# Government Affairs Update - *May 3, 2016*

## State Issues

**House Finalizes FY17 Budget Proposal**
Last week, the Massachusetts House of Representatives finalized its budget proposal for FY17. Over the course of three days, the House adopted relatively few of the 1,307 amendments that had been filed. The final budget amounts to $39.56 billion, approximately $10 million above Governor Charlie Baker's FY17 proposal.

Of particular note, the budget preserves the June 30, 2022 sunset date established by the House Ways & Means Committee for Governor Baker's new $250 million hospital tax. The "tax" would be part of a 5-year Medicaid waiver proposal the Baker Administration is seeking from Washington. The $250 million would be used to leverage federal matching dollars, and $250 million in Medicaid payments would be returned to hospitals. Approximately half of Massachusetts' hospitals will recover more than they pay in, and approximately half of the state's hospitals will be assessed more than they will receive back in Medicaid payments. The tax, as currently drafted, is also slotted to start a year earlier than the new waiver, with the FY2017 proceeds being used by the state to pay for costs associated with expanded coverage under the Medicaid program. In the Governor's budget proposal, the tax would have been permanent; however, in response to hospital concerns, the House Ways and Means, led by committee chairman Rep. Brian Dempsey (D-Haverhill), inserted key language that would sunset the tax on June 30, 2022, the date on which the new waiver would end. Budget advocacy now turns to the Senate.

**State Unveils Medicaid ACO Program**
The Executive Office of Health and Human Services (EOHHS) recently released details on its new Accountable Care Organization (ACO) program for MassHealth, which is expected to fully launch in October 2017. Funding for new investments in participating ACOs and community-based organizations is anticipated in the soon-to-be negotiated Medicaid Waiver, the aim of which is to support these entities in efforts to coordinate and integrate care, as well as to operate under new value-based payment models. The funding is expected to be contingent on the state meeting certain improvement goals, such as reducing the cost trend and avoidable utilization. The financing of the new investments will also partly rely on the proposed $250 million tax on hospitals that will be used to leverage matching federal funds.

The complex program as envisioned by the state would create three different ACO models dependent on their design and how the ACO interacts with MassHealth Managed Care Organizations (MCOs). ACOs would be responsible for total cost of care of their patient populations, with varying degrees of risk to providers. "Downside risk" is essentially the financial loss an ACO could experience if the patient population it serves costs more to care for than anticipated. For some providers downside risk could pose a serious enough obstacle that they might choose not to participate in the program. ACOs also will share in the "upside risk" or savings when the cost of care falls below the amount that would have otherwise been expected.

**Health Policy Commission Approves ACO Certification Criteria**
The Health Policy Commission (HPC) meeting recently voted to approve requirements for provider organizations to be certified as accountable care organizations. Newly formed ACOs will receive "provisional certification" if they meet certain criteria and demonstrate plans to meet other criteria. Provisional certification will enable qualifying ACOs to participate in the MassHealth contracting and payment model described above. The HPC plans to grant full certification sometime within the first performance year, according to materials presented at the meeting.

Under the newly approved criteria, providers seeking to be certified as ACOs would need to demonstrate that they have a "patient-centered, accountable governance structure," participate in quality-based risk contracts, offer population health management programs and coordinate with behavioral health, hospital, specialist and long-term care services, among other requirements. The organizations would also need to

commit to "consumer price transparency," and to adopting and integrating advanced health information technology. Before launching the ACO program, the Commission will next look to build a platform through which providers can apply for certification, draft an application manual and hold provider trainings.

**Safety Net Eligibility Rules Delayed**
The effective date for a series of rule changes that the state proposed to determine who is eligible for services from the Health Safety Net (HSN) has been delayed from April 1 to June 1. The Health Safety Net helps to finance care provided to Massachusetts low-income residents who are uninsured or underinsured.

- One proposed change to the eligibility rules includes altering the retroactive date of coverage. Currently, many patients who get coverage under the Health Safety Net are covered for six months prior to their application. The Executive Office of Health and Human Services (EOHHS) plans to change that to only 10 days retroactive coverage. The concern among hospitals caring for the uninsured and underinsured is that patients don't always apply for coverage at the time they receive care and only realize they need financial assistance after they receive a bill.
- Other changes to the eligibility rules include a new deductible for those earning between 100% and 150% of the federal poverty level (FPL) and the elimination of partial HSN coverage for those earning between 300% and 400% FPL.
- In addition to the two-month delay in the implementation of the controversial changes, EOHHS also announced that it would introduce a new eligibility policy that had not been proposed previously. The policy called "presumptive eligibility" would permit hospitals and community health centers to use a simplified application for determining patients eligible for the Health Safety Net temporarily instead of the full application that is used for all state programs, including MassHealth and ConnectorCare.

