November 10, 2014

Special Edition Health Care Update

Elections Wrap Up, Lame Duck Preview, and a Changing Congress

In this ML Strategies Special Edition Health Care Update, we bring you a detailed look at two of the most pressing health care policy topics facing policymakers:

1) Sorting out Congressional leadership changes post-midterm elections and looking ahead to the upcoming Lame Duck session of Congress; and

2) Monitoring the rapidly escalating effort to combat the Ebola epidemic

Impact of Midterm Elections

On November 4th, voters cast their ballots giving the Republican Party control of the upcoming 114th Congress. Looking ahead to the new Congress, there will be some significant changes to the leadership on Committees of jurisdiction. While leadership will not be officially decided until Congress convenes in January, some predictions are below.

• **Senate Finance Committee:** Senator Orrin Hatch (R-UT) will chair the Committee. As Chairman, Hatch is expected to focus on tax reform and is likely to advance his bill S. 232, to repeal the Affordable Care Act's (ACA) excise tax on medical devices as part of this process. Hatch can also be expected to push for additional transparency from the Department of Health and Human Services (HHS) and support policy changes to the ACA such as we have seen the House pass in the 113th Congress. Senator Ron Wyden (D-OR) will be the ranking member. Hatch and Wyden have a strong working relationship and share interest in tax reform. Wyden is also a strong supporter of the ACA and is unlikely to support repealing or replacing the health care law, be they partial or wholesale proposals. On the whole, Democrats will likely have to cede at least two seats to the Republicans, meaning they will have to drop at least one member from the committee.

• **Senate Health, Education, Labor and Pensions (HELP) Committee:** Senator Lamar Alexander (R-TN) is expected to chair the HELP Committee. Alexander will likely turn first to Ebola, should there be lingering issues unresolved after the Lame Duck. Alexander and the Committee’s current chair, Senator Tom Harkin (D-IA), introduced a bill to accelerate the development of Ebola treatments and vaccines. Alexander will also try to chip away at the ACA. In the past, he has said the Committee will vote early in the next Congress to repeal the ACA, though he conceded that the law will stay in effect as long as President Obama is in office. Alexander is more optimistic about tweaks to the ACA. Among his top priorities are addressing wellness, passing a 40 hour work week bill, and tackling small business insurance.
• **Senate HELP (cont):** The Democrats have yet to pick their ranking member. As Senator Barbara Mikulski (D-MD) will opt for the ranking membership of the Appropriations Committee, Senators Patty Murray (D-WA), Bernie Sanders (I-VT), and Bob Casey (D-PA) could all be the lead Democrat on the Committee. The subcommittee chairs will likely be Senator Mike Enzi (R-WY) for Children and Families, Senator Richard Burr (R-NC) for Primary Health and Aging, and Senator Johnny Isakson (R-GA) for Employment and Workplace Safety.

• **House Energy and Commerce Committee:** Representative Fred Upton (R-MI) will continue to chair the Committee. His agenda will resemble that in the 113th Congress, promoting the 21st Century Cures Initiative, which, among other things, promotes accelerated discovery of cures, streamlined development of drugs and devices, and greater use of health care technology to offset rising health care costs. He will also likely continue to try and reign in various provisions of the ACA. Other than the law’s repeal, which the Committee will likely take up at the start of the next Congress, Upton may seek to scuttle the employer mandate and the medical device tax. In addition, he may seek to overhaul or even dismantle the Independent Payment Advisory Board (IPAB), which would administer provider cuts unilaterally if certain spending thresholds are surpassed. Upton recently released the Committee’s record of success webpage and outlined several priorities for the new Congress, including building on the work already done on the 21st Century Cures Initiative.

