

Client Update

Still in the Waiting Room: Outlook for the Healthcare Industry Under the Trump Administration

NEW YORK

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The 2016 election is likely to have important consequences for the healthcare industry – but the absence of any detailed policy proposals by President-elect Trump, together with the uncertainties of the political process generally, makes it difficult to discern exactly how things will play out in Washington. That said, we won't let the uncertainty deter us from trying to read the tea leaves.

Here's what we know. Mr. Trump talked a lot during the campaign about repealing the Affordable Care Act (ACA) and about deregulation generally. The Trump campaign also issued a short seven-point policy statement regarding healthcare reform, and the Trump transition team released an even briefer 310-word outline after the election. Mr. Trump will have Republican majorities in both the House and the Senate, but the slim Senate majority is not filibuster-proof. Moreover, not all Congressional Republicans share Mr. Trump's perspective on all healthcare issues. And Mr. Trump himself is still refining his views. For example, after a recent meeting with President Obama, Mr. Trump expressed support for retaining certain aspects of the ACA. Finally, Mr. Trump will appoint at least one Supreme Court justice and will fill a number of seats on lower federal courts.

We also know that changes are not likely to be experienced immediately, or all at once. Changes to treaties, statutes and regulations all require time – and often compromise – to take final effect. Changes effected through judicial decisions, particularly at the Supreme Court level, often take even longer to be felt. In addition, the new enforcement and regulatory priorities of various agencies depend not just on filling the top positions in those agencies, but the second and third levels of command as well.

Different sectors within the industry will be impacted in different ways, as the stock markets have already recognized. In the immediate aftermath of the

election, pharmaceutical stock prices rose, largely in line with the S&P 500, presumably on the view that Mr. Trump would exercise a more free-market, less regulation-heavy philosophy that would benefit pharma companies. On the other hand, the stocks of hospitals and other providers fell significantly, likely reflecting investor concerns that a repeal of the ACA could leave millions of Americans uninsured, which would impact hospitals particularly hard since in many cases they treat patients regardless of their ability to pay.

What is certain is that the healthcare industry will continue to evolve in the new political environment, likely in ways that present opportunities and risks for operators and investors in this space.

AFFORDABLE CARE ACT

Significant change to the ACA is inevitable, but the precise shape of that change is less clear than one might think based on Mr. Trump's campaign rhetoric around repeal. Indeed, since the election, Mr. Trump has already proposed retaining both the law's guarantee that consumers cannot be refused coverage due to preexisting conditions and the provision permitting adult children to be covered under their parents' policies through age 26.

Congress' 2015 Repeal of the ACA May Offer a Guide

The bill repealing the ACA that Congress passed (and President Obama vetoed) in 2015 may offer some clues as to what a "repeal" of the ACA might look like this time around. The 2015 measure would have eliminated:

- the individual mandate, which was a penalty assessed on certain people who did not purchase health insurance;
- subsidies available to low- and middle-income consumers to purchase health insurance;
- the "Cadillac tax" on high-cost health insurance plans;
- the excise tax on medical devices; and
- taxes on high earners, which were designed in part to fund the program.

The 2015 measure did not seek to repeal the ACA's prohibition against insurers discriminating on the basis of preexisting conditions, and it retained the strict limits on insurers' ability to charge higher premiums based on health status. Both of these provisions are highly popular and are likely to receive continued bipartisan support. In addition, while the 2015 measure (which covered subsidies and taxes) was passed through the filibuster-proof budget reconciliation process,

many provisions relating to insurance reform likely cannot be altered through the budget reconciliation process because they do not impact federal spending.

The Future of Medicaid Expansion Is in Doubt

Another big question surrounding the ACA is the future of the provisions that expanded Medicaid to include all adults who earn less than 138% of the federal poverty level. The Supreme Court ruled that, while the ACA made the expansion a condition of participating in the Medicaid program, states could opt out without losing their Medicaid funds. Republican-led states split in their response: some, like Ohio and Indiana, accepted the federal aid to expand Medicaid in their state, while others, like Texas and Florida, refused.

