Health Law Connections
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Top Ten Issues in Health Law 2021: Fraud and Abuse Trends to Watch in 2021

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Stark and Anti-Kickback Reform. CMS and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) in November 2020 finalized eagerly awaited changes to the Stark Law and Anti-Kickback Statute regulations, which were proposed in October of 2019. The final rules represent a significant overhaul of the Stark Law and Anti-Kickback Statute regulations. Notably, CMS and OIG have adopted new exceptions and safe harbors intended to accelerate health care's transition to value-based reimbursement and coordinated care. The Stark final rule also clarifies key requirements for compliance, notably Stark's "Big 3" standards of fair market value, commercial reasonableness, and the prohibition on "taking into account" the volume or value of a physician's referrals. Many of the interpretations and positions in the final rules likely will impact future enforcement trends and ongoing False Claims Act whistleblower actions.

Watch for the End of the COVID-19 Flexibilities. Health care leaders have had to navigate a changing fraud and abuse regulatory environment due to COVID-19, but many of these changes are temporary. For example, on March 30, 2020, CMS issued blanket waivers of several Stark Law requirements related to COVID-19 physician arrangements. Soon after, on April 3, 2020, OIG also issued guidance stating that it would not impose administrative sanctions under the Anti-Kickback Statute for certain arrangements covered by the Stark blanket waivers. The waivers have provided needed flexibility to hospitals and health systems as they tackled challenging physician contracting, compensation, and staffing issues during the pandemic. Finally, CMS issued a number of Section 1135 waivers to provide relief from a variety of reimbursement and other regulatory requirements.

During the PHE, providers have entered into arrangements and set up care delivery systems that depend on these flexibilities. Some of these changes have specific conditions. For example, providers that intend to rely on the Stark Law waivers must do so for one of the six identified proper COVID-19 purposes. The waiver guidance also provides 18 distinct waivers and more than 20 examples of specific arrangements that could fall within the scope of one of the waivers. Providers should maintain separate documentation supporting their proper purpose and good faith reliance on the waivers. Providers are reminded that the waivers are only temporary and can be relied upon until the end of the declared PHE. While the pandemic does not appear to be ending soon, hopefully during 2021 it will. At this point, changes may need to be made to arrangements and activities that depend on these actions.

New Enforcement Efforts and Targets. The health care industry should expect COVID-19 to become a significant part of the government's fraud enforcement efforts into 2021 and beyond. The main reason for this shift is the tremendous amount of new federal spending to address the pandemic, including the Provider Relief Fund program in the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Paycheck Protection Program and Health Care Enhancement Act. As many funding recipients know, the HHS, through the Health Resources and Services Administration (HRSA) has issued, and continues to change, a growing body of sub-regulatory guidance in the form of "frequently asked questions" and position statements on many facets of the program, such as the permitted uses for the funds. In addition, HRSA has created reporting obligations for any recipient who has received more than $10,000 from the program, with the first report due February 15, 2021. HHS has said many times that it expects to engage in significant audit activity of funding recipients, and we should also expect scrutiny from the Department of Justice (DOJ) and whistleblowers as time goes on.

Another reason for expecting a COVID-19 shift in fraud enforcement activity is the expansion of telehealth and the other ways in which HHS waived many federal health program requirements to allow greater flexibility in addressing the pandemic. When the dust settles, actions taken under loosened restrictions will likely come under increased scrutiny. We already have started to see an increase in telehealth enforcement in 2020. Notably, telehealth was the focus of the record-setting Health Care Strike Force Taskforce takedown that was linked to $4.5 billion in allegedly false and fraudulent claims. This takedown also involved other high priority areas, including opioids, durable medical equipment, and genetic and other diagnostic testing. The government's likely continued focus on telehealth, combined with the ongoing expansion of coverage for telehealth services, provides an important opportunity for organizations to evaluate their telehealth service offerings and arrangements and to further enhance their related compliance activities in this evolving area.