



The Trump Administration's First 100 Days: Impact on the Health Care Industry – a Work in Progress

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The first 100 days of a new presidential administration serves as a traditional, if somewhat arbitrary, demarcation point. April 29, 2017, serves as the 100th day of the Trump administration, and we now have insight into how the administration may impact the health care industry. For example, over the past 100 days we have seen:

- Efforts to repeal and replace the ACA
- Attempts to reduce regulatory burden on industry
- The appointment of HHS Secretary Price
- Potential changes to the Medicaid program
- Administrative actions related to Health Benefits Exchanges
- Impact on Food and Drug law
- Direction of resources to Fraud and Abuse enforcement

The legislative and regulatory impact on the health care industry remains dynamic, with the potential for change bringing both challenges and opportunities.

Repeal and Replace? The Fate of the American Health Care Act Remains Unsettled

During his presidential campaign, President Trump promised to “repeal and replace” the Affordable Care Act (“ACA”). This promise has manifested in the president’s ongoing support for the American Health Care Act (“AHCA”), the House Republicans’ bill to repeal and replace the ACA. If enacted in its current form, the AHCA would make substantial changes to the Medicaid program, replace the ACA health insurance

subsidies and cost-sharing reductions with less generous tax credits, remove the individual and employer health insurance mandates, and repeal a significant number of the taxes included in the ACA. The Congressional Budget Office estimated that the AHCA would result in a reduction in federal health care spending of approximately \$1.2 trillion over 10 years and leave 24 million more people uninsured by 2026.

Thus far, the AHCA has failed to pass in the House of Representatives due to, among other reasons, disagreements within the GOP caucus. However, just this week, the White House, Freedom Caucus Chairman Representative Mark Meadows, and Tuesday Group leader Representative Tom MacArthur began rolling out an amendment that is being described as a “compromise” that may breathe new life into the AHCA. The proposed amendment would give the Department of Health and Human Services (“HHS”) the ability to grant states waivers for many ACA insurance rules, including the community rating provision, which would allow health insurers to differentiate premiums based on enrollees’ medical conditions. It remains an open question whether an amended AHCA will garner enough votes to pass the House, and even if it does, the bill’s fate in the Senate is murky at best. Nevertheless, Speaker Ryan has expressed his commitment to trying to pass the amended AHCA through the House of Representatives.

It is clear that both the White House and Congress will continue to attempt to repeal and replace the ACA. Beyond fulfilling the Republican Party’s political promise, modifying the ACA is seen as a way to generate federal spending cuts that will offset expected losses of federal revenues in a tax reform plan. Given the scope of the reduction of federal health care spending represented by the AHCA, the impact on the health care industry will be significant. Therefore, it is imperative that stakeholders follow and understand the bill going forward.

Administration Takes Steps Likely to Reduce the Regulatory Burden in the Health Care Industry

Through Executive Orders and proposed budget cuts, the Trump administration has sent a clear signal to industry that it intends to reduce regulatory “red tape.” Specifically related to the health care industry, one of President Trump’s first acts was to issue an Executive Order directing all federal agencies with responsibility for administering the ACA to “exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden . . .” This was the first of two Executive Orders designed to curb both the volume and scope of administrative rulemaking related to health care.

The second Executive Order, commonly referred to as the “2 for 1” order, requires that a federal agency identify two regulations for elimination when issuing a new regulation. The order also requires the cost of the new regulation to be offset by the cost of eliminating the two existing regulations. This order will likely not only limit new regulations, it may also place a target on the back of existing regulations for elimination as the Trump administration seeks to implement its own agenda through regulatory action.

In addition to restricting HHS's ability to promulgate new rules, HHS may also face a reduction of resources under the Trump administration. The president's 2018 budget proposal requests \$69.0 billion for HHS, a \$15.1 billion (or 17.9 percent) decrease from the expected 2017 level of funding. The largest proposed cuts are to (i) the National Institutes of Health, which will result in a reduction of \$5.8 billion, and (ii) the Office of Community Service, which will see a \$4.2 billion reduction associated with the elimination of the Low Income Home Energy Assistance Program and the Community Services Block Grant. Although the president's budget is merely a proposal (largely seen as a political rather than policy document), it provides insight into the administration's priorities and has set the stage for ongoing budget negotiations.

