

NM – Stark Law Q&A*

* This Stark Law Q&A is for educational and informational purposes only. It is not legal analysis, opinion or advice and should not be relied upon as such. Moreover, it does not address state self-referral laws and other potentially applicable federal laws, such as the federal anti-kickback statute. Violation of the Stark Law could result in very serious legal consequences, including monetary penalties. Thus, if you have any questions or concerns about whether your practice complies with the Stark Law, consult with a competent health care attorney.

1. What is the Stark Law?

The Stark Law is a Medicare payment rule named after Rep. Fortney “Pete” Stark. Unless an exception applies, the Stark Law:

- prohibits a physician from making a referral to an entity (including the physician’s own practice) for the furnishing of certain designated health services covered by Medicare if the physician (or an immediate family member) has a financial relationship (ownership or compensation) with the entity; and
- prohibits an entity from submitting a claim or bill to any person for a service or item furnished pursuant to a prohibited referral.

2. What are the penalties for violating the Stark Law?

No payment may be made for a service furnished pursuant to a prohibited referral. Consequently, the billing entity is liable to the Medicare program and beneficiaries for any amounts collected. Persons who submit claims or cause claims to be submitted for services furnished pursuant to a prohibited referral, or who do not promptly refund amounts collected, are subject to civil monetary penalties of up to \$15,000 for each such service, and may be excluded from Federal health care programs. In addition, the U.S. Department of Justice has brought cases under the federal False Claims Act predicated on violations of the Stark Law. Often, these cases are initiated after individuals file a lawsuit under the whistleblower provisions of the False Claims Act.

3. Is Nuclear Medicine imaging a Stark designated health service?

Yes, effective January 1, 2007. The Centers for Medicare and Medicaid Services (CMS) added nuclear medicine services and supplies to the designated health services categories of “radiology and certain other imaging services” and “radiation therapy services and supplies” in its final rule for the Physician Fee Schedule for calendar year 2006 (published on November 21, 2005 (70 FR). **This change will not be effective until January 1, 2007**, providing one year for providers to unwind financial relationships that will not conform to Stark Law.

The professional and technical components of x-ray, ultrasound, (including echocardiography), CT, MRI, nuclear medicine, and bone densitometry procedures covered by Medicare and on the list of CPT/HCPCS codes posted on the Centers for Medicare and Medicaid Services' website (http://new.cms.hhs.gov/MedlearnProducts/40_PhysSelfReferral.asp). Exceptions to the Stark Law are made for:

- x-ray, fluoroscopy, or ultrasonic procedures that require the insertion of a needle, catheter, tube or probe through the skin or into a body orifice;
- procedures that are integral to the performance of a nonradiological medical procedure and performed (i) during the nonradiological medical procedure, or (ii) immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure

4. Is the Stark Law implicated when a physician practice furnishes NM scans to its own patients in its own office?

Yes, but if properly structured the practices' referrals for NM scans can qualify for the Stark Law's exception for in-office ancillary services. This is the exception that is relied upon by practices that provide clinical laboratory, x-rays and other ancillaries to Medicare beneficiaries in their offices.

5. Do radiologists need to be concerned about self-referrals for imaging services?

Referrals for imaging by a radiologist pursuant to a consultation requested by another physician are not "referrals" for purposes of the Stark Law, provided the imaging services are supervised by the referring radiologist or another radiologist in the same group practice. If a radiologist in private practice makes a referral that is not pursuant to a consultation requested by another physician, the referral must qualify for the in-office ancillary services exception (discussed below).

6. What must a physician practice do to ensure that its referrals for NM will qualify for the in-office ancillary services exception?

Two things:

- Satisfy the supervision, location and billing tests of the in-office ancillary services exception; and
- If the practice is a group of physicians, satisfy the Stark Law's definition of a group practice.

7. What does the supervision test require?

The NM must be provided by or under the supervision of the referring physician or if the referring physician is in a group practice, another physician in the same group practice.

8. What level of supervision is required?

The level of supervision that is required for purposes of Medicare coverage. With certain exceptions, NM scans without contrast media require general supervision (which does not require that a physician in the group practice be in the office suite or the building). NM scans with contrast media typically require direct supervision (which means that a physician in the group practice must be in the office suite, but not necessarily the same room, as the NM equipment). (If you do not know what level of supervision is required by Medicare for a particular NM scan, contact your local Medicare Part B carrier, or check the current National Physician Fee Schedule Relative Value File posted on the Centers for Medicare and Medicaid Services' website.)

