Government Affairs Update - *July 19, 2016*

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State Issues

FY17 Budget / Health Safety Net
Governor Charlie Baker has signed a $38.92 billion FY2017 budget, while vetoing $256 million in proposed spending. He also proposed numerous amendments, including an amendment related to the legislature's commitment of $15 million to the Health Safety Net. His amendment would insert the words "up to" into Section 157 of the legislature's final budget (HB4450). The insertion of this language would allow the administration the flexibility to ignore the legislature's commitment of $15 million in state funding for Health Safety Net. The Massachusetts Hospital Association (MHA) has urged the legislature to reject the governor's proposed amendment and re-enact the legislative language in section 157 directing the administration to commit $15 million to the Health Safety Net.

Telemedicine Update
The Health Care Financing Committee recently advanced a re-drafted version of legislation (HB267) that sought to advance and expand access to telemedicine services in Massachusetts. Despite broad support for the original legislation from the 21 organizational members of the MHA "tMED Coalition," including Partners, the provisions of the re-drafted bill proved to be a disappointment. The re-drafted bill (HB4442) eliminates both coverage and payment parity for telemedicine services; instead, it preserves the status quo and even creates new barriers to access by specifically authorizing insurers to subject telemedicine services to prior authorization. MHA and the tMed coalition will now direct attention to expanding telemedicine access by other means and will revisit the legislative effort in 2017 to make Massachusetts the 32nd state to enact telemedicine parity requirements.

Drug Therapy and Data Confidentiality Bills Approved
The Joint Committee on Public Health has approved two hospital-priority bills. The first, HB1971, filed by Rep. Tom Golden (D-Lowell), is a joint effort of MHA and the Massachusetts Society of Health System Pharmacists. It seeks to improve and expand the use of collaborative drug therapy management in hospitals by enabling hospital pharmacists to partner with hospital physicians to manage and resolve medication-related problems and to make decisions concerning drug prescribing and monitoring during an inpatient stay. The bill would improve patient outcomes through: better assessment of patients; earlier initiation and more prompt modification of drug therapies; additional monitoring of patients; and direct administration of drugs. The second bill approved by the committee, HB1895, filed by Rep. Paul Brodeur (D-Melrose), seeks to ensure that proprietary information that providers submit to state agencies as part of healthcare oversight programs is kept confidential by the agencies. Similar language was passed to maintain the confidentiality of proprietary information provided to the Health Policy Commission during cost and market impact reviews. This legislation seeks to extend the same level of confidentiality to data reviews for other information submitted to the Health Policy Commission, Division of Insurance and Center Health Information and Analysis.

House Approves Property Tax for Non-Profit Organizations
Late last week, the House inserted language into its proposed Economic Development bill that would require nonprofit charitable corporations and public charities to pay municipal property taxes for a period of four years following the purchase of real property that had been subject to taxation prior to the purchase by the non-profit or charity (see section 127 of HB4483). The Senate will take action on its version of an Economic Development bill this week, and MHA has delivered the attached letter to the Senate Committee on Bonding opposing section 127 of HB4483.

Federal Issues

House Passes Mental Health Bill
The House voted 422-2 to approve mental health legislation sponsored by Rep. Tim Murphy (R-PA). The Helping Families in Mental Health Crisis Act, H.R. 2646, will move to the Senate for consideration where a vote is expected in the fall. H.R. 2646, would make needed psychiatric, psychological, and supportive services available for individuals with mental illness and families in mental health crisis. Although significantly scaled back from its original version, the bill includes funding for Assertive Community Treatment and bed registry grants, and it codifies CMS' policy to allow states to make capitation payment for enrolled patients with stays of no more than 15 days in Institutions of Mental Disease. The bill keeps the Health Insurance Portability and Accountability Act (HIPAA) intact, but adds non-binding language that states the privacy rule should be revised to allow healthcare professionals to communicate with caregivers of individuals with serious mental illness.

