



Health Policy Briefing

July 17, 2017

Senate Releases Revised BCRA, Delays Vote for Another Week

Senate Republican leadership released a revised version of the Better Care Reconciliation Act (BCRA), which would repeal and replace Obamacare, last week. The measure now includes Sen. Ted Cruz’s (R-Texas) Consumer Freedom Act, which would allow the sale of plans that don’t comply with the Affordable Care Act’s (ACA) insurance regulations on pre-existing conditions and essential health benefits (EHBs). The revised bill includes an additional \$70 billion in new funding over the next seven years aimed at reducing costs for individuals who remain in the regulated-insurance plans. Beginning in 2022, states would begin having to share an increasingly higher portion of this cost. The new BCRA would keep in place several ACA taxes on the high earners, which would result in a revenue stream of nearly \$232 billion over the next ten years. The revised measure includes the addition of \$45 billion to combat the opioid epidemic. It would also allow individuals to use health savings accounts (HSAs) to pay for insurance premiums. Additionally, individuals would be allowed to purchase high deductible catastrophic coverage plans with federal tax credits. Medicaid payments to hospitals for coverage of uncompensated care would be calculated according to the state’s uninsured population, instead of the state’s Medicaid enrollment, as originally drafted.

Majority Leader Mitch McConnell (R-Ky.) announced that the Senate will continue working two weeks into the month-long August recess, which had been scheduled to begin on July 29, in order to complete work on important priorities, including health care reform, reauthorization of the Food and Drug Administration’s (FDA) user fee programs, and raising of the debt ceiling.

Speaker of the House Paul Ryan (R-Wis.) has stated that the House will also remain in session should the Senate pass a health care bill and send it to the lower chamber. A floor vote on BCRA this week was expected to be a possibility, until Sen. John McCain (R-Ariz.) announced over the weekend that he would be absent from the Senate as he recovers from surgery.

The revised bill does not seem to have swayed many Senate Republicans,

Inside

- [House Passes Medical Controlled Substances Transportation Act.....](#)2
- [Appropriators Make Progress of FY2018 Spending Bills.....](#)3
- [Ways and Means Advances Two Medicare Bills.....](#)4
- [House of Representatives Passes FDARA.....](#)4
- [2017 Trustees Report Released; IPAB Not Triggered.....](#)5
- [Upcoming Congressional Meetings and Hearings.....](#)5
- [Recently Introduced Health Legislation.....](#)5

particularly the most moderate members of the party who remain opposed to the scaling back of the Medicaid program. The senators that remain undecided are awaiting the Congressional Budget Office (CBO) score of the latest proposal, while Sens. Susan Collins (R-Maine) and Rand Paul (R-Ky.) remain firmly in opposition to the bill. The American Medical Association (AMA) also announced that it remains opposed to the Senate bill, praising the additional money for opioid addiction but criticizing proposed cuts to the Medicaid program.

Sen. Lindsey Graham (R-S.C.) is working to develop a new approach to ACA replacement with Sen. Bill Cassidy (R-La.). Their plan would repeal the individual and employer mandates, but transform federal funding for Obamacare – \$500 billion over 10 years – into block grants to the states. Insurance regulations on preexisting conditions would be maintained, and taxes created by the ACA, with the exception of the medical device tax, would also remain in place. Sen. Cassidy has suggested offering the plan as an amendment to the BCRA.

Absent the successful passage of a repeal and replace package, lawmakers will be faced with two options: passage of a repeal-only bill, or working in a bipartisan manner on health care reform. Democrats in both chambers are urging their Republican colleagues to begin negotiating bipartisan reforms to the health care system, and some moderate Republicans, like Sen. Susan Collins (R-Maine), appear ready to listen.

The top four Democrats in the Senate – Minority Leader Chuck Schumer (D-N.Y.) and Sens. Dick Durbin (D-Ill.), Patty Murray (D-Wash.), and Debbie Stabenow (D-Mich.) – sent a **letter** to Majority Leader McConnell suggesting ideas that members on both sides of the aisle could support in order to stabilize the insurance market. Proposals include cost-sharing subsidies to help cover expenses for low-income enrollees, assistance for those who have just missed the cutoff to receive subsidies, and allowing Americans with no insurance options on their local exchange to buy insurance in the D.C. marketplace.

