



Health Policy Briefing

November 20, 2017

Tax Reform Passes House, Advances in Senate

The House of Representatives passed legislation to overhaul the tax code by a vote of 227-205 last week. No Democrats voted in favor of the bill, and 13 Republicans voted in opposition. The House bill does not include repeal of the Affordable Care Act’s (ACA) individual mandate. Speaker of the House Paul Ryan (R-Wis.) and Rep. Jenniffer González-Colón have stated that additional tax relief for Puerto Rico following Hurricanes Irma and Maria will be included should the legislation be considered in conference committee with the Senate. GOP leaders hope to send tax reform legislation to the President’s desk by the end of the year.

The Senate Finance Committee advanced its own GOP tax package last week. The plan was approved along a party-line vote of 14-12. The Committee spent four days marking up the bill, which would cut taxes for individuals, reduce the corporate tax rate from 35 percent to 20 percent, and eliminate the individual mandate by reducing the non-compliance penalty to zero effective January 1, 2019. The individual tax cuts would expire after 2025 in order to comply with the budget rules of reconciliation that require the bill to not increase the deficit after 10 years. With 51 votes necessary for passage, the GOP can only afford two Republican defections. Sen. Ron Johnson (R-Wis.) has voiced concerns about the bill due to its treatment of pass-through businesses but has indicated that he would be willing to work with the Committee to address those concerns. Other Republicans have raised concerns about the inclusion of the individual mandate provision and about the bill’s effect on the federal debt. Sen. Lisa Murkowski (R-Alaska) has said that her support may be contingent upon passage of the Alexander-Murray health care compromise that would guarantee continued funding for cost sharing reduction (CSR) payments. Sens. Lindsey Graham (R-S.C.), Lamar Alexander (R-Tenn.), Susan Collins (R-Maine), and Bill Cassidy (R-La.) have met with the President to urge his support for the bipartisan legislation, out of concern that repeal of the individual mandate without the provision of CSR payments will destabilize the individual insurance market. Elimination of the mandate is also opposed by many stakeholders in the health care industry, including the

Inside

- House Passes NDAA FDA Sidecar Bill.....2
- Appropriations Outlook.....2
- E&C Requests SBOMs to Increase Cybersecurity.....3
- Ways and Means Reaches Deal on Medicare Extenders.....3
- Trump Nominates Former Eli Lilly President for HHS Secretary3
- Gene Green to Retire in 2018.....3
- Hospitals File Lawsuit to Block 340B Cuts.....4
- FDA to Develop LDT Certification Process Pilot Program.....4
- Upcoming Congressional Hearings and Meetings.....4
- Recently Introduced Health Legislation.....4

American Hospital Association (AHA), the American Medical Association (AMA), and America's Health Insurance Plans (AHIP).

In response to a request from Finance Committee Ranking Member Ron Wyden (D-Ore.), the Congressional Budget Office (CBO) released estimates that the Senate tax bill would result in \$18 billion less in Medicaid spending, \$4 billion less in spending for CSR payments, \$1 billion less in spending for the Basic Health Program, and \$4 billion more in spending for the Medicare program, due to changes in payments for disproportionate share hospitals (DSH). The CBO has also alerted lawmakers that if they do not pass subsequent legislation to offset the tax bill's \$1.5 trillion deficit increase over the next decade or waive the requirements to provide such offsets, the Office of Management and Budget (OMB) would be required to trigger sequestration cuts. The \$136 billion in cuts – required under the law known as “PAYGO” – could amount to \$25 billion to the Medicare program in fiscal year (FY) 2018. Republican leadership has indicated that the plan will be to waive the PAYGO requirements (which would require 60 votes) – either as part of the Senate tax package or in subsequent legislation. Given that the sequestration would not go into effect until 15 days after the close of the Congress, such a delay would not adversely affect the implementation of the provisions.

Senate Majority Leader Mitch McConnell (R-Ky.) has said that he will bring the legislation to the floor for further debate when the Senate returns after Thanksgiving recess on November 27. If the Senate is successful in passing the tax bill, the measure will need to be reconciled with the House-passed legislation. The House bill contains some significant differences.

