Hogan Lovells

HHS tackles barriers to value-based care: Part two – Substantial Stark Law regulatory revisions proposed

October 18, 2019

Along with proposed Stark Law exceptions designed to accommodate value-based care models, the Centers for Medicare & Medicaid Services (CMS or the agency) proposed additional revisions to the Stark Law regulations (the proposed rule) on October 9, 2019. The proposed revisions, which include extensive clarifications on many Stark Law requirements that have long been viewed as unduly burdensome for compliance-oriented health care providers[1], are part of the Trump administration's goal to reduce regulatory compliance burdens through a "Regulatory Sprint to Coordinated Care." They follow and incorporate feedback from corresponding requests for information the agency issued in summer 2018.

These additional proposals and guidance do not expressly relate to value-based care, but help clarify or reduce some of the more difficult hurdles and technical pitfalls of the Stark Law that hinder greater collaboration among providers and physicians. This alert (part two) summarizes these important Stark Law proposals. Part one of this client alert, available here, focused on the administration's proposals to allow and encourage the shift toward value-based payment under both the anti-kickback statute (AKS) and Stark Law, as well as other key AKS proposals.

Comments on both rules are due by **December 31, 2019**.

Summary of proposed revisions and guidance

- **Commercial reasonableness: not a matter of profit and loss.** In recent years, a provider's "profit" (or lack thereof) on a physician's professional services has been a key area of focus in a number of high-profile Stark Law enforcement cases. In particular, enforcement litigation gave rise to a perception that compensation to a physician exceeding the reimbursement that an entity collects for the physician's professional services may presumptively render an arrangement not "commercially reasonable." Describing this view as a "widespread misconception" of the meaning of commercial reasonableness, CMS acknowledges that the Stark Law has never defined "commercially reasonable" and that the agency has issued very little guidance on the term. To clarify this important issue, the

---

[1] Centers for Medicare & Medicaid Services, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55766 (Oct. 17, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22028.pdf. As further background to the wide-ranging proposals, CMS noted that its review of over 1,100 self-disclosure submissions, most of which involved compensation arrangements, provided additional insight into the degree of risk posed by various financial relationships and circumstances. See proposed rule at 55771.

proposed rule would specify that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. The proposed rule would further refine the focus of the inquiry: an arrangement is commercially reasonable if it furthers the legitimate business purposes of the parties and has similar terms as like arrangements.[2]

As potential examples of legitimate reasons for providers to enter into arrangements that are not directly profitable, CMS noted several examples cited by commenters, such as community need, timely access to health care services, fulfillment of licensure or regulatory obligations, the provision of charity care, and the improvement of quality and health outcomes.[3] In contrast, arrangements failing to meet the commercial reasonableness standard, even if appearing legitimate on the face of an agreement, include duplicate and unnecessary arrangements and those that would violate criminal law.[4]

- **Volume or value of referrals: objective, mathematical test.** The agency proposes to introduce an "objective test" to clarify that compensation "takes into account the volume or value of referrals" **only** if the **formula** used to determine compensation includes the physician's designated health services (DHS) referrals to the entity as a variable **and** there is a positive correlation between referrals and compensation.[5] In commentary, the agency explained that "merely hoping for or even anticipating future referrals…is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals."[6]

  The proposed change suggests that there would be no "volume or value" problem in two often-analyzed situations: (a) where there is a mere statistical correlation between compensation and referrals (without referrals being included in the compensation calculations), and (b) where the parties have considered or anticipated a physician's referrals, in a general sense, when entering into an arrangement. In addition, for fixed, nonvariable compensation, the proposed rule specifies that there would be a "volume or value" problem only if there "is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement" (such as future salary levels that are predicated on reaching certain referral thresholds in prior years). While CMS seeks comments on these proposals, the guidance accompanying the proposed changes appear to have a clarifying and immediate effect – the agency stated that its commentary should be read to "supersede" prior guidance on the subject.[7]

