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The Federal Stark Regulations And Perfusion Practice

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The clinical practice issue of the application of the federal physician self-referral law, the Stark law, and the regulations issued by the Centers for Medicaid and Medicaid Services (CMS), on the employment arrangements of perfusionists, particularly those employed by surgical groups, has been around for over fifteen years. Still, questions are received from AmSECT members. The purpose here is to shed light on why and how Stark does not apply to perfusion employment arrangements. This should not be interpreted as an official position statement of the Society. Interested persons can contact either of the authors at Mike Troike at mtroike@bellsouth.net or Lee Bechtel at balobby@verizon.net.

There have been two revisions/clarifications made to the original Stark physician self-referral law, also known as Stark I, Stark II, and Stark III. Medicare physician self-referral of patients is a different federal statutory provision than the Medicare anti-kickback law and its regulations. People have and do get these confused. Both are complex in their interpretations and application to surgeon group business models and the contractual arrangements with hospitals for perfusion services. There are State physician self-referral laws that could come into play as well as the federal Stark law and regulations. There is a webpage covering the Stark laws at http://starklaw.org/stark_guidelines.htm.

The core principle of the Stark law is focused on physician self-referral to entities in which a surgeon or surgical group, or another physician subspecialty, has an ownership or investment interest in, but at which a surgeon or surgical group does not personally perform the professional services. The core principle and its application covers physician self referral to an entity for a Medicare Designated Health Service (DHS), such as a medical test, and imaging center, a free-standing ambulatory surgical center, or a surgical procedure like CPB, and in which an ownership or investment interest is held, and which can directly receive Medicare payment for a billed service. This is passed through the ownership/investment interest entity back to the referring physician/surgeon or surgical group practice. All of these are important components in the self-referring process.

The players involved must be able to directly bill Medicare for the services rendered, and also not be personally involved in the performance of the service. The Stark law has no application to surgeons employed by a hospital, as with university based hospital open-heart programs. This is normally the case because the surgeons don't separately bill Medicare. Hospital employed perfusionists are not at issue with the Stark regulations for obvious reasons, nor are perfusion service contract companies that bill the

hospital directly for the services being provided. The perfusion services contract company is not in the position to refer patients, cannot bill Medicare separately for services, and payments made by the hospital are to a company which employs medical staff that cannot bill or receive payment for services provided to Medicare patients. Private insurance billing and payment for contracted perfusion services is a different matter and not addressed in this article.

For a few years, there was the creation of physician group owned specialty hospitals which were exempt from the Stark regulations. For a number of reasons, to numerous to address here, Congress enacted and Medicare enforced a ban on physician owned specialty hospitals. The ones that were previously opened are allowed to continue, but this is no longer permissible under federal Medicare law.

There are three remaining business models for perfusion employment arrangements that involve surgical group practices. These consist of (1) perfusionists directly employed by a surgical group; (2) perfusionists employed by a surgical group with the group billing hospitals for the perfusion services provided by its employees; and (3) a surgical group that has separately incorporated perfusionists into a company, and the company billing the hospital. There is essentially no difference between business models (2) and (3), other than the formation of a subsidiary. There is an important difference between business model (1) and the other two. Perfusionists who are on the staff of a surgical group are generally paid from the revenue the group receives for its physician services under the Medicare Physician Fee Schedule (PFS). The physician fee schedule is composed of three components. The Professional Component (PC) is paid for a surgeon's personal work; the Technical Component (TC) covers malpractice insurance costs, office leases, staff support services, and administrative costs. The combination of both of these is the "global fee". The surgical group ultimately decides how to allocate staff salaries and surgical partner salary/compensation after other fixed costs are subtracted. For the most part, the perfusionist's salary comes from the TC component of the global fee charged for each procedure. In model (1), the surgical group is not referring patients to its own staff.

Surgical group businesses models (2) and (3) differ from the first in that the group contracts with the hospital for the perfusion services they provide. In these circumstances, the hospital most likely pays for perfusion services that it does not pay to hospital employed staff perfusionists, out of the hospital's surgical case DRG payment revenues, and the other designated health services provided to Medicare patients at open-heart hospital programs. There is no blanket; all are the same, contractual relationship that can even be speculated on since this is a proprietary financial arrangement. What is known is that in business models (1), (2), and (3) the surgical group and its surgeons are performing surgical designated health services in which the perfusionist is involved - patients are **NOT** being referred to a perfusionist employee or a subsidiary company providing perfusion services that is owned by the surgical group, for services for which there is separately recognized Medicare reimbursement that can be billed for. Perfusionists cannot directly bill Medicare for their services.

The Medicare Physician Fee Schedule (PFS) specifically recognizes eligible providers of services that can bill Medicare for their professional services. There are 20 recognized Medicare PFS medical professionals who can bill independently for their services. Perfusionists are not on this list and are therefore prevented from billing. Most importantly, Medicare provided an explanation in its 2008 Stark III clarification regulations that addresses this matter. It says in part and with clarification added:

> "In the FY 2009 IPPS final rule, *(containing Stark III)* we amended the definition of "entity" at 42 CFR §411.351 to clarify that "[a] person or entity *(a physician/surgeon or group or a hospital are entities)* is considered to be furnishing DHS **if** it is the person or entity that has performed services that are billed as a DHS or presented as a claim to Medicare for the DHS (73 FR 48751). ..... We declined to provide a specific definition of "perform" in the final rule, but stated that it should have its common meaning.... In addition, we stated: "We do not consider an entity that provides personnel.....for performing the service to be performing a separate DHS (73 FR 48726). ..... We delayed the effective date of the amendment to the definition of "entity" until October 1, 2009, in order to afford parties adequate time to restructure arrangements (73 FR 48721)."

The application of the Stark self-referral law and regulations do not apply to perfusionists and their services, regardless of what they are, when provided by a surgical group. Perfusionists and their services are a part of a designated health service, but perfusionists are only personnel involved in the performance of the services that a surgeon or members of a surgical group furnishes as a DHS for Medicare payment policy purposes. Second, perfusionists are not recognized as "eligible providers of services" under the Medicare Physician Fee Schedule and cannot independently bill for services. There is no Medicare payment that can be passed through to the surgical group. In a surgical group employment arrangement perfusionists are employees. A hospital can, and does, use its DRG revenues to pay a perfusion contract company or a surgical group that employs perfusionists, but the surgical group is not an owner/investor with the exceptions noted, that directly benefits financially.

A surgical group, regardless of size, is not self-referring a patient for a Medicare covered surgical procedure when the surgeons are personally involved in the delivery of the service. They cannot self-refer to themselves to receive compensation for procedures they have done with the assistance of a perfusionist. Perfusion services, in and of themselves, are non-eligible and therefore non-reimbursable as a covered service under the Medicare PFS. Surgeons are not self-referring patients to hospitals for compensation for services they are not performing in the hospital.

Having presented this educational information, perfusionists may disagree. The for sure caveat is that an attorney with Stark experience will disagree, as many have made a livelihood from offering legal opinions. The weight of the evidence strongly suggests that the Stark law and regulations do not apply to hospital employed perfusionists, to contract perfusion services companies, nor to perfusionists employed by surgical groups or groups owning a separate perfusion services company. Individual State physician self-referral laws come into play as well as the federal Stark law and regulations, and need to be taken into consideration.