House Passes NDAA FDA Sidecar Bill

The House of Representatives unanimously passed a sidecar measure last week that will allow the Food and Drug Administration (FDA) to retain sole authority to approve drugs and medical devices while also ensuring the Department of Defense (DoD) more rapid access to lifesaving treatments for the battlefield. The National Defense Authorization Act (NDAA) included language that would have allowed DoD to approve some medical products for military personnel. The separate legislative fix (H.R. 4347) was a compromise to preserve the FDA's review power. The bill allows DoD to request that the FDA expedite the approval process for medical treatments through emergency use authorization. The FDA and DoD will be required to meet on a semiannual basis to review the relevant products in the DoD's portfolio and to meet quarterly to discuss high-priority products such as freeze-dried plasma. H.R. 4347 will now go to the Senate. The House will not officially send the NDAA to the upper chamber until the Senate passes the sidecar measure unamended.

Appropriations Outlook

Senate Appropriations Committee Chairman Thad Cochran (R-Miss.) issued a statement last week stressing the need for a budget deal between Congress and the Administration in order to complete work on fiscal year (FY) 2018 appropriations. Lawmakers have yet to reach an agreement on top-line funding levels for defense and non-defense programs. The current continuing resolution (CR) expires on December 8. Sen. Cochran has indicated that he plans to release a chairman's mark next week for the four remaining appropriations bills that have not yet been taken up by the Committee. These include appropriations for Defense, Homeland Security, Financial Services, and Interior-Environment. Some sources say that Congressional leaders are currently discussing a two-year increase in the federal spending caps to raise defense and non-defense funding by a combined \$200 billion. Sen. John Cornyn (R-Texas) has stated that the inclusion of cost-sharing reduction (CSR) payments in the end-of-year spending bill is also a possibility. It is becoming increasingly likely, however, that another short-term CR will be necessary to keep the government operating past December 8.

E&C Requests SBOMs to Increase Cybersecurity

Chairman of the House Energy and Commerce Committee Greg Walden (R-Ore.) is **requesting** that the U.S. Department of Health and Human Services (HHS) strengthen the supply chain of medical devices to improve cybersecurity. In a letter to the Acting HHS Secretary, he asks that the Department begin requiring manufacturers to account for third-party software components used in each of their products – known as software bills of materials (SBOM). The request aligns with a recommendation from HHS’ Health Care Industry Cybersecurity Task Force to better protect technologies relied upon by the health care industry from cyber threats. Rep. Walden requests that HHS develop a plan to coordinate a framework among medical device stakeholders to create, deploy, and leverage SBOMs for health care technologies by December 15.

Ways and Means Reaches Deal on Medicare Extenders

The House Ways and Means Committee announced that they have reached a bipartisan agreement relating to Medicare “extenders.” The legislative package will extend or make permanent a group of Medicare policies known as extenders, most of which are scheduled to expire by the end of the year without action from Congress. The policies were last extended in 2015 through the Medicare Access and CHIP Reauthorization Act (MACRA). The Ways and Means package includes a two-year extension of the Medicare geographic practice cost index (GPCI) for physician payments, a two-year extension of the Medicare Dependent Hospital Program and the Low-Volume Adjustment Program, a five-year extension of the Home Health rural add-on, a two-year extension of the State Health Insurance Assistance Programs (SHIP), and a two-year extension of funding for consensus based entity work on quality measures. The Ways and Means Committee also offers a number of financial offsets for the extenders package, including extension of a policy to redistribute misvalued billing codes, a Medicare Improvement Fund rescission, and modifications to skilled nursing facility (SNF), home health agency, and critical access hospital payments. Last month, a bipartisan Medicare extenders discussion draft was released by the Senate Finance Committee. Unlike the House Ways and Means’ agreement, the draft released by Chairman Hatch (R-Utah) and Ranking Member Wyden (D-Ore.) does not include offset provisions.