- **Inadvertent payment errors do not necessarily cause noncompliance, depending on how they are discovered and addressed.** Overpayments and underpayments in physician relationships resulting from administrative mistakes are a frequent Stark Law challenge for providers. Commentary accompanying the proposed rule states that these errors do not cause Stark Law noncompliance if they are rectified during the "initially anticipated" term of the arrangement and other conditions remain satisfied (e.g., the payments remain fair market value). The agency stated that the conclusion that such errors necessarily caused noncompliance "was never [its] intent."[8] Instead, commentary suggests that the correction of inadvertent payment errors during the term of the arrangement is part and parcel of an

---

[2] CMS solicits comments on an alternative proposal that would be similar to the agency's limited commentary on the term. Under that alternative, a commercial reasonable arrangement would be defined as one that "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."

[3] Proposed rule at 55790.

[4] *Id.*

[5] Proposed 42 Code of Federal Regulations 411.354(d)(5)(i)(A).

[6] Proposed rule at 55794.

[7] Proposed rule at 55792.

[8] Proposed rule at 55810.

effective compliance program. The agency suggests that noncompliance could result, in contrast, where the error is addressed after termination of the arrangement (with the agency suggesting the parties cannot "simply unring the bell" in that situation) or where it would be appropriate under the circumstances to view the error as resulting in a "secondary financial relationship" (e.g., where under-collection of amounts owed may be considered an interest-free loan).[9] To effectuate this guidance, CMS proposes to delete its existing regulations stating that the "period of disallowance" ends no later than the time that, between the parties, overpayments are refunded or additional payments are made to rectify underpayments.[10] The purpose in deleting those provisions is to "no longer prescribe the particular steps or manner for bringing the period of noncompliance to a close."[11]

On the other hand, CMS clarified that the isolated transactions exception does not apply to make-up payments between parties for a series of items or services already provided. In other words, it does not provide an umbrella to retroactively cure payment deficiencies in arrangements for which another exception is applicable (e.g., leases and physician services agreements).

- **Writings compiled after an arrangement has begun.** In recent years, CMS amended the Stark Law regulations to allow parties to obtain signatures on writings up to 90 days following commencement of an arrangement, regardless of whether the lack of signature was inadvertent. Under the proposed rule, parties would be allowed even more flexibility in that the written agreement itself could be completed within 90 days without causing noncompliance.[12] In addition, the agency emphasized that this change is not intended to replace its guidance on a writing being evidenced by a "collection of documents." In other words, a signed writing would need to be in place in some form (whether a formal contract or a collection of documents evidencing the agreement) within 90 days.
- **Changes to exceptions available for leases.** Under the proposed rule, the "fair market value arrangements" exception would be amended to also apply to leases (whereas it currently expressly precludes them).[13] Given the differences in existing exceptions, the practical impact of this change would be to allow additional protection for leases that have a term of less than one year. In addition, commentary to the proposed rule clarifies that the "exclusive use" requirement of the lease exceptions simply means that the lessor cannot be invited to use the space, making clear that the lessee may invite other parties to use the space and that multiple lessees may use the space concurrently. The agency explained that the intent of the "exclusive use" requirement essentially is to prevent sham arrangements where the lessor continues to use space or equipment ostensibly leased to another party.
- **Proposed "limited remuneration" exception for certain arrangements.** The proposed rule would add an exception for arrangements involving low-value payments to physicians (less than US$3,500 per calendar year, adjusted for inflation).[14] While the exception would require fair market value payment and other basic safeguards, the key aspects of this exception are the lack of set in advance, writing, and term requirements.[15]
- **Regained relevance for "payments by a physician" exception.** The Stark Law statute has a very basic exception for situations when a physician makes payment to an entity (as

---

9 Proposed rule at 55808 to 55811.
10 See 42 Code of Federal Regulations 411.353(c)(1)(i)-(iii).
11 Proposed rule at 55810.
12 Proposed rule at 55813.
13 Proposed 42 Code of Federal Regulations 411.357(l).
14 Proposed 42 Code of Federal Regulations 411.357(z).
15 This proposed exception would change the Stark Law analysis, but most applicable AKS safe harbors would continue to require a written agreement. Thus, a signed writing would still be recommended for most arrangements.

