 (introduced by Rep. Adam B. Schiff): Recognizing the importance of vaccinations and immunizations in the United States; Energy and Commerce

S.1130 (introduced by Sen. Chuck Grassley): A bill to amend title XVIII of the Social Security Act to create a sustainable future for rural healthcare; Finance

S.1131 (introduced by Sen. Tammy Baldwin): A bill to require reporting regarding certain drug price increases, and for other purposes; Health, Education, Labor, and Pensions

S.1132 (introduced by Sen. Bill Cassidy): A bill to amend title XVIII of the Social Security Act to make permanent the removal of the rental cap for durable medical equipment under the Medicare program with respect to speech generating devices; Finance

S.1133 (introduced by Sen. James Lankford): A bill to repeal changes made by health care reform laws to the Medicare exception to the prohibition on certain physician referrals for hospitals, and for other purposes; Finance

S.Res.166 (introduced by Sen. Roger Wicker): A resolution supporting the goals and ideals of National Nurses Week, to be observed from May 6 through May 12, 2017; introduced, considered, and agreed to without amendment and with a preamble by Unanimous Consent

H.R.2483 (introduced by Rep. Richard Hudson): To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of a third-party quality system assessment program for devices, and for other purposes; Energy and Commerce

H.R.2485 (introduced by Rep. Sean Patrick Maloney): To require the Administrator of the Federal Aviation Administration to evaluate and consider revising regulations relating to emergency medical equipment requirements for passenger aircraft; Transportation and Infrastructure

H.R.2501 (introduced by Rep. Evan H. Jenkins): To amend title XIX of the Social Security Act to provide States with the option of providing medical assistance at a residential pediatric recovery center to infants under 1 year of age with neonatal abstinence syndrome and their families; Energy and Commerce

H.R.2503 (introduced by Rep. Erik Paulsen): To amend title XVIII of the Social Security Act to promote health care technology innovation and access to medical devices and services for which patients choose to self-pay under the Medicare program, and for other purposes; Energy and Commerce

H.R.2509 (introduced by Rep. Paul Tonko): To amend title XVIII of the Social Security Act to eliminate the 190-day lifetime limit on inpatient psychiatric hospital services under the Medicare Program; Energy and Commerce

S.1147 (introduced by Sen. Robert Menendez): A bill to amend the Public Health Service Act to provide for the expansion, intensification, and coordination of the programs and activities of the National Institutes of Health with respect to Tourette syndrome; Health, Education, Labor, and Pensions

S.1148 (introduced by Sen. Sherrod Brown): A bill to amend title XIX of the Social Security Act to provide States with the option of providing medical assistance at a residential pediatric recovery center to infants under 1 year of age with neonatal abstinence syndrome and their families; Finance

S.1150 (introduced by Sen. John Kennedy): A bill to amend title XIX of the Social Security Act to require States to impose a work requirement for able-bodied adults without dependents who are eligible for medical assistance; Finance

S.1151 (introduced by Sen. Joni Ernst): A bill to amend the Internal Revenue Code of 1986 to provide a nonrefundable credit for working family caregivers; Finance

S.1161 (introduced by Sen. Tammy Baldwin): A bill to amend title 38, United States Code, to eliminate copayments by the Department of Veterans Affairs for medicines relating to preventative health services, and for other purposes; Veterans' Affairs

S.1167 (introduced by Sen. Brian Schatz): A bill to require the Administrator of the Federal Aviation Administration to evaluate and consider revising regulations relating to emergency medical equipment requirements for passenger aircraft; Commerce, Science, and Transportation

S.1169 (introduced by Sen. Richard J. Durbin): A bill to amend title XIX of the Social Security Act to provide States with an option to provide medical assistance to individuals between the ages of 22 and 64 for inpatient services to treat substance use disorders at certain facilities, and for other purposes; Finance

H.R.2516 (introduced by Rep. David Young): To amend the Internal Revenue Code of 1986 to waive the individual mandate in areas with no Exchange plans; Ways and Means

H.R.2531 (introduced by Rep. Jenniffer Gonzalez-Colon): To amend title XVIII of the Social Security Act to apply Medicare part B deemed enrollment process to residents of Puerto Rico; Energy and Commerce, Ways and Means

H.R.2535 (introduced by Rep. James R. Langevin): To amend title XXIX of the Public Health Service Act to reauthorize the program under such title relating to lifespan respite care; Energy and Commerce

H.Res.337 (introduced by Rep. Joyce Beatty): Expressing support for designation of May as Stroke Awareness Month; Energy and Commerce

H.Res.342 (introduced by Rep. Nita M. Lowey): Recognizing the essential contributions of frontline health workers to strengthening the United States national security and economic prosperity, sustaining and expanding progress on global health, and saving the lives of millions of women, men, and children around the world; Foreign Affairs

S.1183 (introduced by Sen. Joe Donnelly): A bill to establish a third-party quality system assessment program; Health, Education, Labor, and Pensions

S.1188 (introduced by Sen. Susan M. Collins): A bill to amend title XXIX of the Public Health Service Act to reauthorize the program under such title relating to lifespan respite care; Health, Education, Labor, and Pensions