Appointment of Secretary Price

Secretary Tom Price, a physician and former congressman from Georgia, was confirmed as the 23rd Secretary of HHS on February 10, 2017. A vocal opponent of the ACA, Secretary Price was an understandable choice given President Trump's repeated promises to repeal the ACA. Over his decade-long career in Congress, Secretary Price garnered a reputation as one of the Republican Party's leading voices on health care. He served on the Ways and Means' Subcommittee on Health, chaired the House Budget Committee, and was also the primary author of [HR 3762](#), a bill repealing the ACA that passed through both the House and Senate before being vetoed by then-President Obama.

The first few months of Secretary Price's tenure have been eventful and at times complicated. Secretary Price has spent time administering the ACA, publically lobbying for passage of the AHCA, and weathering scrutiny over investments he made while in Congress. At the same time, Secretary Price has periodically found his department's messaging at odds with the president's public declarations. In January, for example, as President Trump continued to promise his replacement for the ACA would provide "insurance for everybody," Secretary Price publically clarified that the primary goal of the administration was to ensure universal "access" to coverage. While in that instance Secretary Price appears to have had some influence over the rhetoric coming out of the White House (for example, the president referred to "access to coverage" in his joint address to Congress in February), in other cases, it has been unclear whether HHS and the White House are on the same page. The most significant example of this apparent disconnect occurred in mid-April after [HHS suggested in a statement to *The New York Times*](#) that the administration was likely to continue the ACA's cost-sharing reductions or subsidies—only to strongly contradict the report the next day. This rapid change in messaging reportedly occurred after President Trump called Secretary Price to personally dictate that HHS release a statement stating that no decision had been made on the administration's next steps regarding the cost-sharing reductions. Reports at the time indicate that President Trump was considering using the cost-sharing reductions as a bargaining chip to force Congressional Democrats to cooperate with implementing the president's policy priorities. While the administration's contradictory messaging appeared at the time to evince chaos and draw into question Secretary Price's influence over the administration's strategy on health care, reports this week indicate that the administration plans to continue funding the cost-sharing reductions in the short term. Thus, Secretary Price's position appears to have prevailed.

Understanding Secretary Price’s ideological views on health care is much less difficult than speculating about his influence within the administration. He has consistently been a conservative on health care issues, generally favoring reducing health care regulations and government involvement in health care, supporting tort reform, expansion of health savings accounts, and federal funding of high-risk pools. Thus, it is fair to predict that Secretary Price will use his rulemaking power to loosen Obama-era regulations.

Potential Changes to Medicaid

The most visible manifestation of President Trump’s efforts to change the Medicaid program came in the form of his support for the House Republicans’ bill to repeal and replace the ACA.

The AHCA addresses Medicaid in two key ways. First, the AHCA would bring an end to the expansion of Medicaid for non-disabled adults with incomes up to 133 percent of the Federal Poverty Line. The AHCA, including the so-called “Manager’s Amendment,” would immediately close off the opportunity for the 19 states that have not yet taken up expansion. It would, however, restore the Disproportionate Share Hospital payments to those states, to help hospitals cover costs of uncompensated care. In addition, the bill would phase out the enhanced federal matching percentage for expansion enrollees. The enhanced rate would be available only for people continuously enrolled in Medicaid after the bill’s enactment.

Second, the AHCA would change one of the core tenets of Medicaid financing. The bill proposes to change Medicaid from a pay-as-you-go entitlement—whereby states receive a federal match for whatever they spend—to a fixed annual per capita allotment. Starting in 2019, growth in federal Medicaid payments to states would be fixed at the 2016 level, indexed at the medical component of the Consumer Price Index plus 1 percentage point. This rate is believed to be lower than the actual trend in Medicaid per capita costs and would lead to an ever-shrinking federal share of Medicaid spending unless states act to cut costs. To assist with cost cutting, the bill would relieve states of some of the mandates pertaining to eligibility, benefits, and other features.