In a related note, there has been no resolution yet to the funding reduction proposed by Governor Baker in his FY 2017 budget for the Health Safety Net. Governor Baker's proposal would eliminate the state's customary $30 million contribution to the HSN, which would affect the program in FY2016. The House budget proposal maintains the state's contribution, but only at a $15M level. A reduction in the state's contribution to the HSN would result in a cost-shift to hospitals, as any funding shortfall is absorbed solely by hospitals. The current shortfall is estimated at $90 million. We will continue to monitor these issues very closely.

## Federal Issues

**CMS Delays Hospital Compare Star Ratings**
CMS has announced it will delay until at least July 2016 the release of overall hospital quality "star ratings" on its Hospital Compare website. The ratings were originally scheduled to be released April 21. Over the next two months, the agency also plans to host calls with providers to clear up questions about current methodology and elicit feedback on refining the program.

The delay for the overall star ratings was in response to the significant concerns raised by many in the hospital industry about whether the methodology provides a fair, accurate, and meaningful representation of hospital performance. In addition, a bipartisan group of 60 Senators and 225 Representatives signed letters to CMS Acting Administrator Andy Slavitt urging CMS to delay the release and take time to re-evaluate its methodology. CMS also announced that it is delaying its regularly scheduled update of data on individual Hospital Compare measures until May 4. The House letter was signed by Representatives Richard Neal, Jim McGovern, Seth Moulton, Katherine Clark, and Stephen Lynch of the Massachusetts Congressional delegation.

**House Appropriators Direct FDA Not to Finalize Guidance on Laboratory Developed Tests**

The House Appropriations Committee has approved report language to accompany its Agriculture Appropriations bill that would direct the Food and Drug Administration (FDA) to suspend efforts to finalize its draft guidance for laboratory developed tests and work with Congress to pass legislation that "addresses a new pathway for regulation of LDTs in a transparent manner." The bill and report language are expected to go to the floor in May.

**CMS Issues FY 2017 IPPS Proposed Rule**

**On April 18, the Centers for Medicare and Medicaid Services (CMS) released the fiscal year (FY) 2017 inpatient prospective payment system (IPPS) proposed rule. The proposed rule would increase** Medicare payment rates by 0.85% in FY 2017 compared to FY 2016, after accounting for inflation and other adjustments required by law.

The proposed rule included an initial market-basket update of 2.8% for those hospitals that were meaningful users of electronic health records (EHR) in FY 2015 and that submit data on quality measures, less a productivity cut of 0.5% and an additional market-basket cut of 0.75%, as mandated by the Affordable Care Act (ACA). The proposed rule is posted here and will be published in the April 27 Federal Register and comments will be accepted through June 17. Below you will a few selected highlights from the rule.

- Two-Midnight Rule Relief
  CMS backed down from its two-midnight rule and proposed two adjustments to reverse the effects of the two-midnight rule's 0.2% cut, which was implemented in FY 2014. It proposed a permanent adjustment of approximately 0.2% to remove the cut prospectively for FYs 2017 and onward, and a temporary adjustment of 0.6% to address the retroactive impacts of the cut for FYs 2014, 2015 and 2016.

- Proposed DSH Payment Cuts
  CMS continues to implement changes to Medicare disproportionate share hospital (DSH) payments. Beginning in FY 2014, hospitals started receiving 25% of what they would have received under the former statutory Medicare DSH formula. The remaining 75% was adjusted and redistributed to hospitals as uncompensated care payments. In the FY 2017 proposed rule, CMS proposes two changes to the methodology for distributing these funds, including using data from three cost reporting periods instead of one cost reporting period. For FY 2018, CMS proposes to incorporate uncompensated care cost data from Worksheet S-10 of the Medicare Cost report.

- Medicare Graduate Medical Education
  CMS proposes changes to graduate medical education (GME) for urban hospitals with rural training track (RTT) programs to allow five years rather than the current three years to establish the actual number of full time equivalent (FTE) residents training in the urban hospital's rural training track. The rural track FTE limitation would take effect beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track program. This proposal will give rural training tracks a sufficient amount of time to establish a rural track FTE limitation that reflects the number of the residents that will actually train when the program is fully established. However, FTEs in rural tracks at urban hospitals are immediately subject to the three-year rolling average and are subject to the indirect medical education (IME) intern-resident bed (IRB) ratio cap for hospitals with established FTE caps.