It is also possible that Medicaid may be redesigned. Some Republicans (including Mr. Trump) have proposed curbing the expansion of Medicaid costs at the federal level through the use of Medicaid block grants, whereby the federal government would provide each state with a block grant of federal funds (*i.e.*, an annual fixed sum) to finance that state's Medicaid program. If the state's costs exceeded the block grant, the state would be responsible for financing those costs or would need to cut coverage. Currently, the federal government has an open-ended commitment to help states cover their Medicaid costs but, in exchange, requires those states to cover certain groups of people. Other Republicans have alternatively proposed allowing each state to choose between block grants and a per capita allotment, whereby states would be given a set amount of money per enrollee (which would increase each year).

An important real-world reminder is that when Congress "repealed" the ACA last year, members could vote for the repeal knowing that it was certain to be vetoed. It is unclear whether there is enough support and fortitude to pass the same repeal (or move to a system of block grants or per capital allotments), knowing it will have actual consequences, including for many of Mr. Trump's supporters. Several Republican senators from states with large populations of Medicaid beneficiaries were opposed to the repeal of the Medicaid expansion. With a narrow Republican majority, it is therefore uncertain if there are enough votes to roll back the expansion or alter Medicaid funding.

Trump Has Identified a Few Key Features of an ACA Replacement

Mr. Trump's post-election 310-word outline on healthcare identified a few priorities that his administration might include in an ACA replacement, including:

- making premiums tax-deductible;

- expanding the availability of Health Savings Accounts, which allow people to set aside pre-tax dollars for health expenses; and
- permitting the purchase of insurance plans across state lines.

It is unclear how the last proposal would work in practice as most managed care plans feature local networks of providers, so an insured in one state might need to go to out-of-network providers, or travel to in-network providers, for all of her health care if the plan were based in another state. Mr. Trump has also proposed working with high-risk pools to cover individuals with pre-existing conditions who have not maintained continuous coverage previously. However, if all of the ACA's insurance market reforms remain intact, it is not clear whether and for what group high-risk pools would be needed.

What is the Bottom Line?

Any changes to the ACA will have significant and varied implications for different sectors within the healthcare industry:

- For medical device manufacturers, a repeal of the excise tax would be an outright win.
- The balance of bargaining power between insurers and providers may change if the ACA is dramatically altered, although we do not know yet which side will benefit from that development.
- Tax deductions for premiums and increased usage of Health Spending Accounts may increase consumption of healthcare products and services by middle- and upper-income consumers, which would benefit hospitals and other providers.
- Non-partisan experts estimate that an ACA repeal similar to the 2015 bill passed by Congress would lead to more lower-income people being uninsured, particularly if the Medicaid expansion is rolled back. Hospitals, which have benefitted from reduced levels of bad debt and charity care write-offs as the ACA has reduced the uninsured population, may see those gains eliminated in whole or in part.
- The pharmaceutical industry may similarly lose out on drug purchases by people that formerly received free or subsidized insurance but can no longer afford it.

PRESCRIPTION DRUG PRICING

Conventional wisdom is that Mr. Trump's election and the continued Republican majorities in Congress will benefit the pharmaceutical industry

relative to the alternative because Hillary Clinton and Congressional Democrats had actively called for controlling prescription drug prices. In addition, the pharmaceutical industry scored a major victory in defeating Proposition 61, a California ballot initiative that would have prohibited California state agencies from buying prescription drugs at prices higher than those paid by the U.S. Department of Veterans Affairs.

While Mr. Trump is regarded as business-friendly and did not make prescription drug pricing a major issue in his platform, he has expressed support for introducing more competition into the healthcare marketplace. And a couple of his campaign proposals, if implemented, could have the effect of depressing prescription drug prices:

- *Permitting the Centers for Medicare & Medicaid Services (CMS) to negotiate drug prices* – Currently, CMS is prohibited from negotiating prescription drug prices. Earlier in his campaign, Mr. Trump took the position (one shared by many Democrats) that this prohibition should be lifted so that CMS could use its enormous purchasing power to negotiate significant discounts to the prices of drugs covered by Medicare Part D. However, repeal of this prohibition seems unlikely as the prohibition has strong support among Congressional Republicans and Mr. Trump stopped raising this issue as a major campaign point over the summer.
- *Allowing the importation of cheaper foreign drugs* – Mr. Trump and certain members of Congress have supported lifting the ban on American consumers purchasing prescription drugs overseas (where drugs are in some cases cheaper, due to price controls or otherwise) and importing them into the U.S. However, there is strong Congressional opposition to lifting this ban, in part due to safety and quality issues if unregulated drug importation were legalized. In any event, Mr. Trump's recent 310-word healthcare plan does not include this policy point, so it is not clear whether Mr. Trump continues to view this as a priority.

