

## Client Alert

### Health Care Update: What is Happening with 21st Century Cures, the Trump Team & ACA Repeal/Replace?

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While most of the country is turning its attention from the recent election and preparing for the upcoming holidays, Congress is still poised to pass significant legislation before the end of the year and – as part of their closing deliberations – may take a fourth quarter shot at a long-awaited health care bill. Meanwhile, the Trump team is trying to figure out how to best repeal and replace the Affordable Care Act and what to do with the 20 million people who have recently obtained coverage through the law. The health care world is changing on a daily basis and we are following it every step of the way to keep you updated. Here is the latest:

#### 21st Century Cures: Fred Upton's Last Stand

Congress is preparing to pass a 21st Century Cures bill that will affect policies of the FDA, NIH, and the Office of the National Coordinator for Health IT (ONC), to the great pleasure of the outgoing House Energy and Commerce (E&C) Committee Chairman Fred Upton (R-MI). House and Senate negotiators made significant progress prior to leaving town last week for the Thanksgiving recess and finally appear ready to pass the legislation in the next couple of weeks. Chairman Upton and Rep. Diana DeGette (D-CO) led bipartisan discussions of the 21st Century Cures bill at the beginning of the 114th Congress, and the full House approved it overwhelmingly in July 2015. The Senate followed with the "Innovations Act," consisting of 19 different bills, which each passed out of the Health, Education, Labor, and Pensions Committee (HELP) earlier this year. Now, both Senate Majority Leader McConnell (R-KY) and House Speaker Paul Ryan (R-WI) have made its passage a priority in the Lame Duck session, and it just might get done in the waning days of the 114th Congress.

But what will a reconciled bill include? We believe that a final reconciled bill will make changes in research, funding, and approvals of drugs and devices. Specifically it is expected to provide: (1) up to \$5 billion in new funding for NIH, (2) money for drug researchers, (3) authority for faster FDA approval of new drugs and medical devices, (4) a new FDA antibiotics program, and (5) at least \$1 billion for new opioid abuse prevention and treatment programs consistent with the recently passed Comprehensive Addiction and Recovery Act ("CARA"). The bill will likewise promote more competition in the brand, generic, and specialty drug marketplace, in addition to focusing on health information technology ("health IT"). It attempts to promote interoperability of electronic health records, including changes in process for standards development and product certification, and will prohibit practices that interfere with the sharing of health information for patient care, so-called "information blocking." Finally, in a nod to the outgoing Obama Administration, the final legislation will likely include pieces of the Precision Medicine Initiative and a significant portion of the White House's Cancer Moonshot that has been spearheaded by Vice President Joe Biden.

Keep your eye out for the 21st Century Cures Bill to become law before the holidays. If it does, it will be a noteworthy bipartisan accomplishment that could restore some faith in the ability of Congress to do health care legislation before the ACA fight of 2017. It will also lead to a flurry of activity at HHS, as they work to implement these sweeping legislative changes. It will be important to see who is appointed to lead HHS under the new administration and these key agencies.

### **ACA Repeal and Replace**

The repeal – or at least substantial modification – of the Affordable Care Act (ACA) is now a virtual certainty. Congressional Republicans have promised to scrap the law since its passage in 2010 and attempted to make good on that promise in January 2016, passing a repeal measure that President Obama promptly vetoed. Now, they appear to have a partner in President-elect Trump and are expected to move quickly to finally repeal the law in early 2017. Trump has named multiple former Bush Administration officials to lead its health reform efforts, reassuring some observers that the transition team roster includes professionals who understand health policy and government process. The devil is in the details, however, and actually repealing and replacing will require significant negotiation to avoid a Democratic filibuster.

