

LEGISLATIVE UPDATE

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Overview

With Congress in recess from April 7-24, staffers continue to work to finish FY17 appropriations before the April 28th Continuing Resolution (CR) expires while also getting started on the FY18 appropriations process. Congress is close to a deal on wrapping up FY17 that largely ignores the FY17 Supplemental proposal from President Trump that aimed to cut domestic programs to pay for increases for Defense. Similar cuts are in President Trump's FY18 "Skinny Budget" he released last month, but the full FY18 budget proposal is delayed until mid-May so Congress is waiting to act on the appropriations and National Defense Authorization Act (NDAA) bills until then. Another hot topic is Obamacare repeal and replace. With the American Health Care Act (AHCA) pulled from the House floor due to a lack of sufficient support among both moderate and conservative Republicans, Republicans have been to amend it and have pledged along with President Trump to revive this effort. Meanwhile, the Senate confirmed Neil Gorsuch to the Supreme Court in an historic overturning of the filibuster for Supreme Court nominees, and will continue to hold confirmation hearings for the remaining 500+ political appointees Trump is in the process of selecting.

Budget and Appropriations

FY17 Appropriations in Congress

Congress will return on April 24th with five days to unveil, debate, and pass a FY17 spending bill, or trigger a government shutdown. Both parties acknowledge they do not want a shutdown and bipartisan leadership has quietly negotiated an omnibus spending bill that would fund the government through the end of FY17. Any spending measure needs at least eight Democratic votes in the Senate to be enacted. Fortunately, on March 8th the House worked behind the scenes with the Senate to craft a bipartisan FY17 Defense Appropriations bill that overwhelmingly passed the House and is expected to pass the Senate just as successfully. It will be key in completing the omnibus bill, however other obstacles will delay related legislation. Because Congress missed the April 15th target date for adopting a federal budget outline for the second year in a row, it will slow down Republican leadership's plan to enact massive tax reform by the month-long August recess.

FY17 Defense Appropriations Bill Passed the House

The Defense Appropriations bill that passed the House provides \$577.9 billion—an increase of \$5.2 billion over FY16 enacted level. This includes \$516.1 billion in base discretionary funding and \$61.8 billion in Overseas Contingency Operations (OCO)/Global War on Terrorism (GWOT) funding. When combined with the \$5.8 billion in supplemental funding enacted in the

CR that passed in December, the total defense funding for FY17 is \$583.7 billion, an increase of \$10.9 billion over FY16. More details are included in the last Legislative Update, but of interest is the \$10 billion increase in funding for Medical Equipment, Combat Support Medical to \$69.7 million, \$11.9 billion for Medical Support Equipment, and the \$107.3 billion for Medical Advanced Technology. Also, the Advanced Technology Development for Warfighter Advanced Technology increases by \$13 billion to \$51.3 billion and the Aviation Advanced Technology increases from \$94.2 billion to \$112.2 billion while most other aviation accounts remain level.

FY17 Defense Supplemental Proposed by President Trump

On March 16th, President Trump requested supplemental funding for FY17 that included an additional \$30 billion for the Department of Defense (DoD) and an additional \$3 billion for the Department of Homeland Security (DHS). Specifically, it included \$24.9 billion in the DoD base budget for readiness needs, maintenance and modernization and \$5.1 billion in the OCO budget to defeat ISIS and support Operation Freedom's Sentinel in Afghanistan. It also included an additional \$3 billion for DHS implementation of his executive orders on border security and to build a wall along the southern border. With the House-passed Defense FY17 bill already negotiated with the Senate and being used as the vehicle for an omnibus bill for FY17, much of Trump's Supplemental provisions are unlikely to be included, especially since it proposed slashing several domestic programs in the Departments of State, Health and Human Services, Housing and Urban Development, Agriculture and Education to pay for these Defense increases. Cuts to Pell grants, AmeriCorps and Senior Corps volunteer programs, the Community Development Block Grant, R&D programs (\$3 billion), and NIH (over \$1.2 billion) are all included. Senate Republicans are wary of Democrats blocking measures that would fund the wall, which could turn into a government shutdown, an embarrassing outcome so soon after the Obamacare repeal and replace fiasco.

