

[Health Law Daily Wrap Up, STRATEGIC PERSPECTIVES: Pandemic response, fraud and abuse top Biden's enforcement priorities, \(Mar. 24, 2021\)](#)

Health Law Daily Wrap Up

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By Patricia K. Ruiz, J.D.

Industry experts predict increased enforcement in areas of fraud and abuse, health care kickbacks, and pandemic-related waivers.

The COVID-19 public health emergency, in combination with the Biden Administration's desire to restore credibility to the Department of Justice (DOJ), has created opportunities to turn focus to legal and regulatory enforcement in the health care industry. This Strategic Perspective details how President Joe Biden's picks for key positions in his Cabinet have exemplified this administration's intentions to increase enforcement and provides predictions from industry experts that these efforts will focus on fraud and abuse, health care kickbacks, and pandemic-related waivers.

Key nominations to Biden's Cabinet

On March 18, 2021, the Senate [confirmed](#) Xavier Becerra by a vote of 50 to 49. Becerra, the former attorney general for the State of California, comes from a robust background of enforcement, and industry experts see his nomination by President Biden as a commitment to protecting the administration's commitment to accountability.

In his role as California Attorney General, Becerra led an enforcement team that was particularly active in the health care industry, noted [Brenna E. Jenny](#), a partner at [Sidley Austin](#) and former principal deputy general counsel for HHS and chief legal officer for CMS. The enforcement team focused on a range of issues including antitrust, marketing of medical devices, arrangements affecting drug prices, and data privacy. The California Department of Justice also created a new section dedicated to health care rights and access.

"Becerra is accustomed to exercising enforcement discretion in ways that strategically direct resources to advance policy goals," Jenny told Wolters Kluwer. "[HHS] is not always thought of as an enforcement agency, but it does have fairly significant authority to engage in civil administration enforcement actions, and I expect that under a Secretary Becerra, HHS will take on a more active enforcement role, rather than waiting for the [DOJ] to take on a case."

On March 10, 2021, the Senate confirmed longtime federal appeals court judge Merrick Garland to lead the DOJ as President Biden's attorney general. President Biden is [said](#) to have selected Garland for the role because he viewed him as someone who could restore credibility to the DOJ, as well as independence from the White House on criminal matters.

Under Garland, the DOJ is likely to show strong deference to and support of federal agencies undertaking enforcement actions, as Garland often articulated this perspective from the bench, according to a [blog post](#) by Jenny and other Sidley attorneys. However, this may be challenging considering the reforms implemented by the former administration, including a stronger stance regarding the permissible uses of guidance documents in enforcement actions.

"President Biden's selection of [Becerra] to lead HHS, and [Garland] to lead the DOJ should garner providers' attention," said [Robert Hussar](#), a partner at [Rivkin Radler](#) and former First Deputy with the New York State Office of the Medicaid Inspector General. "They have both established themselves as independent, active, and formidable prosecutors that have made a career out of holding both entities and individuals accountable for corporate misdeeds and misuse of the public resources."

Enforcement priorities

In the transition from the previous administration, and especially considering the changes in the health care landscape due to the coronavirus pandemic, industry experts say fraud and abuse will remain one of the top priorities of the Biden Administration, particularly under the False Claims Act (FCA). Health care kickbacks will also be a focus of the new administration, as these arrangements can drive up health care costs, putting the Medicare Trust Fund at risk. Industry experts also identified emergency waivers under the coronavirus pandemic as a main focus of the Biden Administration's enforcement activities.

Fraud and abuse. "The swift and significant shift of enforcement activity and resources away from areas such as immigration and election issues will free up significant resources and allow independent career prosecutors to return to their familiar and long-standing roles of pursuing unscrupulous providers," Hussar said. He emphasized the increased use of data-mining and artificial intelligence, which allows the government to monitor providers in a more effective and efficient manner.

Jenny also highlighted the value of data analytics, which she said both the Criminal and Civil Divisions of the DOJ have publicly recognized, acknowledging they have increasingly relied on their own data analytics to identify outliers and troubling trends. This work, she said, guided how the DOJ selects subjects for investigation.

"I don't think the role of the traditional whistleblower will ever go away," she said, "but DOJ's new initiative means that health care corporate compliance programs need to evolve alongside law enforcement and incorporate data analytics to stay ahead of DOJ scrutiny."

False Claims Act. While FCA enforcement has substantially dropped since 2012, according to a [blog post](#) by attorneys with Skadden, Arps, Slate, Meagher & Flom LLP, the industry should not expect this trend to continue. Whistleblower, or *qui tam*, claims have driven FCA enforcement over the past 20 years, with the DOJ choosing from the pool of such whistleblower actions on which suits to pursue. The Skadden attorneys stated that the industry should expect an uptick in *qui tam* filings, as the Biden Administration's DOJ will be more welcoming to these actions.

"I also foresee a significant uptick in FCA cases with a particular focus on fraud and abuse related to stimulus measures passed to combat the coronavirus pandemic," Hussar said, pointing to the trillions of dollars infused into the health care industry through the Paycheck Protection Program, provider relief funds, Operation Warp Speed, and the American Rescue Plan.

These stimulus actions "will serve as a rich and long-lasting source of FCA cases in the health care arena," Hussar said, predicting false or misleading certifications of eligibility and impending audits of how funds were utilized. These will largely serve as the basis for enforcement actions, he said. The industry can expect an increase in enforcement coordination between HHS and DOJ with the establishment of an FCA work group comprised of representatives from the DOJ and the HHS Office of Inspector General (OIG), which will focus on pursuing individuals and entities who seek to defraud HHS programs.

