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What the Trump Administration Means for Health Care

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In early January, Republicans took the first step toward repealing the Affordable Care Act (ACA). Using a process known as reconciliation, Congress passed a budget resolution that set the stage for repeal of many existing ACA provisions. In his first press conference since the election, President Trump commented on two issues related to health care, laying out a timeline for repeal of the ACA and pledging to force drug makers to bid for government business.

In light of these recent developments, we are updating this article to reflect our current thinking as of January 20, 2017. (The original article was published on November 11, 2016 and updated on December 20, 2016.) This version includes our views on how reconciliation will affect the ACA and how Trump's stance on drug pricing will impact biopharma.Given the fluidity of the situation, we will continue to update our analysis as we gain a clearer picture of the new administration's proposed health care reforms.

On January 20, 2017, a new US president was sworn in whose health care agenda represents an about-face from the previous eight years. Donald Trump has promised to repeal and replace the ACA—which has served as the cornerstone of President Obama's health care agenda—and introduce new health care reforms that follow free-market principles.

But the transition will not be simple. The health care industry and the US government have never been more interconnected—and their relationship has never been more complicated. Trump's efforts to replace the ACA will have profound implications for our health care system across payers, providers, biopharma, and medtech. While a repeal of the ACA is an immediate priority for the Trump administration, many more reforms will follow as the administration seeks to fulfill its promise not just to repeal but to replace.

Companies have been asking, Will the Trump administration support further innovation in payment models? Will merger and acquisition (M&A) regulations intensify? Will the government take a more active role in setting prices? Is regulatory oversight of medtech and biopharma likely to expand? And how will this affect access to health insurance and out-of-pocket expenses for consumers?

With so many fundamental issues in play, it's only natural to question what will happen next. But that's only half of the equation. Health care executives also need to be asking themselves, What should we be doing to prepare for the changes to come? And how can we mitigate risk in an environment punctuated by so much uncertainty?

The Republican Path Forward

The GOP platform advocates minimal government involvement in health care, limited industry regulation, a shift from public to private administration of health care, and increased payer competition. While a number of proposals have been put forward by different leaders within the party, Republican priorities generally include the following goals:

- Eliminate the individual mandate (which requires citizens to maintain health insurance).
- Eliminate mandated benefits, such as the ACA's ten "essential health benefits."
- Expand access to tax-free health savings accounts (HSAs) as a supplement to high-deductible plans.
- Create high-risk health insurance pools for individuals with chronic conditions.
- Reform Medicaid and Medicare by converting Medicaid to block grants, raising the Medicare eligibility age, and moving toward a privatized Medicare system, like Medicare Advantage (MA).
- Create a centralized fund to support "disproportionate share" hospitals, which treat indigent and uninsured patients.
- Repeal the medical device excise tax and the Cadillac tax (a 40% excise tax on high-cost employer health insurance plans).

Given their majority in the House and Senate, Republicans will have an opportunity to repeal major portions of the ACA without significant compromise. Two key votes occurred during the week of January 9—the final week of legislative activity prior to inauguration—when Congress passed a budget resolution. The resolution instructs congressional

committees in both chambers to consider proposals and draft legislative text. During this committee phase, we expect to see specific language repealing portions of the ACA. The House and Senate committees must craft the reconciliation bill by the nonbinding deadline of January 27.

Despite this move to speed legislative action, it is unclear whether Republicans agree on how and when to move forward, creating uncertainty as to whether we will see repeal *and* replace or repeal *then* replace. Some Republicans, including Senator Rand Paul of Tennessee and Senator Susan Collins of Maine, have voiced strong opposition to repealing the ACA until a clear plan has been crafted. House speaker Paul Ryan has also said he would push for repeal and replace. The Republicans have yet to resolve differences and align on a single plan, though the congressional Republican retreat in Philadelphia in late January may provide an opportunity for them to do so.

The only aspects of the ACA that can be repealed during the reconciliation process are those that impact the budget. These include:

- Premium subsidies for low-income Americans, used to help pay premiums and deductibles
- Federal funds for states to offer Medicaid coverage to anyone earning less than ~$16,000 per person or ~$33,000 per a family of four
- The individual mandate requiring individuals to either purchase coverage or pay a penalty
- The employer mandate requiring large employers to offer affordable coverage
- Taxes on high-income individuals, prescription drug companies, and medical device companies

Two Key Nominations

The nominee for secretary of HHS, Tom Price, a former orthopedic surgeon and six-term Republican congressman from Georgia, is a long-time critic of the ACA. His most recent bill, the 2015 Empowering Patients First Act, aimed to fully repeal the ACA and offered tax credits for the purchase of individual and family health insurance policies. Many of his proposals have been incorporated into the House Republicans' "Better Way" agenda.