Medical R&D Funding in DoD

On March 29th, G2G witnessed the Senate Defense Appropriations Subcommittee's hearing with the Surgeons General of the armed forces, including the SG of the Army, Lieutenant Nadja West, SG of the Air force Lieutenant General Mark A. Ediger, and SG of the Navy, Vice Admiral C. Forrest Faison III. Senators expressed their concerns about veterans' healthcare access and providing access for veterans at military treatment facilities for primary care. They also probed the potential overlap in Defense research with NIH's research, to which the Surgeons General collectively agreed that NIH research is both necessary and complimentary to the military research. Finally, Senators raised health concerns such as tobacco use in the military, access to proper childcare for military children with developmental disabilities, and the need for funding the Peer Reviewed Military Research Program (PRMRP) to address rare diseases like ALS. The Surgeons General urged maintaining ample medical R&D funding to help maintain readiness and allow the military to increase agility in responding to fast changing medical gaps. The hearing also addressed the newly updated Electronic Health Record system, but many Senators expressed disappointment in the millions of dollars spent, time wasted, and lack of interoperability at this stage, two years after the award was made to fix the EHR problems within DoD.

Health

American Health Care Act (AHCA)

On March 23rd, House Republicans and the Trump Administration pushed for an Obamacare repeal and replace bill, the AHCA, but met significant opposition and ultimately had to remove it from consideration on the House floor. Several moderate Republicans and the conservative Freedom Caucus announced that they would oppose the bill during a frenetic 24-hour period leading up to this decision. The Freedom Caucus opposed AHCA because it did not go far enough to replace Obamacare, but moderate Republicans opposed the bill because of the loss of coverage for their constituents and the potential of rising insurance costs. House Democrats and progressive groups were strongly opposed to the bill and were not included in efforts to craft it. Off the Hill, major lobbying organizations also opposed the bill. The Heritage Action, FreedomWorks, and the Cato Institute, were also opposed, arguing that the bill didn't go far enough. Meanwhile, AARP, the American Medical Association and the American Hospital Association all strongly opposed the AHCA due to the cuts in major preventative health funds and decreased Medicare and Medicaid coverage. The battle is not over though as the House Rules Committee met on April 6th to vote on an amendment to the AHCA to create a \$15 billion Federal Invisible Risk Sharing Program to help states reduce premiums by reimbursing health insurance issuers for high cost individuals beginning in 2018. But the revised AHCA still needs to garner more support before it can be brought to the House floor for a vote.

Obamacare's Exchanges and Subsidies in Question

In addition to the AHCA being on hold, health insurance companies are leaving the health exchanges and the cost-sharing subsidies totaling \$7 billion that insurers rely upon to lower costs for Obamacare's poorest customers are in limbo. Although CMS Administrator Seema Verma met with insurers this week, who urged this funding continue, she would not indicate what will happen. Both President Trump and HHS Secretary Tom Price are mum as well. Ironically, House Republicans sued the Obama Administration over the subsidy program (which is still pending in court) and now, if it is not maintained as some Republicans are now supporting, millions of Americans will lose health insurance because insurers will likely leave the marketplaces and collapse the exchanges. Some expect Trump to use the subsidy funding issue as leverage to negotiate with Democrats, who are adamant that they won't negotiate on subsidies. However, facing significant pressure at home and in town hall events, several Republicans want to keep the cost-sharing subsidies as long as Obamacare is still in place. Either way, insurers have until June to decide whether to withdraw from the marketplaces.