Conference on Opioid Legislation and House Vote
The House and Senate conferees both passed S. 524, the Comprehensive Addiction and Recovery Act (CARA), which would authorize the Attorney General and Secretary of Health and Human Services to award grants to address the national epidemics of prescription opioid abuse and heroin use, and provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes. Democratic conferees had voiced strong opposition to the bill given the total lack of funding but were unsuccessful in adding House and Senate amendments that would have provided states' $920 million in funding. Senator Lamar Alexander (R-TN) argued that the Conference Committee should focus on policy and leave matters of funding to the Labor-HHS appropriations process. The agreement was sent to the President, marking the first major reform of the country's substance abuse policies in more than a generation. The legislation was important politically to a number of vulnerable Republican Senators who face difficult re-election campaigns in the Fall, particularly Senators Ayotte of New Hampshire and Portman of Ohio.

President Obama Takes Administrative Action on Opioid Crisis
On July 6, the Obama Administration announced several actions to expand access to opioid addiction treatment, to strengthen prescription drug monitoring, to enable safer disposal of unneeded drugs, and to accelerate research on pain and opioid misuse and overdose. Included in the proposal is an HHS-decision to increase from 100 to 275 the number of patients that qualified physicians can treat with buprenorphine for opioid use disorders. For more information on the White House announcement, click here.

House Members Urge CMS to Waive FFS Barriers to Alternative Payment Models
Seventy members of the House of Representatives have urged the Centers for Medicare & Medicaid Services to waive fee-for-service regulations, such as the 25% Rule for long-term care hospitals, that limit care coordination and collaboration for acute care hospitals and post-acute care providers entering into alternative payment models with downside risk. "The continued application of FFS regulatory barriers within downside risk payment reform models often hinders providers' ability to identify and place beneficiaries in the most clinically appropriate setting," the House members wrote (attached). "It also inhibits their ability to test new, more patient-centered and streamlined clinical pathways." The representatives also encouraged CMS to consider new payment approaches for inpatient rehabilitation facilities and LTCHs. "These higher-cost settings face challenges within downside risk payment reform models because currently, any new efficiencies achieved are not reflected in their per-discharge Medicare reimbursement," they wrote. "Hospitals and other stakeholders, in order to effectively partner with these settings within downside risk payment reform models, need more flexibility." The letter was spearheaded by Reps. Pat Tiberi (R-OH) and Ron Kind (D-WI).

Analysis finds bias in CMS's overall hospital star ratings methodology
The Centers for Medicare & Medicaid Services' approach to overall hospital quality star ratings appears to have several shortcomings, according to a new analysis (attached) by an expert in econometrics, commissioned by the American Hospital Association. "While it appears to give the impression of being rigorous and objective the estimation aspect is highly dependent on choice of measures and the weighting scheme is entirely subjective and highly determinant of the final outcomes," writes Francis Vella, chair of the Department of Economics at Georgetown University, among other concerns. Commenting on the

study AHA President and CEO Rick Pollack said, “Patients need reliable information to make important choices regarding their health care. And hospitals and health systems need reliable information so that they can continue to improve the quality of the care delivered. CMS star ratings misses the mark on both accounts.” CMS delayed the release of the ratings in April after AHA and 285 members of Congress raised concerns about the agency’s methodology.

House Hearing Examines Ways to Strengthen National Trauma System
The House Energy and Commerce Subcommittee on Health held a hearing on legislation to strengthen the national trauma system. One proposal, the Protecting Patient Access to Emergency Medicines Act (H.R. 4365), would clarify that medications governed by the Controlled Substances Act may be administered by emergency medical services practitioners pursuant to a standing order issued by a physician medical director of an EMS agency.

GAO issues update on drug shortages
The number of new drug shortages has generally decreased since 2011, while the number of ongoing shortages remains high, according to a new report by the Government Accountability Office. The report, mandated by the FDA Safety and Innovation Act of 2012, examines 2010-2015 data on drug shortages from the University of Utah Drug Information Service; Food and Drug Administration efforts to prioritize reviews of drug submissions to address shortages; trends in FDA warning letters issued to sterile injectable manufacturing establishments for noncompliance with manufacturing standards; and certain factors that may affect shortages of sterile injectable drugs, such as a decline in the number of suppliers, FDA warning letters and relatively low profit margins for generic drugs. According to the report, there were 136 new drug shortages in 2015, down from 257 in 2011, while the number of ongoing drug shortages increased to 291 from 184 over the period.