Trump has also nominated Seema Verma as CMS administrator (a position that reports to the HHS secretary). As president of a health care consultancy in Indiana, Verma worked closely with Governor Mike Pence to expand Indiana's Medicaid eligibility under the ACA. The Healthy Indiana Program (HIP) 2.0, of which Verma was architect, represents a significant departure from traditional Medicaid. HIP incentivizes individuals to become good stewards of their health care dollars by, for example, requiring co-pays and monthly contributions to an HSA.

Implications for the Industry

Republican health care reforms will have the biggest impact in five areas: the individual market, Medicaid and Medicare, payment models, consumer choice, and drug pricing.

Dramatic Changes to the Individual Market. The Republican agenda aims to create a market that will look quite different from today's system in several ways:

- **New Payers and Insurance Policies.** If the ACA's essential health benefits are no longer mandated, we could see a proliferation of new health insurance policies offered on the market—and new entrants to provide them. Insurance plans that were barred under the ACA, including catastrophic coverage and "minimedical," or "limited benefit" plans (previously offered by larger companies that employ a lot of hourly, lower-wage workers), could make a comeback as payers experiment with leaner coverage and narrower networks. As the private market shifts to lower-costs plans, coupled with increased use of HSAs, we anticipate a rise in the number of high-deductible health plans.
- **Loss of the Individual Mandate.** The individual mandate will most likely go away. However, Trump has indicated that he may keep one of the most popular ACA benefits—guaranteed issue—which allows citizens access to health insurance regardless of health status or preexisting conditions. Under this scenario, payers could find themselves in the unenviable position of either charging exorbitant premiums for individuals with costly conditions or abandoning the individual market altogether. While Trump has proposed high-risk insurance pools for chronic conditions, which would mitigate some of this effect, many medical costs in the individual market are driven by acute and episodic events that cannot be addressed prospectively, such as accidents, cancer, and childbirth. Therefore, other risk management mechanisms (such as a requirement for continuous coverage) will need to be put in place to protect against preexisting-condition exclusions and other high-cost cases.
- **Emergence of ACA "Islands."** While we expect the ACA to be rolled back, it is quite possible that some states will implement their own versions (as Massachusetts did in 2006). Without federal subsidies, this would be fiscally difficult,

but economically thriving states such as California, Washington, and New York have a vested interest in ACA-like programs as important enablers of their labor markets. These states have actively managed their own exchanges and experienced lower-than-average rate increases, which makes it more feasible for them to maintain the ACA at the state level.

Increased Privatization and Deregulation of Medicaid and Medicare. Republicans have floated proposals to shift Medicaid to a block grant program. This would give states more autonomy, but at lower funding levels than they experience today; therefore, states would have to modify eligibility rules, reduce coverage, or chip in funds themselves.

The GOP has also proposed raising the eligibility age for Medicare and potentially even shifting the program to a premium-support model. Shifting more or even all Medicare members to a privatized MA model would be a change for most seniors (68% of whom receive government-administered, fee-for-service Medicare), but this model has relatively few drawbacks for either the government or the private sector. Private-insurance-based MA plans have a track record of containing costs better than fee-for-service CMS plans, while delivering better-quality outcomes.

Changes in Payment Models. Under Republican leadership, we expect to see several changes in payment models:

CMS Reimbursement. In the near term, Republicans will likely continue to reduce CMS reimbursement rates for providers. While not explicitly in their platform, it's a fiscally conservative move that frees up dollars for other programs (funding high-risk pools, for example). Additionally, this would ease the transition of Medicare to a private model, making it easier for insurers to be competitive with the government's fee-for-service programs.

The Center for Medicare & Medicaid Innovation. The CMMI has developed and launched several pilots in value-based payment models (like bundled payments for joint replacements). Given that Tom Price and other GOP lawmakers have heavily criticized the CMMI, we expect to see fewer mandatory initiatives.

Accountable Care Organizations. It is quite likely that we will see a rollback of government support for many alternative payment models, including the ACOs that have emerged in recent years. While these programs have shown some positive results, the overall outcomes have been lackluster, and they would make an easy target for a legislature looking to strip regulation and reduce administrative complexity.

Disproportionate-Share Hospitals. The Republican plan explicitly seeks to reinstate the disproportionate-share hospital funding that compensates hospitals for treatment of uninsured individuals. This is an important safety net for hospitals, since their treatment of uninsured patients will likely rise following the rollback of ACA subsidies and Medicaid expansion.

Increased Role of the Consumer. The ACA exchanges enabled individuals to evaluate health products from a more consumer-based mindset, and Republican reforms seek to introduce further consumer choice into the health care system.

