

Pre-Publication Draft

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**STARK AND MEDICARE'S PHYSICIAN
REIMBURSEMENT RULES:
UNRAVELING THE KNOTS**

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Stark says that today he'd go back and strip down the original fuzzy language so the law simply forbids kickbacks. "I think we would have stopped more of the shenanigans that way," he says. He concedes that he created a whole cottage industry of entrepreneurs and Stark law firms that create and sign off on convoluted legal arrangements between doctors and their vendors. 'I get little thanks for it,' he says.
-- David Whelan, *Stark Regrets: I Shouldn't Have Written That Law*, Forbes, Nov 2007¹

Introduction

In 2009 I wrote an article titled "Getting The Team Paid: How Medicare Physician Payment Policies Impede Quality"². To write it was highly cathartic for me; and the Stark statute garnered 8 pages of my attention in a 40 page piece. I have often said that the statute is the single worst piece of legislation I have dealt with in my entire legal career, casting the anti-kickback statute as a model of clarity and the HIPAA privacy and security regulations as a Golden Books classic. The Stark statute is overly detailed, but in a way that gives rise to more questions than answers. I have also often said that the drafters were not unduly burdened by any knowledge of the way Medicare worked, with their indiscriminate use of terms such as 'personal supervision', 'direct supervision' and 'incident to' which have long had specific meanings under Medicare physician reimbursement principles. The complexity it creates is unsatisfying to clients and even to lawyers like me who know it intimately.

It is little remembered that the one attempt for at least partial repeal occurred during the budget stand off between Newt Gingrich and President Clinton. Clinton vetoed the Balanced Budget Act of 1995. The government shut down; and Mr. Clinton, with time on his hands, fell in with Ms. Lewinsky. At least that has always been how I interpreted what happened. The Balanced Budget Act of 1995 would have liberalized the Stark prohibitions on compensation arrangements, would have removed the references to compensation within group practices and would have expanded the types of facilities in which physicians could be invested and refer, subject to some conditions, among other things.³ There has been little attempt to repeal it since.

¹ Later in a bit of revisionist history, he was quoted as saying the law was just supposed to be about kickbacks and as it stands now should be repealed. Carlson, "Pete Stark: Repeal The Stark Law", (Aug 2, 2013), Modern Healthcare <http://www.modernhealthcare.com/article/20130802/blog/308029995>

² HEALTH LAW HANDBOOK (2009 Ed) WestGroup, pp. 35-77

³ §8201 of the Balanced Budget Act of 1995 HR 2491; see Teach and Saner, "A Proposal To Streamline the Stark Self-Referral Law (October 11, 1995 Fraud and Abuse Seminar, American Health Lawyers Association Archive archive.healthlawyers.org/google/health_law_archive/program_papers/1995_FA/%5B1995_FA%5D%20A%20Propo... - 2007-04-12

Despite the reams of regulations interpreting it, and the explosion of settlements and verdicts about its violation, some of the most essential features of the law have not even worked. In particular, the proliferation of the use of in office ancillary services, and even more specifically, high end imaging, has been noted since about 2005.⁴ Although MedPac has long taken the position that it is the fee for service Medicare physician payment system that is the culprit in spurring heightened utilization of services, as we have moved into an environment of more value based payment modifiers one might well expect the Stark statute to have less meaning. But until its repeal, understanding the connections between Stark and Medicare reimbursement principles will remain essential for physician practices seeking to avoid becoming targets of whistleblowers or the government.

The Scope of Stark

The Stark statute itself is part of Title XVIII of the Social Security Act which is the section of the Act which governs the Medicare program. The Stark provisions⁵ prohibit a physician or immediate family member from referring a patient for designated health services to an entity with which the physician or immediate family member has a financial relationship, unless the relationship complies with an applicable exception. Stark has no relevance if any of the following three elements is not present: (1) a referral as defined by the statute and regulations has occurred; (2) there is a financial relationship between the referred to entity and the referring physician or immediate family member; and (3) the referral is for designated health services.

One of the most interesting aspects of the definition of a 'referral' is that on one hand it is very broad in that it includes not only directing a patient to a source for care, but also merely creating a plan of care or treatment which includes the designated health services. But a referral is defined narrowly to include only a referral for designated health services. Stark has no power over a referral that is not for a designated health service. In yet another manifestation of the lack of understanding of Medicare by the Stark law drafters, the statutory definition of a referral is limited to requests for "an item or service for which payment may be made under Part B"⁶, yet the list of designated health services includes inpatient hospital services and home health agency services which are only paid for by Part A. In all of the cases and settlements to date, no one has pointed out this bizarre discrepancy.

Following the statute, the regulatory definition of 'referral' incorporates the ordering of, the request by a physician for, or the certifying or recertifying the need for any designated health service for which payment may be made under Medicare Part B including the request for a consultation with another physician and any test or procedure ordered by or

⁴ See MedPac, "Report to The Congress: Medicare and The Health Care Delivery System", June 2011, pp 31-32.

