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Forecasting Healthcare Regulatory Developments in a Biden Administration

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ALERTS

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President Joe Biden was sworn into office on January 20, 2021. As with any incoming administration, new policies will be pursued while those of the previous administration are furthered, abandoned, or undone. The federal government is an enormous bureaucracy with several layers and, therefore, converting policies into quantifiable results takes months or even years. Early indicators of policies' prioritization, implementation, or their likelihood of success can provide a head start to regulated businesses scanning the horizon. It is in that spirit that Wilson Sonsini offers the insights below to forecast how the Biden administration will shape the healthcare ecosystem for the years to come.

CMS

- *Medicare-For-All*—Medicare-For-All is unlikely to be on the table. During the 2020 Presidential election campaign, Bernie Sanders's platform included Medicare-For-All, which would provide universal healthcare for all Americans. Then, candidate Biden said he would veto any such bill that crossed his desk as President given the astronomical cost, estimated at $35 trillion. President Biden is expected to maintain his position. To pay for a Medicare-For-All program, taxes would need to increase. Most Americans have been hit hard by the global COVID-19 pandemic, and the new administration will not want to raise taxes to fund the new program. In addition, Medicare-For-All is a divisive program and one that would require bipartisan support to be sold to Americans. Given the myriad issues President Biden must address, Medicare-For-All is not expected to be a goal of this administration. However, this does not mean that lower-cost health insurance options for all will not be a top priority for President Biden. President Biden has repeatedly said that lowering healthcare costs and increasing pricing transparency are essential and that no American should be surprised when they receive their bill for healthcare services.
- *Recovery Audit Contractor Audits*—Recovery Audit Contractor (RAC) audits will likely increase during the Biden administration. The RAC program was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The RACs are responsible for identifying Medicare overpayments and underpayments and for highlighting common billing errors, trends, and other Medicare payment issues. In addition to collecting overpayments, the data generated from RAC audits allows CMS to make changes to prevent improper payments in the future. The RACs are paid on a contingency fee basis and, therefore, only receive payment when recovery is made. In 2010, the Obama administration directed federal agencies to increase the use of auditing programs such as the RAC to help protect the integrity of the Medicare program. The RAC program is relatively low cost and high value for CMS. It is likely that the healthcare industry will see growth in this area under the Biden administration.
- *Negotiating Drug Prices*—The Biden administration may push to repeal CMS's prohibition on negotiating drug prices. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prohibits the U.S. Department of Health and Human Services (HHS) from interfering with "the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered

part D drugs," thus leaving pricing negotiations to plan sponsors and pharmaceutical manufacturers. Candidate Biden stated that Medicare has significant leverage to reduce drug prices for beneficiaries. In fact, in 2019 the House of Representatives passed bill H.R.3 that would have allowed Medicare to negotiate prices for certain drugs beginning in fiscal year 2023. The bill also would have allowed private insurers to benefit from the negotiated prices. It was last read in the Senate in September 2020. It is expected that President Biden will either push that bill or seek similar legislation, including out-of-pocket caps for beneficiaries.

