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Trump Policy Actions Could Reshape Health Care and Life Sciences Landscape

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In 2018, President Donald Trump and numerous executive branch agencies announced proposals that, if implemented, will reshape the landscape for virtually every sector of the health care industry. Many of these proposals are consistent with the administration's deregulatory agenda, from relaxation of health insurance rules to a decidedly pro-business approach, to enforcement of federal health care fraud and abuse laws. Other proposals have enjoyed more bipartisan support and have been driven by the rapid introduction of big data and other digital technologies into the health care space. Still others, most notably the president's proposals to reign in drug prices, are more in line with the views of many Democratic lawmakers. This creates a challenge for congressional Republicans and some agency heads to do something about drug prices while staying true to the administration's overall goal of driving economic growth through market-friendly approaches.

With major bipartisan health care legislation unlikely in the newly elected Congress, those in the health care industry should closely follow the administration's executive actions, which may be the most accurate reflection of the future regulatory landscape.

Affordable Care Act

Despite failing to repeal and replace the Affordable Care Act (ACA) in 2017, the Trump administration continued to take steps to weaken some of the ACA's requirements and push market-driven approaches to health care reform. These efforts began with an executive order on the president's first day in office and have included the Labor Department's proposal to expand association health plans, which operate largely outside the ACA framework; expanding the short-duration coverage rule that permits low-cost/low-coverage plans to operate free of ACA requirements; and allowing states to alter their essential health benefit requirements, reduce transfers among insurers under the risk adjustment program and diminish required insurer medical-loss ratios.

Despite the administration's regulatory efforts, much of the ACA remains largely in place. The cost of coverage in the individual market for people who lack subsidies has grown substantially, but marketplace premiums and insurer margins are stabilizing, and new insurers are entering some markets. The availability of premium tax credits has been a balancing force that has offset the shocks the individual market continues to absorb, according to the health policy nonprofit The Commonwealth Fund. The number of uninsured individuals increased by 700,000, to 27.4 million in 2017, the first increase since passage of the ACA in 2014, according to the nonprofit Kaiser Family Foundation.

The December 2018 federal district court decision in Texas declaring the ACA unconstitutional in light of Congress' elimination of the individual mandate makes the law's fate even more uncertain as the decision is appealed. The administration is likely to proceed cautiously in its litigation strategy through the appeals process in order to avoid disrupting the current ACA coverage for millions of Americans, especially in the lead-up to the 2020 elections.

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Digital Health Initiatives

In the past five years, an explosion in digital health innovation has prompted policymakers to address a number of regulatory issues, with technologies emerging to encourage healthy lifestyles; facilitate disease prevention; enable early diagnosis; identify treatment options; support disease management; and assist health care professionals, patients and caregivers in a wide range of scenarios. These technologies promise better-informed decisions, new treatment options and more efficient services. They also involve new challenges, including products that are ill-suited to the Food and Drug Administration's (FDA) traditional medical device regulatory paradigm, manufacturers and developers that have not previously been regulated by the FDA, increased cybersecurity risks, and interoperability demand.

In July 2017, just two months after taking office, FDA Commissioner Scott Gottlieb announced the agency's Digital Health Innovation Action Plan, which recognized that "digital technology has been driving a revolution in health care" and outlined the agency's "vision for fostering digital health innovation while continuing to protect and promote the public health." In the 18 months since, the FDA has devoted significant attention to meeting these goals, including in many ways reimagining its regulatory approach. At the same time, it is clear that more change is in store, as the FDA continues to evaluate and amend its approach to meet the demands of the rapidly evolving digital health space, including with a request for comment regarding regulation of apps to be used with prescription drugs.

The FDA's creative approach to regulating this evolving space is not without its critics. On October 10, 2018, a group of Democratic senators sent Gottlieb a letter seeking extensive information about the FDA's regulation of digital devices and questioning its authority to implement a novel digital health software precertification (Pre-Cert) program that would exempt certain products from FDA premarket review and expedite the process of getting others to market.

