



## Health Policy Briefing

November 13, 2017

### Tax Reform Advances in the House, Commences in the Senate

The House Ways and Means Committee reported out H.R. 1, the Tax Cuts and Jobs Act, on Thursday, advancing it after four days of debate along a party line vote. No health related provisions of H.R. 1 were amended or added during the markup. Additional amendments are not expected to be allowed on the floor. The bill does not include repeal of the individual mandate. Chairman Kevin Brady (R-Texas) has said that other Affordable Care Act (ACA)-related industry taxes, like the medical device and health insurance taxes, will be dealt with before the year's end but won't be included in the current tax bill. House Republicans plan to send the legislation to the floor this week, with the goal of having a bill on the President's desk by the end of the year.

A Chairman's mark of the Senate tax bill -- a conceptual outline of expected legislative text that could still change before the bill is officially introduced -- was released last week, though Senate Finance Committee Chairman Orrin Hatch (R-Utah) has said that a lot of work remains to be done on the bill. The committee typically marks up based on conceptual language instead of legislative text. The Senate tax plan would establish seven tax brackets, instead of the four proposed by the House, lower the top tax rate from 39.6 to 38.5 percent, and fully repeal state and local tax deductions. It does not currently include repeal of the individual mandate and also leaves the medical expense deduction in place. It does provide that certain research or experimental expenditures paid or incurred beginning after 2023 are required to be capitalized or amortized over a five-year period (or 15 years for research conducted outside of the U.S.). It would also alter the rare disease tax credit, which currently stands at 50 percent for qualified clinical trial expenses. The House bill completely eliminates the orphan drug tax credit, but the Senate bill would limit it to fifty percent of qualified clinical testing expenses for the taxable year as exceeds 50 percent of the average qualified expenses for the three previous taxable years. If there are no qualified clinical expenses during at least one of the three preceding years, the credit is equal to 25 percent of qualified expenses. The credit will also be limited if the clinical research being done on the drug is for an already approved use of the product that is not for a rare disease.

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The Trump Administration has reportedly prepared an executive order that would eliminate or weaken Obamacare's individual mandate, but is waiting to see whether such a provision will be included in one of the GOP tax bills. Multiple reports indicate that the executive order would broaden the hardship exemptions to the requirement that individuals demonstrate proof of insurance in order to avoid a penalty. Hardship exemptions are currently granted in some extraordinary circumstances – such as the death of a family member, bankruptcy, natural disaster, or when a person cannot afford to pay his or her utilities. The order apparently awaits approval at the Office of Management and Budget (OMB).

According to a new analysis from the Congressional Budget Office (CBO) and the Joint Committee on Taxation (JCT), repealing the individual mandate would increase the number of uninsured by four million in 2019 and 13 million in 2027, while reducing the deficit by \$338 billion over the next decade. The agencies conclude that repeal of the mandate will increase premiums in the individual marketplace by approximately 10 percent, though the markets themselves would remain stable in most areas of the country.

### *NDAAs Proceed with Plan for DoD Drug Approval Panel*

The Department of Defense (DoD) and the Food and Drug Administration (FDA) have signed off on a potential fix to a controversial provision within the National Defense Authorization Act (NDAA). While the NDAA will still include a broadly written provision to grant the Defense Department broad powers to deploy products like freeze-dried plasma that have been held up by the FDA, the agencies and relevant lawmakers tentatively settled on using a separate legislative vehicle to override the controversial provision. The new language, backed by the Senate HELP and House Energy and Commerce committees (those with jurisdiction over the FDA), is modeled on compromise language that the panels proposed days ago and would instead require the FDA to expedite reviews upon DoD request, among other measures.

