The Public Health Emergency Is Finally (Almost) Over: What Does That Mean for Stark Law and Anti-kickback Statute Compliance?

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The COVID-19 public health emergency (PHE) will expire at the end of the day on May 11, 2023, which is less than three months away. In the early days of the pandemic, the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) and numerous other state and federal agencies issued a variety of waivers, enforcement discretion, FAQs and other guidance largely geared towards supporting health care providers' ability to operate and continue to serve patients during unprecedented times. As the PHE draws to a close, the future of the flexibilities that have been in place for almost three years is taking divergent paths. Some items will remain in place, others will be gradually phased out and many will end suddenly on May 11. The flexibilities available to providers since early 2020 related to compliance with the Stark Law and Anti-kickback Statute fall into this latter category.

Recap of Stark Law Waivers & Anti-kickback Statute Enforcement Discretion

On March 30, 2020, CMS issued blanket waivers of certain aspects of the Stark Law. The waivers did not mean everything about the Stark Law was put on hold; rather, they were available for specific referral and financial relationships that were solely related to at least one "COVID-19 purpose". A "COVID-19 purpose" included the following:

- Securing services of physicians and other practitioners to furnish services.
- Ensuring the ability, or expanding the capacity, of providers to address patient and community needs.
- Addressing medical practice or business interruption.
- Diagnosis or medically necessary treatment of COVID-19.
- Shifting the diagnosis and care of patients to appropriate alternative settings.

CMS waived application of the Stark Law for 18 different types of financial and referral relationships as long as they were related to a COVID-19 purpose. For example, under the waivers a hospital might pay physicians at rates that exceeded their agreed-upon compensation and fair market value for furnishing professional services to COVID-19 patients, provide free medical office space on the hospital campus to allow physicians to provide services to hospital patients who do not require inpatient care or lend money to

physician practices to offset lost income resulting from cancellation of elective procedures due to COVID-19. Along similar lines, a physician group practice might elect to furnish designated health services in a location that does not meet the tests required under the in-office ancillary services exception such as by bringing a mobile diagnostic imaging center to a hospital campus and sharing that center with other groups and thereby freeing up hospital space for COVID patients. Shortly after announcing the Stark Law waivers, the HHS Office of Inspector General (OIG) announced that it would exercise its enforcement discretion under the Anti-kickback Statute for remuneration related to COVID-19 that was covered by 11 of the 18 the Stark Law blanket waivers.

What Does the End of the Waivers Mean?

The end of the waivers on May 11 means that providers subject to the Stark Law and Anti-kickback Statute will not be able to rely on the flexibilities that were in place during the PHE for their relationships going forward. Rather, any financial and referral relationships after that date will need to comply with these laws just as they were required to do so prior to March 2020.

However, the current version of these laws is not the same as that which was in place prior to the pandemic. Both laws have been subject to significant modifications during the course of the PHE and there have also been important enforcement developments that could affect compliance. Providers that operated under the waivers and that need to bring financial relationships into compliance with traditional exceptions will need to bear all of this in mind. Key developments include the following:

- The December 2, 2020 Final Rule that "modernized and clarified" the Stark Law (the "MCR") revised a number of critical Stark Law principles, including the definition of fair market value and commercial reasonableness, the analysis to be applied in determining whether compensation takes into account the volume or value of referrals or other business generated, the test for determining whether an indirect compensation arrangement exists and the indirect compensation exception most often used to insulate those arrangements. The MCR also made changes to a number of other commonly used Stark Law exceptions.
- Changes to the definition of "group practice" that were made as part of the MCR, but that were given a delayed effective date of January 1, 2022. Key changes included new guidelines on sharing profits from ancillary revenue (such as imaging, clinical lab and physical therapy services) among group practice physicians. Many physician-owned clinics compensate their doctors in ways that are permitted only for qualifying group practices so maintaining compliance with the updated definition is critical.
- Court decisions that should focus providers' attention on what "fair market value" means. In *U.S. v. Medtronic* (2022 WL 541604), a recent decision addressing a False Claims Act case against Medtronic based on allegations that the Anti-kickback Statute was violated, a California federal court found that it was plausible that paying a physician $3200 as a stipend for proctoring services intended to reflect 8 hours of work exceeded fair market value and was thus was an inducement to generate business. The court also indicated that fair market value is not sufficient to establish compliance, noting that "even