The Trump administration has signaled to states that it intends to use its regulatory powers to alter the character of Medicaid, both by rolling back some rules and by granting new kinds of waivers. As described in a “Dear Governor” letter, HHS Secretary Tom Price and CMS Administrator Seema Verma indicate their endorsement of states wanting to inject personal responsibility features into Medicaid—work requirements and cost sharing, principally. CMS also indicates that it will reduce the hurdles to states seeking state plan amendments and waivers, provided they do not add to federal Medicaid costs.

Impact of Administrative Actions on the Health Benefits Exchanges

Since taking office, the administration has taken steps it says are designed to “stabilize” the markets. However, many see these steps as weakening rather than strengthening the markets, and some of the steps seem to have been needed to counteract uncertainties created by the administration itself.

Perhaps the greatest source of market uncertainty has come from the administration's ongoing refusal to take an explicit position on whether it will continue to fund the cost-sharing reduction subsidies provided for under the ACA. The House of Representatives went to court to challenge the Obama administration's payment of the cost-sharing reductions, arguing that funding for these payments had not been legally appropriated. Prior to the election, a federal district court ruled in favor of the House on the appropriations question and the Obama administration appealed. While the new administration could have withdrawn this appeal and allowed the negative ruling to stand, likely leading to a full collapse of the exchange markets, it took a different tack, allowing payment of the subsidies to continue. The House and the Trump administration together asked the appeals court for a delay "to allow time for a resolution that would obviate the need for judicial determination of this appeal, including potential legislative action." Recently, during an interview, the administration committed to funding the cost-sharing reductions, but later clarified that this would apply solely while the related lawsuit is pending. The president then threatened to withhold these payments in order to incentivize Democrats to negotiate on changes to the health law. However, recent reports indicate that as part of ongoing negotiations to fund the federal government and avoid a government shutdown, the administration has told Democrats that it will continue to fund the cost-sharing reductions but has not committed to funding on a long-term basis.

The administration has taken other actions that have had the effect of subtly undermining the exchange markets. This includes the administration's extension of the availability of Transitional Policies, also known as "Grandmothered Policies," through the end of 2018. Ultimately, these policies have enabled many to remain in health coverage that does not comply with the ACA's requirements, keeping enrollees from inclusion in the ACA issuers' risk pools. Secretary Price also issued a notice encouraging the states to apply for waivers under Section 1332 of the ACA to reinforce or reform their insurance markets, creating further uncertainty for health plans considering whether or not to participate in the exchanges in 2018.

CMS recently released the final version of a Market Stabilization rule, published in a proposed version back in February. The rule makes several changes sought by issuers but leaves the subsidy question unaddressed. Specific changes effectuated under the rule include shortening the open enrollment period, tightening verification requirements for Special Enrollment Periods, and allowing issuers to require enrollees to pay premium debt owed to that issuer or a member of that issuer's group before applying payments toward current year coverage. The rule further increases the amount considered to be a "de minimis" variation in determining the actuarial value of the coverage under the ACA. This change will enable issuers to charge higher cost-sharing, which CMS believes could help issuers keep their plan cost-sharing the same from year to year and put downward pressure on premiums. In addition to promulgating the Market Stabilization Rule, CMS also extended the timeline for plans to apply to participate in the exchanges by approximately six weeks, allowing issuers additional time to assess the market prior to committing.

The actions taken by CMS under the Trump administration have sought to lessen the burden on plan issuers in an attempt to ensure their continued participation in the exchanges. However, the primary issue affecting the stability of the market

involves the adequacy of payments to issuers, particularly for the cost-sharing reductions. That is an issue that must be addressed in the very near future to forego any additional instability in the affected markets.

Impact on Food and Drug Law

A significant focus of President Trump's administration during the first 100 days has been on cutting Food and Drug Administration ("FDA") regulations, limiting tax dollars allotted to the agency, and seeking confirmation of a new FDA commissioner. Though President Trump held meetings with drug manufacturers and commented on the increasing cost of drugs, he did not propose legislation aimed at reducing drug prices.