Thus, the underlying NDAA, which will be considered later this week, will still contain a provision (section 732 of Senate's version of the NDAA, H.R. 2810) which would allow the DoD to have its own drug and device approval process, amidst a disagreement with the Food and Drug Administration (FDA) over the approval of freeze-dried plasma. The Pentagon argued that the product, which has not been approved beyond limited use by the FDA, improves the chances of survival for military personnel on the battlefield. The FDA says that full approval could come as early as next year. Public health experts, including **five** former FDA commissioners, argue that creating a new process could undermine the safety and effectiveness of products used for the armed forces. Previously, Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee Lamar Alexander (R-Tenn.), along with Sen. Richard Burr (R-N.C.) and Chairman of the House Energy and Commerce Committee Greg Walden (R-Ore.), **have** voiced concerns with the FDA-related provision.

### *Judiciary Committee Investigates Allergan and Sovereign Immunity*

The House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet held a hearing last week on the legitimacy of an agreement between pharmaceutical manufacturer Allergan and a Native American tribe, which agreed to exclusively license six patents for the eye drug Restasis back to the company in exchange for ongoing payments. Allergan claims that as a sovereign entity, the tribe places the patents outside the jurisdiction of the U.S. Patent Trial and Appeal Board. A challenge to the patents brought by a rival company is pending before the board. Allergan claims that the Board's process is flawed and unfair, and that the patents should be reviewed in federal court. During the hearing, Committee members heard testimony from four patent law experts. Chairman Bob Goodlatte (R-Va.) expressed concerns that the use of sovereign immunity to serve the interests of private companies unrelated to the tribes weakens the intellectual property system as a whole.

### ***Lawmakers Urge Inclusion of UDI in Claims***

Sens. Elizabeth Warren (D-Mass.) and Chuck Grassley (R-Iowa) have requested additional information about the Centers for Medicare and Medicaid Services' (CMS) position on the inclusion of unique device identifiers (UDIs) on Medicare claim forms. In a **letter** to CMS Administrator Seema Verma, the lawmakers outline conflicting statements made by CMS on the issue. They argue that it is “essential that the Medicare system support the post-market surveillance of risky medical devices, both to improve patient care and to support program integrity.” The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has previously recommended that the UDI information be included on Medicare claims.

### ***Lawmakers Request Report on ID Modeling***

House Energy and Commerce Committee leadership have **written** to the Government Accountability Office (GAO) to request a review of how the federal government uses predictive models to inform decision-making. The GAO recently reported that models could accurately predict infectious disease outbreaks and allow for better planning and deployment of public health resources. Chairman Greg Walden (R-Ore.), Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-N.J.), and Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-Colo.) request that the GAO conduct an additional study to assess the challenges in conducting emerging infectious disease modeling, which could include a lack of sufficient data and methods.

### ***Goodlatte Announces Retirement Plans***

Chairman of the House Judiciary Committee Bob Goodlatte (R-Va.) announced that he would not be seeking reelection next year. Rep. Goodlatte's chairmanship will end in December due to term limits. The announcement brings the total number of House member retirements this year to 14, twelve of which are Republicans.

### ***WHO Updates Antibiotics Policy, E&C Requests Info on Superbugs***

The World Health Organization (WHO) issued a **statement** on Tuesday urging a reduction in the use of medically important antibiotics in food producing animals and a complete restriction on the use of antibiotics to promote growth or deter disease without diagnosis. According to WHO, sick animals should be treated with the drugs “least important” to human health. The organization believes such actions are necessary to reduce antimicrobial resistance across the globe. The U.S. Department of Agriculture has responded that the WHO guidelines do not align with U.S. policy and are not backed by sound science.

Leadership on the House Energy and Commerce Committee have **written** to the Government Accountability Office (GAO) requesting that the agency study the epidemiology of superbugs in order to ensure the nation's preparedness to respond to strains of bacteria resistant to several types of antibiotics. The letter was signed by Chairman Greg Walden (R-Ore.), Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-N.J.), and Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-Colo.).

## Opioid Epidemic Updates

More than 900,000 pounds of prescription drugs were collected during the 14th annual Prescription Drug Take Back Day last week. The event, organized by the Drug Enforcement Administration (DEA), was particularly important this year in light of the declaration of the opioid epidemic as a public health emergency.

