



## Health Policy Briefing

November 23, 2015

### Senate Fast Tracks Reconciliation Bill

Before adjourning for a week-long recess, Senate Majority Leader Mitch McConnell (R-Ky.) used a procedural motion to allow reconciliation legislation to skip the Senate’s committee process and be placed directly on the Senate calendar for action on the floor. McConnell also provided assurances that the package will include repeal of Planned Parenthood funding. There had been speculation last week that the Planned Parenthood provision had been dropped due to opposition from some moderate Republicans. Absent Democratic support for the bill, McConnell will need the support of 51 Republican senators for reconciliation to pass. Republicans currently hold a 54-member majority in the Senate, and Sen. Mike Lee (R-Utah), Sen. Ted Cruz (R-Texas) and Sen. Marco Rubio (R-Fla.) have already suggested they will oppose the legislation because it does not fully repeal the Affordable Care Act (ACA). The package will be taken up after Congress returns from their Thanksgiving recess.

### National Drug Control Strategy Released

The White House Office of National Drug Control Policy released its updated strategy last week. The document requests Congress to give Medicare the authority to restrict at-risk patients to a single primary care doctor and a single pharmacy to prescribe and fill their medications. This ‘lock-in’ practice is known as Drug Utilization Review and Restriction (DURR). 46 states and the District of Columbia Medicaid programs currently use DURR, but it is not explicitly permitted in the Medicare Part D statute and would require legislation to permit its use in Part D prescription drug plans.

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### ***Energy and Commerce Approves Five Public Health Bills***

The House Energy and Commerce Committee approved five pieces of public health legislation last week. The Microbead-Free Waters Act of 2015 (H.R. 1321) would ban cosmetic and beauty products that contain synthetic plastic microbeads. The Medical Controlled Substances Transportation Act (H.R. 3014) would allow registered physicians to transport and administer controlled substances to patients at other practice settings and disaster areas. The Common Sense Nutrition Disclosure Act of 2015 (H.R. 2017) is aimed at providing clarity and flexibility for small businesses subject to menu-labeling requirement regulations. The Ensuring Terminated Providers Are Removed from Medicaid and CHIP Act (H.R. 3716) addresses the problem of health care providers terminated from Medicaid in one state who still participate in Medicaid and CHIP programs in other states. The Medicaid Directory of Caregivers Act (H.R. 3716) would require state Medicaid programs that operate under fee-for-service and/or primary care case management programs include a directory of physicians who served Medicaid patients in the prior 12 months on the Medicaid program's website. The bills now await consideration by the full chamber.

### ***FDA Releases Report on Laboratory Developed Tests***

The Food and Drug Administration (FDA) released a [report](#) last week titled *The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies*. While laboratory developed tests (LDTs) are subject to both the Federal Food, Drug, and Cosmetic Act and the Clinical Laboratory Improvement Amendments, the FDA has historically exercised enforcement discretion towards these tests. In this report, the FDA makes the case for their proposal to increase oversight of LDTs. The report details 20 cases of faulty LDTs that may have caused or have caused harm to patients in the absence of compliance with FDA requirements. In some cases, false positives resulted in unnecessary treatment. In the case of false negatives, LDTs failed to detect potentially life-threatening diseases. Other case study examples provide information with no relevance to the intended disease or condition. During a congressional hearing on the subject, Director of the Center for Devices and Radiological Health Jeffrey Shuren said that he expects the FDA guidance on LDTs to be released by early next year.

### ***Tiberi to Chair Ways and Means Health Subcommittee***

Last week, it was decided that Rep. Pat Tiberi (R-Ohio) will take the gavel on the House Ways and Means Health Subcommittee. Tiberi is the fourth-ranking Republican on the committee and will be giving up his chairmanship of the Trade Subcommittee. He lost to Kevin Brady (R-Texas) earlier this month in the race to choose Speaker of the House Paul Ryan's (R-Wis.) replacement as the chairman of the full committee. Rep. Brady previously chaired the Health Subcommittee. The Subcommittee's jurisdiction includes the Medicare program and issues dealing with the Affordable Care Act (ACA). Rep. Dave Reichert (R-Wash.) will replace Tiberi as chairman of the Trade Subcommittee.