Sen. Tom Carper (D-Del.) is also working to connect members from both sides of the aisle on a bipartisan bill to fix the problems he sees facing the ACA, such as the cost of premiums and the strength of the exchanges. Sen. Carper says he has already spoken with one-third of GOP senators about introducing a bill that would be moved through the Senate through regular order.

In the House, a group of 10 Democrats have unveiled a plan titled “Solutions Over Politics.” They propose to create a \$15 billion permanent reinsurance program, reduce copays and deductibles for low-income families, provide premium assistance, and continue cost sharing reduction payments to insurers. The group supports the creation of a Medicare buy-in option for those nearing retirement age, and are pushing for the expansion of tax credits based on age, geography, and income. They also support aligning the open enrollment period with tax filing season, along with robust marketing strategies to increase enrollment. They would also expand the availability of catastrophic health plans that include EHBs and coverage of primary care for young enrollees. The group is led by Reps. Kurt Schrader (D-Ore.), Ami Bera (D-Calif.), and Ann McLane Kuster (D-N.H.), co-chairs of the Affordable and Accessible Health Care Task Force. They plan to petition for cosigners on a letter to Speaker of the House Paul Ryan (R-Wis.) requesting the creation of a task force on stabilizing the individual marketplace.

House Passes Medical Controlled Substances Transportation Act

The House of Representatives has passed legislation that would allow health practitioners to transport controlled substances across state lines. Under H.R. 1492, the Medical Controlled Substances Transportation Act, emergency medical services personnel and sports team physicians could register with the Drug Enforcement Administration (DEA) to transport controlled substances and administer them to patients outside of their registered work places. After 72 hours, the medicines would need to be returned to where they are stored, and doctors would be required to maintain records of where the medication was administered. Schedule I drugs are excluded from the changes in the legislation. H.R. 1492 passed by a vote of 416-2.

Appropriators Make Progress of FY2018 Spending Bills

Despite the inability of House Republicans to reach an agreement on a fiscal year (FY) 2018 budget resolution, Congressional appropriators made significant progress last week on a number of individual spending bills for the coming fiscal year.

The House Appropriations Committee unanimously advanced a \$20 billion spending bill that would give the Food and Drug Administration (FDA) \$5.1 billion in total spending for the coming fiscal year, with \$2.8 billion derived from taxpayer funding and the remainder funded by user fees. This is an increase of \$500 million for the agency over current spending levels. Despite a failed attempt to strike the provision, the appropriations bill reported out by the Committee would prevent the FDA from requiring retroactive safety reviews of e-cigarettes already on the market. House appropriators also released the FDA report language last week. Lawmakers direct the FDA to loosen policies on compounded medication. The appropriators are concerned that the FDA's strict interpretation of the Drug Quality and Security Act jeopardizes the availability of compounded medications for office use, which they say was intended to be allowable under the 2013 law. Additionally, appropriators comment on the definition of distribution of compounded drugs within the State MOU, and express concerns that the agency's advisory committee on compounded medication does not adequately represent the interests of providers and patients. The report language instructs the FDA to spend \$60 million on efforts related to continuous drug manufacturing, and \$24.6 million on a medical countermeasures initiative. Instead of finalizing draft guidance on laboratory-developed tests (LDTs), lawmakers tell the FDA to work with Congress on a new regulatory pathway. In order to increase enrollment and retention in cancer clinical trials, particularly for minorities, the FDA is directed to reconsider its guidance on third-party expense payments to research participants.

The House Appropriations Committee also released its Labor/HHS/Education 2018 budget proposal. The bill includes \$156 billion in total discretionary spending, \$5 billion below the current fiscal year. The U.S. Department of Health and Human Services (HHS) would receive \$77.6 billion, \$542 million less than current spending levels.

