Prepared by Strategic Management Services, LLC
December 3, 2020

CMS Finalizes Changes to the Stark Law Regulations.

The Centers for Medicare & Medicaid Services (CMS) recently released a final rule to reduce the regulatory impact and burden of the physician self-referral law (Stark law). The Stark law prohibits physicians from referring patients for certain designated health services (DHS) payable by Medicare to entities in which they or their immediate family members have financial interests, unless a statutory or regulatory exception applies. In turn, these entities may not bill Medicare for prohibited referred services. Since the Stark law had not been significantly updated since 1989, the final rule modernizes the regulations to align with the current health care landscape of value-based health care and reduce unnecessary burden on physicians and other health care providers. The final rule revises and creates new exceptions, amendments, and guidance regarding the Stark law for certain value-based compensation arrangements. Additionally, CMS removed certain unnecessary requirements for some regulatory exceptions.

CMS finalized the following new exceptions and revisions to the Stark Law:

Value-Based Care and Care Coordination Exceptions. CMS finalized the three proposed exceptions for certain value-based compensation arrangements when they meet specific requirements based on the arrangement's characteristics and the financial risk undertaken by the parties involved. The exceptions apply to arrangements relating to care for both Medicare and non-Medicare patients. The three exceptions are:

1. Assumption of full financial risk - The exception protects remuneration pursuant to value based-arrangements between value-based enterprise (VBE) participants in a VBE that has assumed full financial risk for all patient care items and services for a target patient population for a specified time period. For Medicare beneficiaries, the VBE is fully financially responsible for all Medicare Part A and B covered items and services. In the final rule, CMS modified the proposed policy by extending the "pre-risk" period from six months to 12 months;
2. Assumption of meaningful downside financial risk - The exception protects remuneration paid under a value-based arrangement where the physician assumes meaningful downside financial risk for a failure to achieve the purposes of the VBE. In the final rule, CMS changed the financial risk the physician is responsible for from no less than 25 percent of the received renumeration as originally proposed to no less than 10 percent;
3. No consideration of risk - The third exception in this category applies to value-based arrangements regardless of the level of financial risk assumed. The arrangements protected by these exceptions must fit certain requirements to satisfy the exceptions.

CMS finalized a policy implementing exceptions for indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships, i.e., chain of

ownership interests and financial interests, between the physician and a third party. CMS clarified that the value-based arrangement exception applies regardless of whether the entity furnishing designated health services is a managed care organization (MCO) or independent practice association (IPA).

Cybersecurity Technology and Related Services. CMS finalized a new exception to protect arrangements involving the donation of certain cybersecurity technology and related services. Additionally, CMS retained the 15 percent cost-sharing requirement for all physician recipients of donated EHR items or services. However, CMS modified the timeframe in which physician recipients must pay the cost-sharing amount for donations subsequent to the initial donation from prior to the receipt of an initial donation to payment at "reasonable intervals."

Like the revisions to the Anti-Kickback Statute, the final rule also permits the donation of EHR items and services that are "equivalent" to items or services that the physician recipient has previously obtained, which will allow for the donation of replacement EHR technology in the same manner as new EHR technology.

Changes Regarding Fundamental Terminology and Requirements. The final rule updates definitions to key terms used in evaluating Stark Law requirements, including commercial reasonableness, fair market value, and general market value. The final rule also provides clarifying circumstances for parties to consider in determining whether compensation takes into account the volume or value of referrals, or the value of other business generated by a physician.

CMS finalized "commercially reasonable" to mean "*the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty*." Of note, CMS also notes that an arrangement may be considered commercially reasonable regardless of whether it results in profit for one or more of the parties.

CMS finalized separate definitions of fair market value as applied generally, as applicable to the rental of equipment, and as applicable to the rental of office space. Generally, fair market value is defined as "*the value in an arm's-length transaction, consistent with the general market value of the subject transaction.*" Fair market value in relation to equipment rental is defined as "*the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction*." Finally, fair market value in relation to the rental of office space is defined as "*the value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction*." CMS did not finalize its proposal to reference "*like parties and under like circumstances*" in regard to the definition of fair market value for office space and equipment rentals.

CMS also finalized the definition of "general market value" as it applies to asset acquisitions, compensation for services, and rental of equipment of office space.