FDA User Fee Agreements

The Senate HELP and House Energy & Commerce Committees continue to make progress on the FDA user fee reauthorization for the Medical Device User Fee Agreements (MDUFA) and the Prescription Drug User Fee Agreement (PDUFA). During hearings, FDA's post-market surveillance activities and the need to pass the user fee agreements expeditiously were repeatedly addressed. Congress is expected to complete work by the August recess before the current agreement expires on September 30th.

Next FDA Commissioner

On April 5th, the HELP Committee held a hearing on the nomination of Scott Gottlieb to be the next FDA Commissioner. Committee members raised issues related to conflicts of interest, opioids, vaccines, food supply security, generic drug competition, prescription drug prices, and the Administration's proposed hiring freeze. No specific issues related to medical technology were raised. Gottlieb provided general answers with few specifics. The committee will vote on Gottlieb's nomination at the end of April or early May and should be confirmed.

Opioids Crisis

On March 30th, Senators Rob Portman (R-OH) and Amy Klobuchar (D-MN) introduced the Prescription Drug Monitoring Act to require the use of prescription drug monitoring programs (PDMPs) in all states that receive certain federal funding and require states to make their PDMP data available to other states. Under the bill, drug dispensers would be required to examine state data to determine if a patient fits a pattern of opioid abuser before making a prescription, and report to the PDMP each opioid prescription.

Telehealth in CMS

Senators Cory Gardner (R-CO) and Gary Peters (D-MI) reintroduced legislation to expand Medicare beneficiary access to telehealth and remote monitoring services. The legislation would require CMS's Center for Medicare & Medicaid Innovation (CMMI) to examine whether delivery reform initiatives, such as ACOs and bundled payments, can demonstrate how telehealth and remote monitoring services can help providers achieve program goals. AdvaMed and other organizations strongly support this bill.

Medicare Payment Models

At the Physician-Focused Payment Model Technical Advisory Committee, HHS Secretary Tom Price said innovative payment models could work better than fee-for-service Medicare and might stop doctors from leaving the profession at middle age because they feel burned out. The Committee called PTAC was created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to recommend alternative payment models to hold clinicians accountable for cost and quality of care. The models are intended to offer doctors added incentive payments for offering coordinated and cost-efficient care in a collaborative setting. PTAC began accepting letters of intent from stakeholders on October 1, 2016 and began accepting proposals for physician-focused payment models on December 1, 2016, which it is reviewing.

Veterans Affairs

VA Choice Program Reauthorized

President Donald Trump just signed legislation extending the Veterans' Choice Program, ahead of its anticipated expiration in August. It allows the Veterans Affairs Department to spend nearly \$1 billion in remaining funds to widen veterans' access to private-sector health care in response to a growing demand for medical treatment outside the VA. The bill also calls for fixes to alleviate some of the Choice Program's problems, including long wait times.

Economic Development

Government Reorganization

A presidential memorandum that went into effect on April 13th calls for an evaluation of the structure of the federal government and lifts a blanket federal hiring freeze, replacing it with hiring targets in line with the administration's budget proposal. The Office of Management and Budget (OMB) Director, Mick Mulvaney, said this could lead to downsizing the workforce and changes to the basic functions and responsibilities of many agencies – all part of Trump's campaign pledge to “drain the swamp” in the federal government.

Job Growth

The U.S. economy added 98,000 jobs last month, well below the expected increase of 180,000. The Dow decreased about 2 percent over March, while bond yields and the dollar are lowering as well. Labor force participation remained low at 63 percent, unchanged from February and close to its lowest level since the 1970s.

Tax Reform

To garner Democratic support for tax reform, Republicans are discreetly floating the option of a payroll tax cut. The idea is to cut the payroll tax almost entirely, apart from Medicare taxes, and pay for that reduction by eliminating labor deductibility. Some Democrats expressed support, however, Senate Majority Leader Mitch McConnell (R-KY) is skeptical of bipartisan cooperation on tax reform. McConnell reiterated that he anticipates using reconciliation to move any tax measure through the Senate, a strong-arm parliamentary tactic that would sideline Democrats.