### ***Bipartisan, Bicameral Request to Eliminate the Cadillac Tax***

A bipartisan, bicameral group of lawmakers have **written** to the President requesting a meeting to discuss the elimination of the “Cadillac Tax.” The 40 percent excise tax on high-cost health insurance plans was included as a part of the Affordable Care Act (ACA) and is set to take effect in 2018. The tax will impact plans with costs exceeding \$10,200 for individuals and \$27,500 for families. It was meant to restrain health care costs, but both Republicans and Democrats have expressed concerns that it will simply result in the shifting of costs to patients. “In order to avoid hitting the tax, employers are raising deductibles and increasing other out-of-pocket expenses for beneficiaries,” the lawmakers write. “This provision and its impact on American workers is not acceptable.” The members of Congress request a meeting with the President to discuss repeal of the tax as soon as possible. The letter was signed by Sen. Dean Heller (R-Nev.), Sen. Sherrod Brown (D-Ohio), Sen. Martin Heinrich (D-N.M.), Rep. Joe Courtney (D-Conn.) and Rep. Frank Guinta (R-N.H.). Each has sponsored legislation to repeal the tax, which is projected to bring in \$91 billion in revenue over ten years.

### **NIH Update**

#### ***House Members Push for an Increase in NIH Funding***

A bipartisan group of more than 100 members of the House of Representatives have **written** to the leaders of the House Appropriations Committee in support of a funding boost for the National Institutes of Health (NIH). The letter calls for \$32 billion to be appropriated to the agency, \$2 billion above fiscal year (FY) 2015 levels. “Insufficient funding for NIH has a serious, wide-ranging impact on our nation’s health and our capacity for medical innovation in the 21st century,” the members wrote. “If we are serious about breaking new ground in our understanding of complex diseases like Alzheimer’s and cancer, and if we hope to accelerate the speed with which new cures, treatments and vaccines are developed, then it’s absolutely essential that we increase funding for medical research at NIH.” The letter was led by Rep. Susan DelBene (D-Wash.).

### **Upcoming Congressional Meetings and Hearings**

*Senate Special Aging Committee hearing on prescription drug prices; time and place TBA; December 9*

### **Health Legislation Recently Introduced**

***H.R.4011 (introduced by Ruben Gallego): A bill to increase the number of graduate medical education positions treating veterans, to improve the compensation of health care providers, medical directors, and directors of Veterans Integrated Service Networks of the Department of Veterans Affairs, and for other purposes; to the Committee on Veterans’ Affairs, and in addition to the Committees on Ways and Means, and Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 16***

***H.R.4015 (introduced by Rep. Frank Pallone Jr.): A bill to amend title III of the Public Health Service Act to authorize and support the creation of cardiomyopathy education, awareness, and risk assessment materials and resources by the Secretary of Health and Human Services through the Centers for Disease Control and Prevention and the dissemination of such materials and resources by State educational agencies to identify more at-risk families; to the House Committee on Energy and Commerce; November 16***

***H.R. 4052 (introduced by Rep. Maxine Waters of California): A bill to amend the Public Health Service Act to prioritize the treatment of veterans with traumatic brain injuries through the National Health Service Corps, and for other purposes; to the Committee on Energy and Commerce; November 17***

**Health Legislation Recently Introduced cont.**

*H.R. 4053 (introduced by Rep. Maxine Waters of California): A bill to authorize the Secretary of Veterans Affairs to make grants for repair and remodeling of community centers, clinics, and hospitals that serve veterans; to the Committee on Veterans' Affairs; November 17*

*H.R. 4055 (introduced by Rep. Ellison): A bill to amend title IV of the Social Security Act to address the increased burden that maintaining the health and hygiene of infants and toddlers places on families in need, the resultant adverse health effects on children and families, and the limited child care options available for infants and toddlers who lack sufficient diapers, which prevents their parents and guardians from entering the workforce; to the Committee on Ways and Means; November 18*

