Katten

Health Care Advisory

CMS Proposes Sweeping Revisions to the Stark Law

October 17, 2019

"CMS Proposes Sweeping Revisions to the Stark Law" is Part I of a two-part series discussing the US Department of Health and Human Services' (DHHS) recent proposed rules revising the Stark Law and the Anti-Kickback Statute as part of DHHS' Regulatory Sprint to Coordinated Care. This Part I installment relates to the Stark Law proposed rule.

KEY POINTS

- On October 17, 2019, CMS proposed rules to modernize and clarify the Stark Law regulations. The proposed changes impact virtually all existing Stark Law exceptions.
- The proposals include new exceptions for value-based arrangements (VBAs), donations of cybersecurity technology and limited remuneration without a written agreement.
- CMS also proposes several clarifications that negate arguments raised to support Stark Law allegations against providers in high profile cases. In particular, CMS proposes to:
  - clarify that arrangements that do not result in profit may still be commercially reasonable;
  - establish an objective, mathematical test for determining whether compensation takes into account the "volume or value" of a physician's referrals to or other business generated for an entity;
  - clarify that an employed physician's productivity bonus does not take into account the volume or value of the physician's referrals solely because hospital services are billed each time the physician personally performs a service; and
  - Delete the condition that an arrangement not violate the Anti-Kickback Statute from every exception where it appears today.
- Comments on the proposed rules are due by December 31, 2019.

On October 17, the Centers for Medicare & Medicaid Services (CMS) published for public comment a proposed rule to establish new exceptions and clarify existing Stark Law[1] regulations entitled, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations". Generally, the Stark Law prohibits physicians from making referrals for certain designated health services (DHS) to an entity with which he or she has a financial relationship unless an exception applies. The Stark Law is a strict liability statute, meaning that a financial relationship must meet every aspect of a regulatory exception in order to be immune from liability.

[1] Section 1877 of the Social Security Act.

In the regulatory preamble, CMS acknowledges that the Stark Law and its existing regulations were initially enacted to prevent fraud and abuse under a fee-for-service payment model. Recognizing that the Stark Law may impede the transition to value-based care models that align payment with the quality and cost-effectiveness of care, CMS proposes specific Stark Law exceptions for value-based arrangements (VBAs). Among other things, a VBA must involve a value-based activity that is reasonably designed to achieve at least one "value based purpose," defined as:

1. coordinating and managing the care of a target patient population;
2. improving the quality of care for a target patient population;
3. appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
4. transitioning from care delivery and payment mechanisms based on volumes to mechanisms based on the quality and cost control of care for a target patient population.

The making of a referral would ***not*** be a value-based activity.

VBAs

CMS proposes exceptions to protect the following three types of VBAs:[2]

- **Full Financial Risk (§ 411.357(aa)(1)):** This exception would apply to VBAs between value-based entity participants that assume full financial risk. The value-based entity must be financially responsible for the cost of all patient care items and services. CMS explains that full financial risk could include capitation payments or a global budget and the financial risk must be prospective. Further, the proposed exception requires that: (a) the remuneration paid is not to reduce medically necessary care; (b) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals, the arrangement satisfies the special rules on compensation; and (c) records are retained for at least six years.
- **VBAs With Meaningful Downside Financial Risk to the Physician (§ 411.357(aa)(2)):** This exception is available for remuneration resulting from value-based activities that is paid under a VBA where the physician is at meaningful downside financial risk[3] for failure to achieve the value-based purpose for the entire term of the VBA. CMS proposes that: (a) the arrangement must be in writing; (b) the remuneration methodology must be set in advance; (c) the remuneration paid is not to reduce medically necessary care; (d) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals the arrangement satisfies the special rules on compensation; and (e) records are retained for at least six years.
- **VBAs (§ 411.357(aa)(3)):** This exception would protect remuneration for value-based activities of any VBA regardless of the level of financial risk involved. Much like the previous exceptions, CMS proposes that: (a) the arrangement must be in writing — including specific requirements of the writing to outline the arrangement; (b) the performance/quality metrics are used to measure the recipient; (c) the remuneration methodology must be set in advance; (d) the remuneration paid is not to reduce medically necessary care; (e) the remuneration is not conditioned on referrals of patients who are not part of the target patient population, and if remuneration is otherwise conditioned on referrals, the arrangement satisfies the special rules on compensation; and (f) records are retained for at least six years. CMS also is seeking comment on whether to include a recipient financial contribution requirement under this exception.

---

[2] CMS also proposes to update the Indirect Compensation Arrangement exception (42 C.F.R. § 411.357(c)(4)) and the Group Practice definition (42 C.F.R. § 411.352) to specifically apply to VBAs. Further, CMS solicits comment on whether it should require price transparency in every VBA exception..