HHS Proposes Changes to Medicare Appeals Procedures
The Department of Health & Human Services has released a proposed rule that would make changes to the procedures for Administrative Law Judge appeals of payment and coverage determinations for items and services provided to Medicare beneficiaries, in addition to other Medicare appeals. Specifically, the proposed rule would allow attorney adjudicators to hear appeals in lieu of ALJs in some cases and allow the HHS Departmental Appeals Board to designate certain decisions as precedential. Comments on the proposed rule are due August. 29.

CMS Releases 2017 OPPS/ASC Proposed Rule
The Centers for Medicare & Medicaid Services proposed to update hospital outpatient prospective payment system rates by 1.55% in calendar year 2017 compared to CY 2016. The rule also proposes to implement the site-neutral provisions of Section 603 of the Bipartisan Budget Act of 2015, which requires that, with the exception of dedicated emergency department services, services furnished in off-campus provider-based departments that began billing under the OPPS on or after Nov. 2, 2015 would no longer be paid under the OPPS; instead these services would be paid under other applicable Part B payment systems beginning Jan. 1, 2017. CMS proposes that, in 2017, the physician fee schedule would be the applicable payment system for the site-neutral rates for the majority of services furnished in a new off-campus PBD. Specifically, CMS would pay physicians furnishing services in these departments at the higher “nonfacility” PFS rate. There would be no payment made directly to the hospital by Medicare. Existing off-campus PBDs that expand their services to include those in new clinical families would receive the site-neutral rate for those services. In addition, any existing off-campus PBD that relocates after Nov. 2 would lose its excepted status and be subject to site-neutral payments. An existing off-campus PBD that undergoes a change of ownership would only maintain its excepted status if the new owner accepts the existing Medicare provider agreement from the prior owner.

CMS does propose to offer greater flexibility in the meaningful use of electronic health records under the Medicare program by shortening the reporting period for 2016 from a full year to 90 days for all hospitals and physicians. CMS also proposes, beginning in 2017, to remove two measures for eligible hospitals and critical access hospitals – computerized provider order entry and clinical decision support – and reduce the requirements for patients to view, download and transmit their information from 5% to at least one patient. Stage 3 of meaningful use would still be required by all hospitals in 2018. However, the thresholds for most measures would be reduced to the level required in Modified Stage 2. Comments on the rule are due September. 6.

CMS releases home health proposed rule
The Centers for Medicare & Medicaid Services released the proposed rule for the home health prospective payment system for calendar year 2017, which, after all policy changes, would reduce home health payments by 1.0% from 2016 payment levels. CMS proposes a 2.8% market-basket update and 0.5 percentage point cut for productivity, as mandated by the Affordable Care Act. It also would apply the second of three planned 0.97 percentage point cuts to account for estimated case mix growth from CYs 2012 through 2014 that the agency states was unrelated to increases in patient acuity. The rule also would implement the final year of the four-year phase-in of the rebasing of this payment system, as mandated by the ACA; modify the methodology for calculating outlier payments; add four new measures to the HH Quality Reporting Program reflecting Medicare spending per beneficiary, preventable hospital readmissions, discharges to community and medication reconciliation; and make several changes to the measures and scoring approach of the HH Value-Based Purchasing program, a mandatory payment model for all home health agencies in nine states. The rule will be published in the July 5 Federal Register with comments accepted through August 26.

Senate Holds Hearing on Proposed Medicare Part B Drug Demonstration
The Senate Finance Committee held a hearing on the Centers for Medicare & Medicaid Services' proposed payment demonstration for Medicare Part B drugs. Patrick Conway, M.D., CMS acting principal deputy administrator, said the agency is reviewing comments on the proposed rule "to determine whether adjustments are needed. Our goal is to be responsive to the public comments and input from Congress while preserving the integrity and effectiveness of the model." Committee Republicans have urged CMS to withdraw the proposal, while Democrats have said the model could reduce access to care and medications.