On the Democratic side, with Representatives Henry Waxman (D-CA) and John Dingell (D-MI) retiring, Representative Frank Pallone (D-NJ) is in line to be ranking member. However, Minority Leader Pelosi has been a strong advocate for Representative Eshoo to take the Ranking Membership. With top slots opening up on other committees because of midterm losses, some congressional analysts believe that Pallone could end up moving back to the Natural Resources committee in place of Rep. Peter DeFazio (D-OR), who is likely to become Ranking Member on the House Transportation and Infrastructure Committee, following the loss of current Ranking Member Nick Rahall (D-WV). Of the 10 or so House Democrat losses, including Representatives John Barrow (D-GA) and Brad Schneider (D-IL), that are official, the majority of them have indicated explicitly, or have been characterized by others, as Pallone supporters- so it will be interesting to see how that plays out if it comes down to the last few votes.

• **House Ways and Means Committee:** Representatives Paul Ryan (R-WI) and Kevin Brady (R-TX) are jockeying for the chairmanship, but it is widely believed that Representative Ryan will most likely prevail. Like Senator Hatch, Ryan will focus on tax reform. He will inherit Chairman Camp’s template, which he’ll likely keep with some changes. This effort could very well effect the health care community should Ryan join Senator Hatch in an attempt to repeal the medical device tax. Ryan will also address health care, separate from taxes, including holding hearings to critique the law and to demand more transparency and build on efforts in the 113th Congress to pursue Medicare fraud, waste, and abuse legislation. Representative Sander Levin (D-MI) is expected to remain the Ranking Member. However, House Democrats are eyeing Representative Chris Van Hollen (D-MD) to rejoin the committee. A budget expert with a strong grasp on tax policy, Van Hollen could serve as a vocal counterweight to Ryan, reprising a role he played opposite Ryan on the Budget Committee.

### Lame Duck Preview

President Obama, who began his presidency with a Democratic majority in the Congress, will now round out his last two years in office with a Republican majority. This leaves the upcoming Lame Duck session as the last opportunity for the president and his Democratic colleagues in the Senate to set the legislative agenda.

Among one of the items most likely to pass is the FY 2015 appropriations legislation. With no appropriations legislation finalized prior to recessing for elections, Congress approved a short-term Continuing Resolution (CR) funding the Federal government at Fiscal Year 2014 levels through December 11, 2014. Before the CR expires, the Lame Duck Congress will likely pass either: 1) another short-term CR running through February or March 2015; 2) a long-term CR for the remainder of the fiscal year ending on September 30, 2015; or 3) an Omnibus appropriations bill setting new spending levels for FY15. Additionally, in the days after the midterm election, President Obama submitted an emergency funding request of $6.18 billion for the fight against Ebola and will push Congress to pass the request during the Lame Duck.
The Lame Duck offers some hope of passing a permanent solution to the Medicare physician payment formula, also known as the “SGR” or the “Doc Fix.” Looking to vehicles such as tax extenders or an omnibus spending bill, Congress still must determine how to pay for reforming the SGR. Members of the House GOP Doctors Caucus wrote to House leadership requesting that Congress take up SGR reform before the end of the year. The letter notes that the Lame Duck is a unique opportunity to bring much-needed stability to the Medicare program that will benefit seniors and physicians alike and requested more discussions on offsetting an SGR repeal.

While stakeholders and experts remain skeptical that such an effort would be successful, lawmakers are pulling out all the stops to engage industry to support a potential SGR fix this year. However, the current temporary extension of the SGR patch continues through March 2015, meaning that action could slip to next year.

Should Congress attempt to push through a comprehensive SGR bill in the Lame Duck, this would provide a vehicle for other Medicare proposals that are kicking around the House Ways and Means Committee—including Representative Brady’s draft fraud, waste, and abuse package, Protecting Integrity in Medicare Act of 2014 (PIMA), and Medicare extenders. Representative Brady reportedly wanted to introduce PIMA in the Lame Duck and, if there is bipartisan interest, pass the legislation under suspension. However, there has been no groundwork laid for this package in the Senate, so passing the package without a larger vehicle (such as SGR) may be unlikely.