⁵ 42 USC §1395nn

⁶ 42 USC §1395nn(h)(5)(A)

to be performed by (or under the supervision of) that other physician.⁷ In a separate clause in the definition, as in the statute, referral also includes the establishment of a plan of care by a physician that includes the provision of any designated health service for which payment may be made under Medicare -- without limiting it to Part B.⁸ That provision is not explicitly consistent with the statute.

Also fairly surprising have been some judicial views of the scope of Stark. When it was enacted, the following provision was inserted in Title XIX, the Medicaid section of the Social Security Act, dealing with federal financial participation paid to the states to operate their Medicaid programs.:

Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section [1395nn](#) of this title) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under subchapter XVIII of this chapter if such subchapter provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this subchapter in the same manner as such subsections apply to a provider of such a service for which payment may be made under such subchapter.⁹

When the Stark I regulations were published in 1998, the regulators said, "We do not believe these rules and sanctions apply to physicians and providers when the referral involves Medicaid services."¹⁰ In 2001, the regulators in publishing Phase I of the Stark II regulations said that Phase II of the regulations would address the Medicaid provisions.¹¹ When the Phase II regulations were published, the regulators demurred again, addressing only Medicaid prepaid plans.¹² The Phase III regulations in September 2007 didn't even bother to mention Medicaid. Since then not a word of regulation has been published implementing the Medicaid federal financial participation provision. How will the determination that federal money should be withheld or not paid be made? Would this be done claim by claim, which is implied in the service by service analysis? How could that be accomplished? Would payments be recouped from the states by the federal government? What data will be shared? And how and when? The provision as drafted seems virtually impossible to implement in the absence of regulations. This has not daunted either whistleblowers or judges.

⁷ 42 CFR §411.351 Definitions "Referral" (1)(i)

⁸ Id at (ii)

⁹ 42 USC §1396b(s)

¹⁰ 63 Fed Reg 16659-01 (Jan 9, 1998)

¹¹ 66 Fed Reg 856 (Jan 4, 2001)

¹² 69 Fed Reg 16055 (March 26, 2004)

In US ex rel Schubert v. All Childrens Medical Center¹³ the whistleblower brought Stark and false claims charges against a pediatric hospital, asserting that physicians employed by the hospital were over compensated. In denying the defendant's motion for summary judgment, looking at the applicable federal financial participation provision, the court held that even when the regulators had said that their published proposed rules did not apply to Medicaid physicians and providers directly, the regulators had also said "these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. The state may pay for these services, but cannot receive FFP for them."¹⁴ In the infamous Halifax case, also brought by a relator challenging physician compensation arrangements, among other things, the court took note of the FFP provision in refusing to dismiss the Medicaid allegations.¹⁵ In yet a third Florida District Court case, the court sweepingly included Medicaid in the types of prohibited referrals addressed by Stark. In US ex rel Osheroff v. Tenet Healthcare Corp¹⁶ the issue was the hospital making available to its referring physicians office space at lower than fair market value rent. With no discussion of the issue, though, it is hard to imagine how the law could be implemented, but for purposes of verdicts and settlements, the actual practicality of the law apparently is not very relevant.

Definition of a Group

Because the Stark statute is a general prohibition subject to complying with specific exceptions, to navigate successfully through Stark requires a detailed understanding of the applicable exceptions. The good news is, one must only qualify under one exception to be safe. However, each transaction has to be analyzed to determine whether it meets an exception. As an example, the employment exception may well protect the compensation paid to a physician for performing a service, but the technical component of that service is not protected unless it complies with the in office ancillary services exception, if it is a designated health service. Many people believe that there is an exception for "group practice." In fact, this is a misperception. Rather, the definition of a group practice must be met in order to qualify for several of the exceptions upon which physicians rely in their referrals.

There is much in the definition of a group practice which has no particular interconnectedness with Medicare reimbursement rules. This includes that the group must be a single legal entity; it must consist of at least two physician members defined as shareholders, partners, or bona fide employees; the physicians must provide the full range of care that they otherwise provide; on an average basis together they must spend 75% of

¹³ 2103 WL 6054803 (M.D. Fla 2013)

¹⁴ 63 Fed Reg 1659 at 1704 (Jan 9, 1998)

¹⁵ US ex rel Elin Baklid-Kunz v. Halifax Hosp. Medical Center, 2012 WL 921147 (M.D. Fla. 2012)

¹⁶ 2012 WL 287264 (S.D. Fla. 2012)

their time with the group; the expenses and overhead must be distributed according to methods previously established; and the group must operate as a unified business.¹⁷

The eighth criterion to qualify as a group states that "members of the group must personally conduct no less than 75% of the physician-patient encounters of the group practice."¹⁸ This is another example of imprecise use of language in the context of Medicare reimbursement. There is, in fact, a Medicare definition for a reimbursable physician service under Medicare Part B.