- The National Institutes of Health (NIH) would receive \$35.2 billion in the next fiscal year, \$8.6 billion above the President's request and \$1.1 billion over current spending levels. The proposal would require NIH to reimburse grantee research institutes for facility and administrative costs, in opposition of the President's budget proposal. HHS would not be allowed to cap reimbursements for these overhead costs.
- The Centers for Disease Control and Prevention (CDC) would receive a total of \$7 billion, a decrease of \$198 million compared to the current fiscal year, but a much more modest cut than contained in the President's budget. The bill includes \$1.45 billion for the CDC's Public Health Preparedness and Response programs, an increase of \$45 million.
- The Centers for Medicare and Medicaid Services (CMS) would receive \$3.5 billion, \$219 million less than FY2017, and \$127 million below the FY2018 budget request.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) would be funded at \$3.5 billion, \$306 million below current levels but \$68 million above the President's request.
- The Office of the National Coordinator (ONC) would receive \$39 million in funding, totaling a 35 percent cut, in line with the Administration's budget request.
- The Agency for Healthcare Research and Quality (AHRQ) would be cut by \$24 million, but would be maintained as a standalone agency. The Administration had proposed making AHRQ a part of NIH.

The bill would prohibit the use of any new discretionary funding to implement the Affordable Care Act (ACA). The spending bill was advanced out of Subcommittee by a vote of 9-6, and will be marked up by the full Appropriations Committee on July 19.

In the Senate, appropriators advanced their first FY 2018 spending bill, unanimously approving appropriations for Military Construction and Veterans Affairs. The bill includes \$88.9 in discretionary funding, \$246 million below the President's request but \$1.8 billion above current spending levels. The Department of Veterans Affairs (VA) would receive \$78.4 billion in appropriations, a \$4 billion increase over current spending.

In related news, Minority Leader Chuck Schumer (D-N.Y.) has issued a warning to House Republicans that inclusion of money for the construction of a border wall in FY 2018 appropriations could lead to a government shutdown. The House

Homeland Security spending bill would appropriate \$1.6 billion for such purpose.

The Congressional Budget Office (CBO) also released its report on the President's budget last week, and found that a \$720 billion deficit would remain within the next decade. The Administration has claimed that its plan would result in a surplus by 2027.

Ways and Means Advances Two Medicare Bills

The House Ways and Means Committee advanced two pieces of legislation dealing with the Medicare program last week. H.R. 3178, introduced by Chairman Kevin Brady (R-Texas) and Ranking Member Richard Neal (D-Mass.), is a package of changes to the Medicare Part B home infusion and dialysis benefits. It would create a transitional payment for providers of home infusion services before 2021, and would extend a demonstration project that pays for in-home administration of intravenous immunoglobulin (IVIG). The Medicare Part B Improvement Act would also allow dialysis centers to use telehealth for home patient monitoring. H.R. 3168, sponsored by Health Subcommittee Chairman Pat Tiberi (R-Ohio) and Ranking Member Sander Levin (D-Mich.), would make permanent Medicare Advantage special needs plans (SNPs) for institutionalized beneficiaries, and would reauthorize for five years SNPs for those with chronic conditions and for those that are dually eligible for Medicare and Medicaid. Additionally, it would narrow the conditions that individuals must meet in order to enroll in a chronic SNP. SNP authorization expires at the end of 2018. H.R. 3168 would also create a grievance and appeals process for SNP beneficiaries. The Centers for Medicare and Medicaid Services (CMS) would begin assessing quality data at the plan level, rather than the contract level, so that SNP beneficiaries can better assess a plan's performance.

House of Representatives Passes FDARA

The House of Representatives passed legislation (H.R. 2430) to reauthorize the Food and Drug Administration's (FDA) user fee programs for five years by voice vote last week. Since advancing out of the Energy and Commerce Committee, several revisions were made to the legislation. A provision regarding pediatric drugs and devices was added, which will give the FDA authority to require that cancer drugs be studied in children. The agency will also be able to conduct earlier meetings with product sponsors about pediatric trials. The bill was amended to require that the FDA act within eight months on any generic drug application for a product on the FDA's drug shortage list, for a product that has no more than three equivalents on the market, or for a product for which there are no patents blocking its ability to come to market. The House-passed bill also includes a provision requiring manufacturers seeking approval of a drug that has the same active ingredient as a drug already on the market to demonstrate clinical superiority in order to gain the orphan drug designation.

