
Biden Health Care Enforcement Priorities

March 17, 2021

The Biden Administration is expected to devote significant resources to investigating fraud and abuse in the health care industry. Not only will the Biden Administration likely continue investigating traditional health care priorities, but it likely will exercise heightened scrutiny over the use of funds relating to the COVID-19 pandemic and other current issues, such as nursing home care and the opioid epidemic. We also anticipate additional resources devoted to these investigations overall. Below, we outline each of the Biden Administration's most likely enforcement priorities in this industry.

Pandemic-Related Fraud

Like the housing and financial crisis in 2007–2008, which triggered substantial federal government spending and corresponding oversight and enforcement actions for many years, the COVID-19 pandemic has injected billions of federal dollars into the U.S. economy across multiple sectors, with health care companies as major recipients of government aid. As with any program involving significant federal monies, there will likely be commensurate attention devoted to oversight and investigations involving these funds.

Acting Assistant Attorney General (AAG) Brian Boynton recently highlighted pandemic-related fraud as a top enforcement priority for the Department of Justice (DOJ), in particular with regards to the False Claims Act (FCA). While the health care industry is no stranger to FCA enforcement—with 80 percent of all 2020 FCA recoveries related to health care¹—the federal spending to address the COVID-19 pandemic has only heightened the scrutiny facing the health care industry. In a speech on February 17, 2021, Acting AAG Boynton emphasized that “[t]he Civil Division is working closely with various Inspector Generals and other agency stakeholders to identify, monitor, and investigate the misuse of critical pandemic relief monies.”² We can “expect this collaborative effort to translate

¹ Department of Justice Press Release, Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021).

² See Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

into significant cases and recoveries.”³ Hundreds of billions in pandemic relief funds were directed towards the health care industry, making pandemic-related enforcement a significant risk for the industry going forward.

HHS Provider Relief Fund

Fraud related to the U.S. Department of Health and Human Services (HHS) Provider Relief Fund is particularly likely to result in enforcement actions during the Biden Administration. The HHS Provider Relief Fund was created by the CARES Act to offer financial assistance to qualified health care providers for health care-related expenses or lost revenue due to COVID-19. Health care provider recipients of such payments, including hospitals and doctors, have mandatory reporting requirements and must sign an electronic attestation confirming receipt of funds and their agreement to certain terms and conditions.⁴ These terms and conditions require recipients to make a number of certifications, implicating the risk of false certifications and FCA enforcement. For example, recipients must certify that the funds “will only be used to prevent, prepare for, and respond to coronavirus,” and not to pay other unrelated expenses.⁵

Improper use of provider relief funds may also result in criminal prosecution. The first prosecution occurred in February 2021, when an individual was charged for misappropriating provider relief funds by issuing checks to her family members for personal use.⁶ Though early prosecutions will likely focus on individuals and the most egregious cases, as enforcement continues it is likely to broaden in scope. As evidenced by Acting AAG Boynton’s remarks, DOJ will have a close eye on potentially fraudulent use of these funds, and both civil and criminal enforcement in this area will be a priority.

Telehealth

The Biden Administration is also likely to be keenly focused on telehealth-related fraud, especially given the increased usage of telehealth during the pandemic.⁷ By 2025, the global telehealth market is expected to reach \$191.7 billion—nearly five times the estimated size of the market in 2020.⁸ In a recent telehealth-related enforcement action, DOJ charged 86 defendants across the nation for violating the Anti-Kickback Statute, alleging \$4.5 billion in false billings from fraudulent

³ *Id.*

⁴ US Dep’t of Health and Human Services, CARES Act Provider Relief Fund: For Providers, (last accessed Mar. 8, 2021).

⁵ US Dep’t of Health and Human Services, Acceptance of Terms and Conditions, (last accessed Mar. 8, 2021).

⁶ Department of Justice Press Release, *Woman First in the Nation Charged with Misappropriating Monies Designed for COVID Medical Provider Relief* (Feb. 11, 2021).