Trump Nominates Former Eli Lilly President for HHS Secretary

President Trump has announced his plans to nominate former Eli Lilly & Co. president Alex Azar to be the next Secretary of the U.S. Department of Health and Human Services (HHS). Former Secretary Tom Price, MD resigned from the Cabinet position in late September following reports of taxpayer-funded private jet travel. Azar’s ties to the pharmaceutical industry are expected to be scrutinized by Senate Democrats. While the Senate Finance Committee has jurisdiction to vote on the nomination and advance it for consideration by the full Senate, the nominee will also appear at a hearing before the Senate Health, Education, Labor, and Pensions (HELP) Committee next week. Azar will likely be questioned about his stance on the implementation of the Affordable Care Act (ACA), as well as the issue of rising drug costs. Azar has spoken on the subject several times in the past, remarking that other parts of the supply chain such as insurers and drug plans also bear responsibility for the increasing cost of prescription medications. Azar previously served as general counsel (2001-2005) and deputy secretary (2005-2007) of HHS during the Bush administration. He then served for a decade at Eli Lilly as senior vice president of corporate affairs and communications leading the company’s U.S. operations. He is also the chairman and founder of Seraphim Strategies, LLC, a strategic consulting firm focused on the biopharmaceutical and health insurance industries.

Gene Green to Retire in 2018

Rep. Gene Green (D-Texas) will not seek reelection when his current term expires. After having served for more than two decades in the House, Green expressed his wish to spend more time with his family. Green currently serves as the Ranking Member of the House Energy and Commerce Health Subcommittee.

Hospitals File Lawsuit to Block 340B Cuts

Three hospital groups have filed a lawsuit against the Administration to block steep cuts to the 340B drug discount program. The American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals argue that the Centers for Medicare and Medicaid Services' (CMS) plan to cut payments for physician-administered drugs by more than 28 percent beginning January 1 threatens patient access to care for uninsured and other vulnerable populations. Lawmakers have introduced bipartisan legislation in the House of Representatives to prevent the cuts from going into effect. The bill (H.R. 4392) was introduced by Reps. David B. McKinley (R-W.Va.) and Mike Thompson (D-Calif.) last week.

FDA to Develop LDT Certification Process Pilot Program

The Food and Drug Administration (FDA) plans to launch a program in the coming months to certify laboratories that develop diagnostic tests, instead of writing regulations for the tests themselves. The laboratory-developed test (LDT) precertification process will be modeled after the agency's pilot approval program for manufacturers of digital health products. The LDT plan will not overlap with the rules of the Clinical Laboratory Improvement Amendments (CLIA) administered by the Centers for Medicare and Medicaid Services (CMS). If the pilot program is successful, the FDA plans to seek legislation to codify it into law.

Upcoming Congressional Hearings and Meetings

The House Committee on Oversight and Government Reform field hearing on Combating the Opioid Crisis; 12:30 p.m., Chevy Chase Auditorium – 1st Floor, Johns Hopkins Hospital, 1800 Orleans Street Baltimore, MD 21287; November 28

Senate Health, Education, Labor, and Pensions Committee hearing on the Nomination of Alex Azar to serve as Secretary of Health and Human Services; 9:30 a.m., 430 Dirksen Bldg.; November 29

Senate Health, Education, Labor, and Pensions Committee hearing “The Front Lines of the Opioid Crisis: Perspectives from States, Communities, and Providers;” 10:00 a.m., 430 Dirksen Bldg.; November 30

Senate Judiciary Committee hearing to examine firearm accessory regulation and enforcing Federal and state reporting to the National Instant Criminal Background Check System (NICS); 10:00 a.m., 226 Dirksen Bldg.; December 6

Recently Introduced Health Legislation

H.Res.617 (introduced by Rep. Tom Emmer): Expressing support for the designation of the third Thursday of November as “World Wide Pressure Injury Prevention Day”; Oversight and Government Reform

H.R.4374 (introduced by Rep. Greg Walden): To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes; Energy and Commerce, Armed Services

H.R.4385 (introduced by Rep. Rosa L. DeLauro): To amend the Federal Food, Drug, and Cosmetic Act to restrict direct-to-consumer drug advertising; Energy and Commerce