The Senate does not plan to vote on reauthorization until it completes work on health care reform. Sen. Ron Johnson (R-Wis.) announced that he would use procedural hurdles to delay reauthorization if his right to try bill is not included in the user fee package or given a floor vote. S. 204, the Trickett Wendler Right to Try Act, would increase access to experimental drugs for terminally ill patients.

Chairman on the Senate Health, Education, Labor, and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) has said that he hopes a vote on reauthorization will take place before August recess, set to begin the week of August 14. The user fees are scheduled to expire on September 30, but if Congress does not pass legislation by August 1, the FDA will be forced to begin the process of sending out notices of potential layoffs to thousands of employees.

The White House continues to express concerns about the reauthorization bill, noting in a statement of administration policy (SAP) that the legislation would require significant taxpayer investment in FDA's medical product review programs.

2017 Trustees Report Released; IPAB Not Triggered

The **2017 Medicare Trustees Report**, which projects the long-term finances of the Medicare program, was released last week. The Board of Trustees finds that Medicare spending will not trigger the Independent Payment Advisory Board (IPAB) until 2021. The Board had previously forecast that the cost-cutting panel would be triggered this year. The 2017 report also indicates that the Medicare trust fund will remain solvent until 2029, a year later than previously predicted, though the reason for the slowdown is unclear.

Upcoming Congressional Meetings and Hearings

House Energy and Commerce Oversight and Investigations Subcommittee hearing on “Examining HRSA’s Oversight of the 340B Pricing Program;” 10:15 a.m., 2322 Rayburn Bldg.; July 18

House Ways and Means Oversight Subcommittee hearing on “Efforts to Combat Waste, Fraud, and Abuse in the Medicare Program;” 10:00 a.m., 1100 Longworth Bldg.; July 19

House Appropriations Committee markup of the FY18 Labor, Health and Human Services, and Education Appropriations Bill; 10:00 a.m., 2359 Rayburn Bldg.; July 19

House Energy and Commerce Health Subcommittee hearing “Examining Bipartisan Legislation to Improve the Medicare Program;” 10:00 a.m., 2123 Rayburn Bldg.; July 20

Recently Introduced Health Legislation

H.R.3163 (introduced by Rep. Patrick J. Tiberi): To amend title XVIII of the Social Security Act to provide for a home infusion therapy services temporary transitional payment under the Medicare program; Energy and Commerce, Ways and Means

H.R.3164 (introduced by Rep. Diane Black): To amend title XVIII of the Social Security Act to expand access to home dialysis therapy; Energy and Commerce, Ways and Means

H.R.3166 (introduced by Rep. Lynn Jenkins): To amend title XVIII of the Social Security Act to provide under the Medicare program for independent accreditation for dialysis facilities and assurance of high quality surveys with respect to such facilities; Energy and Commerce, Ways and Means

H.R.3168 (introduced by Rep. Patrick J. Tiberi): To amend title XVIII of the Social Security Act to provide continued access to specialized Medicare Advantage plans for special needs individuals, and for other purposes; Ways and Means, Energy and Commerce

H.R.3171 (introduced by Rep. Mike Bishop): To amend title XVIII of the Social Security Act to provide that certain orthotist’s and prosthetist’s clinical notes under Medicare be treated as part of the patient’s medical record; Energy and Commerce, Ways and Means

H.R.3172 (introduced by Rep. Kevin Brady): To amend the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 to extend the Medicare Patient IVIG Access Demonstration Project; Energy and Commerce; Ways and Means

H.R.3173 (introduced by Rep. Kenny Marchant): To amend title XVIII of the Social Security Act to create alternative sanctions for technical noncompliance with the Stark rule under Medicare, and for other purposes; Energy and Commerce, Ways and Means