HHS

- *Healthcare Prosecutions*—Both government-initiated litigation and qui tam suits appear set for continued growth in 2021. Healthcare fraud and abuse dominated 2020 federal False Claims Act (FCA) recoveries, with almost 85 percent of FCA proceeds derived from HHS. The rising tide of healthcare enforcement payouts reflects the continually expanding role of healthcare in the U.S. economy and especially healthcare paid for by government insurance programs. President Biden chose former California Attorney General Xavier Becerra to lead HHS. Becerra appears to have been selected less for his background as a prosecutor than for his history as a top defender of President Obama's 2010 health care reform legislation. While in Congress, Becerra was a leading advocate for passage and as California's attorney general, and he has repeatedly defended the law against challenges, including before the U.S. Supreme Court. Becerra's incoming team is, in any case, expected to generally ramp up law enforcement activities—both to punish healthcare fraud and abuse and as an exercise of HHS's policy-making authorities.
- *Anti-Kickback Statute*—With more than $1 billion of FCA payouts in 2020 derived from federal AKS settlements alone, HHS's heavy reliance on this one authority likely results from its singular breadth and usefulness in addressing varied forms of costly fraud and abuse. For these same reasons, prosecutors and qui tam relators will likely continue to focus their efforts on AKS enforcement in the Biden administration, despite the recent regulatory carveouts from the AKS and an emerging legal challenge from drug manufacturers. In late 2020, OIG-HHS finalized an array of new AKS regulatory safe harbors from prosecution, chiefly related to value-based coordinated care arrangements. The same rulemaking expanded and simplified existing safe harbors, including the widely applicable personal services and management safe harbor. These new constraints on prosecutorial authority are fairly technical in nature, however. Given the myriad business and charitable arrangements on which the AKS bears, these changes should not slow the pace of AKS enforcement. Neither should the pace be slowed by an interesting challenge to the AKS that drug manufacturers are set to pursue in 2021. During 2019-2020, law enforcement reached many AKS settlements with leading drug manufacturers and independent charity patient assistance programs (PAPs). Basically, prosecutors have assembled a series of strong cases alleging large manufacturers and PAPs have colluded to circumvent patient cost-sharing obligations and thereby pump up demand for high-cost treatments. Pfizer, Regeneron, and Teva have struck back. These companies have brought free speech lawsuits challenging restrictions on their PAP donations that HHS has imposed under the AKS. Although widely regarded to be very unlikely to succeed, these new cases have the potential to disrupt how OIG-HHS has used the AKS to police industry practices.
- *Telehealth/COVID-19*—We expect two major enforcement trends to continue into the new administration. The first is an unprecedented crackdown on telehealth fraud. On September 30, 2020, the inter-agency National Health Care Take Down Initiative announced that it charged hundreds of defendants allegedly responsible for—among other things—$4.5 billion in false and fraudulent claims relating to telehealth advertisements and services. The telehealth executives charged allegedly operated businesses that used mass media promotions to draw unsuspecting Medicare and Medicaid beneficiaries into brief telephone consultations with physicians and other medical practitioners under contract with the telehealth companies. The practitioners then ordered unnecessary durable medical equipment, genetic and diagnostic tests, and medications ostensibly on behalf of the beneficiaries. The practitioners were, in turn, paid by the telehealth executives on the basis of the practitioners' contrived orders—contrary to the AKS discussed in the preceding paragraph. This crackdown on telehealth—while massive in scope—centered on unquestionably fraudulent medical practice. It never addressed the nuanced and technical forms of abuse that can arise relating to billing or coding for telehealth services. These Takedown cases were first initiated while at the same time telehealth has made phenomenal progress, largely as a result of the COVID-19 national health emergency. We expect to see large-scale telehealth-related enforcement of an increasingly sophisticated nature in 2021. COVID-19 will continue to be a top public health and economic priority in the Biden administration—it is also rapidly ascending as a law enforcement priority. HHS administered hundreds of billions of dollars in spending to directly address the public health crisis. HHS directed billions more in varied economic supports to healthcare providers squeezed by lockdowns, delayed elective procedures, and other economic fallout. In so doing, government intervened in the health sector on an unprecedented scale, in real-time, and relied on ad hoc oversight. The healthcare sector must therefore expect large

enforcement efforts in 2021 arising out of COVID-19. Beyond targeting dealers in sham treatments and protections, government officials and qui tam relators are eager to redress perceived widespread misuse of public funds.

Cybersecurity

- *Safeguarding Biotechnology Infrastructure*—President Biden's first national security directive, "United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness" (Jan. 21, 2021) makes clear that "protect[ing] our biotechnology infrastructure from cyber attacks and intellectual property theft" will continue to be a top priority. COVID-19 vaccine data is a target, not just for intellectual property theft, but also for potential disinformation campaigns. For example, hackers who stole vaccine data from the European Medical Agency changed safety and effectiveness data before making that data public. After the European Medical Agency hack, we anticipate U.S. and other regulators will likely be looking closely at vaccine data and thinking about ways to prevent and mitigate similar hacking and disinformation campaigns that could undermine the public's confidence in the safety and effectiveness of COVID-19 vaccines and the supply chain.
- *Cybersecurity Incentives*—New legislation may offer incentives for cybersecurity efforts. H.R. 7898, a small and overlooked provision of the National Defense Authorization Act, will provide incentives for implementing "recognized security practices," specifically allowing HHS to take these into account when making determinations regarding fines or penalties under the HIPAA Security Rule. We'll be watching for a notice of proposed rulemaking in the first half of 2021. Covered entities and business associates can take steps now to align their security policies and procedures to the NIST Cybersecurity Framework and other widely used industry standards.
- *Immunity Passports*—One of the key cybersecurity issues in 2021 is the hopeful question of how to safely get back to normal as more people are vaccinated and/or recover from COVID-19. Initially, the World Health Organization raised caution regarding proposals for "immunity-passports," but a call for experts was raised in December 2020 to bring together technologists, privacy and cybersecurity experts, and public health policy leaders to develop technical specifications and standards for the Smart Vaccination Certificate, with interoperability on an international level. The Ada Lovelace Institute has summarized a number of international and U.S. federal and state level efforts here. To get people back to work and able to travel freely again, protecting vaccination and immunity records from disclosure, fraud, and manipulation will be vital. We anticipate that health tech will be a key player in the development of standards, apps, and other tools for this purpose, and that the impact of this effort will benefit employers, the travel and hospitality industry, and others more broadly.