A Government Accountability Office (GAO) **report** released last week has found that the Centers for Medicare and Medicaid Service (CMS) failed to identify a significant number of seniors at risk for becoming addicted to prescription painkillers. The agency only flagged 33,223 Medicare beneficiaries at high risk of opioid abuse, while 727,016 were actually at risk of receiving high doses of opioids. The report was originally requested by Sens. Pat Toomey (R-Pa.) and Tim Kaine (D-Va.).

## CMS Finalizes Cuts to 340B

In a final rule released this month, the Centers for Medicare and Medicaid Services (CMS) finalized its proposal to reduce Medicare reimbursement for separately payable outpatient drugs purchased by hospitals under the 340B drug discount program from average sales price (ASP) plus six percent to ASP minus 22.5 percent. The goal of the policy is to align Medicare payment with the amount that hospitals are actually spending to acquire the drugs. Rural sole community hospitals, children's hospitals, and some cancer hospitals will be exempt from the drug payment reductions, scheduled to take effect on January 1, 2018.

## Upcoming Congressional Hearings and Meetings

*Senate Finance Committee Open Executive Session to Consider an Original Bill Entitled the Tax Cuts and Jobs Act; 3:00 p.m., 215 Dirksen Bldg.; November 13*

*Senate Health, Education, Labor, and Pensions (HELP) Committee hearing "Gene Editing Technology: Innovation and Impact;" 10:00 a.m., 430 Dirksen Bldg.; November 14*

*Senate Health, Education, Labor, and Pensions (HELP) Committee hearing "Encouraging Healthy Communities: Perspective from the Surgeon General;" 10:00 a.m., 430 Dirksen Bldg.; November 15*

*House Appropriations Military Construction, Veterans Affairs and Related Agencies Subcommittee oversight hearing on Veterans Affairs Electronic Health Record; 10:00 a.m., 2362-A Rayburn Bldg.; November 15*

*Senate Health, Education, Labor, and Pensions (HELP) Committee nomination hearing; 2:30 p.m., 430 Dirksen Bldg.; November 15*

*Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies Hearing on VA Efforts to Prevent and Combat Opioid Over Medication; 2:30 p.m., 124 Dirksen Bldg.; November 15*

## Recently Introduced Health Legislation

*H.R.4236 (introduced by Rep. Brian K. Fitzpatrick): To ensure that the prescription drug monitoring program of each State receiving funds through the Account for the State Response to the Opioid Abuse Crisis meets certain minimum requirements, and for other purposes; Energy and Commerce*

*H.R.4242 (introduced by Rep. David P. Roe): To amend title 38, United States Code, to establish a permanent VA Care in the Community Program, and for other purposes; Veterans' Affairs*

*H.R.4243 (introduced by Rep. David P. Roe): To establish a commission for the purpose of making recommendations regarding the modernization or realignment of facilities of the Veterans Health Administration, to improve construction and management leases of the Department of Veterans Affairs, to amend and appropriate funds for the Veterans Choice Program, and for other purposes; Veterans' Affairs, Rules, Appropriations*

*H.R.4245 (introduced by Rep. Timothy J. Walz): To direct the Secretary of Veterans Affairs to submit to Congress certain documents relating to the Electronic Health Record Modernization Program of the Department of Veterans Affairs; Veterans' Affairs*

*H.R.4249 (introduced by Rep. Stephanie J. Murphy): To provide housing and Medicaid assistance to families affected by a major disaster, and for other purposes; Energy and Commerce, Financial Services*

*H.R.4256 (introduced by Rep. Brett Guthrie): To amend the Public Health Service Act to authorize the expansion of activities related to Alzheimer's disease, cognitive decline, and brain health under the Alzheimer's Disease and Healthy Aging Program, and for other purposes; Energy and Commerce*

*H.R.4259 (introduced by Rep. Sean Patrick Maloney): To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to award grants for naloxone rescue kits in public libraries, and for other purposes; Energy and Commerce*

*S.2076 (introduced by Sen. Susan M. Collins): A bill to amend the Public Health Service Act to authorize the expansion of activities related to Alzheimer's disease, cognitive decline, and brain health under the Alzheimer's Disease and Healthy Aging Program, and for other purposes; Health, Education, Labor, and Pensions*

