

## **Alert** | Health Care & FDA Practice



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### **President-Elect Biden's Key Health Care Campaign Issues**

Health care was a priority on the campaign trail, suggesting key issues such as the Coronavirus Disease 2019 (COVID-19) pandemic, stabilizing the insurance marketplace through the Affordable Care Act (ACA), and responding to the Supreme Court's ACA decision will be top priorities during President-elect Biden's first term. Many of these issues were discussed during the presidential campaign and may be modified where legislative solutions are necessary.

This GT Alert identifies health care issues and potential pathways of consideration.

#### **COVID-19 Response**

To address the COVID-19 pandemic, President-elect Biden has taken actions such as announcing a COVID-19 taskforce made up of physicians and health experts. The three co-chairs include: Dr. Vivek Murthy, Surgeon General during the Obama administration; Dr. David Kessler, Food and Drug Administration (FDA) Commissioner under Presidents Bush and Clinton; and Dr. Marcella Nunez-Smith, Associate Dean for Health Equity Research at Yale University. The taskforce is planning work with state and local health officials to address the virus and its racial disparities and to develop a plan for reopening schools and businesses.

In addition, President-elect Biden may extend the Public Health Emergency (PHE) (currently set to expire Jan. 21, 2021) in order to continue work to expedite FDA products through the Emergency Use

Authorization (EUA) authority until such time as vaccines have been distributed and administered and there is a significant reduction in COVID-19 cases.

### *Health Care Provider Relief*

President-elect Biden has stated that he will focus on providing relief funds to health care providers, with an emphasis on rural hospitals already financially constrained before COVID-19. He has also stated that he will ensure hospitals are not cutting the pay of doctors and nurses during this emergency and that the allocation of federal dollars should be conditioned on an explicit commitment to not cut back on wages or benefits of hospital-based health care workers. As funds are disbursed, President-elect Biden has stated he will work to ensure the administration is tracking what else hospitals require to address such needs in future legislation and budgets.

### **Affordable Care Act**

President-elect Biden strongly supports strengthening and expanding the ACA in several ways:

- (1) By ensuring access to affordable plans within the State Marketplace (Exchanges) by offering a Medicare-like public option. Under this proposal, a government-run option would be offered on the Exchanges that would compete with private plans;
- (2) By expanding federal premium subsidies to include people who make more than 400% of the federal poverty level. Premium subsidies would be capped at a maximum of 8.5% of income and would be tied to more generous “gold” plans, which have lower deductibles and out-of-pocket costs than the “silver” plans currently used to determine premium subsidies;
- (3) By permitting individuals with access to employment-based coverage to purchase individual coverage through the Exchanges;
- (4) By providing funds for states to manage the Exchanges and bolster local marketing and consumer outreach efforts to support enrollment activities in both the Exchanges and Medicaid;
- (5) By eliminating the offering of certain plans that do not meet the minimum standards of coverage under the ACA;
- (6) By expanding coverage of low-income Americans by enrolling them in Medicaid (in those states that have expanded their Medicaid programs to include those making less than 138% of the federal poverty level) or enrolling them in the public option premium-free;
- (7) By allowing undocumented immigrants to enroll in plans offered on the Exchanges. Such individuals would not, however, be eligible for federal subsidies; and
- (8) By lowering Medicare eligibility to 60, making approximately 20 million Americans eligible for Medicare. This would allow seniors to leave their employer-provided plan or any other plan available through the Exchanges before they reach retirement age of 65. President-elect Biden has also indicated he would like Medicare to be expanded to include dental, vision, and hearing coverage.

Many of these options will require congressional action.

### *ACA Supreme Court Case*

The Supreme Court review of the validity of the ACA may cause President-elect Biden to offer additional changes to stabilize the ACA. *California v. Texas* (known as *Texas v. U.S.* in the lower courts) was argued before the Supreme Court on Tuesday, Nov. 10, 2020. A group of 20 states, led by Texas, sued the federal government in February 2018, seeking to have the entire ACA struck down. They argued that the entire ACA became unconstitutional when Congress eliminated the penalty for individuals who fail to obtain health insurance. There are 21 states, led by California, defending the ACA. The Fifth Circuit issued a ruling stating the individual mandate was unconstitutional because it can no longer be justified as a tax and remanded the case to the lower court to determine what portions of the ACA are or are not severable from the individual mandate.

The Supreme Court has agreed to review four legal questions in the case. First, the Court will consider whether Texas and the individual plaintiffs have standing to bring the lawsuit to challenge the individual mandate. If so, the Court will determine whether the 2017 Tax Cuts and Jobs Act (TCJA) rendered the individual mandate unconstitutional. If the mandate is unconstitutional, the Court will decide whether the rest of the ACA can survive. Finally, if the entire ACA is held invalid, the Court will resolve whether the entire law should be unenforceable nationwide or whether it should be unenforceable only to the extent that provisions injure the individual plaintiffs.

Although it is unlikely that the law in its entirety will be struck down, certain provisions could be struck down or remanded for further review. A final decision could be made in 2021.

### *Value-Based Payment*

A key policy component of the ACA is to improve the quality of care and reduce costs. To that end, the ACA: (1) strengthened the laws to prohibit fraud and abuse in federal health care programs; (2) mandated reporting and disclosure requirements to make pricing and potential conflicts of interest transparent in the health care industry; and (3) created The Center for Medicare and Medicaid Innovation (the Innovation Center) to support testing and developing payment arrangements and delivery models that drive up quality and reduce costs as opposed to incenting volume and utilization of services.

In addition to focusing on health care choice, President-elect Biden's health care plan looks to reduce health care costs and to make the health care system easier to navigate. As discussed above, he supports a public option, reducing costs by negotiating lower prices from hospitals and other health care providers, including moving reimbursement away from volume to payment for value-based care.

The Innovation Center's efforts made under the Obama and Trump administrations for providers to assume some level of medical risk for services could continue under the Biden administration. Such arrangements may focus on supporting and integrating community-based organizations that work to address social determinants of health and lower racial disparities in health care. Therefore, value-based care also will aim to close racial disparities in health care among racial groups by engaging with community health centers.

### **Moonshot – Cancer Prevention, Treatment, and Education**

President-elect Biden will likely continue his efforts to encourage FDA and the National Institutes of Health (NIH) to find cures for cancer, as the "Cancer Moonshot" was intended to support cancer research, including prevention and treatment. The Cancer Moonshot to accelerate cancer research aims to make

more therapies available to more patients, while also improving the ability to prevent cancer and detect it at an early stage.

### Drug Pricing

During the campaign, President-elect Biden called for greater cost transparency in the pricing of drugs – both for the government as a purchaser and for consumers. First, the Biden administration will seek to eliminate the “non-interference clause” under Part D that restricts CMS from negotiating prices for drugs. The administration will also seek to limit the reimbursement for Part B drugs. These drugs are generally administered by health care professionals, and include infusion and non-self-administered drugs. The Biden administration could set up a new arm of the U.S. Department of Health and Human Services (HHS) to establish prices for new breakthrough drugs not subject to competition and enable drugs to be imported from countries that have already negotiated the lowest prices.

### Closing

The issues discussed above comprise only part of the health care-related issues that may be under consideration during the first year of President-elect Biden’s administration. The Biden administration could address other areas regulated by HHS and FDA, including the regulation of food and dietary supplements, transparency of reporting requirements in clinical trials, and remote patient monitoring/telehealth.

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