⁷ As noted by Acting AAG Boynton, “I also expect a continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic.” Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

⁸ PR Newswire, *The Worldwide Telehealth/Telemedicine Industry is Estimated to Reach \$191.7 Billion by 2025* (Dec. 8, 2020), (last accessed Mar. 11, 2021).

telehealth kickback schemes.⁹ Though DOJ prosecuted these schemes in 2020, the focus on telehealth kickback schemes likely will continue during the Biden Administration. Additionally, though the CARES Act significantly eased telehealth regulations, these relaxed provisions are set to expire at the end of the COVID-19 public health emergency, and enforcement of prior, more stringent, telehealth requirements will resume. It is, therefore, important to be mindful of the changing regulations in this area to avoid becoming the subject of a DOJ enforcement action.

Foreign Corrupt Practices Act (FCPA)

While the SEC has yet to announce any FCPA settlements in 2021, just last year the SEC brought several major FCPA enforcement actions against life sciences and pharmaceutical companies, settling with companies including Alexion Pharmaceuticals, Inc. (\$21 million), Cardinal Health Inc. (\$8 million), and a European pharma company and its current and former subsidiaries (\$340 million).¹⁰ Given President Biden's priorities, we expect enforcement trends in this area to continue, especially because the global pandemic increases FCPA risks, as individuals may be more likely to offer or receive bribes due to shutdowns and other government policies (such as restrictions on the export of PPE supplies).

Opioid Epidemic

The opioid crisis continues, with the CDC reporting over 81,000 drug overdose deaths in the United States in the 12-month period ending May 2020—the highest number ever.¹¹ Enforcement of opioid-related fraud and abuse has been a major priority of the federal government in recent years, and two of the largest FCA recoveries ever obtained from the health care industry were obtained from opioid manufacturers.¹² Acting AAG Boynton made clear in his February remarks that criminal and civil enforcement actions against pharmaceutical companies involved in opioids will remain a key FCA enforcement priority under President Biden, with a focus on false and misleading marketing, kickbacks, and the distribution of medically unnecessary opioids.¹³

⁹ Department of Justice Press Release, *Operation Rubber Stamp: Major Health Care Fraud Investigation Results in Significant New Charges* (Oct. 7, 2020).

¹⁰ US Securities and Exchange Commission, *Spotlight: SEC Enforcement Actions: FCPA Cases*, (last accessed Mar. 8, 2021). See also Kimberly A. Parker et al., *Global Anti-Bribery Year-in-Review: 2020 Developments and Predictions for 2021* (Jan. 28, 2021).

¹¹ Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

¹² Department of Justice Press Release, *Justice Department Recovers over \$3 Billion from False Claims Act Cases in Fiscal Year 2019* (Jan. 9, 2020).

¹³ Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021) (“We anticipate continued focus on pharmaceutical companies that marketed opioids with false and misleading statements, paid kickbacks to increase prescriptions, or targeted health care practitioners with a known pattern of problem prescribing.”).

Nursing Homes and Skilled Nursing Facilities

Again as emphasized by Acting AAG Boynton, a “continuing priority” for DOJ is “preventing the abuse and exploitation of our senior citizens.”¹⁴ Last year, the DOJ announced the launch of its “National Nursing Home Initiative” to “coordinate and enhance civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents.”¹⁵ Though this initiative was launched under the Trump Administration, the Biden Administration is likely to continue this enforcement initiative.

