PUBLICATION

Washington, D.C. Update – March 2016

Authors: Sheila P. Burke
March 31, 2016

FY2017 Budget and Appropriations
With only a handful of items currently active on the House and Senate agendas, FY17 appropriations legislation is the major legislative game in town. The House and Senate Appropriations Committees are moving forward with annual spending legislation for the fiscal year that begins October 1. The Military Construction and Veterans Affairs (MilCon/VA) appropriations bill, the first of 12 annual spending bills, was approved by a House Appropriations subcommittee on March 23 and will be marked up by full committee on April 13. The Senate committee is tentatively scheduled to begin the markup process in early May. Nevertheless, continuing divisions among House Republicans over a long-term budget blueprint deemed essential by House GOP leaders for moving on the FY17 bills puts the House and Senate on a potential collision course that could significantly delay bicameral agreement on final legislation until the fall.

The House and Senate Appropriations Committees are currently drafting legislation based on the FY17 discretionary spending limits enshrined in last fall's sequestration relief budget deal (the Bipartisan Budget Agreement, or BBA). That deal fully paid for $80 billion in extra discretionary spending above sequestration-imposed levels for FY16 and FY17, with $551 billion for defense spending and $518 billion for non-defense spending in FY17. Consideration of appropriations legislation is usually preceded by adoption in both chambers of an annual budget resolution. Last fall's sequestration relief bill waives the need for a budget resolution in the Senate, but not the House. There, House fiscal conservatives unhappy with last fall's BBA are withholding support for the House budget resolution without assurance that it will include at least $30 billion in additional cuts to mandatory spending beyond the agreed upon FY17 BBA spending. The demand for additional cuts puts House Speaker Paul Ryan (R-WI) in a quandary. On the one hand, such cuts are opposed by the Obama Administration and are a non-starter in the Senate, where Democrats can block legislation. On the other hand, Speaker Ryan has a repudiated top-down leadership style and seeks to accommodate competing views and build consensus within his conference. Although the current dispute does not prevent the House Appropriations Committee from approving bills at higher BBA spending levels, Speaker Ryan wants to delay floor consideration until a budget resolution is passed with the support of a majority of Republicans.

Takeaway: Until the House spending dispute is resolved, the end game for the FY17 appropriations bills remains uncertain. With the House and Senate Appropriations Committees moving forward with spending bills at higher BBA levels, pressure will increase on Speaker Ryan to skip the budget resolution, alienating elements of his party, and pass spending bills with the support of Democrats. Alternatively, Speaker Ryan could delay floor action on committee-approved appropriations bills until after the November elections and gage the political tea leaves at that time. This approach would require Congress to pass a temporary stopgap funding bill to keep the government operating past the fiscal year deadline of October 1.

The Fight Against the Zika Virus
Congress is considering a number of Zika-related actions, most significantly the Obama Administration's $1.9 billion supplemental spending request. The request, according to the White House, "supports the necessary steps to fortify our domestic health system, detect and respond to any potential Zika outbreaks at home, and to limit the spread in other countries." House and Senate Republicans have suggested the administration first spend unused funds allocated to fight Ebola. The administration has asserted that very little of that money

remains unallocated and that interrupting ongoing programs would lead to incomplete projects and additional problems in the future. Of the $1.9 billion requested, $828 million is committed to the Centers for Disease Control and Prevention, $246 million to the Centers for Medicare and Medicaid Services (CMS) (for Puerto Rico and territorial efforts), $130 million to the National Institutes of Health, $10 million to the Food and Drug Administration, $335 million for USAID, $295 million for other Health and Human Services activities and $41 million for the Department of State.

While the spending request remains outstanding, the Senate quietly approved a bill making a future Zika virus vaccine eligible for the FDA's priority review process.

Takeaway: Given broader disagreements over the budget and appropriations process and the ongoing two-week congressional recess, the fate of the Zika emergency supplemental appropriations bill remains uncertain. April may offer additional clarity regarding the bill's chances of moving forward.

Combating America's Opioid Abuse Problem
By a vote of 94 to 1, the Senate passed the Comprehensive Addiction Recovery Act, an effort to fight America's growing opioid abuse problem. The act authorizes money for various treatment and prevention programs, strengthens prosecution drug monitoring programs and increases the number of disposal sites for prescription medications. However, Senate Republicans rejected an accompanying measure supported by Democrats (and five Republicans) that would have provided $600 million in funding to pay for some of the programs the bill authorizes.

Takeaway: Supporters of action to combat the nation's opioid abuse problem applauded the passage of a rare bipartisan measure. In particular, passage of the bill is a significant boost to several Republican Senators facing reelection in states hard-hit by the surge in opioid abuse – including Sen. Rob Portman (R-OH) and Sen. Kelly Ayotte (R-NH). However, the fate of the legislation is uncertain in the House as the companion bill does not have strong Republican support. The House Education and Workforce, Judiciary, and Energy and Commerce Committees are working on the issue.