[3] CMS proposes to define "meaningful downside risk" to mean that the physician is responsible for paying no less than 25 percent of the value of the remuneration (including in-kind remuneration) the physician receives under the VBA.

Proposed exceptions

In addition to the foregoing, CMS proposes the following two new exceptions:

- **Limited Remuneration to a Physician** (42 C.F.R. § 411.357(z)): Protection for limited remuneration to a physician that does not exceed an aggregate of $3,500 per year (adjusted annually for inflation) ***regardless of whether the arrangement is in a writing signed by the parties***.
- **Cybersecurity Technology and Related Services** (42 C.F.R. § 411.357(bb)): Protection for arrangements involving the donation of cybersecurity technology and related services.

Changes to existing Stark Law regulations

Finally, CMS proposes a number of changes and clarification to existing regulations:

- **Commercially Reasonable:** CMS clarifies that compensation arrangements that do not result in profit may still be commercially reasonable and solicits comment on two alternative definitions of commercially reasonable.
- **Volume or Value Standard and Other Business Generated:** Under the proposed bright line test, only when the mathematical formula used to calculate the amount of compensation includes as a variable referrals or other business generated, ***and*** the compensation amount correlates therewith, would compensation be deemed to take into account the volume or value of referrals or other business generated. Fixed rate compensation would take into account the volume or value of referrals only if a predetermined tiered approach based on the physician's prior referrals is used to determine the compensation amount.
- **Fair Market Value (FMV) Definition:** The proposed definition would eliminate the connection to the volume or value of referrals standard. In addition, three FMV definitions are proposed — a general definition, equipment rental and office space rental. Further, CMS proposed to clarify the definition of "general market value" to reflect the price that assets, services or rental property would bring as a result of *bona fide* bargaining between the parties in the subject transaction at the time. Per the preamble, "market value is based solely on the economics of the subject transaction and should not include consideration of other business the parties may have with one another."
- **Designated Health Services:** The definition of DHS would clarify that an inpatient hospital service does not constitute DHS payable by Medicare if the furnishing of the service does not affect the Medicare payment amount under IPPS.
- **Referral:** A referral would not be an "item or service" for which payment may be made under any Stark law exception.
- **Anti-Kickback Statute Compliance:** Lack of an Anti-Kickback Statute violation would no longer be an element of any Stark Law exception.
- **Patient Choice/Directed Referrals:** CMS proposes to make several exceptions that otherwise permit directed referrals subject to the special compensation rule at § 411.354(d)(4), which among other things prohibits directed referrals if the patient expresses a preference for a different supplier or provider, an insurer requires a different provider/supplier or the patient's physician determines that the referral is not in the patient's best medical interests.
- **Isolated Financial Transaction:** A new "isolated financial transaction" definition would exclude payment for multiple services provided over an extended period.
- **Period of Disallowance:** CMS proposes to delete the rules regarding a period of disallowance found at § 411.353(c)(1) as "overly proscriptive and impractical."
- **Signature or Writing Requirement:** A new rule would allow for temporary noncompliance with the writing or signature requirement of any compensation exception. The writing requirement or the signature requirement would be satisfied if: (a) the compensation arrangement satisfies all requirements of an applicable exception

other than the writing or signature requirement(s); and (b) 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.

- **Equipment and Space Leases:** CMS clarifies that the lessor (or any person/entity related to the lessor) is the only party that must be excluded from the use of space or equipment under § 411.357(a)(3) and (b)(2) for the lease to meet the exclusivity requirement.
- **Physician Practice Signature Requirement in Recruitment Arrangements:** CMS proposes to require a physician practice to sign a recruitment arrangement only if the physician practice does not pass directly through to the physician all remuneration paid by the hospital.
- **Compensation Unrelated to DHS:** Compensation would relate to DHS if the item or service relates to patient care services.
- **Electronic Health Records Items and Services:** CMS proposes to permit donations of cybersecurity software, to remove the sunset provision, update the definitions of electronic health record and interoperable, and modify the physician contribution requirement.
- **Assistance to Compensate a Nonphysician Practitioner:** CMS proposes to define "NPP patient care services" to mean direct patient care services furnished by an NPP or tasks performed by an NPP to promote the care of patients of the physician or entity with which the NPP has a compensation arrangement.

Conclusion

Given the breadth of the proposed changes, providers should carefully consider how their physician arrangements might be impacted and whether to submit comments to CMS.

CONTACTS

Katten's Health Care team continues to monitor this proposed rule. For more information, contact:

Lisa Atlas Genecov
+1.214.765.3676
lisa.genecov@katten.com

Laura Keidan Martin
+1.312.902.5487
laura.martin@katten.com

Joseph V. Willey
+1.212.940.7087
joseph.willey@katten.com

Rachel A. Adams
+1.212.940.8509
rachel.adams@katten.com