

# CMS FINALIZES UPDATES TO THE STARK LAW TO REDUCE REGULATORY BURDENS AND PROVIDE FLEXIBILITY TO PROVIDERS

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## Health Care Alert

By: Carolyn Fixel Merritt, Kelsey U. Jernigan, Hannah C. Maroney, Macy L. Flinchum

On 2 December 2020, the Centers for Medicare & Medicaid Services (CMS) published a Notice of Final Rulemaking in the *Federal Register* (Final Rule)<sup>1</sup> modifying the regulations implementing the federal physician self-referral law (the Stark Law).<sup>2</sup> In the Final Rule, CMS largely finalizes many of the proposals set forth in the Proposed Rulemaking issued on 17 October 2019 (Proposed Rule), with certain modifications. CMS has indicated that many of the changes to the Stark Law are intended to provide additional flexibility and reduce administrative burden to health care providers in structuring arrangements to comply with the Stark Law, driven by the Department of Health and Human Services' initiative to accelerate the transformation of the health care system to better pay for value and promote care coordination, titled the "Regulatory Sprint to Coordinated Care." The final regulations go into effect on 19 January 2021, with the exception of the amendments to the group practice definition in 42 C.F.R. § 411.352, which are effective beginning 1 January 2022.

The Final Rule finalizes many of the proposals that CMS described in the Proposed Rule, which, unsurprisingly received substantial positive feedback from the health care industry. Overall, the new Stark Law exceptions and updated interpretations of key concepts builds significant flexibility into the technical Stark Law regime and will likely achieve the stated intent of reduced regulatory burden. We anticipate that the amendments and clarified policies will impact a multitude of arrangements between institutional health care providers and physicians.

This Alert focuses on the amended definitions, new nonvalue-based care exceptions, and significant policy clarifications included in the Final Rule, each of which is described in further detail in K&L Gates' White Paper on the 2020 Final Rule Changes to the Stark Law, available [here](#). The changes related to value-based care finalized in the Final Rule, including the new Stark Law exception for value-based arrangements, will be addressed in an upcoming K&L Gates Alert.

The key changes to the Stark Law include the following:

- **New and Changed Definitions for Fundamental Terms:** In the Final Rule, CMS adds a regulatory definition for "Commercially Reasonable," a requirement included in multiple Stark Law exceptions but not previously defined in regulations. The Final Rule also significantly amends the definitions of "Fair Market Value" and "General Market Value."
- **New "Volume or Value" Standard:** CMS amends its interpretation of the "volume or value" and "other business generated" standards referenced throughout Stark Law exceptions by codifying a new special rule on compensation that defines exactly when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties. In addition to the new

regulatory explanation of the “volume or value” standard, the Final Rule includes substantial guidance as to determining whether compensation arrangements take into account the volume or value of referrals or other business generated between the parties.

- **New Exception for Limited Compensation to a Physician:** CMS finalizes a new Stark Law exception that protects remuneration to a physician up to an aggregate annual amount of US\$5,000, which does not need to be set forth in a signed writing or establish compensation that is set in advance.
- **New Exception for Cybersecurity Technology and Related Services:** CMS finalizes a new Stark Law exception to protect certain donations of cybersecurity technology and related services.
- **Additional Flexibility Related to the Signature and Writing Requirements:** In the Final Rule, CMS amends the Stark Law to clarify that arrangements are “deemed” to be set in advance if the aggregate compensation, unit of compensation rate, or specific compensation formula is set out in writing (through a collection of contemporaneous documents) before the furnishing of items, services, space, or equipment for which the compensation is to be paid. CMS also adds a regulatory provision detailing the requirements for compensation terms to be modified during the term of an arrangement, permitting compensation to change as frequently as the parties' desire so long as certain requirements are met, such as the modified compensation being set in advance, in writing, and prior to the items, services, equipment, or space being furnished.
- **Other Definition Changes:** In addition to updating and adding the definitions for fundamental terminology such as “commercially reasonable” and “fair market value,” CMS also finalizes amendments to existing definitions of “DHS,” “Physician,” “Referral,” and “Remuneration,” as well as adding a definition for “Isolated Financial Transaction.”
- **Amendments to Existing Regulations:** CMS further finalizes proposals to amend the requirements for a group practice related to payment of profit shares and productivity bonuses, amend the special rule on compensation related to directed referral requirements, amend the exception for assistance to a physician to compensate a nonphysician practitioner, amendments to decouple the anti-kickback statute from the Stark Law, and other further outlined changes outlined in our accompanying [White Paper](#).

K&L Gates' health care practice routinely assists health systems, hospitals, and other providers and suppliers with legal advice regarding Stark Law compliance, including provider contracting, transactional due diligence, internal compliance reviews and submission of Self-Referral Disclosure Protocols, and general strategic considerations.

## FOOTNOTES

<sup>1</sup> Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020).

<sup>2</sup> 42 U.S.C. § 1395nn; 42 C.F.R. §§ 411.350 *et seq.*

## KEY CONTACTS



**CAROLYN FIXEL MERRITT**  
OF COUNSEL

RESEARCH TRIANGLE PARK  
+1.919.466.1246  
CAROLYN.MERRITT@KLGATES.COM



**KELSEY U. JERNIGAN**  
PARTNER

RESEARCH TRIANGLE PARK  
+1.919.466.1113  
KELSEY.JERNIGAN@KLGATES.COM

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