August 18, 2020

- **Lesson 3 from the Novartis settlements: an ongoing lack of corporate integrity ushers in a potential new era of dreadnaught Corporate Integrity Agreements ("CIAs").**
  - Over the past two weeks we outlined two lessons learned from the recent settlements between the Department of Justice and Novartis Pharmaceuticals Corporations ("Novartis"): one regarding improper use of charitable foundations to cover patient copayment obligations, and the other addressing blatant foreign and domestic bribery schemes that led Norvartis to settle alleged violations of the False Claims Act ("FCA") and Foreign Corrupt Practices Act. The third and final lesson: years of improper behavior of the scale exhibited by Novartis reflects a deep-rooted problem that the government will seek to remedy through a CIA that applies significantly more corporate controls than typical CIAs.
  - On July 1, 2020, contemporaneous with the FCA settlements, Novartis entered into a 109-page CIA with the Department of Health and Human Services Office of Inspector General ("HHS-OIG"). The five-year CIA addresses the conduct at issue in the FCA violations and is Novartis-specific. Highlights include:
    - Mandated reduction in paid speaker programs, the amount spent on the programs, and a $10,000 cap per speaker;
    - Speaker programs may only occur within 18 months of the FDA product approvals and in a virtual, remote format;
    - Required measures to promote independence from any patient assistance programs to which Novartis contributes;
    - Implementation of a comprehensive monitoring program and engagement of an Independent Review Organization;
    - Hiring and retention of a Chief Compliance Officer ("COO"), creation of a Compliance Committee, and engagement of an independent Compliance Expert; and
    - Novartis board members, executives, and independent compliance monitors are required to provide regular compliance certifications.
  - The comprehensiveness of the CIA likely is attributable to Novartis's status as a repeat offender. The activities that served as the basis for the two FCA settlements occurred shortly after Novartis entered into a 2010 CIA with HHS-OIG as part of a separate settlement and which was extended for five years in 2015. Still, it could have been worse – the CIA does not require a corporate monitor to make reports directly to the government.
  - **Key Takeaway**: CIAs in the health care space are often boilerplate documents that outline standard reporting requirements. They do not typically contain provisions requiring the appointment of COOs, compliance committees, and independent compliance experts. To be sure, the rigor of the Novartis CIA's monitoring program is understandable as an attempt to correct a repeat offender, but it may well be looked back upon as an evolutionary benchmark for best compliance program practices in the future. With Democrats positioned to make electoral gains this Fall and possibly win the White House, the next Administration's regulators may seek to wield the bulked-up Novartis CIA as a new floor for compliance programs, rather than an outlier.

- **Expect Possible Increased Antitrust Scrutiny of Large and Small Health Care Deals Under a Potential Biden Administration**.
  - With the table all but set for the election in November, prudence dictates considering what health care policy might look like under a potential Biden administration.
  - Although much of the focus has been on what changes might be made to expand health insurance coverage to more Americans, the prospect for shifts in antitrust enforcement priorities at the Federal Trade Commission (FTC) also warrant attention.
  - The Biden-Sanders Unity Task Force Recommendations reflect two areas of particular significance:
    - vigorous use of the antitrust laws to fight against "mega-mergers" in the hospital, insurance, and pharmaceutical industries that would raise prices for patients by undermining market competition;
    - incorporation of broader review criteria into regulator's analytical considerations, "including in particular the impact of corporate consolidation on the labor market, underserved communities, and racial equity"; and
    - the FTC and the Department of Justice Antitrust Division have already emphasized that promoting competition in labor markets, especially with respect to health care workers during COVID-19, is an important policy goal.
  - Past statements of Commissioner Chopra, one of two current Democratic FTC commissioners also provide insight into potential shifts:
    - In July 2020 Chopra issued a statement targeting private equity (PE) firms engaging in unreported roll-up acquisitions in the health care sector, observing that the median size of such transactions fall under the Hart-Scott-Rodino reporting thresholds and positing that they result in higher costs and "reduction in quality of care."
    - Accordingly, Commissioner Chopra suggested the FTC conduct an industry-wide study pursuant to Section 6(b) of the FTC Act to understand if non-reportable transactions in the health care sector have resulted in firms acquiring market power. A previous statement also advocated for a similar Section 6(b) study.
    - Commissioner Chopra suggests consideration of changes to the HSR Act based on the findings of the study.
  - **Key Takeaway**: The makeup of the FTC could look very different next year depending on the outcome of the election. If so, health care acquisitions may receive particularly close examination from the FTC. Review of large deals would be reinvigorated and there is likely to be a new focus on non-reportable PE transactions in the health care field. Moreover, the impact of consolidation on health care labor markets will likely receive increased attention. Providers and their counterparties should note that this extra scrutiny could affect both deal timing and certainty.
- **Reliance on agency-published Frequently Asked Questions ("FAQs") and similar internet pronouncements: the devil is in the details**.
  - The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has been accepting inquiries from health care providers and industry stakeholders regarding the application of OIGs enforcement authorities, namely the Federal Anti-Kickback Statute ("AKS")

and Beneficiary Inducement Civil Monetary Penalty ("Beneficiary Inducement CMP"), to existing or proposed business arrangements directly related to the pandemic. OIGs responses to such inquiries are posted online as answers to FAQs.

- On August 4, 2020, OIG tackled the following question: "Can clinical laboratories offer free COVID-19 antibody testing to Federal health care program beneficiaries who are contemporaneously receiving other medically necessary blood tests during the COVID-19 public health emergency?"
  - In its response, OIG states that providing free laboratory testing to Federal health care program beneficiaries implicates both the AKS and the Beneficiary Inducement CMP. Despite those concerns, however, OIG reasons that it provides substantial public health benefits and "pose[s] a sufficiently low risk of fraud and abuse," as long as certain enumerated safeguards are put in place.
- In a previous issue, we observed that the pandemic seems to have pushed us fully into the age of rulemaking via the internet, often in the form of FAQs on agency websites. Although the internet allows agencies to publish policy positions quickly, this approach can also muddy the waters regarding what guidance is "official" and what is merely an informal opinion.
- For example, the OIG FAQs are nothing more than "informal feedback" that "will not result in prospective immunity or protection from OIG administrative sanctions or prospective immunity or protection under Federal criminal law." Furthermore, OIG states that its informal feedback applies only to arrangements in existence during the COVID-19 public health emergency.
- Unlike the OIG FAQs, agencies such as the Small Business Association have published certain of their FAQs in the Federal Register as interim final rules, giving such FAQs the force and effect of law.
- **Key Takeaway**: As state and federal pronouncements continue to be issued at a quick pace, health care providers and industry stakeholders must understand the nature of any particular pronouncement published on an agency website and pay close attention to whether they have the force and effect of law or are otherwise qulified by the issuing authority, and then determine what level of reliance is appropriate.

Contacts

Mark S. Hedberg
mhedberg@HuntonAK.com

Matthew D. Jenkins
mjenkins@HuntonAK.com

Holly E. Cerasano
hcerasano@HuntonAK.com

Kevin Hahm
khahm@HuntonAK.com

Sean B. O'Connell
soconnell@HuntonAK.com