**Ebola Epidemic and Lame Duck Response**

On November 4th, President Obama convened his national security and public health teams to discuss Ebola preparedness at home and the whole-of-government approach to contain the epidemic at its source in West Africa. The President’s advisors noted HHS’ efforts to ensure U.S. hospitals and the broader health system are prepared to identify, isolate, and treat patients. The team also discussed the screening of individuals traveling from the affected West African countries and the monitoring requirements these individuals are subject-to upon arrival in the U.S. There was consensus that, despite initial signs of progress in Liberia, the international community must continue to attack the problem aggressively at the source of the epidemic in West Africa.

Following this meeting, the Obama Administration announced it is seeking $6.18 billion through an emergency funding request to Congress to enhance efforts to address the Ebola crisis. The White House has requested $2.43 billion for HHS, including $1.83 billion for the Centers for Disease Control (CDC) to prevent, detect, and respond to the Ebola epidemic, $333 million for the Public Health and Social Services Emergency Fund (PHSSEF) for health worker training, manufacturing of synthetic therapeutics and vaccines, and modeling and genetic sequencing of the Ebola virus, $238 million for the National Institutes of Health (NIH) to conduct clinical trials of investigational vaccines and therapies, and $25 million for the Food and Drug Administration (FDA) to regulate Ebola vaccines and therapeutics. The Administration is also requesting $1.98 billion for USAID to scale up foreign assistance in West Africa, $127 million for the Department of State to support UN Mission for Ebola Emergency Response (UNMEER) operations, and a $1.54 billion contingency fund.

The President communicated this request to Congress in a November 5th letter to congressional leadership requesting that Congress consider his Administration’s $6.18 billion emergency appropriations request to implement a comprehensive strategy to contain and end the Ebola outbreak at its source in Africa, enhance domestic preparedness, speed procurement and testing of vaccines and therapeutics, and accelerate global capability to prevent spread of future infectious diseases. President Obama urged expeditious consideration of the proposal.

As we enter the Lame Duck, Congress is expected to tackle Ebola as a priority when it reconvenes. On November 12th, the Senate Appropriations Committee will hold a hearing on the U.S. Government response to the Ebola outbreak. Witnesses will include HHS Secretary Sylvia Matthews Burwell, CDC Director Dr. Tom Frieden, National Institute of Allergy and Infectious Diseases (NIAID) Director Dr. Anthony Fauci, DHS Secretary Jeh Johnson, Deputy Secretary of State for Management and Resources Heather Higginbottom, USAID Assistant Administrator for Democracy, Conflict, and Humanitarian Assistance Nancy Lindborg, Assistant Secretary of Defense for Special Operations and Low Intensity Conflict Michael Lumpkin, and Joint Chiefs of Staff Deputy Director for Political-Military Conflict James Lariviere.
On the heels of the Appropriations Committee hearing, the House Foreign Affairs Committee will hold a November 13th hearing to examine international and U.S. efforts to combat the Ebola epidemic in West Africa. The hearing, "Combating Ebola in West Africa: the International Response," will feature witnesses including: USAID Administrator Rajiv Shah, State Department Deputy Assistant Secretary for the Bureau of African Affairs Bisa Williams, DOD Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict Michael Lumpkin, DOD Deputy Director for Politico-Military Affairs (Africa) Major General James Lariviere, and DOD Joint Staff Surgeon Major General Nadja Y. West.

As Congress turns its attention to the Administration's response, the FDA continues to work with industry to develop a vaccine to combat Ebola. Outlining a plan at an American Society of Tropical Medicine and Hygiene conference last week, Dr. Luciana Borio, head of the FDA's Ebola response team, said the FDA is taking a "novel" approach and will test multiple drugs at once in an umbrella study with a single comparison group. This plan is intended to accelerate the testing process as patients will be paired with a drug and with someone from a comparison group to look for patterns.

