

STARK LAW UPDATES

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At the end of 2015, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that resulted in major changes to the federal physician anti self-referral law (the “Stark Law”).¹ Those changes, most of which went into effect on January 1, 2016, include the addition of two new exceptions: one pertaining to the recruitment of non-physician practitioners; the other concerning timeshare arrangements.²

Stark Law Basics:

The Stark Law prohibits physicians from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship - unless an exception to the law applies.³ The law sets forth numerous exceptions that apply to ownership arrangements, compensation arrangements, or both.⁴

The Stark Law is a strict liability statute, meaning that parties can be held accountable for violating the law regardless of whether they intended to do so.⁵ Penalties for violations may include refund obligations, False Claims Act liability, exclusion from participation in federal health care programs, fines of \$15,000 per illegal referral, and penalties of up to \$100,000 for each scheme or arrangement intended to circumvent the law.⁶

New Exception – Non-Physician Recruitment:

Responding to a need for increased access to primary care services, this new Stark Law exception allows hospitals, federally qualified health centers, and rural health clinics (“Entity”) to provide remuneration to a physician for recruiting a non-physician practitioner into the Entity’s service area.⁷ Non-physician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical social workers, and clinical psychologists.⁸

¹ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for VY 2016, 80 FR 70866-01 (November 16, 2015).

² 42 C.F.R. § 411.357(x); 42 C.F.R. § 411.357(y)

³ 42 C.F.R. § 411.353

⁴ 42 C.F.R. § 411.357

⁵ 42 U.S.C § 1395nn(g)

⁶ *Id.*

⁷ 42 C.F.R. § 411.357(x)

⁸ *Id.*

In order to qualify for this exception, an arrangement must comply with various requirements, including the following:

- Substantially all of the services provided by the non-physician practitioner must be primary care or mental health services;
- In the year prior to the commencement of the non-physician practitioner's compensation arrangement with the physician, he or she may not have (i) practiced in the geographic area served by the Entity, or (ii) been employed by a physician with a medical practice located in the geographic area;
- The Entity can provide remuneration for only the first two consecutive years of the non-physician practitioner's engagement;
- The physician cannot impose practice restrictions on the non-physician practitioner that unreasonably restrict the non-physician practitioner's ability to provide care in the geographic area served by the Entity;
- The remuneration must be limited to no more than 50% of the aggregate compensation, signing bonuses, and benefits paid to the non-physician practitioner; and
- The Entity may provide remuneration to the same physician no more than once every three years, though exceptions to this requirement may be made under certain circumstances.⁹

New Exception – Timeshare Arrangements:

CMS has also added an exception that permits physicians and physician organizations or hospitals to share “space, equipment, personnel, items, supplies or services” through non-exclusive timeshare arrangements.¹⁰ When a physician organization or hospital provides space or equipment to a referring physician, such arrangements generally create a financial relationship that implicates the Stark Law. In order to comply with the law, timeshare arrangements previously needed to be structured in such a way so as to satisfy the Stark Law “Rental of Office Space” or “Rental of Equipment” exceptions (the “Rental Exceptions”).¹¹ Traditional timeshare arrangements in which physicians share space or equipment on a non-exclusive or “as needed” basis do not meet the Rental Exceptions requirements that the physician enter into a formal lease agreement providing for the exclusive use of the space or equipment for at least a term of one year.¹²

The new “Timeshare Arrangements” exception allows for non-exclusive or “as needed” timeshare arrangements under certain conditions, including the following:

⁹ *Id.*

¹⁰ 42 C.F.R. § 411.357(y)

¹¹ 42 C.F.R. § 411.357(a); 42 C.F.R. § 411.357(b)

¹² *Id.*

- The arrangement must be set out in writing – identifying the premises, equipment, personnel, items, supplies, and/or services covered by the arrangement – and signed by the parties;
- The arrangements may only be between a physician (or physician organization) and a hospital or physician organization of which the physician is not an owner, employee, or contractor;
- The “space, equipment, personnel, items, supplies or services” must be used predominantly for the provision of evaluation and management services to patients;
- The arrangement must not be conditioned on the licensee’s referral of patients to the licensor;
- Any licensed equipment must meet certain criteria (no advanced imaging, radiation therapy, or clinical/pathology lab equipment) and be located in the space where evaluation and management services are provided;
- The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business between the parties; and
- The arrangement must not convey a possessory leasehold interest in the office space that is the subject of the arrangement.¹³

Conclusion:

Physicians and entities seeking to take advantage of either of the two new Stark Law exceptions must ensure that their financial arrangements strictly comply with each provision of the relevant exception. Healthcare providers who have questions regarding Stark Law compliance are strongly encouraged to seek legal assistance to help navigate the maze of compliance steps needed to ensure that an arrangement meets the requirements of the Stark Law.

¹³ 42 C.F.R. § 411.357(y)