compared to an entity paying a physician), that applies to any payment for clinical laboratory services or any fair market value payment for anything else. The regulatory equivalent of this exception applies only if no other Stark Law exception is applicable. In prior commentary, for anything other than clinical laboratory services, CMS explained its view that the "payments by a physician" exception was essentially closed by the regulatory publication of the "fair market value arrangements" exception, which applies to payments made either by or to a physician.[16] The proposed rule would change the existing landscape by limiting the payments by a physician exception to arrangements for which no statutory exception is applicable.[17] Because there is no statutory "fair market value arrangements" exception, the "payments by a physician" exception (with no writing or "volume or value" requirements) would be more available. Specifically, it would apply to any items or services furnished by an entity to a physician for which there is no specific statutory exception (therefore excluding leases, for example).

- **Trimmed liability for DHS furnished to an inpatient.** Under the proposed rule, services such as diagnostic imaging and laboratory services furnished to a hospital inpatient would not be considered to be Stark Law DHS if they do not affect Medicare reimbursement under the Inpatient Prospective Payment System (IPPS).[18] One impact of this change is with respect to specialists ordering diagnostic services pursuant to a consultation requested by an attending physician. If the hospital had a noncompliant financial arrangement with the specialist, IPPS reimbursement would not be disallowed simply on account of the specialist ordering services that do not change IPPS reimbursement (assuming that financial relationships with other relevant physicians remain compliant).

- **Wider use of carve-out for items and services "used solely" to collect specimens.** The existing carve-out to the definition of "remuneration" applicable to specimen collection supplies does not apply if the supplies are considered "surgical." In a 2013 advisory opinion, CMS found that certain biopsy brushes would be considered surgical and would therefore not qualify for this protection. The proposed rule would delete the existing regulatory language stating that the carve-out for collection supplies does not include surgical items, and seemingly allow for more flexibility with respect to items such as biopsy brushes.[19]

If you are interested in commenting or have questions about the proposed rules, please do not hesitate to contact the Hogan Lovells lawyer with whom you regularly work or any Hogan Lovells lawyer listed on this alert.

---

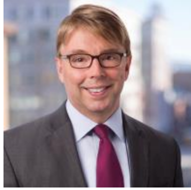
16 Compare to the personal services exception, for example, which only applies to payments to a physician for services rendered to the entity.

17 Proposed 42 Code of Federal Regulations 411.357(i)(2).

18 Proposed 42 Code of Federal Regulations 411.351 (definition of "designated health services"); Proposed rule at 55805.

19 Proposed 42 Code of Federal Regulations 411.351 (definition of "remuneration"). CMS did not discuss the impact, if any, if the surgical collection supplies are used in connection with a billable physician service. In addition, on a very general level, CMS stated that how an item is actually used affects the determination of whether or not is "used solely" for specified purposes (with the very basic hypothetical example of a collection device used as a doorstop not being "used solely" to collect specimens).

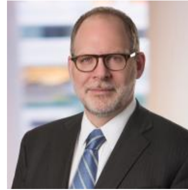
Contacts



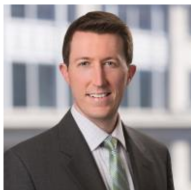
Ronald L. Wisor, Jr.
Partner, Washington, D.C.
T +1 202 637 5658
ron.wisor@hoganlovells.com

Helen R. Trilling
Partner, Washington, D.C.
T +1 202 637 8653
helen.trilling@hoganlovells.com

Jonathan L. Diesenhaus
Partner, Washington, D.C.
T +1 202 637 5416
jonathan.diesenhaus@hoganlovells.com



Thomas Beimers
Partner, Minneapolis, Washington, D.C.
T +1 612 402 3025 (Minneapolis)
T +1 202 637 5600 (Washington, D.C.)
thomas.beimers@hoganlovells.com



David E. Thiess
Senior Associate, Washington, D.C.
T +1 202 637 5773
david.thiess@hoganlovells.com

www.hoganlovells.com

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses.
The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members.
For more information about Hogan Lovells, the partners and their qualifications, see www. hoganlovells.com.
Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.
© Hogan Lovells 2019. All rights reserved.