Health care kickbacks. "Across the health care industry, kickbacks have become perhaps the single biggest driver of enforcement activity, and that is a trend likely to continue," Jenny said. "Kickbacks increase the cost of health care borne by the federal government, at a time when the Medicare Trust Fund is predicted to become insolvent by 2024."

Arrangements that are viewed as undermining safeguards on drug pricing will be an area of continued focus for the government, demonstrated by the wave of enforcement actions over the past few years relating to patient assistance programs. Jenny told Wolters Kluwer that she expects the government to target other arrangements in different forms that are viewed as having the effect of driving up prices.

The Anti-Kickback Statute (AKS) "incorporates incredibly broad prohibitions, reaching business practices that would not be unlawful in other industries," Jenny said. "That makes it a highly effective tool for bringing defendants to the settlement table to negotiate global resolutions, even extending to other theories of liability that would otherwise be ones a defendant would be more willing to litigate."

Pandemic-related enforcement. The sheer number of emergency regulatory waivers that have been promulgated to allow the health care and life sciences industries to adapt to the public health emergency—such as the relaxation of typical encounter and documentation requirements—have created increased opportunities for fraud and abuse. The suspension of many in-person visits, prior authorization requirements, and written consent requirements have eased barriers to access needed care, but these changes also undermine program integrity efforts. Under the Biden administration, "providers should anticipate further scrutiny, including more intense audit initiatives beyond typical medical documentation reviews, in an effort to identify and combat fraud, waste, and abuse," Hussar said.

In the Sidley [blog post](#), the authors state that they anticipate that HHS and the DOJ will scrutinize providers' and hospitals' use of emergency waivers during the coronavirus pandemic. Providers who do rely on the waivers "must ensure they are operating within the four corners of the waivers, as the waivers apply only 'absent any determination of fraud or abuse.'" Then, once the public health emergency has passed, providers must quickly return to compliance with pre-pandemic requirements. Even those acting in good faith may be subject to at least a DOJ document request. "The scope of the current waivers is unprecedented, and private whistleblowers, particularly those who are current or former employees, may be apt to misunderstand the propriety of their employer's changed business practices and file a *qui tam* lawsuit under the FCA," the authors wrote.

Considering the significant increase in government spending surrounding COVID-19, the Skadden attorneys [anticipate](#) that the increase in enforcement will be correspondingly robust. This trend began in 2020, and they anticipate that the focus on enforcement will continue throughout the pandemic, as state and federal enforcement agencies detect, investigate, and prosecute pandemic-related fraud and abuse.

FDA enforcement activities. The FDA takes a risk-based approach to its priorities, and [Rebecca Wood](#), partner at Sidley Austin and former Chief Counsel to the FDA, expects that many areas of recent FDA enforcement focus will continue. As one of these areas, she highlighted the FDA's commitment from the beginning of the coronavirus pandemic that it would target false and misleading statements about COVID-19 medical countermeasures. Wood also told Wolters Kluwer that the FDA has focused for some time on warning letters relating to compounding, CBD, and opioids, and she expects that focus to continue.

"We may also see a renewed focus on government actions targeting off-label promotion, as tends to be a priority in Democratic administrations," Wood said. "Such actions will need to navigate First Amendment developments in the courts that offer increasing protections for truthful and non-misleading speech about FDA-regulated products."

Areas in need of enforcement

Even with the Biden Administration's increased enforcement, industry experts identified several areas that could benefit from extra attention, namely consumer protection and access to care, as well as agencies' compliance with the Administrative Procedure Act in the promulgating of new requirements.

Consumer protection and access to care. To protect the public at large during the coronavirus pandemic, Hussar emphasized the need of the federal government to pursue false advertising and fraudulent billing actions against manufacturers and distributors of counterfeit personal protective equipment (PPE), unapproved tests, and hoax treatments and cures for COVID-19. However, Hussar argued that oversight of the access to and quality of mental health and substance use disorder services is another area deserving of enforcement attention and resources.

"It goes without saying that the need for these services has grown exponentially over the past year due to both the obvious, but also the less-visible consequences of [the coronavirus pandemic]," Hussar said. The need for access to mental health services has already been expanding as a result of the opioid epidemic, and ensuring adequate and equal access to appropriately credentialed providers is essential during this time.

Further, Hussar said, "the next four years will clearly demonstrate that we are at the early stages of a rising tide of consumer protection measures. Price transparency, protections against surprise billing, and HHS' OCR Right

to Access audits will be just a few of a multitude of policy initiatives and enforcement efforts to empower and protect patients."

Agencies' compliance with APA. While she believes HHS and DOJ have continued robust enforcement activities over the past few years, Jenny said that she believes regulated entities need to police how agencies like HHS issue and use sub-regulatory guidance documents.

"The Administrative Procedure Act imposes very specific guardrails that generally prohibit agencies from imposing binding new obligations unless they do so through notice-and-comment rulemaking," Jenny said. With the growth in the administrative arena, federal agencies face temptation to include new obligations into sub-regulatory guidance documents, which has become a growing source of frustration for regulated entities. Jenny noted that, under the former administration, federal agencies tightened up their practices in this regard, and HHS issued new regulatory reform use intended to improve how the department issues guidance documents. This included an administrative petition process that allows interested parties to make challenges to guidance documents they consider to be unlawful.

"I hope that regulated entities hold agencies like HHS accountable for complying with their own regulations and the Administrative Procedure Act," Jenny said.

Conclusion

While fraud and abuse always remain constant in the field of health care compliance, regulation of the health care industry is constantly shifting, particularly taking into consideration the vast number of changes occurring as a result of the coronavirus pandemic. As the Biden Administration begins to pick up speed, check back with Wolters Kluwer for the latest on the government's enforcement actions.

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