Proposed Changes in the Medicare Part B Drug Payment Model
CMS released its highly anticipated Part B Drug Payment Model proposed rule. To address CMS concerns that the current Average Sales Price (ASP) +6% methodology may incentivize the ordering of higher cost Part B drugs, CMS intends to test alternative reimbursement models to improve outcomes and reduce Part B drug expenditures. The proposed five-year model would be implemented in two phases in select geographic areas. Beginning in the fall of 2016, Phase I would test the impact of a reduced add-on payment amount of 2.5% plus a flat fee of $16.80 (i.e., ASP+2.5% +$16.80). Beginning no earlier than January 1, 2017, Phase II would test the impact of using value-based purchasing (VBP) tools alone and in combination with ASP+2.5%+$16.80. The reduction in the ASP add-on payment is expected to have the most impact on hospitals and physicians using higher cost drugs, such as oncologists and other specialty practices, first shifting costs under Phase I and then generating savings under Phase II.

Importantly, CMS is seeking public comment on both phases of the proposed model as well as on how to create value-based purchasing arrangements with drug manufacturers under Medicare fee-for-service (FFS) for drugs, whether to revitalize the competitive acquisition program (CAP) and whether the agency should pursue bundled or episode-based payments that move beyond FFS.

Takeaway: Given the increased attention on drug pricing, we expect the Administration to move forward with its proposal and ultimately use this demonstration to guide future changes to Medicare Part B drug reimbursement.

TRICARE Reform Gets Serious

Because of concerns regarding escalating costs, TRICARE has become the focus of reform efforts both on Capitol Hill and throughout the military. Continuing a conversation that began last year with the final report of the Military Compensation and Retirement Modernization Commission, the Administration's proposed FY2017 budget incorporates a number of reforms, including dividing TRICARE into two programs, an HMO similar to TRICARE Prime that is limited to areas around military hospitals and clinics, and a hybrid of TRICARE Extra and Standard that would allow beneficiaries to use civilian doctors. The budget also includes efforts to improve access to managed care and incentivizes greater and more efficient use of military medical staffs and treatment facilities.

Congress has also contributed to the debate over the future of TRICARE, holding five hearings on the subject since December. In particular, members of Congress expressed concern about proposed increases in out-of-pocket expenses for TRICARE beneficiaries. Responding to a question on what beneficiaries would receive for their higher payments, Dr. Jonathan Woodson, Assistant Secretary of Defense for Health Affairs, said the proposal includes a "modest fee increase that gives better freedom," and with the preferred provider organization option, the referral requirement (what Woodson described as a "major dissatisfier to our beneficiaries") would go away.

Takeaway: We expect this debate to continue throughout 2016 as numerous congressional committees (led by the House and Senate Armed Services Committees) will examine the Administration's proposal and potentially move forward with some sort of TRICARE reform.

Medical Innovation Effort Continues

The Senate Health, Education, Labor and Pensions (HELP) Committee announced it will hold a third and final meeting to consider legislation related to medical innovation on April 6. In February and March, the Senate passed 14 separate medical innovations bills out of committee. Each of the bills is expected to reach the Senate floor, where they may be considered later this year. As part of this legislative package, the Senate is also considering proposals to authorize the president's Precision Medicine and Cancer Moonshot initiatives. The House aims to reconcile the 21st Century Cures legislation with the Senate package and pass a bill in advance of the summer recess.

Takeaway: The Senate's companion to the House's 21st Century Cures legislation continues to move through committee. Despite funding challenges, the package may reach the Senate floor before the end of the year.

Renewed Congressional Interest in Telemedicine

Introduced on February 2, the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act represents a multi-year effort by members of Congress and numerous interested patient and provider groups seeking to expand access to telehealth services by the Medicare program. Among other provisions, the CONNECT Act would create a bridge program to assist Medicare providers' transition to the new Merit-Based Incentive Payment System (MIPS) under the Medicare Access and CHIP Authorization Act (MACRA) by removing many of the 1834(m) restrictions to using telemedicine and remote patient monitoring. These restrictions include originating site restrictions, geographic limitations, restrictions on store-and-forward technologies and limitations on distant site providers. According to the bill's supporters, increased access to telehealth and remote monitoring services is expected to generate $1.8 billion in savings over the next ten years.