H.R.4390 (introduced by Rep. Greg Gianforte): To reauthorize the rural emergency medical service training and equipment assistance program under section 330J of the Public Health Service Act; Energy and Commerce

H.R.4392 (introduced by Rep. David B. McKinley): To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation relating to changes in the payment amount for certain drugs and biologicals purchased under the 340B drug discount program shall have no force or effect, and for other purposes; Energy and Commerce, Ways and Means

H.R.4394 (introduced by Rep. Dina Titus): To direct the Secretary of Health and Human Services to make available a public option for health insurance coverage for individuals residing in an area without a qualified health plan available through an Exchange, and for other purposes; Energy and Commerce

S.2121 (introduced by Sen. Dean Heller): A bill to amend title XVIII of the Social Security Act to require reporting of certain data by providers and suppliers of air ambulance services for purposes of reforming reimbursements for such services under the Medicare program, and for other purposes; Finance

S.2125 (introduced by Sen. Jean Shaheen): A bill to improve the State response to the opioid abuse crisis; Health, Education, Labor, and Pensions

H.R.4404 (introduced by Rep. Tom Emmer): To amend title XXI of the Social Security Act to provide for an exception to the reduction to State allotments under the Children's Health Insurance Program for fiscal year 2018; Energy and Commerce

H.R.4408 (introduced by Rep. John Katko): To amend the Controlled Substances Act to establish additional registration requirements for prescribers of opioids, and for other purposes; Energy and Commerce, Judiciary

H.R.4411 (introduced by Rep. Sean Patrick Maloney): To direct the Secretary of State to make available to the Director of the Centers for Disease Control and Prevention copies of consular reports of death of United States citizens, and for other purposes; Energy and Commerce, Foreign Affairs

S.2131 (introduced by Sen. Patty Murray): A bill to amend title 38, United States Code, to authorize the Secretary of Veterans Affairs to furnish medically necessary transportation for newborn children of certain women veterans, and for other purposes; Veterans' Affairs

S.2132 (introduced by Sen. Al Franken): A bill to amend the Internal Revenue Code of 1986 to ensure that working families have access to affordable health insurance coverage; Finance

S.2134 (introduced by Sen. Tammy Baldwin): A bill to require the Secretary of Veterans Affairs to establish processes to ensure that non-Department of Veterans Affairs health care providers are using safe practices in prescribing opioids to veterans under the laws administered by the Secretary, and for other purposes; Veterans' Affairs

H.Res.627 (introduced by Rep. Lynn Jenkins): Recognizing that access to hospitals and other health care providers for patients in rural areas of the United States is essential to the survival and success of communities in the United States; Energy and Commerce

H.R.4418 (introduced by Rep. Suzanne Bonamici): To amend the Public Health Service Act to provide for a demonstration program to facilitate the clinical adoption of pregnancy intention screening initiatives by health care providers; Energy and Commerce

S.Res.336 (introduced by Sen. Elizabeth Warren): A resolution recognizing the seriousness of Polycystic Ovary Syndrome and expressing support for the designation of the month of September 2018 as "Polycystic Ovary Syndrome Awareness Month"; Health, Education, Labor, and Pensions

S.2137 (introduced by Sen. Joe Donnelly): A bill to amend the Rural Development Act of 1972 to improve access to grants for evidence-based substance use disorder treatment services in rural areas, and for other purposes; Agriculture, Nutrition, and Forestry

S.2146 (introduced by Sen. Tom Udall): A bill to extend the full Federal medical assistance percentage to urban Indian organizations; Indian Affairs

S.2156 (introduced by Sen. Claire McCaskill): A bill to amend title XVIII of the Social Security Act to provide fairness in hospital payments under the Medicare program; Finance

S.2157 (introduced by Sen. Richard J. Durbin): A bill to require drug manufacturers to disclose the prices of prescription drugs in any direct-to-consumer advertising and marketing to practitioners of a drug; Health, Education, Labor, and Pensions