

ML Strategies Provides Outlooks for Fall & Lame Duck

August 31, 2016 | Blog | By [Kate F. Stewart](#)

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Our colleagues at [ML Strategies](#) recently published their Outlook for Fall & Lame Duck, summarizing what to expect from Washington for the remainder of 2016. The full Outlook is available [here](#), and the portion related to health care is excerpted below.

Congress returns after Labor Day for a four-week sprint that will likely be centered on funding the government by way of a continuing resolution. Since Congress was last in session, the landscape on a number of health care issues remains unchanged. The Senate version of the House-passed Cures package is still in limbo, and mental health reform is no closer to the finish line than it was after the House finally passed its package after months of negotiating. Congress will have an opportunity to advance some issues in September before returning its focus to the 2016 election. After which there will be a, post-election, "lame duck" legislative session – the scope of potential activity for which are uncertain at this point – to put the finishing touches on the 114th Congress. Here's a look at issues that will likely come up in September:

Zika Virus: Members of both parties are calling on Congress to address the Zika virus crisis, and the consequences of not doing something could be far greater if left unaddressed before the election. While both sides are sticking to their own proposals, which have been non-starters for the other thus far, should Republicans move to address this through appropriations, Democrats would almost certainly join the effort.

Funding Response for Opioid Crisis: Addressing the opioid crisis remains a top issue on the campaign trail – especially in pivotal swing states like Pennsylvania, New Hampshire, and Ohio – and appears likely to be addressed this month. When the Senate passed the Comprehensive Addiction and Recovery Act (CARA) earlier this year, Democrats argued that the bill lacked sufficient concrete funding, which Republicans countered would be taken care of during the appropriations process. If Republicans move to add significant funding through appropriations, Democrats would be hard-pressed to fight it.

EpiPens: A high-profile issue that has emerged in the past few weeks is the soaring costs of EpiPens. A pack of EpiPens once cost \$100, but has grown to about \$600 this year. Several members of Congress are looking into this issue, including Senator Grassley (R-IA), Chairman of the Senate Judiciary Committee, who in 2014 led an investigation into price hikes of a pair of Hepatitis C drugs. While Mylan, the manufacturer of EpiPens, recently announced that it would offer 50 percent off vouchers for their product, it sure fuels the sentiments on and off Capitol Hill about prescription drug costs.

Medicare Part B Demo: Should CMS move forward with the Part B demonstration project, by proposing a rule this fall, we could see a Congressional Review Act challenge, potentially forcing CMS to pull the proposal, which could drive a wedge between some Democrats and the White House.

After September 30, Congress will be on recess until November 14th. Much of the forthcoming work for a lame-duck session will depend on the outcome of the election, and how the Senate and House majorities look heading into the next Congress. Here are some potential issues that could come up following the election:

Mental Health Reform: If the Senate flips to a Democratic majority, Democrats will likely want to work up a version of mental health legislation for the next Congress. If the Senate does not flip, there is the potential for it to get done this year. With more than 400 votes for the House-passed mental health package, there is momentum behind the effort.

21st Century Cures: While securing passage this summer for the Senate Cures package was thwarted by funding concerns from senators on the Senate Committee on Health, Education, Labor, and Pensions (HELP), Chairman Lamar Alexander (TN) remains optimistic about passage this year. If the Senate can pass its version of the 21st Century Cures Act, Speaker Paul Ryan has said he is willing to work out the differences through a conference. Should the effort fail to materialize in 2016, conventional wisdom is that Cures is likely to be included in the User Fee Acts (UFAs) reauthorization next year.

Looking Ahead to 2017 and the Medical Device User Fee Agreement (MDUFA), in a draft deal announced in late August, device companies agreed to pay nearly \$1 billion to the FDA between 2018 and 2022, a 68 percent increase from the previously brokered deal. Details of the deal thus far are sparse but the FDA

has said that the increase in payments will provide “critical resources” to its medical device review program. With the final recommendations being presented to Congress in early 2017, this fall will be when stakeholders launch their advocacy campaigns to hit the ground running in the next Congress. Regardless of who is in the majority, MDUFA is up for reauthorization at the end of September 2017, and will be a key priority for the committees of jurisdiction.

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