H.R.3178 (introduced by Rep. Kevin Brady): To amend title XVIII of the Social Security Act to improve the delivery of home infusion therapy and dialysis and the application of the Stark rule under the Medicare program, and for other purposes; Energy and Commerce, Ways and Means

H.R.3181 (introduced by Rep. Diane Black): To amend title XVIII of the Social Security Act to encourage Medicare beneficiaries to voluntarily adopt advance directives guiding the medical care they receive; Energy and Commerce, Ways and Means

S.1526 (introduced by Sen. Jon Tester): A bill to appropriate amounts to the Department of Veterans Affairs to improve the provision of health care to veterans, and for other purposes; Veterans' Affairs

S.1527 (introduced by Sen. John McCain): A bill to appropriate amounts to the Department of Veterans Affairs to improve the provision of health care to veterans, and for other purposes; Appropriations

S.1529 (introduced by Sen. Heidi Heitkamp): A bill to amend the Internal Revenue Code of 1986 to expand eligibility for the refundable credit for coverage under a qualified health plan; Finance

S.1530 (introduced by Sen. Christopher A. Coons): A bill to amend title XVIII of the Social Security Act to encourage Medicare beneficiaries to voluntarily adopt advance directives guiding the medical care they receive; Finance

H.R.3192 (introduced by Rep. Joseph P. Kennedy, III): To amend title XXI of the Social Security Act to ensure access to mental health services for children under the Children's Health Insurance Program, and for other purposes; Energy and Commerce

H.R.3194 (introduced by Rep. Sean Patrick Maloney): To provide for an extension of the authority of the Secretary of Veterans Affairs to provide for the conduct of medical disability examinations by contract physicians; Veterans' Affairs

S.1533 (introduced by Sen. Chuck Grassley): A bill to amend title XIX of the Social Security Act to cover physician services delivered by podiatric physicians to ensure access by Medicaid beneficiaries to appropriate quality foot and ankle care, to amend title XVIII of such Act to modify the requirements for diabetic shoes to be included under Medicare, and for other purposes; Finance

S.1545 (introduced by Sen. Mark R. Warner): A bill to amend title XIX of the Social Security Act to provide the same level of Federal matching assistance for every State that chooses to expand Medicaid coverage to newly eligible individuals, regardless of when such expansion takes place; Finance

S.1546 (introduced by Sen. Mark R. Warner): A bill to amend the Patient Protection and Affordable Care Act to provide greater flexibility in offering health insurance coverage across State lines; Health, Education, Labor, and Pensions

H.R.3224 (introduced by Rep. Gregg Harper): To amend title XVIII of the Social Security Act to clarify reasonable costs for critical access hospital payments under the Medicare program, and for other purposes; Ways and Means, Energy and Commerce

H.R.3236 (introduced by Rep. Devin Nunes): To amend titles XI and XVIII of the Social Security Act to improve provider and supplier cost reporting of ambulance services under the Medicare program, and for other purposes; Ways and Means, Energy and Commerce

H.Res.443 (introduced by Rep. Mike Gallagher): Recognizing the importance and effectiveness of trauma-informed care; Energy and Commerce

S.1550 (introduced by Sen. Luther Strange): A bill to improve the authority of the Secretary of Veterans Affairs to hire and retain physicians and other employees of the Department of Veterans Affairs, and for other purposes; Veterans' Affairs

S.1553 (introduced by Sen. Ron Johnson): A bill to amend the Controlled Substances Act to list fentanyl analogues as schedule I controlled substances; Judiciary

S.1554 (introduced by Sen. Edward J. Markey): A bill to require certain practitioners authorized to prescribe controlled substances to complete continuing education; Health, Education, Labor, and Pensions

S.1566 (introduced by Sen. Jon Tester): A bill to amend title 38, United States Code, to expand eligibility for mental health services from the Department of Veterans Affairs to include members of the reserve components of the Armed Forces, and for other purposes; Veterans' Affairs

S.1567 (introduced by Sen. Joe Donnelly): A bill to amend title 38, United States Code, to clarify the authority of the Secretary of Veterans Affairs to disclose certain patient information to state controlled substance monitoring programs, and for other purposes; Veterans' Affairs