CMS proposes to recalibrate the scope and application of the Stark regulations

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As part of the long-awaited proposed changes "to modernize and clarify" the regulations that interpret the Physician Self-Referral Law (the "Stark Law") released on October 9, 2019, the Centers for Medicare and Medicaid Services (CMS) is proposing to recalibrate the scope and application of the regulations. These clarifications provide helpful insight into how CMS interprets the Stark Law and, in some instances, proposes to modify the existing regulations.

Specifically, CMS is proposing to:

- Decouple the Stark Law from the Anti-Kickback Statute and other federal/state laws
  CMS is proposing to remove from all Stark exceptions the requirement that the Stark financial relationship must also comply with the Anti-Kickback Statute and other federal and state billings and claims submission laws and regulations. CMS no longer believes that this requirement is necessary or appropriate, in part because noncompliance with the Stark Law does not turn solely on a violation of these other federal/state laws. CMS cautions, however, that removing this requirement does not affect parties' obligation to comply with or liability under these laws and regulations.

- Revise the definition of "designated health services"
  CMS is proposing to clarify that a hospital inpatient service is not a designated health service (DHS) if furnishing the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System. For example, if a non-admitting physician orders an X-ray after the patient has been admitted to the hospital, that X-ray is not a DHS (and the claim for the X-ray would not be tainted by a noncompliant

financial relationship) because the rate of Medicare reimbursement is already set in the diagnosis-related group. By contrast, if an admitting physician has a noncompliant financial relationship, all of the inpatient hospital services are DHS and could not be billed to Medicare. If finalized, this change could result in much lower or even no Stark damages when a hospital identifies a noncompliant financial relationship with a physician. However, this change will not apply (i) if the admitting physician has a noncompliant financial arrangement with the hospital; (ii) if the inpatient services result in an outlier payment; or (iii) to outpatient services.

- Revise the definition of "physician"
  To make the definition of "physician" in the Stark regulations consistent with the definition of "physician" in section 1861(r) of the Social Security Act, including all statutory limitations imposed on the definition of "physician" by section 1861(r), CMS is proposing to delete the current regulatory definition and simply cross-reference section 1861(r) in the Stark regulations definition of "physician."

- Clarify the definition of "referral"
  CMS is proposing to revise the definition of "referral" to explicitly state that a physician's referrals are not items or services for which payment may be made under the Stark Law and that the Stark Law exceptions do not protect payments for a physician's referrals.

- Revise an exception in the definition of "remuneration"
  CMS is proposing to remove from the definition of "remuneration" the current language excluding "surgical items, devices, or supplies" from the exception to the definition for items or devices used "solely" for specified purposes, regardless of whether the item or device is classified as a surgical device. If finalized, the exception would apply to the provision of items, devices or supplies that are used solely to (i) collect, transport, process or store specimens for the entity providing the items, devices or supplies, or (ii) order or communicate the results of tests or procedures to the entity. CMS clarified that the phrase "used solely for" does not mean that the item or device cannot qualify for the exception if it could theoretically be used for other purposes. Rather, the exception is available as long as the item, device or supply is in fact used only for the appropriate purpose.

- Clarify availability of the isolated transactions exception
  CMS clarified that the isolated transactions exception is not available to protect payments for multiple services furnished over an extended period of time, even if there is only a single payment for all services. CMS is aware that parties have attempted to use the isolated transactions exception to protect single payments for multiple services furnished over time when, after the services had been provided, they discovered that they failed to meet the writing requirement in the personal services or fair market value exceptions. CMS emphasized that "[t]he exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law" or to avoid compliance with the requirements of applicable exceptions, such as the personal services exception. This may be bad news for parties who relied on the isolated transactions exception to resolve these types of noncompliant arrangements. However, CMS is proposing other ways to resolve these situations, such as a 90-day period to reduce arrangements to writing and a new exception for limited remuneration to a physician.

- Modify guidance on the "period of disallowance"
  CMS is proposing to delete the "period of disallowance" rules, which describe the period during which a physician may not make referrals to a DHS entity, and the DHS entity may not bill Medicare for the referrals, due to a Stark violation. In explaining why it is proposing to delete these rules, CMS indicated that it believes the rules are overly prescriptive and impractical and are not being used by the industry as intended. CMS explained that the period of disallowance rules were intended to provide definite, practical steps to end a period of disallowance for those who chose to use them but were never intended to prescribe the only way to end a period of disallowance. CMS has observed, however, that the rules came to be treated as the only way to end the period of disallowance. CMS is now acknowledging that there are no definite rules for establishing in every case when a financial relationship has ended and, as a result, this analysis should

occur on a case-by-case basis. Thankfully, CMS made clear that the deletion of this language from the regulations will not affect parties who have previously relied on it.

In this part of the proposed rule, CMS is proposing a number of clarifications and changes to the Stark Law that will help the industry interpret the regulations and properly use the Stark exceptions. The proposed changes will likely generate many public comments regarding how these proposals will impact real-life arrangements. Public comments are due by December 31, 2019. As a result, CMS will not finalize the proposed Stark Law changes until 2020.

This publication is part of a series of updates regarding CMS and OIG's proposed fraud and abuse law changes. Bricker & Eckler's health care attorneys will continue to publish analyses of the proposed rule.

Authors