*H.Res.610 (introduced by Rep. Rick W. Allen): Expressing support for the designation of November 9, 2017, as "National Diabetes Heart Health Awareness Day", coinciding with American Diabetes Month; Energy and Commerce*

*H.R.4275 (introduced by Rep. Mark DeSaulnier): To provide for the development and dissemination of programs and materials for training pharmacists, health care providers, and patients on indicators that a prescription is fraudulent, forged, or otherwise indicative of abuse or diversion, and for other purposes; Energy and Commerce*

*H.R.4284 (introduced by Rep. Robert E. Latta): To establish a Federal Coordinator within the Department of Health and Human Services, and for other purposes; Energy and Commerce*

*S.Res.322 (introduced by Sen. Jeanne Shaheen): A resolution supporting the goals and ideals of American Diabetes Month; Health, Education, Labor, and Pensions*

*H.Con.Res.91 (introduced by Rep. James P. McGovern): Expressing the sense of Congress that public health professionals should be commended for their dedication and continued service to the United States on "Public Health Thank You Day", November 20, 2017; Energy and Commerce*

*H.R.4297 (introduced by Rep. Larry Bucshon): To amend title XVIII of the Social Security Act to provide information regarding vaccines for seniors as part of the Medicare & You handbook and to ensure that the treatment of cost sharing for vaccines under Medicare part D is consistent with the treatment of vaccines under Medicare part B, and for other purposes; Energy and Commerce*

*S.Res.324 (introduced by Sen. Bill Nelson): A resolution designating November 9, 2017, as "National Diabetes Heart Health Awareness Day", coinciding with American Diabetes Month; submitted, considered, and agreed to without amendment and with a preamble by Unanimous Consent*

*S.Res.325 (introduced by Sen. Thomas R. Carper): A resolution expressing support for designation of the week of October 29 through November 4, 2017, as "National Obesity Care Week"; submitted, considered, and agreed to without amendment and with a preamble by Unanimous Consent*

*S.2103 (introduced by Sen. Mazie Hirono): A bill to amend title XVIII of the Social Security Act to provide information regarding vaccines for seniors as part of the Medicare & You handbook and to ensure that the treatment of cost sharing for vaccines under Medicare part D is consistent with the treatment of vaccines under Medicare part B, and for other purposes; Finance*

*H.R.4333 (introduced by Rep. John J. Faso): To provide for the issuance of a Lyme Disease Research Semipostal Stamp; Oversight and Government Reform, Energy and Commerce*

*H.R.4334 (introduced by Rep. J. Luis Correa): To provide for certain reporting requirements relating to medical care for women veterans provided by the Department of Veterans Affairs and through contracts entered into by the Secretary of Veterans Affairs with non-Department medical providers, and for other purposes; Veterans' Affairs*

*H.R.4345 (introduced by Rep. Charlie Crist): To direct the Attorney General to establish and carry out a Veteran Treatment Court Program; Judiciary*

*H.R.4353 (introduced by Rep. John Lewis): To amend the Public Health Service Act to require reporting by the National Institutes of Health on requests for funding research that were not granted and had the greatest potential for improving public health, and for other purposes; Energy and Commerce*

*S.Res.329 (introduced by Sen. Elizabeth Warren): A resolution expressing support for the designation of October 2017 as "National Audiology Awareness Month"; submitted, considered, and agreed to without amendment and with a preamble by Unanimous Consent*

*S.2107 (introduced by Sen. Dean Heller): A bill to amend title 38, United States Code, to require the Under Secretary of Health to report major adverse personnel actions involving certain health care employees to the National Practitioner Data Bank and to applicable State licensing boards, and for other purposes; Veterans' Affairs*

*S.2117 (introduced by Sen. Bill Nelson): A bill to amend title 10, United States Code, to expand eligibility for the TRICARE program to include certain veterans entitled to benefits under the Medicare program due to conditions or injuries incurred during service in the Armed Forces and to waive the Medicare part B late enrollment penalty for such veterans, and for other purposes; Veterans' Affairs*