Science and Innovation

Low R&D Spending

Over the last decade, China has increased its spending on research and development by 90 percent while U.S. spending has remained flat and if that trend continues, China will pass the U.S. in R&D spending by 2020, according to a recent report out of the University of Arizona. Many in higher education are using this information to argue low R&D funding is contrary to the goal of making the U.S. more competitive with China.

White House Office of Innovation

President Trump announced the creation of the White House Office of American Innovation (OAI) to “make recommendations to the President on policies and plans that improve Government operations and services, improve the quality of life for Americans now and in the future, and spur job creation.” The new office, led by White House senior advisor Jared Kushner, will create task forces to focus on initiatives such as implementing regulatory and process reforms and developing workforce of the future programs. This is nothing new as every president since Jimmy Carter has created a regulatory reform panel, but this may open doors for nonprofits and startups to promote regulatory improvements to the government grant-making process and other rules.

Small Businesses

Congressional Caucus on Microbusiness

On March 28th, Representatives Tim Ryan (D-OH), Pat Tiberi (R-OH), Barbara Comstock (R-VA), and Anna Eshoo (D-CA) announced the creation of the bipartisan Congressional

Microbusiness Caucus. Defined as any firm of 1-9 employees, microbusiness employees make up 11 percent of the workforce. The Caucus will address the unique challenges and opportunities facing these businesses and work to overcome the obstacles and regulatory barriers preventing entrepreneurs from starting and scaling their business. The Caucus plans to hold briefings and other events to facilitate discussion on relevant issues. Top priorities include establishing a federal definition of microbusiness, ending the Internet sales tax for microbusiness, providing portable employee benefits options, and reforming EITC to make quarterly payment options. Rep. Ryan is hosting a roundtable in his district to launch the Caucus on May 9th.

Small Business Cybersecurity

A bipartisan group of senators is looking to bolster resources for small businesses to safeguard their digital assets from cyber threats. Five Senators- Sens. Brian Schatz (D-HI), James Rich (R-ID), John Thune (R-SD), Maria Cantwell (D-WA), and Bill Nelson (D-FL)- introduced the MAIN STREET Cyber Security Act, which would direct the National Institute of Standards and Technology (NIST) to consider small businesses when updating its cybersecurity framework and offer consistent resources for small businesses that decide to use the framework. NIST produces a widely-respected framework for improving critical infrastructure cybersecurity that federal agencies and departments as well as private-sector entities have the option of using. The legislation earned immediate backing from business organizations like the U.S. Chamber of Commerce and the National Small Business Association.

Improving Small Business Competition

House Small Business Committee members introduced legislation to improve small business performance and competition. The Clarity for America's Small Contractors Act of 2017, sponsored by Chairman Steve Chabot (R-OH), aims to improve opportunities for small businesses to compete for federal contracts by reforming federal contracting rules such as improving reporting on small business goals, achieving uniformity in procurement terminology, and clarifying the role of small business advocates. The Developing the Next Generation of Small Business Act of 2017, sponsored by Ranking Member Nydia Velazquez (D-NY) aims to create improvements to small business development centers, the women's business center program, and the SCORE program, which helps entrepreneurs and small businesses grow. Finally, Senator James Lankford (R-OK) introduced the Small Business Regulatory Flexibility Improvements Act to require federal agencies to analyze the full impact of a proposed regulation on small businesses during the rulemaking process. A similar bill has already passed the House.

Non-Profits

Some 4,500 organizations have co-signed a letter to Congress requesting the current law, called the Johnson Amendment, that protects non-profit organizations from partisan politics and being asked to contribute and endorse candidates be maintained. The Governor and Attorney General of Texas, in contrast, sent a letter to 23 Republicans in Congress urging them to weaken the Johnson Amendment as soon as possible. While most Republicans and Democrats do not support this, leadership still has not taken any clear stance on the issue.