The most impactful action President Trump has taken to shape the FDA has been to seek confirmation of his nominee Scott Gottlieb, M.D., for FDA commissioner. Dr. Gottlieb, who currently awaits a full vote by the Senate for confirmation, is a former deputy commissioner of the FDA who also previously worked as a pharmaceutical consultant in the private sector. His confirmation passed the Senate Health, Education, Labor and Pensions Committee on Thursday, April 27, 2017, and is seen as a moderate-by-comparison choice, not likely to face a Democratic filibuster. As discussed in our [client alert](#) earlier this month, Dr. Gottlieb is likely to support the policy visions contained within the 21st Century Cures Act ("Cures Act"), which passed with sweeping bi-partisan support in December 2016. Dr. Gottlieb seems to especially support provisions within the Cures Act regarding the promotion of alternative data sources, trial designs, and pathways to market that are meant to expedite the drug approval process.

While Dr. Gottlieb is anticipated to be confirmed without great difficulty, President Trump's proposed budget cuts and current regulatory restrictions may present substantial hurdles for Dr. Gottlieb to implement the Cures Act and improve FDA's drug approval process. President Trump's proposed budget also calls for significant increases to FDA user fees, which are a vital and significant source of funding for the agency; however, proposed congressional budgets only provide for moderate increases to these fees. If FDA's funding is cut and the shortfall is not met by increased user fees, many initiatives, like those established by the Cures Act, could face significant delay until funding is restored.

Fraud and Abuse Enforcement

The federal government's enthusiasm for efforts to curb fraud, waste, and abuse will not wane under the Trump Administration. Despite proposing a significant reduction in HHS overall funding level, the president's 2018 budget proposal provided for a \$70 million increase in funding for the Health Care Fraud and Abuse Control program. The budget proposal noted that from 2014 to 2016, the program had a return on investment of five dollars for every dollar spent. As a result of the high return on investment in government fraud investigations, the Trump administration is unlikely to reduce efforts to enforce fraud and abuse laws any time soon.

Separately, Attorney General Sessions has signaled that the Department of Justice will likely continue to support the private use of the False Claims Act

(“FCA”) through qui tam lawsuits. During his confirmation hearings, Sessions stated:

I think [qui tam actions] are valid and an effective method of rooting out fraud and abuse. I even filed one myself one time as a private lawyer. . . . It has saved this country lots of money and probably has caused companies to be more cautious because they can have a whistleblower that would blow the whistle on them if they try to do something that’s improper. So, I think it’s been a very healthy thing. .

. .

Similarly, Deputy Assistant Attorney General Terry McFadden has suggested that the Trump administration will continue to focus on individual accountability, as reflected in the “[Yates Memo](#).” In recent remarks related to enforcement of the Foreign Corrupt Practices Act, Deputy McFadden stated:

... [T]he department continues to prioritize prosecutions of individuals who have willfully and corruptly violated the FCPA – Attorney General Sessions has noted the importance of individual accountability for corporate misconduct. Finally, and just as successive Deputy Attorneys General under both Republican and Democratic administrations have directed, the department regularly takes into consideration voluntary self-disclosures, cooperation and remedial efforts when making charging decisions involving business organizations.

The Next 100 Days

While the first 100 days of the Trump administration have already impacted the health care industry, more changes are on the horizon. Repeal and replacement of the ACA remains a live issue, with Congress beginning to consider the amended AHCA this week. The administration has yet to address its long-term plans for the ACA’s cost-sharing reductions, and at some point in 2017, Congress will need to reauthorize funding for the Children’s Health Insurance Program—otherwise, states will begin running out of funds in December. The regulatory space remains equally dynamic, as President Trump’s “2 for 1” Executive Order continues to require that new regulations be accompanied by the repeal of two older regulations. Driven by the need to implement the administration’s policy goals, this may place regulations—including those governing health care providers, insurance companies, pharmaceutical companies, and medical device manufacturers—on the proverbial chopping block.

Stakeholders in the health care industry should continually assess how potential changes could impact their current and future operations. Doing so will place stakeholders in the best position to address challenges, mitigate risk, and take advantage of opportunities that a changing health regulatory environment may provide.

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