Today, health care decisions are typically made by doctor and patient, with little concern for costs. But HSAs will change this. HSAs encourage consumers to set aside money to pay for their own health care when they get sick. If scaled over time, as Republicans have proposed, HSAs would put much more discretion into the hands of patients. Given the choice between a $25,000 partial knee replacement and a modestly priced biologic injection, patients will likely choose the more cost-effective option. As consumers pay more attention to the costs of drugs, medtech products, in-network versus out-of-network visits, co-pays, and deductibles, health care companies will need to significantly enhance their engagement with patients as decision makers. It remains to be seen how much consumer pressure can or will drive costs from the system, but all health care companies will need to articulate their value proposition in compelling, transparent, and easy-to-understand ways that help consumers evaluate tradeoffs.

Changes in Drug Pricing. While Republicans have typically taken a laissez-faire approach to pharmaceutical pricing, Trump and his close advisor Newt Gingrich have been more outspoken. In his press conference, Trump took direct aim at drug makers (http://www.wsj.com/articles/trump-attacks-drugmakers-on-pricing-1484167641), which sent biotech stocks into a tailspin (http://fortune.com/2017/01/11/trump-drug-prices-biotech-stocks/). In his remarks, Trump suggested that CMS should be allowed to negotiate pricing and that suppliers should be forced to shift manufacturing to the US—a move that would likely raise prices for low-cost generics. Hours after the press conference, the Senate narrowly rejected (by 52 to 46) a proposal to allow importation of cheaper prescription drugs from Canada, with 12 Republicans supporting the drug import measure and 13 Democrats opposed. Party crossover on this vote, the President's comments, and long-standing Democratic support for such moves (notably from Senator Amy Klobuchar, of Minnesota, who has publicly urged Trump to allow the government to negotiate prices with biopharma) indicate that this issue may have the power to unite enough members of both parties to pass legislation.

Medicare and Price Negotiation. Currently, the prescription drug benefit for Medicare patients is administered by third-party private payers. Since these private payers already negotiate with drug manufacturers for formulary access, a

change to the current model would not be likely to affect drugs filled through pharmacy benefits. However, the impact on Part B drug spending (which is directly reimbursed by Medicare) could be quite significant. For instance, if the administration scraps the current model, which allows free pricing and reimbursement based on the average sales price, and instead invites manufacturers within a drug class to submit competing bids, biopharma may experience very significant price erosion.

Drug Reimportation. Proposals that would allow the CMS to bargain and create more price transparency have the potential to be near-term bipartisan and populist wins; however, this would be decidedly difficult to implement, given that both the Food and Drug Administration and the government of Canada have refused to provide quality assurance for imported drugs. Despite the Senate's recent rejection of the proposal to import cheaper prescription drugs from Canada and other countries, we expect this issue will continue to draw attention from legislators given bipartisan interest in addressing drug prices.

Calls for Price Transparency. The focus on price transparency has both benefits and risks for biopharma companies. The biggest risk is that all agencies will start demanding prices that are now reserved for certain organizations (such as the US Department of Veterans Affairs). California recently proposed a ballot initiative that would have required state agencies to pay no more than the VA pays for prescription drugs. The ballot initiative was defeated, but such proposals could regain momentum. That said, price transparency will ensure that all value chain participants, such as pharmacy benefit managers, doctors, and hospitals, are held to the same standard for their slice of drug profits.

Rollback of CMMI Initiatives. As we mentioned earlier, there may be some rollback of CMMI initiatives, such as the CMS proposed rule to lower reimbursement from 106% of the average sales price for Part B drugs to 102.5%. This initiative was intended to reduce incentives for physicians to prescribe higher-priced drugs, and a rollback would have a positive effect on specialty drug sales.

Response from Industry Trade Associations

Changes in health care policy have significant repercussions for the broader health care industry—and the American economy overall. Industry trade groups have quickly mobilized in advance of the presidential transition to advocate for their industries and tease out the implications of ACA repeal.

Payers. America's Health Insurance Plans (AHIP), a leading trade association for payers, has expressed concern that repealing the ACA without an immediate replacement will bring further instability to the nascent marketplaces. AHIP is calling for Congress to extend an ACA reinsurance program, which is set to expire this year, until 2019, as a means to cushion insurers against financial losses from enrolling high-risk, costly individuals. The trade group also advocates cost-sharing reductions that reimburse insurers when they provide discounts to low-income ACA enrollees. Significantly, AHIP did not advocate for the individual mandate, one of the most unpopular elements of the ACA. Instead, AHIP has suggested that alternatives are needed to encourage young and healthy individuals to sign up for coverage.

Providers. The American Hospital Association (AHA) and the Federation of American Hospitals (FAH) have publicly stated that repeal of the ACA without a replacement could cost hospitals hundreds of billions of dollars. They describe the loss of coverage as an "unprecedented public health crisis." In the event of an ACA repeal, the AHA and FAH have urged Congress to allow hospitals to be reimbursed for Medicare and Medicaid patients at pre-ACA levels (the ACA reduced the payments hospitals receive for these patients because they benefit from the newly insured seeking care).