Drug Pricing Receiving Scrutiny From All Sides

Trump Administration. No sector of the health care industry has drawn more criticism from the president and his administration than the pharmaceutical industry. Continuing his comments from the 2016 campaign trail, Trump has attacked drug manufacturers for high drug prices, in some cases calling out companies by name. He has asserted that U.S. consumers pay more for the same drugs than consumers in other developed countries. The administration's drug pricing blueprint proposes three changes to how Medicare pays for certain drugs (so-called Part B drugs): replace the current model, where physicians buy and bill for drugs, with a system of private pharmaceutical vendors; use a flat fee in place of the current reimbursement price (which is average sales price plus 6 percent); and implement international reference pricing. The proposals would be implemented in stages beginning in 2020, but their success remains to be seen — previous administrations unsuccessfully attempted the first two initiatives.

The Trump administration also could move forward with a proposal to rework the safe harbors under which drug manufacturers provide rebates and discounts to insurance plans and pharmacy benefit managers, which critics contend would result in higher profits to middlemen but would not result in direct discounts to consumers.

FDA. The FDA, which historically has eschewed calls for it to regulate drug prices, also has taken up the issue — albeit indirectly — by pushing for faster generic drug approvals and promoting competition. One focus Gottlieb has championed involves lowering the regulatory barriers to entry in areas with a single or small number of approved products.

Congress. For its part, Congress has shown more appetite for investigating manufacturing pricing practices than enacting legislation to lower drug prices. That may change in 2019, with Democrats taking control of the House of Representatives. (See "Preparing for Democratic Oversight Investigations.") House Democrats are likely to push proposals to bolster the ACA, expand Medicare and target drug prices, but these efforts may be focused more on framing issues for the 2020 elections than on enacting legislation that can make it through the Republican-controlled Senate. Nevertheless, key Democrats have promised to introduce legislation that would allow the Centers for Medicare and Medicaid Services to negotiate directly with drugmakers under Medicare Part D, the optional prescription drug benefit under the federal health insurance program. While the Republican-led

Senate may not be willing to go that far, pressure from the House could force the Senate to do something about drug prices. Republican senators have introduced legislation to increase competition through faster generic approvals and held hearings on proposals to loosen Part D coverage mandates, and the Senate could take up one or more of these plans to demonstrate action.

Health Care Enforcement Takes Pro-Business Turn

The administration's pro-business approach has been most pronounced in the area of enforcement of health care fraud and abuse laws. Two Department of Justice (DOJ) policy initiatives already are being implemented by federal prosecutors in the courts. The first announced that prosecutors could no longer use violations of subregulatory guidance as evidence of wrongdoing in affirmative enforcement proceedings, including actions under the civil False Claims Act (FCA). The second policy stated that the DOJ will move affirmatively to dismiss nonmeritorious FCA actions (rather than simply decline intervention and allow the private *qui tam* litigator to pursue the case on his or her own). In the final weeks of 2018, the DOJ exercised this authority by moving to dismiss 11 FCA cases alleging that the operation of nurse educator programs by pharmaceutical manufacturers resulted in improper inducements to physicians. Rulings on one or more of the DOJ motions are expected in early 2019.

More generally, DOJ enforcement actions against health care organizations have declined in the past two years, as reflected in the number of and amounts recovered in major health care fraud settlements. This can be attributed to a number of factors, including the diversion of DOJ health care fraud resources to opioid cases, the administration's more business-friendly approach to white collar enforcement, and the Justice Department's focus on violent crime and immigration matters. Despite a coming change in leadership at the DOJ, the department's less aggressive approach to health care fraud enforcement against traditional industry participants is likely to continue through at least 2020.

Conclusion

Health care will remain a key political and policy issue in Washington, D.C., and the tone the House Democrats set will be closely watched. Expect executive agencies to continue to push proposals to bring more competition and market forces to the health care system, and foster more innovation around digital health issues.

Meanwhile, actions by the White House are more difficult to predict. The president likely will continue his criticism of drug prices and will encourage executive agencies and Congress to take action, but with Congress divided and a presidential election looming, major legislative action is unlikely.

The legislative and regulatory landscape will remain dynamic, and health care companies and other stakeholders will need to keep abreast of policy developments in this challenging environment.

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