*H.R. 4058 (introduced by Rep. Shuster): A bill to require that in cases of health insurance coverage cancelled pursuant to requirements under the Patient Protection and Affordable Care Act cancellation notices provided to enrollees include a statement such cancellation is because of such Act; to the Committee on Energy and Commerce; November 18*

*H.R. 4059 (introduced by Rep. Black): 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; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 18*

*H.R. 4062 (introduced by Rep. Marchant): A bill to amend title XVIII of the Social Security Act to remove the enrollment restriction on certain physicians and practitioners prescribing covered outpatient drugs under the Medicare prescription drug program; to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 18*

*H.R. 4063 (introduced by Rep. Bilirakis): A bill to improve the use by the Secretary of Veterans Affairs of opioids in treating veterans, to improve patient advocacy by the Secretary, and to expand the availability of complementary and integrative health, and for other purposes; to the Committee on Veterans' Affairs, and in addition to the Committee on Armed Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 18*

*H.R. 4075 (introduced by Rep. Sessions): A bill to amend the Federal Food, Drug, and Cosmetic Act to establish new procedures and requirements for the registration of cosmetic manufacturing establishments, the submission of cosmetic and ingredient statements, and the reporting of serious cosmetic adverse events, and for other purposes; to the Committee on Energy and Commerce; November 18*

*H.R. 4077 (introduced by Rep. Williams): A bill to amend title XVIII of the Social Security Act to provide for a Medicare established provider system under which providers of services and suppliers representing a low risk for submitting fraudulent Medicare claims are provided certain claim review protections; to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 18*

*H.R. 4080 (introduced by Rep. Cartwright): A bill to amend title 38, United States Code, to provide for unlimited eligibility for health care for mental illnesses for veterans of combat service during certain periods of hostilities and war; to the Committee on Veterans' Affairs; November 19*

**Health Legislation Recently Introduced cont.**

*H.R. 4090 (introduced by Rep. Blackburn): A bill to amend the Social Security Act to improve choices available to Medicare eligible seniors by permitting them to elect (instead of regular Medicare benefits) to receive a voucher for a health savings account, for premiums for a high deductible health insurance plan, or both and by suspending Medicare late enrollment penalties between ages 65 and 70; to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 19*

*H.R. 4103 (introduced by Rep. Cramer): A bill to amend title 38, United States Code, to improve the provision of medical care to veterans at critical access hospitals; to the Committee on Veterans' Affairs, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned; November 19*

*H.R. 4111 (introduced by Rep. Lance): A bill to include skilled nursing facilities as a type of health care provider under section 254(h) of the Communications Act of 1934; to the Committee on Energy and Commerce; November 19*

*H.R. 4125 (introduced by Rep. Watson Coleman): A bill to direct the Secretary of Veterans Affairs to conduct a study on the feasibility of the Secretary entering into public-private partnerships to improve the access of veterans to medical facilities in densely populated communities and rural communities; to the Committee on Veterans' Affairs; November 19*

*S.2282 (introduced by Sen. Orrin G. Hatch): A bill to amend the Public Health Service Act to reauthorize the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory, and for other purposes; to the Committee on Health, Education, Labor, and Pensions; November 16*

*S. 2296 (introduced by Sen. Cornyn): A bill to amend the Internal Revenue Code of 1986 to expand workplace health incentives by equalizing the tax consequences of employee athletic facility use; to the Committee on Finance; November 18*

*S. 2297 (introduced by Sen. 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; to the Committee on Finance; November 18*

*S. 2311 (introduced by Sen. Heller): A bill to amend the Public Health Service Act to authorize the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, to make grants to States for screening and treatment for maternal depression; to the Committee on Health, Education, Labor, and Pensions; November 19*

*S. 2312 (introduced by Sen. Thune): A bill to amend titles XVIII and XIX of the Social Security Act to make improvements to payments for durable medical equipment under the Medicare and Medicaid programs; to the Committee on Finance; November 19*