Even if the Trump administration does not pursue these proposals, the pharmaceutical industry may remain subject to intense public scrutiny and a relatively hostile political environment. Recent high-profile price increases by drug manufacturers have subjected them to a torrent of media and Congressional criticism that shows few signs of abating. A Senate hearing on Mylan's EpiPen, the subject of the most recent drug pricing controversy, is scheduled for November 30, and there have been calls by Congressional Republicans and Democrats to require greater disclosure of prescription drug price increases.

PRICING OF MEDICAL SERVICES

As part of the Trump campaign's stated aim of creating consumer-focused healthcare, Mr. Trump has argued that hospitals and other healthcare providers should promote greater pricing transparency, allowing individuals to shop to find the best prices for medical examinations and procedures. However, aside from elective cosmetic procedures, most medical procedures are not priced like simple commodities. Instead, hospitals determine rates through negotiation with insurers – the results of which are kept confidential – and typically offer discounts to uninsured patients. At a minimum, we would expect that hospital pricing may be subject to significant political scrutiny.

In addition, it is likely that medical providers will continue to experience a shift from volume-based to value-based payment models, particularly as this shift has received bipartisan support in Congress.

TAX REFORM

The current U.S. tax regime of high corporate tax rates and penalties for repatriating foreign earnings incentivizes U.S. healthcare companies with foreign operations to divert profits offshore and keep them permanently reinvested there. Some have taken a step further and have become subsidiaries of foreign merger partners (through “inversion” transactions). For many U.S. healthcare companies, these tax-driven arrangements are a matter of necessity in an internationally competitive environment. Leaders in Congress concerned about these developments are eager for significant tax reform, and some believe that the outcome of the election creates an opportunity, which has not been present in the recent past, for major tax legislation.

Although details of any legislation are speculative at this time, the broad themes are likely to be removing the disincentive to invest domestically and encouraging the repatriation of offshore earnings.

In June 2016, House Republicans prepared a tax policy paper (known as the “Blueprint”), which many believe will be the starting point for legislation. The most important provisions of the Blueprint are:

- The corporate tax rate would be a flat 20%.
- Businesses could immediately expense 100% of the costs of business investment (including in plants and equipment, but excluding investments in land).

- Accumulated offshore earnings (whether or not they are ultimately repatriated) that are held in cash or cash equivalents would be subject to an immediate 8.75% tax, and accumulated offshore earnings held in other forms would be taxed at a 3.25% rate (which could be paid over an 8-year term).
- Prospectively, foreign earnings and distributions from foreign subsidiaries would be exempt from U.S. tax, thereby eliminating the penalty for repatriating earnings (*i.e.*, removing the “lockout effect”).
- Interest expense in excess of interest income would be non-deductible.

With the exception of the last proposal concerning the disallowance of interest expense, these provisions, if enacted, could be expected to remove a disincentive to invest in the U.S. and to stimulate the repatriation of foreign earnings, which could be used to spur investment and acquisition activity or be distributed to shareholders.

REDUCTION IN FEDERAL REGULATION

In keeping with his business-friendly message, Mr. Trump has voiced his general commitment to regulatory reform, including implementing measures to reduce the size of the federal government and decrease the costs of regulatory compliance for U.S. businesses and shifting regulatory responsibilities – especially with regard to health insurance – from the federal government to the states.

The First 100 Days Action Plan that the Trump campaign released in late October includes proposals to, among other things, place a hiring freeze on federal employees and require that, for every new federal regulation, two existing regulations be eliminated. In addition, both the First 100 Days Action Plan and the 310-word health plan released after the election highlight the need to “reform” the Food and Drug Administration (FDA). Both plans emphasize the need to “cut red tape” and approve “new and innovative medical products.” Although details of the proposed reform have not been made available, it could include accelerating the process to approve new drugs, approving new uses for already-approved drugs and lowering the bar to approving generic drugs. While FDA reform could potentially make the approval process more rapid and less burdensome for pharmaceutical and biotech companies, it could also result in introducing heightened competition into the marketplace.

FREE TRADE AGREEMENTS

Opposition to free trade agreements has been a pillar of Mr. Trump's platform. The pharmaceutical industry, which operates globally and relies on manufacturing conducted outside of the U.S., is generally in favor of free trade.

