

Report on Medicare Compliance Volume 28, Number 36. October 14, 2019 CMS Proposes Stark Makeover, With New FMV Definition, Value-Based Care Exceptions

By Nina Youngstrom

In a jam-packed Stark Law^[1] regulation proposed Oct. 9, CMS both refashioned exceptions that have been the bane of hospitals and physicians—and often powered false claims lawsuits—and introduced new exceptions for value-based care. If the regulation is finalized, there will be new definitions of fair market value, commercially reasonable, and volume or value of referrals, and providers could share payments in “value-based enterprises” without running afoul of the Stark Law, under certain conditions. A new limited compensation exception also made its debut.

The proposal, Modernizing and Clarifying the Physician Self-Referral Regulations,^[2] is the fruit of HHS’s Regulatory Sprint to Coordinated Care and CMS’s Patients over Paperwork Initiative, and was announced in tandem with a related proposal from the HHS Office of Inspector General.^[3]

“It would be pretty impactful if finalized,” says attorney Neal Shah, with Polsinelli in Chicago. “The set of changes would make Stark more predictable, and could make it easier for hospitals to avoid a lot of the common areas of inadvertent, technical noncompliance we often see.”

The Stark Law bars Medicare payments for designated health services (DHS) referred by physicians who have a financial relationship with the entity providing the DHS, unless an exception applies. Violations of the Stark Law have been the premise of countless False Claims Act^[4] lawsuits and settlements.

Two of the proposals clarify the Stark Law’s definitions of commercially reasonable and fair market value, which are pillars of virtually every exception. In Stark regulations over the years, CMS has described arrangements as commercially reasonable if the DHS entity considers them prudent even without the physician’s referrals.

CMS is proposing two options for the definition of “commercially reasonable”: (1) “the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements,” or (2) “the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.”

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