The renewed interest in telehealth and remote patient monitoring has spurred other efforts to expand access to these services. As part of the proposed FY2017 budget, the Obama Administration proposed eliminating a number of the otherwise applicable Part B requirements that certain covered services be provided exclusively through face-to-face encounters. This month, the bipartisan Energy and Commerce Committee Telehealth

Working Group – Reps. Greg Walden (R-OR), Doris Matsui (D-CA), Peter Welch (D-VT), Bob Latta (R-OH), Gregg Harper (R-MS), Bill Johnson (R-OH) and Markwayne Mullin (R-OK) – sent a letter to CMS calling for telemedicine to be part of MIPS and the alternative payment models under MACRA. In addition, CMS has already elected to waive the originating site and geographic limitations as part of its Next Generation Accountable Care Organization (ACO) Model, but has not yet done so for the other ACO models.

Takeaway: The broader support for telehealth and remote patient monitoring is a critical step in expanding access to these services. While the Administration is increasingly willing to test the impact of telemedicine, the challenges in Congress will be the cost of such services and the need for a related health care measure to be considered that would be used as a vehicle. Senator Mark Warner (D-VA) said the CONNECT for Health Act could become part of broader legislation expected to emerge from the Senate Finance Committee's chronic care working group (of which Senator Warner is a co-chair), a move that would increase the bill's chances of advancement. However, Senate Finance Committee Chairman Orrin Hatch has also noted that the legislation should be budget neutral and is waiting for a score from the Congressional Budget Office (CBO) before moving forward.

Medicare Doctor Pay Overhaul Forthcoming
On March 25, the Center for Medicare and Medicaid Services (CMS) submitted a proposed rule overhauling the Medicare physician payment structure to the Office of Management and Budget (OMB) for final review. The rule, titled "Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APM) in Medicare Fee-for-Service," will be a key tool for carrying out the payment changes mandated in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). At a March 17 hearing of the House Energy and Commerce Health Subcommittee focused on the repeal of the Medicare Sustainable Growth Rate formula, Dr. Patrick Conway, Chief Medical Officer for CMS, told the panel that doctors and others with an interest in Medicare policy will have 60 days after the rule is publicly released to comment before the proposed rule is finalized.

Takeaway: The forthcoming release (possibly as soon as later this week) of regulations resulting in a major overhaul of the Medicare physician payment structure is sure to be a significant event resulting in considerable debate.

Short-Term FAA Reauthorization Moves Forward
President Obama is expected to sign H.R. 4721, the Airport and Airway Extension Act, a short-term authorization of Federal Aviation Administration (FAA) programs. With the agency's current authorization expiring at the end of March, and with the House and Senate on divergent paths to a long-term bill, the two chambers have settled on an extension until July 15, 2016. Before enactment, the extension bill had to return to the House when the Senate objected to the House version which would have extended the agency's authority only until July 15, 2016, but would have extended the fee collections (passenger, cargo and fuel excises) used to replenish the Airport and Airway Trust Fund through March 2017. The Senate objected to the disparate expiration dates for the House bill's reauthorization and fee collection provisions, and the House ultimately agreed to extend both only until mid-July.

With a three and one-half month patch, attention will return to a long-term FAA reauthorization after Congress returns from its Easter break. The challenge then will be to reconcile the competing House and Senate bills on several fronts, most notably the House proposal to privatize the U.S. Air Traffic Control (ATC) system. The House bill would separate ATC from the FAA and place it under a separate, nonprofit organization, funded primarily with user fees. The Senate bill would not privatize the ATC.

Takeaway: There will be a significant push to enact a long term FAA reauthorization by July 15, particularly since Congress will adjourn July 16 for its summer break, not returning until September 5. In addition, in the aftermath of the terrorist attacks in Brussels, some members are calling for additional airport security reforms to be added to the FAA measure. Whether the two chambers can work out differences by July 15, particularly on the question of ATC privatization, is an open question. If not, there would likely be another extension as lawmakers would be reluctant to risk a shutdown of the agency, particularly in the current security environment.

New FLSA Overtime Exemption Regulations Forthcoming
On March 14, the Department of Labor (DOL) sent a final rule on administrative and executive (white collar) exemptions to the Fair Labor Standards Act's overtime requirements to the White House Office of Management and Budget (OMB). OMB has up to 90 days to review the revised regulations before they are published in the *Federal Register*. A final rule could be released as early as this spring.

The final text of the rule is not yet public, but the proposed text (released in July 2015) included:

- More than doubling the annual salary required for an employee to be considered exempt from overtime or minimum wage from $23,660 annually to $50,440 annually and implementing an automatic adjustment;
- Raising the minimum salary test for "highly-compensated" individuals from $100,000 per year to $122,148 and implementing an automatic adjustment; and
- Seeking further input on whether DOL should amend the duties test for the exemptions.

Takeaway: The release of the final DOL rule is expected sometime this spring, about three to four months ahead of the timing that was anticipated by employers. Employers should begin analyzing the potential changes as soon as possible in order to ensure they are ready when the final rule is released.