Mr. Trump voiced his strenuous opposition to the Trans-Pacific Partnership (TPP) throughout the campaign, and the TPP has effectively died since the election, with the Obama administration acknowledging last week that there is no path forward for the twelve-nation pact. The collapse of the treaty may have mixed consequences for different subsectors within the pharmaceutical industry. For example, manufacturers of branded pharmaceutical products generally supported provisions of the TPP that would have expanded patent protections and market exclusivity for new pharmaceutical products and provided a harmonized and more predictable framework for addressing third party challenges to intellectual property underlying their pharmaceutical products (modeled on the Hatch-Waxman Act). However, some industry players were also concurrently lobbying against other provisions of the TPP that would have shortened the period for data exclusivity protection for biologics to less than the period granted under U.S. law, while other players (such as generics companies) and patient advocacy groups were lobbying in favor of shortening those exclusivity periods.

Whether Mr. Trump would actually seek to renegotiate or withdraw from the North American Free Trade Agreement (NAFTA) remains to be seen. Doing so could jeopardize pharmaceutical companies' cross-border operations in Mexico and Canada and roll back the intellectual property protections under the treaty. However, Congressional approval may well be required to abrogate a treaty entered into by the U.S., potentially presenting a real obstacle to the success of such a proposal. In any event, Mr. Trump's positions on free trade agreements may make it more difficult for the pharmaceutical industry to use free trade agreements to gain access to new markets in the future.

ANTITRUST MERGER REVIEW

Many sectors within the healthcare industry have experienced waves of consolidation. These mergers have come under increased regulatory scrutiny. Notably, this summer, the U.S. Department of Justice sued to block two major mergers in the health insurance sector: Anthem Inc.'s proposed \$54bn acquisition of Cigna Corp. and Aetna Inc.'s \$37bn acquisition of Humana Inc.

While the traditional assumption is that merger review by antitrust authorities is more lax during Republican administrations than during Democratic

administrations, Mr. Trump has made a number of statements that could put that assumption in doubt. He has, for example, been vocal in advocating for increased competition in the marketplace with respect to drug pricing, healthcare services and insurance offerings. During the campaign, he also praised the enforcement of antitrust laws to prevent the formation of large corporate conglomerations. Most recently, he criticized AT&T's planned takeover of Time Warner and said he would seek to block the merger.

While it is too early to tell what the antitrust enforcement priorities will be under a Trump administration, many observers believe that a more merger-friendly climate is ahead. The CEO of Aetna stated last week that Aetna's stock rose significantly after the election because investors believed the Department of Justice under the Trump administration will be more likely to approve the Aetna-Humana merger. However, the prospect of the change in administration is unlikely to have an immediate or direct effect on the Department of Justice's conduct of the pending lawsuits against the health insurance mergers to the extent those lawsuits proceed to trial before the inauguration.

ENFORCEMENT PRIORITIES

The healthcare industry is affected not just by what laws and regulations are on the books, but also how they are enforced. Mr. Trump has yet to name his Attorney General so it is difficult to identify the enforcement priorities of the Trump administration when it comes to healthcare. The Obama Justice Department made healthcare fraud a high priority and was also, in the aftermath of the 2008 market collapse, focused on individual criminal culpability in healthcare as well as other industries. Mr. Trump's voters may favor an ongoing focus on individual criminal prosecutions as part of their disaffection with corporate elites; on the other hand, Republican administrations tend not to pursue such cases with as much vigor.

The Obama administration also brought a significant number of high-profile bribery cases against the healthcare industry under the Foreign Corrupt Practices Act (FCPA), racking up enormous penalties. Mr. Trump has called the FCPA a "horrible law" so it seems that he may not favor as aggressive an approach to FCPA enforcement. A reduced risk of investigation and enforcement in the FCPA area might well benefit healthcare companies operating globally.

The False Claims Act (FCA) is another statute that looms large in the healthcare space. If the Department of Justice elects to pursue fewer FCA cases against healthcare companies, that may leave more cases to be brought by private

plaintiffs. That may reduce healthcare companies' ultimate exposure, but would create more potential for harassing litigation by private parties in the interim.

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Much more will be known in the coming weeks and months about the Trump administration's plans and how they may impact the healthcare industry, as he makes key appointments and presumably begins to release more detailed policy proposals. Likewise, we will likely develop a better sense for the views of the new Congress. One thing is clear: significant changes are likely coming and they will present both benefits and disadvantages for players in the healthcare sector.