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Implementation of the Affordable Care Act

In-Patient Hospitalization Guidance: HHS and the Internal Revenue Services (IRS) released guidance stating that group health plans must cover hospitalizations in order to satisfy minimum value under the ACA. The guidance, which will be followed up by proposed regulations, states the agencies "believe that plans that fail to provide substantial coverage for in-patient hospitalization services or for physician services” do not meet minimum value requirements.

Other Federal Regulatory Initiatives

CMS Innovation Center Webinar: On November 10th, the Centers for Medicare & Medicaid Services (CMS) Innovation Center will hold a webinar to provide an update on the work of the Center and the models being tested to improve care for patients, communities, and lower costs. Dr. Patrick Conway, CMS Deputy Administrator for Innovation and Quality and CMS Chief Medical Officer, will be the lead presenter in the webinar.

New Members of the Health IT Policy Committee: HHS Secretary Burwell announced the appointment of a new member to the Health Information Technology Policy Committee (HITPC) and renewed appointments for three members of the Health IT Standards Committee (HITSC). The new appointment is Anjum Khurshid, director of the health systems division of the Louisiana Public Health Institute.

HHS Survey on Health Coverage: The HHS Assistant Secretary for Planning and Evaluation (ASPE) released the findings of a survey of health insurance coverage for 2013 and 2014. Among other things the survey finds that, as of June 2014, 10.3 million nonelderly Americans, age 18 to 64, gained health insurance coverage since the beginning of the ACA open enrollment.

HRSA Awards Mental Health and Substance Abuse Funding: The Health Resources and Services Administration (HRSA) announced $51.3 million in ACA funding to support 210 health centers in 47 states to establish or expand behavioral health services for nearly 440,000 people.

ONC Data Sheds Light on Attestation Rates: The Office of the National Coordinator for Health IT (ONC) released a data analytics update on the 2014 attestation experience. The update shows that 4,656 doctors and other eligible providers and 258 hospitals had attested to Stage 2.

CDC Releases Monitoring Guidance for Ebola: The CDC released updated monitoring and movement guidance defining four risk levels based on degree of exposure to Ebola. The guidance helps to ensure a system is in place to quickly recognize symptoms that may necessitate a person be routed to medical care.
**Other Health Care News**

**Study of Marketplace Insurance Premiums:** The Robert Wood Johnson Foundation and the Urban Institute released a study of public filings from 17 states and Washington, DC of marketplace insurance premiums in early approval states. The report finds that premium increases will be low, with 10 states increasing only 5 percent, 2 states increasing more than 5 percent, and 6 states seeing premium reductions.

**Specialty Providers Press NAIC on Access:** The Alliance of Specialty Medicine sent a letter to the National Association of Insurance Commissioners (NAIC) regarding draft policy models for individual and small group market health insurance coverage. The Alliance urged NAIC to ensure consumers have access to specialists without suffering high out-of-pocket costs.

**WHO Recommends Overdose Policies:** The World Health Organization, estimating that 69,000 people die a year from opioid overdose, advised that those likely to witness an overdose incident, such as family members, should be given access to the opioid antidote naloxone and trained in its use. The FDA approved use of naloxone injectors for family use in April 2014.

**Survey of ICD-10 Preparation:** The American Health Information Management Association and the eHealth Initiative released a survey of health delivery organizations and clinicians finding that 65 percent of respondents indicated that they could begin end-to-end testing prior to the fourth quarter of 2015 but that there remain concerns that revenue will decrease during the first year of ICD-10 compliance.

**Georgetown University Survey of Children’s Insurance:** Georgetown University’s Center for Children and Families found that in 2013, for the first time in five years, children’s health uninsured rates did not drop. The 2013 rate was 7.1 percent, compared to 7.2 percent in 2012. Since 2008, the number of uninsured children has shrunk from 6.9 million to 5.2 million.

**Upcoming Congressional Hearings**

*Senate*

On November 12th, the Senate Appropriations Committee will hold a hearing on the U.S. Government response to the Ebola outbreak.

*House*

On November 13th, the House Committee on Foreign Affairs will hold a hearing titled, “Combating Ebola in West Africa: The International Response.”