The Health Care Transformation Task Force, a 43-member group (including 6 of the top 15 health care systems and 4 of the top 25 payers), sent a letter to Trump, Pence, and members of Congress from both parties calling on government leaders to support the continued transition from a fee-for-service to a value-based model.

Industry mobilization efforts have just begun and we anticipate many additional voices to emerge as the administration lays out more of its agenda. While there is broad consensus that change involves significant risk, there is little consensus on what effective change would look like.

How Health Care Companies Can Prepare

With so many reforms coming and so much uncertainty around the details, health care companies need to prepare for the most likely scenarios while readying themselves for a wide range of possible outcomes.

Payers. Payers need to reassess where to play and answer hard questions about where they can win. While a newly deregulated individual market may seem attractive, this market segment has yielded low margins (or been entirely unprofitable) for most payers under both the ACA and pre-ACA scenarios. Meanwhile, many payers have ignored or

underinvested in employer-sponsored insurance, which looks to remain the dominant path for nonsenior insurance in the US. With the potential for this space to become more competitive as restrictions are dropped, payers will need to up their game.

In addition, payers will need to reassess their Medicaid and Medicare strategies. If these sectors move toward 100% privatization, the potential market opportunity will be significant. While the experience curve is steep, even those not doing well today will need to take a fresh look at these segments and weigh the risks against the now-larger rewards.

While it is possible that Republican efforts to increase competition across state lines will yield some additional opportunities for payers, the reality is that network building and pricing are based on metropolitan statistical areas, and many payers operate fluidly across states today. As a result, this is unlikely to be a near-term focus for payers.

Finally, payers will need to pursue partnerships and integration with providers to help keep costs down. In a future where cost is paramount, having meaningful control over care delivery will be a key differentiator.

Providers. For providers, revenues and margins will be further constrained. As CMS rates compress and the pool of paying individuals and Medicaid customers shrinks, systems with high exposure to these segments will need to shore up revenues or change their cost structures. While reestablishment of disproportionate-share hospital payments will provide some cushion, most health systems will experience a decline in revenue (particularly those that have been competitive in winning new ACA-funded patients). As consumers bear greater costs and select high-deductible plans, they may delay care, put pressure on primary care physicians to provide specialist care, and more actively weigh the pros and cons of seeking additional care.

To stay competitive, providers need to keep delivery costs down and appeal to consumers, who will increasingly have a choice about where to be treated. As the number of uninsured will likely increase, providers should expect increased uncompensated utilization of ERs serving low-income populations, and they will need to consider how they can reach more patients with the ability to pay. Physicians will likely gain more protection from medical malpractice, which will reduce legal costs.

Some providers will continue to pursue value-based health care and forge partnerships with payers to capture more patient volume. For others, their market structure will keep them in a fee-for-service world for now, while they optimize delivery costs to remain in competitive brackets. In either case, continued M&A activity will be helpful in improving economies of scale, geographic reach, and differentiated service lines.

Biopharma. Demographic trends and the increasing use of specialty medicines suggest that spending on drugs will continue to rise, resulting in continuing pressure on biopharma to address costs.

Given the likelihood that consumers will have to bear more of their own health care costs, biopharma companies should be prepared to address a consumer base that is less able to pay high prices. Without yearly out-of-pocket maximums, many specialty medications will no longer be affordable for a significant number of patients, and the public outcry over the high costs of important, life-saving drugs may intensify. For non-Medicare patients, biopharma companies can partially address this issue by beefing up co-payment assistance cards and providing foundation support for the uninsured. Companies will also need to carefully manage price levels and price increases, since calls for transparency will continue.

While it's still unclear what specific short-term policies the incoming administration may adopt, biopharma companies should prepare for a gradual transition from fee-for-service to value-based health care. The Medicare Access and CHIP Reauthorization Act (MACRA) was passed with overwhelming bipartisan support in 2015. Even if some elements come under pressure, such as the ability of CMMI to test alternative payment models, MACRA has at its core a clear objective: to move from the current fee-for-service structure (which tends to reward volume) to one that pushes a certain amount of financial risk onto providers, and hence recruits them in the effort to control costs and improve quality of care. If cost becomes a more important factor in prescribing decisions, physicians may prescribe less or choose less expensive alternatives, including generics, biosimilars, and older drugs.

To thrive in the value-based environment, biopharma companies will need to demonstrate superior clinical outcomes and/or lower overall costs. This means providing clear clinical and observable evidence of the effectiveness of their products, as well as experimenting with alternative payment models and “beyond the pill” solutions to increase benefits and reduce risk.