Electronic Health Records

Federal enforcement directed at electronic health records (EHR) activities is also likely to continue, especially where there are concerns related to the payment of unlawful kickbacks. Recent EHR-related settlements include: \$18.25 million related to allegations that an EHR vendor made unlawful payments to improperly influence medical providers;¹⁶ \$63.5 million to resolve allegations that a pathology laboratory company provided EHR subsidies to referring physicians;¹⁷ and \$145 million to resolve allegations that an electronic health records vendor solicited and received kickbacks from an opioid company in exchange for utilizing its EHR software to influence physician opioid prescriptions.¹⁸

Executive Orders

Since his inauguration, President Biden has issued several executive orders related to health care. These executive orders provide further insight into President Biden’s health care industry enforcement priorities. Key executive orders in this area include:

- *Executive Order on Strengthening Medicaid and the Affordable Care Act.* One of President Biden’s first executive orders was to order a review of current regulations that may hinder Medicaid and the Affordable Care Act (ACA). In doing so, President Biden also revoked several of former President Trump’s executive orders, including executive orders 13765 of January 20, 2017 (Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal) and 13813 of October 12, 2017 (Promoting

¹⁴ Department of Justice Press Release, *Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference* (Feb. 17, 2021).

¹⁵ Department of Justice Press Release, *Department of Justice Launches a National Nursing Home Initiative* (Mar. 3, 2020).

¹⁶ Department of Justice Press Release, *Electronic Health Records Technology Vendor to Pay \$18.25 Million to Resolve Kickback Allegations* (Jan. 28, 2021).

¹⁷ Department of Justice Press Release, *Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians* (Jan. 30, 2019).

¹⁸ Department of Justice Press Release, *Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations* (Jan. 27, 2020).

Healthcare Choice and Competition Across the United States).¹⁹ This order signals that the Biden Administration intends to strengthen both Medicaid and the ACA. Providers and hospitals involved in Medicaid and the ACA should therefore ensure their compliance programs are in order.

- *Executive Order on a Sustainable Public Health Supply Chain.* President Biden signed this order on January 21, directing immediate actions to secure supplies necessary for responding to the pandemic, including “mechanisms to address points of failure” in health care supply chains. The order also directs the Secretaries of Defense, HHS, and Homeland Security to provide recommendations to address the pricing of pandemic supplies, including the use of reasonable pricing clauses in federal contracts and investment agreements. Given the desire to create a sustainable U.S. supply chain and avoid price gouging, health care suppliers that enter into agreements with the federal government should pay attention to future developments in this area.²⁰
- *Executive Order on Ensuring an Equitable Pandemic Response and Recovery.* In this January 21 executive order, the Biden Administration made clear its priority to ensure that the U.S. pandemic response does not leave disadvantaged communities behind. It is likely that the Biden Administration will have an increased focus on the equitable provision of health care, so all involved in the health care industry should ensure compliance with nondiscrimination laws and other programs that require equitable treatment of marginalized or disadvantaged groups.²¹

Conclusion

Ultimately, many of the enforcement priorities of the Biden Administration are priorities that continue across administrations. However, we can expect increased investigative resources and focus on the health care industry during the Biden Administration. And we are likely to witness enforcement actions in new areas created by the distribution of massive amounts of federal aid in response to the COVID-19 pandemic. Companies in the health care industry will remain under heavy scrutiny—especially if participating in pandemic relief programs—so it is essential to be mindful of the risks involved and to ensure robust compliance and monitoring programs are in place to mitigate those risks.

¹⁹ Executive Order on Strengthening Medicaid and the Affordable Care Act (Jan. 28, 2021), (last accessed Mar. 8, 2021).

²⁰ Executive Order on a Sustainable Public Health Supply Chain (Jan. 21, 2021), (last accessed Mar. 8, 2021). See also Barry J. Hurewitz, Ari Holtzblatt & David Lehn, *COVID-19: The Biden Administration’s National Strategy and Plans for the Defense Production Act* (Jan. 27, 2021).

²¹ Executive Order on Ensuring an Equitable Pandemic Response and Recovery (Jan. 21, 2021), (last accessed Mar. 8, 2021). See also Debo P. Adegbile, Brenda E. Lee, Peggy Otum, Tania Faransso, and Rebecca Cooper, *President Biden’s Executive Actions: Focus on Diversity and Equity*, WilmerHale (Jan. 22, 2021).

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