9. What does the location test require?

The NM must be furnished either in the *same building* as the offices of the practice or, in the case of a group practice, the scans may be furnished in another building, provided the space is owned or leased (for at least six months) by the group on a full-time basis (7/24) and used exclusively by the group.

The criteria for what constitutes the “same building” are technical and require a careful examination of the particular facts to ensure that all elements of the criteria are met. Generally this requires locating the NM equipment in a building that satisfies one of the following three concepts:

- The building is the principal place of practice for the referring physician or group, and the practice furnishes some services in the building unrelated to Stark designated health services.
- The building is where the referring physician practices medicine at least one day per week and is the principle place where the patients receiving the radiology or imaging services receive physician services. Some of the practice's services in the building are unrelated to Stark designated health services.
- The building is where the referring physician or other members of his or her group practice provide physician services to patients at least one day per week and the imaging is ordered during a patient visit in the building or the physicians are present in the building during the imaging. Some of the practice's services in the building are unrelated to Stark designated health services.

The supervision requirement (Question #8) could also affect a practice's decision where to locate the scanner, because of the need to have a physician in the office suite for NM requiring direct supervision.

10. Can mobile imaging facilities satisfy the location test?

Generally not, only if the mobile facility is leased by a group practice on a full-time (7/24) basis for a term of at least six months, and is used exclusively by the group. A mobile facility is not considered to be in the "same building," even if docked in an interior garage of the building. However, a practice is always free to purchase the technical component of a Medicare-covered diagnostic test from a mobile operator, provided the practice does not mark up the cost of the test to Medicare (see Question #16).

11. What does the billing test require?

With certain technical exceptions, the NM must be billed under the name and billing number of the practice.

12. Does a practice's claims for the professional component of NM referred by a physician in the practice have to qualify for the Stark exception?

Yes, if the referring physician has a financial relationship (ownership or compensation) with the billing practice, the professional interpretations of the scans referred by the physician must also qualify for a Stark exception (*unless* the referring physician performs the interpretation). In most cases, the practice will have to rely on the in-office ancillary services or physician services' exceptions. In either case, the interpretation must be provided in the practices facilities. (These restrictions only apply if the referring physician's practice bills for the professional component. If the reading radiologist bills separately and does not otherwise have a financial relationship with the referring physician, no exception is required for the professional component.)

13. What must a physician group do to satisfy the Stark Law definition of a group practice?

Because the Stark Law definition of a group practice is so detailed and technical, a complete answer to this question is beyond the scope of this Q&A. However, a group of physicians that are genuinely integrated financially and practicing through a single legal entity through the shared use of space and equipment can typically satisfy the definition. The most common mistake made by a group practice is not ensuring that its compensation methodology is consistent with the Stark group practice definition (see Question #14).

14. Does the Stark definition of a group practice place any restriction on how a physician group can distribute profits from the technical component of NM?

Yes. The group practice definition prohibits a group from distributing profits (including from the technical and professional components of NM) in a manner that relates directly to the volume or value of the physician's referrals for designated health services. For example, a physician cannot be paid 50 percent of the profits from NM performed by the group on the basis that the physician ordered 50 percent of the scans. However, this definition permits a group to allocate profits (including from the technical and professional components of NM) on a per capita basis or on the basis of the distribution of the group's practice revenues attributed to services that are not designated health services (e.g., based on personally-performed services).

15. Can multiple physician practices share a NM facility under the Stark Law?

Yes, provided the practices are located in the "same building" (see Question #9) and each practice satisfies the in-office ancillary services exception and group practice definition mentioned above. However, please note that shared arrangements require careful structuring and should not be attempted without the assistance of competent health care regulatory counsel.

16. Does the Stark Law apply to NM scans purchased by a medical practice?

Yes. By virtue of the purchase of the NM scan by a physician practice, a financial relationship under the Stark Law is created such that the law applies. There may be an exception available (e.g., for items or services purchased by physicians at fair market value), but whether any exception would apply would depend upon the particular factual circumstances. Separately, at least Medicare billing rules concerning purchased diagnostic tests prohibit payment for such tests unless the supplier and the supplier's net charge is identified, and payment will not be made for a mark up of the cost of the test.

17. What other laws are most likely to have a significant effect on the development and operation of an in-office NM business?

Other Medicare reimbursement rules, state certificate of need and licensing laws, and state physician self-referral laws. Further, it is possible that the federal anti-kickback law could be implicated as well. Thus, a practice that wishes to develop an in-office NM business should consult with a competent health care attorney.