

Part B Insider (Multispecialty) Coding Alert

Fraud & Abuse: Don't Bank on the Stark Revamp Until 2021

Tip: Get your ducks in a row before the PHE ends.

If you were counting on the feds to finalize the Stark Law updates by year end, you may find recent events disheartening. The final rule release is not expected until next August, but experts warn that providers should start transitioning away from COVID-19 blanket waivers sooner rather than later.

Pocket This Stark Rundown and Timeline

Last year, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that rolled back and streamlined the Physician Self-Referral Law, commonly referred to as the Stark Law.

Refresher: In a nutshell, Stark essentially was designed to prevent conflicts of interest. It bars physicians from referring Medicare or Medicaid beneficiaries to a designated health services (DHS) in which they or their family members have an ownership interest - unless, of course, an exception applies.

Stark is not a criminal statute, which means you won't go to jail if you break only this law. It's a civil statute enforced by CMS. If you violate Stark, you could face civil monetary penalties (CMPs) and exclusion from Medicare and other federal health programs.

Now: CMS announced that though it had promised finalized Stark exceptions and changes by August 2020, it needs more time. "We are still working through the complexity of the issues raised by comments received on the proposed rule and therefore we are not able to meet the announced publication target date," according to an extension published in the Federal Register on Aug. 27.

In the notice, CMS indicates it now plans to release the final rule by Aug. 31, 2021.

Heads up: Some of the expected changes will require "providers to restructure their financial relationships upon the implementation of the new rules. As such, it is hoped that CMS can finalize the rule sooner than its new deadline," say attorneys **Timothy Fry** and **Gretchen Townshend** with McGuireWoods in the firm's FCA Insider blog.

Plus: The HHS Office of Inspector General (OIG) hasn't released its Anti-Kickback Statute (AKS) final rule either, nor an update - even though it released AKS proposals in tandem with CMS last fall.

"The OIG has not announced a similar extension for its proposed rule on the AKS. It is unclear whether the OIG must issue a similar extension notice, but there is speculation that OIG may also be delaying finalizing changes to the AKS," say attorneys **Karen S. Lovitch** and **Rachel Yount** with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. in legal analysis.

See the Stark details at www.govinfo.gov/content/pkg/FR-2020-08-27/pdf/2020-18867.pdf.



Plan Now for Post-COVID Compliance

At the end of March, CMS retroactively added 18 Stark-related blanket waivers to its cache of COVID-19 flexibilities. The OIG followed suit with its own AKS waiver list in early April, adding a frequently asked question set to be updated daily with stakeholder questions.

According to federal guidance, the Stark and AKS waivers will end when the public health emergency (PHE) concludes. However, there is speculation that some of the COVID-19-inspired rollbacks may become permanent or be adapted to align with some of the changes in the proposed rules.

"If this public health emergency continues for an extended period of time, which may be the case, and providers and facilities do not take undue advantage of the additional benefits as a means to induce or pay for referrals or other business generated, then CMS or OIG could determine that the Stark Law and AKS, respectively, should be amended to encompass the waivers on a permanent basis," acknowledge attorneys **Marianne Garner** and **Scott Shanker** of Butler Snow LLP in online analysis.

Caveat: In its FAQs, OIG mentions that its feedback on both Stark and AKS waivers is solely related to the pandemic and that fighting fraud is still its primary concern. Moreover, in the original waiver materials, OIG warned that it reserves the right to alter or "reconsider" flexibilities and "modify or terminate this policy statement."

Plus, since there is no "grace period to unwind temporary arrangements after the COVID-19" pandemic ends, providers may want to start thinking about how they're going to address the "practical implications" of day-to-day business without the blanket waivers, suggest Garner and Shanker.

"While fair market value requirements have been waived in certain circumstances, parties should still conduct a risk assessment under other applicable federal and state fraud and abuse laws, rules and regulations," Garner and Shanker say.

Resources: Review the Stark Law blanket waivers' announcement from March 30 at www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

See CMS' April 21 explanatory guidance on Stark waivers at www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf. Find the OIG policy statement at <https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf>.