In terms of clarification regarding whether compensation correlates with the volume or value of referrals or business generated, CMS provides clarification in regard to 1) compensation from an entity providing designated health services (DHS entity) to a physician and 2) compensation from a physician to a DHS entity. For compensation from a DHS entity to a physician, CMS finalized a policy that the compensation only will be deemed to take into account the volume or value of referrals or business generated if there is a positive correlation between the compensation and the volume or value of the referrals or business generated. In other words, the physician stands to receive additional compensation based on an increase in referrals or business generated. For compensation from a physician to a DHS entity, CMS finalized a policy that compensation will only be deemed to take into account the volume or value of referrals or business generated if there is a negative correlation between compensation and the volume or value of referrals or business generated. In other words, the physician pays less to the DHS entity based on an increase in referrals or business generated.

CMS finalized a policy, in relation to both types of compensation, prohibiting both the existence of the compensation arrangement and the amount of the compensation from being contingent on the volume or value of the physician's referrals to a provider, practitioner, or supplier, regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician.

Patient Choice and Directed Referrals. CMS finalized a new condition requiring that neither the existence of the compensation arrangement nor the amount of the compensation paid to the physician may be contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier; however, compensation may be an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

Qualifications for Group Practices. In the final rule, CMS updated provisions related to the distribution of profits from designated health services that are directly linked to a physician's participation in a value-based enterprise, confirming that the exception requires that compensation paid to a physician who is a member of a group practice may not be determined in any manner that accounts for the volume or value of referrals. Additionally, profit shares and productivity bonuses paid to a physician in a group may not be determined in any manner that takes into account the volume or value of the physician's referrals.

CMS also finalized its revision to the productivity bonus deeming provision, noting that the bonus will be deemed not to relate directly to the volume or value of a physician's referrals if it is based on the physician's total patient encounters or relative value units (RVUs) personally performed by the physician.

Ownership and Investment Interest. CMS finalized its proposal to expand the concept of titular interest, which was originally used in the context of compensation arrangements, to ownership or investment interest provisions. CMS noted that there a few fraud and abuse implications, since a physician with a titular ownership or investment interest in a possible referral recipient would not increase the financial interest of the physician.

CMS also declined to extend safeguards to employee stock ownership plans (ESOPs), noting that there are sufficient regulatory and legal protections within the Employee Retirement and Income Security Act (ERISA) that are applicable to ESOPs to prevent program and patient abuse.

Special Rules on Compensation Arrangements. CMS finalized a grace period of 90 days to satisfy the writing requirements for many arrangement exceptions, including for the rental of office space, the rental of equipment, personal service arrangements, and fair market value compensation. However, CMS noted that any formula for calculating compensation should be set out in advance and documented in some manner.

Exceptions for Rental of Office Space and Rental of Equipment. CMS finalized its proposal to modify the statutory text to clarify that in relation to the rental of office space and equipment exceptions, the only party that must be excluded from using the space or equipment is the lessor. CMS also clarified that the exclusive use requirement does not prohibit multiple lessees from using a rented space or equipment concurrently.

Exceptions for Physician Recruitment. CMS finalized its proposal to eliminate the signature requirement for a physician practice that receives no financial benefit under a recruitment arrangement to reduce undue burden on certain physician practices. However, the practice must sign the writing documenting the arrangement if the hospital's renumeration to the physician passes through the practice.

Exceptions for Remuneration Unrelated to the Provision of Designated Health Services. CMS sought comments in the proposed rule on whether it should limit what it considers to be "*renumeration related to the provision of designated health services*" to remuneration paid explicitly for a physician's provision of designated health services to a hospital's patients. CMS did not finalize this proposal over concerns raised by commenters on uncertainty regarding how the proposed exception would be applied.

Exceptions for Payments by a Physician. CMS is modifying its interpretation of the payment by physician regulatory exception, which had historically been interpreted as a catch-all provision, applying to items and services furnished by physicians to entities and items and services furnished by entities to physicians. CMS finalized a policy that the regulatory exception would not be available to protect compensation arrangements specifically addressed by one of the other statutory exceptions, including, but not limited to, exceptions for the rental of office space and equipment, bona fide employment relationships, and personal service arrangements.

Exceptions for Assistance to Compensate a Nonphysician Practitioner (NPP). CMS is finalizing its proposal to define NPP patient care services as they relate to the limited expansion of the physician recruitment exception to apply if the NPP has not practiced in the geographical area served by the hospital within one year of the start of the compensation arrangement. CMS finalized NPP patient care services to mean "*direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement*."

The rule will be effective 60 days after it is published in the Federal Register on December 2, 2020.

The final rule is available at:
https://public-inspection.federalregister.gov/2020-26140.pdf