some fair market value payments will qualify as illegal kickbacks, such as when the payor has considered the volume of reimbursable business between the parties, in providing compensation and otherwise intends for the compensation to function as an inducement for more business". For support, the court cited a 2020 federal court decision that noted "remuneration may violate the Anti-kickback Statute 'regardless of whether the payment is fair market value for services rendered'". The *Medtronic* case is scheduled for trial this summer, with a start date currently set for July 11, 2023.

- The 2022 Medicare Physician Fee Schedule revised the Stark Law's definition of indirect compensation arrangement to address relationships for the rental of equipment or office space. This rulemaking also established an updated test for defining individual units of compensation, which is important for purposes of determining whether an indirect compensation arrangement exists.
- Revisions to the Self-Referral Disclosure Protocol to require updated forms and document submissions for disclosures made after March 1, 2023. These changes include a new "Group Practice Information Form", which is intended to capture self-disclosures of violations of the in-office ancillary services or physician services exceptions based on the failure to meet the regulatory definition of group practice.

What Should Providers be Doing?

Not all providers relied on the Stark Law and Anti-kickback Statute waivers during the PHE. For those that did, however, it will be important to act promptly to ensure they have a full accounting of arrangements that used the waivers. Any such arrangements will need to be revisited to ensure either that the arrangement is concluded by May 11 or, if it needs to continue, modified so that it complies with the Stark Law and Anti-kickback Statute after that date. Any changes made to existing arrangements will need to be done in accordance with the Stark Law's guidelines on amending existing financial relationships.

A wide variety of arrangements could fall into this bucket. For example, the waivers gave hospitals and other entities flexibility to provide free telehealth equipment to physician practices to facilitate telehealth visits for patients who are observing social distancing. As of May 11, parties operating under a relationship like this would need to revise this arrangement if it will continue after that date so that it meets all elements of an exception—for example, for equipment lease or fair market value arrangements. Nine of the eighteen waivers permitted compensation that was either above or below fair market value. Any arrangements that relied on waivers related to fair market value and that will continue after May 11 will need to be reassessed to ensure payment terms satisfy applicable regulatory guidelines going forward. In addition, the waivers permitted loans between physicians and entities that had interest rates that were below fair market value or were otherwise made on terms not available from commercial lenders. CMS has made clear that repayment terms agreed to prior to the end of the PHE can continue to govern the relationship after the PHE ends. However, any disbursement of loan proceeds after May 11 would not qualify for the waivers and would need to satisfy the requirements of an applicable Stark Law exception. Similarly, the waivers established flexibility for parties to operate under business arrangements that were not documented in writing but otherwise complied with the requirements of a relevant exception. Parties will want to evaluate whether any such

arrangements have since been formalized in a written document.

Both CMS and OIG made clear that the burden is on providers to maintain records documenting how they complied with the waivers. These records must be produced to HHS upon request. There can be little doubt that increasing scrutiny of provider activity during the PHE will occur in coming months and years and compliance with the Stark Law and Anti-kickback Statute, which is often prosecuted under the False Claims Act, is likely to feature prominently in any initiatives in this regard. Organizations that have not already compiled and organized records of their compliance with the waivers would be wise to do so soon. This could be more difficult than expected, given the time pressures and unparalleled demands of the pandemic, particularly in the early days, and what that meant for organizations that were forced to scramble on a variety of fronts to grapple with COVID-19. The further parties get from the beginning of the pandemic, the harder it may become to locate documentation related to how a particular arrangement was established solely for COVID-19 purposes.

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If you have questions about the impending end of the Stark Law and Anti-kickback Statute waivers, please contact Jesse Berg (jesse.berg@lathropgpm.com / (612) 632-3374) or your Lathrop GPM attorney.