Cannabis

- *DHHS and Cannabis*—The inauguration of President Biden and Vice President Kamala Harris seems likely to usher in a new era in the federal government's approach to the regulation of cannabidiol (CBD) and cannabis (marijuana) products. Biden has already announced California Attorney General Xavier Becerra as his pick to lead the HHS. Becerra is a well-known supporter of legalization. He vocally opposed the Sessions U.S. Department of Justice's (DOJ) attempts to crack down on legal medical marijuana businesses in California as Attorney General and voted in favor of several bills related to loosening cannabis regulation and promoting access while serving in the House of Representatives.
- *FDA and Cannabis*—Biden has yet to announce an appointment for U.S. Food and Drug Administration (FDA) commissioner. Janet Woodcock and Josh Sharfstein seem to be frontrunners in the discussion. Both, however, seem to be proponents of safe consumption of marijuana and CBD. Prior to her appointment as acting commissioner of the FDA, Woodcock served as the director of the Center for Drug Evaluation and Research, where she was responsible for denying an anti-legalization group's request to place marijuana and its derivatives on a list of restricted substances on the grounds that the enforcement was "not necessary for the protection of public health." Her record is otherwise fairly sparse with regard to CBD and marijuana regulation. Sharfstein has a history of support for legal medicinal cannabis. As Maryland's health secretary, Sharfstein backed medicinal legislation in 2013. Since then, he authored a 2019 paper in the *New England Journal of Medicine* urging Congress to act to create a law that solves current issues in CBD regulation, citing the potential for CBD to have "beneficial effects for the safety of all supplements and foods in the United States." Another long-shot consideration for the job is Amy Abernethy, who currently heads the FDA's CBD Working Group. Importantly, none of the three support unfettered legalization. Instead, each seeks to expand and clarify the current regulatory regime through expanded research initiatives and legislation that allows for safe access.
- *Descheduling Cannabis*—A Gallup poll found that a record 68 percent of Americans—including half of Republicans—support the full legalization of marijuana. The likely avenue for

decriminalization of marijuana is the Marijuana Opportunity, Reinvestment, and Expungement (MORE) Act. Kamala Harris is the Senate sponsor of the Act and it has already been approved by the House of Representatives. The MORE Act ambitiously seeks to deschedule marijuana from the Controlled Substances Act while simultaneously implementing a slew of criminal and social justice reforms in an effort to remedy past harms in communities most affected by the war on drugs.

ONC

- *Health IT*—Micky Tripathi was appointed by President Biden to run the Office of the National Coordinator for Health Information Technology (ONC). As the longtime CEO of the Massachusetts e-health Collaborative (MAeHC) and most recently Chief Alliance Officer at Arcadia, Tripathi spent many years building health information exchanges at the state and national level. He is a vocal supporter of interoperability standards, including Fast Healthcare Interoperability Resources (FHIR). Tripathi has served on numerous boards and advisory committees supporting interoperability and health information exchange.
- *Interoperability Regulations*—As the head of ONC, it is likely that Tripathi will continue to push for the implementation of the interoperability regulations that were finalized last spring. The regulations, issued in conjunction with CMS, adopt the FHIR standard and promote information exchange. They make it easier for patients to access and control their health data. The regulations also allow for third-party application developers to create tools that will enable better coordination across healthcare silos. The implementation is important for the exchange of health data and the advancement of digital health tools. The original implementation dates were pushed back in response to COVID-19. Enforcement discretion is expected through the summer.
- *COVID-19*—In addition to the Interoperability Regulations, it is likely that Tripathi will look to leverage health information exchange and data sharing to improve the nation's response to COVID-19. Being able to easily share data across the healthcare and public health ecosystems will facilitate a more coordinated response to the pandemic.

Federal Contracting

- *Buy American Rules*—On January 25, 2021, the Biden administration issued an executive order to which companies that do business with the U.S. government covered by "Made In America Laws," such as the Buy America Act (the BAA), should pay attention. The order announces the Biden administration's policy to "maximize the use of goods, products, and materials produced in, and services offered in, the United States" in connection with federal contracts. It directs the Federal Acquisition Regulatory Council (FAR Council) to consider amending the Federal Acquisition Regulation to i) replace the BAA's current component test with a new test based on "the value that is added to the product through U.S.-based production or U.S. job-supporting economic activity," and ii) increase the percentage of domestic content required in order for an item to qualify as a domestic end product. It also directs the FAR Council to develop recommendations to remove the BAA exception for commercial item information technology items. The order doesn't stop there; among other things, it also directs the creation of a new "Made in America Office" that will review proposed waivers of "Made In America Laws," the implication being that obtaining waivers may become more difficult.

Wilson Sonsini will be closely following healthcare and other regulatory developments. For questions, please contact a member of the firm's FDA Regulatory, Healthcare, and Consumer Products practice.