The Trump Administration is likely to announce an ACA Repeal bill with provisions that they expect House and Senate Parliamentarians to allow into a budget reconciliation bill within a week or two of taking office. Another option would be to announce an ACA Repeal and Replace bill modeled after Speaker Ryan's "Better Way" and decide to argue provision by provision with the Parliamentarians to get as much as possible into the budget reconciliation bill. Because a reconciliation bill requires only a simple majority to pass each chamber – a particularly important point in the Senate where it could avoid the promised Democratic filibuster – it is likely the Republicans' only option to pass the long-promised repeal, though the replacement portion would need to be done through the regular process and would only pass with the support of at least eight Democrats, assuming that all fifty-two Senate Republicans support it.

The Congressional Budget Act of 1974 created the modern process known as "reconciliation." Under this process, Congress passes a "Budget Resolution" each spring which directs Congressional committees as to how to prepare a federal budget and "reconciliation" provisions direct Congress to pass certain laws pertaining to spending, expenses or revenues. A "budget reconciliation bill" is exempt from the sixty vote Senate filibuster rule, meaning that it can pass the Senate with a simple fifty-one vote majority. Another key component to a "budget reconciliation bill" is that the scope of amendments is limited, thus making it harder for opponents to attempt last-minute changes on the Senate floor. The Senate Republican majority, therefore, can draft the budget reconciliation bill in committee, get Parliamentary clearance, and send it to the floor for fifty-one votes to pass with limited amendments and no ability for the Democrats to filibuster. President Reagan famously persuaded Congress to use reconciliation to pass major spending cuts during his presidency, welfare reform was passed using it in 1996, and it was ironically used by Democrats to pass significant portions of the ACA in 2010. While the rules typically prevent passing a provision in a budget reconciliation bill that will cost money, the majority party can override it as we would expect them to do with ACA repeal provisions.

The ACA repeal provisions likely to survive the Parliamentarians and end up in a Reconciliation bill include repeal of the three big ACA taxes – the Medical Device Tax, the Health Insurance Provider Fee, and the Cadillac tax. However, as long as the more substantive provisions of the law remain in place, repealing the taxes could bankrupt the ACA before the market is ready to offer alternatives or Americans with ACA plans can get tax credits for replacement plan premiums, likely creating the market chaos that Republicans have pledged to avoid.

Therefore, it is much more likely that “Repeal and Replace” will be a multi-year process during which the three main ACA taxes would be phased out and gradually replaced with an alternative approach that is expected to be built around the framework already proposed by House Republicans. That “replacement” would likely include providing Americans with more incentives to utilize health savings accounts (HSAs), refundable tax credits to pay premiums for new plans, permitting the purchase of insurance across state lines, the re-establishment of high-risk pools, FDA reforms similar to those included in 21st Century Cures, and possibly new provisions to modernize Medicare. A new ACA might also jeopardize Medicaid expansion, in favor of state innovation grants that reward state-led efforts to reduce premiums and the rate of uninsured. The Republican plan will be rooted in the belief that the marketplace will adapt and create new plan models to accommodate the approximately 20 million individuals currently covered by ACA plans.

The highlights of the January 2016 repeal measure provide a glimpse into where the 2017 repeal discussions will likely begin:

- Individual and employer mandates eliminated by removing financial penalties for failure to obtain or offer coverage.
- No further Medicaid expansion and gradual reversal of previously-approved expansion.
- Federal exchange would be shuttered.
- Elimination of reinsurance, risk adjustment, and risk corridor programs.
- Repeal of Medical Device and so-called Cadillac taxes.

Accomplishing this, however, is not without political risk; many toss-up states that supported Republicans also expanded Medicaid, for example, and may push for more moderate reforms. At the same time, some Republicans may be reticent to pass a partisan bill that causes some individuals to lose insurance coverage gained under the ACA without a viable alternative in place.

While Congress develops and enacts amendments or alternatives to the ACA, the President-elect may use executive discretion through his appointees to modify ACA regulations or simply choose not to enforce certain provisions—such as the individual and employer mandates and other tax penalties. And the new Administration may put the brakes on any reinsurance payments to health plans until the Treasury Department has been paid. Health plans participating in the 2017 marketplaces may be in for a bumpy ride.

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