

## CHANGES TO THE STARK LAW'S SPECIAL RULES ON COMPENSATION TO CREATE FLEXIBILITY AND REDUCE CONFUSION FOR PHYSICIANS AND OTHER PROVIDERS

**Overview.** In the Final Rule revising the federal Physician Self-Referral Law (Stark Law), the Centers for Medicare and Medicaid Services (CMS) implemented several important changes to the special rules on compensation.

**Introduction.** CMS published a Final Rule in the Federal Register on December 2, 2020, overhauling the regulations governing the federal Stark Law. These revisions include clarifying the phrase “set in advance,” modifying the requirements for directed referrals, and providing an objective test for determining whether compensation takes into account the volume or value of referrals. Importantly, these changes reduce unnecessary regulatory burden on health care physicians and other providers and suppliers, create flexibility for physicians and other providers to structure certain compensation arrangements, and reduce confusion, consistent with many other changes in the Final Rule. These changes went into effect on January 19, 2021.

**The Expanded “Directed Referral” Standard.** Recognizing that health systems, managed care organizations, and other entities employing or contracting for the personal services of physicians can have a legitimate business interest in steering patients to particular practitioners or facilities within the health system or managed care organization, CMS made three significant changes to directed referral requirements:

- Any changes to the compensation (or formula for determining the compensation) must be made prospectively;
- The physician’s compensation *may* take into account the volume or value of anticipated or required referrals (*i.e.*, deletion of the requirement that the payment *does not* take into account the volume or value of anticipated or required referrals); and

**PRACTICE NOTE:** CMS no longer believes that compensation predicated on the physician making referrals of DHS to a particular physician or provider should be evaluated for compliance with the volume or value standard. With the removal of this language, the directed referral requirement will no longer trigger analysis for compliance with the

- Regardless of whether the physician’s compensation takes into account the volume or value of referrals by the physician, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician’s referrals to the particular physician or other provider.

DISCLAIMER: The information presented is not meant to constitute legal advice. Please consult your attorney for advice on a specific situation. Of particular importance, many states have similar Stark and/or AKS laws that prohibit kickbacks and/or restrict physician self-referrals. The information presented is current as of the initial date of publication. Readers are encouraged to check government and other relevant websites for the most up to date information.

**PRACTICE NOTE:** However, the Final Rule includes specific language that the physician may be required to refer an established percentage or ratio of the physician’s referrals to a particular physician or provider. While CMS does not state if any percentage or ratio is too high, CMS did state that an arrangement that required 90 percent of patients to be referred to a particular physician or provider was permissible.

The referral requirement does not apply if:

- The patient expresses a preference for a different clinician, practitioner, or supplier;
- The patient’s insurer determines the clinician, practitioner, or supplier; or
- The referral is not in the patient’s best medical interests (in the physician’s judgment).

**Compensation Arrangements that Take into Account the Volume or Value of Referrals or Other Business Generated (OBG).** To provide the healthcare industry with “objective tests for determining whether compensation takes into account the volume or of referrals or other business generated by the physician...,” CMS defines when compensation from or to a physician takes into account the volume or value of referrals or other business generated by the physician. CMS divides the “volume or value of referrals” and OBG definitions into two contexts:

*Compensation Received by a Physician.* Compensation received by a physician takes into account the volume/value of referrals or other business generated by the physician *only if* the formula used to calculate the physician’s compensation includes the physician’s referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in the physician’s compensation that *positively correlates* with the number or value of the physician’s referrals to the entity.

**PRACTICE NOTE:** For example, a positive correlation exists if a physician’s compensation increases as the number of the physician’s referrals to the entity increases, or if the physician’s compensation decreases as the number of its referrals decreases.

*Compensation Paid by a Physician.* Compensation paid by a physician takes into account the volume/value of referrals or other business generated *only if* the formula used to calculate the entity’s compensation includes the physician’s referrals to or other business generated for the entity as a variable, resulting in an increase or decrease in the entity’s compensation that *negatively correlates* with the number or value of the physician’s referrals to or other business generated for the entity.

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**PRACTICE NOTE:** Under these definitions, a hospital's payment of a fixed salary to a physician will never offend the volume/value standards, even if the compensation is above fair market value. This is consistent with CMS' policy that the volume/value of referrals and other business generated standards are independent of the fair market value standard.

**The New Indirect Compensation Arrangement Definition.** The test for when a chain of financial relationships creates an indirect compensation arrangement (the indirect compensation definition) has been critical to Stark Law analysis for a long time. The new indirect compensation definition revolutionizes the indirect compensation definitional analysis. While not eliminating the indirect compensation exception, CMS has redesigned the indirect compensation definition so that few non-abusive unbroken chains of financial relationships will need the exception; in any event, it seems unlikely that any arrangement that satisfies the new indirect compensation definition would qualify for the exception. Due to these changes and the complexity of the Stark Law analysis, it is highly advised that physician's consult with an attorney when establishing or reviewing any compensation arrangements.

The new indirect compensation definition includes the following new elements and modifies previous elements – *all of which must exist*:

1. There must be an unbroken chain of financial relationships (any kind) running between the referring physician and the DHS entity;
2. At least one link in the chain must be compensation running towards the physician (the Relevant Compensation) and, if there is more than one such link, the one closest to the physician is the Relevant Compensation;
3. The aggregate Relevant Compensation *varies with* the volume or value of referrals or other business generated for the DHS entity down the chain;
4. The Relevant Compensation's "individual unit of compensation" is:
  - a. Not fair market value; or
  - b. Includes the physician's referrals to or other business generated for the DHS entity as a variable, resulting in an increase or decrease in the unit of compensation that positively correlates with the number or value of the physician's referrals to or OBG for the DHS entity down the chain.
5. The DHS entity knows or should know that the aggregate Relevant Compensation *varies with* the volume or value of referrals or other business generated for the DHS entity.

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**PRACTICE NOTE:** Key implications of the new definition include the following:

- Relevant Compensation that is a fixed or flat aggregate amount, such as a guaranteed salary, will not create an indirect compensation arrangement, regardless of whether the Relevant Compensation is FMV or not.
- Unit-based compensation, such as a rate of compensation per work RVU, resulting in *aggregate* compensation that “varies with” the number or value of the physician’s referrals or other business generated for a down-the-chain DHS entity (because of the correlation between the two), will only create an indirect compensation arrangement with the DHS entity if the “individual unit of compensation” is not FMV *or* is subject to an adjustment (the unit rate) based on the *number* or *value* of the physician’s referrals or OBG for the DHS entity.

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