PUBLICATION

Increased Flexibility Under the Stark Law for Signature AND Writing Requirements

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As CMS works to modernize and clarify the Physician Self-Referral (Stark) Law, the proposed rule published on October 17, 2019 includes a proposed revision that would provide greater flexibility for many nonabusive arrangements. Based on comments received, as well as experience with the Voluntary Self-Referral Disclosure Protocol (SRDP), CMS has reconsidered its stance on temporary noncompliance with the signature and writing requirements of various compensation arrangement exceptions.

CMS policy regarding a grace period for satisfying the writing requirements of a Stark Law exception has formerly been that such a grace period posed a risk of program or patient abuse. However, in reviewing SRDP submissions, CMS has found many compensation arrangements with "short periods of noncompliance" dealing exclusively with the writing or signature requirements. CMS found these arrangements otherwise fully satisfied the requirements of an applicable compensation exception, and the writing or signature deficiency was often the result of parties commencing the arrangement before key arrangement terms could be reduced to writing. As a result, CMS now considers such a grace period as not posing a risk of program or patient abuse and proposes a rule that affords a significant increase of flexibility for entities and physicians in their compensation arrangements.

Under the current regulations, each category of compensation arrangements must meet specific requirements to qualify for an applicable exception to the Stark Law general prohibition. Over the past decade, CMS has gradually increased the flexibility of the special rule for signature requirements, including eliminating a distinction between inadvertent and non-inadvertent failure to obtain signatures as well as eliminating the restriction to utilize the special rule only once every three years for the same physician. However, in 2015 and again in November 2018, CMS guidance declined to extend the temporary noncompliance grace period to the writing requirement of applicable exceptions to compensation arrangements. CMS reasoning included concern that an entity could potentially manipulate such a rule to compensate a physician for the volume or value of referrals during the grace period, as well as concern for an entity's inability to meet the "set-in-advance" requirement if "the only documents stating the compensation term of an arrangement were generated after the arrangement began."

For arrangements requiring parties' signatures in writing, the rules treat the signature requirement element as a procedural or "form" requirement and allow parties 90 days from the inception of the arrangement to obtain the required signatures. Thus, an entity complies with Stark Law, for the purpose of the subject arrangement, and can submit claims and receive payments for designated health services (DHS) if the compensation arrangement between the referring physician and the entity met all the requirements of the applicable exception, except for the signature requirement, and the required signatures are obtained within 90 days.

The current CMS proposal would eliminate the existing rule for temporary noncompliance with signature requirements and codify in its place the statutory special rule for temporary noncompliance enacted by the Bipartisan Budget Act of 2018. The statutory rule tracks the current rule, but also clarifies that the parties must obtain required signatures "not later than 90 consecutive calendar days immediately following the date on

which the compensation arrangement became noncompliant." Further, under the newly codified rule, CMS proposes to extend the temporary noncompliance grace period to the writing requirement.

Under such grace period, CMS would consider the writing requirement or the signature requirement satisfied if:

1. the compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s); and

2. the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception.

CMS notes these requirements would not be mutually exclusive. An arrangement neither in writing nor signed may still be compliant under the proposed rule, provided that both the required writing and signature(s) are obtained within the 90-day period and all other requirements of the applicable exception are met (including those relating to fair market value compensation and the volume or value of referrals).

Significantly, CMS issued a retraction of any previous statements suggesting compensation rates must be set out in writing before items or services are furnished to meet the set in advance requirement. Although there will be no change to § 411.354(d)(1) (considering compensation to be set in advance if it is "set out in writing before the furnishing of items or services"), CMS reconciles this as a "deeming provision" and demonstrates how parties may meet the requirement without first reducing the compensation to writing. For instance, parties may agree to a rate of compensation before furnishing services, but do not reduce such rate to writing before the first payment is made under the arrangement. A determination that the compensation was set in advance could be made if (i) the first payment is documented, (ii) sufficient documentation is compiled to satisfy the writing requirement in the first 90 days, and (iii) the agreed rate of the arrangement is evidenced by the same and consistent with the documented payment (i.e., no change in rate during the 90-day period).

Depending on facts and circumstances, even if the rate of compensation was not set in advance, CMS suggests parties may also be able to avail themselves of the newly proposed limited remuneration exception under § 411.357(z). If finalized, the documentation and initial payments under the proposed new exception could be employed in some circumstances to satisfy the set-in-advance requirement if the parties subsequently decided to extend the arrangement for a longer term. This proposed exception, which does not include a writing or signature requirement, could afford some short-term arrangements (90 days or less) new protection that was not previously available when writings nor signatures were never obtained. CMS also notes the various ways by which set-in-advance compensation could be documented, including, but not limited to, a collection of emails or texts as well as similar payments between parties from prior arrangements.

Takeaway

If these proposed changes are finalized, it is likely that many technical violations of the Stark Law will be avoided. CMS has proposed greater flexibility for arrangements to permit both a writing and a signature to occur within 90 days for arrangements that otherwise meet an applicable exception. We expect that this proposed change will receive considerable support in the comments submitted to CMS in response to the proposed rule. Hopefully CMS will offer greater clarity on when the set-in-advance element is met for compensation without a writing to ensure that CMS's intended increase in flexibility can be put into practice. Without certainty of satisfying this element, the potential for strict liability responsibility may limit the proposed flexibility somewhat. We caution that these are proposed revisions and are not applicable until CMS issues a final rule, hopefully next year.