**CMS Issues LTCH PPS Proposed Rule for FY 2017**

CMS has issued its long-term care hospital prospective payment system (LTCH PPS) proposed rule for FY 2017. The rule proposes a 2.7% market- basket update, a 0.5% cut for productivity and an additional 0.75% cut as mandated by the ACA. The proposed rule also notes that FY 2017 will be the second year of the two-year transition to a dual-rate payment system for LTCHs, which was mandated under the Bipartisan Budget Act of 2013 and represents a transformative change for the field. During this phase-in, site-neutral cases are paid a 50/50 blend of the LTCH PPS and site-neutral rates. The proposed rule

would increase traditional LTCH PPS rates by a net of 0.3%, while CMS projects that net payments for site-neutral cases would drop by 21%. When accounting for all the rule's provisions, LTCH payments are estimated to decrease by 6.9% compared to FY 2016 payment levels. CMS is also proposing to replace the current 25% Rule guidelines with a streamlined version, for implementation when the current 25% Rule relief expires in 2017. The proposed rule will be published in the April 27 Federal Register and comments will be accepted through June 16. The proposed rule is posted here.

**AAMC Expresses Concerns about Potential Subpoenas from House Panel on Infant Lives The** House Select Investigative Panel on Infant Lives issued subpoenas to various organizations with connections to human fetal research. In response to these subpoenas, the AAMC with the Association of American Universities (AAU), and the Association of Public and Land-grant Universities (APLU) sent a letter to the Panel's Chair Marsha Blackburn (R-TN) and Ranking Member Jan Schakowsky (D-IL), expressing strong concerns with request for the names of researchers, students, and other staff involved in research that uses fetal tissue.

The attached letter raised concerns over pressure to hand the Panel "the identities and other personal information not only of researchers but also of graduate students and trainees, health care providers, and administrative and support staff." The letter asked the panel to work toward a bipartisan solution to promote the security of these individuals and their institutions, saying, "Without such protections in place, we urge the panel not to force organizations to release individually identifiable information." Democrats on the panel have also criticized Chairwoman Blackburn for the subpoenas seeking researchers' names.

**Senate HELP Committee approves final bills for medical innovation package**
The Senate Health, Education, Labor and Pensions Committee has approved the last five in a package of bipartisan bills expected to serve as a companion to the House-passed 21st Century Cures Act. This package of bills include provisions aimed at helping the National Institutes of Health and Food and Drug Administration hire and retain talent (S. 2700); approving antibacterial drugs to treat serious medical conditions in limited populations (S. 185); implementing a Precision Medicine Initiative (S. 2713); promoting the inclusion of minorities in clinical research (S. 2745); and streamlining administrative requirements for NIH researchers and grant recipients (S. 2742). Committee Chairman Lamar Alexander (R-TN) said senators continue to negotiate an NIH innovation fund as part of the package, which also includes legislation aimed at making electronic health records more interoperable (S. 2511); requiring makers of reusable medical devices such as duodenoscopes to submit proposed cleaning instructions and validation data to the FDA before marketing (S. 2503); and excluding from FDA regulation as medical devices most software used for electronic patient records (S. 1101).

**HHS Proposes Raising Physician Prescribing Limit for Opioid Treatment**
The Department of Health and Human Services (HHS) issued a proposed rule that would double the number of patients a qualified physician may treat with buprenorphine. The controlled substance is one of three drugs approved by the FDA for medication-assisted treatment of opioid dependence. The Substance Abuse and Mental Health Services Administration (SAMHSA) rule would allow qualified practitioners to request approval to treat up to 200 patients a year if they have maintained an active waiver to treat up to 100 patients for a year and have subspecialty board certification in addiction medicine or addiction psychiatry, or practice in a qualified practice setting as defined in the rule. In addition, they would have to reaffirm their eligibility every three years; attest that they will adhere to evidence-based treatment guidelines; and provide or connect patients to necessary behavioral health services; among other conditions. The rule also would allow practitioners with a 100-patient limit to request to serve up to 200 patients for up to six months in an emergency. The proposed rule is available at here and the HHS factsheet is posted at here.

**NIH Panel to Help Cancer Moonshot Initiative**
The National Cancer Institute has announced a Blue Ribbon Panel of scientific experts, cancer leaders and patient advocates that will inform its goals for the vice president's National Cancer Moonshot Initiative. The panel will serve as a working group of the presidentially appointed National Cancer Advisory Board.

“This Blue Ribbon Panel will ensure that, as [the National Institutes of Health] allocates new resources through the Moonshot, decisions will be grounded in the best science,” said Vice President Joe Biden. “I look forward to working with this panel and many others involved with the Moonshot to make unprecedented improvements in prevention, diagnosis and treatment of cancer.”