A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.¹⁹

The term "encounter" is otherwise used in connection with the requirements for care plan oversight services.²⁰ There, the statement is made that "only evaluation and management services are acceptable prerequisite face to face encounters for care plan oversight. EKG, lab, and surgical services are not sufficient face to face services for CPO."²¹ Similarly, face to face encounters are required to qualify services for claims submission by home health agencies as well as durable medical equipment suppliers.²² The term "encounter" is also used in the description of shared visits²³ as well as in the description of billing where more than half of the service is counseling or coordination of care.²⁴

Taken together, it is difficult to know whether this 75% rule pertains exclusively to visits or would also include surgical procedures and telehealth services. The rule was published in 2001. Then, the only clarification was that the calculation was to be made "per capita and not on time,"²⁵ distinguishing it from the other 75% rule which is based on time. There has been no further elucidation of its meaning. As an example of how this could play itself out in a way that could be detrimental to a physician practice, in a

¹⁷ 42 CFR §411.352(a-f). See Gosfield, "The Imperative of Complying with the Stark Group Practice Definition," Compliance Today. (in press)

¹⁸ 42 CFR §411.352(h)

¹⁹ Medicare Benefit Policy Manual Ch. 15 §30A

²⁰ Medicare Benefit Policy Manual Ch. 15 §30G

²¹ Medicare Benefit Policy Manual Ch. 15 §30.6

²² 42 CFR §410.38(g); 42 CFR §424.22

²³ Medicare Claims Processing Manual Ch. 12 §30.6.1B

²⁴ Medicare Claims Processing Manual Ch. 12 §30.6.1C

²⁵ 66 Fed Reg 905 (Jan 4, 2001)

two physician practice which performs in office intravenous drug infusions, patients may come multiple times a week where no physician is involved in seeing them. The volume of services taken as a whole, where the patient is seen by ancillary personnel face to face in the office, could distort the calculation of what qualifies as an encounter. Until some enforcement, in the absence of a Stark Advisory Opinion (of which there have been only 12 since 1998),²⁶ there is no way to know.

The definition of a group practice also addresses its internal compensation formulae:

“A physician in a group practice may be paid a share of overall profits of the group or a productivity bonus based on services personally performed or incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.”²⁷

That provision reaches directly into the private practices of private practices. For the entire history of the statute, it had been impossible to imagine that the government would ever actually enforce it. It took until August 14, 2014 for the OIG and a US Attorney’s Office to publish a settlement agreement which required a cardiology group to pay the government more than \$1.3 million for improper compensation from September 1, 2007 through August 31, 2008.²⁸ The primary allegation was that the New York Heart Center partner compensation was determined using a formula that took into account the volume or value of his or her ordering of designated health services, specifically CT scans and nuclear diagnostic tests that were not personally performed by the compensated physician.

1. Profit Sharing

Profit sharing is the mechanism whereby excess revenues are shared among physicians who did not personally perform the services. Under the regulations, those dollars must be allocated in accordance with a formula. Profit sharing is allocating the fruits of others’ labors from designated health services, for example, sharing diagnostic testing revenues among the ordering practitioners. There is no obligation to pay profit sharing as unearned income or a return on investment. Profit sharing can be allocated as employment compensation. However, that allocation would not fall under the employment exception under Stark, which does not permit compensation in a manner that takes into account (directly or indirectly) the volume or value of referrals. Because the statute and regulations address compensation within a group as a predicate definition, compliance with its requirements must be present before an exception applicable to a group practice can be applied. The employment exception explicitly does not prohibit payment of remuneration in the form of a productivity bonus based on services

²⁶ http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html

²⁷ 42 USC §1395nn(h)(4)(B)(i)

²⁸ Settlement Agreement between United States of America and Cardiovascular Specialists P.C., d/b/a New York Heart Center, Aug 14, 2014.

personally performed by the physician.²⁹ By contrast, the regulations addressing profit-sharing merely restrict allocation to that which is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician.³⁰ The regulation goes on to describe overall profits to mean the group's entire profits derived from DHS payable by Medicare or Medicaid, or the profits derived from DHS payable by Medicare or Medicaid of any component of the group that consists of at least five physicians. The salient point here is that "overall profits" does not mean the overall profits of the entire group, but only those derived from DHS.³¹

The regulations offer three safe harbors, deeming compliance to be met if the group's profits are divided per capita, or revenues are distributed based on the distribution of revenues attributed to services that are not DHS, but here they go further to say "payable by any federal health care program or private payor";³² or revenues derived from DHS constitute less than 5% of the group practice's total revenues and the allocated portion of the revenues to each physician constitutes 5% or less of his or her total compensation from the group. The last category is rarely seen.

The allocation based on non-DHS revenues tends to be the most significant basis for allocation of profit sharing. There is no one formula for allocating the profits. Some groups do it on the basis of visits. Others allocate in accordance with work RVUs. Some do it on number of patients. According to the rules, any sub pod must consist of at least five physicians. In a group practice of fewer than five physicians, all must be paid in accordance with the same formula, which does not mean the same amount. Not everyone must be included in profit sharing. Non-shareholders can be paid profit sharing. Independent contractors can be paid profit sharing. Although you cannot pay in accordance with current ordering practices, there is nothing to prohibit looking at a rolling average of say, two years of ordering practices and projecting it forward. That would neither directly nor indirectly reflect the volume or value of current DHS referrals. In very large groups, I have seen and helped construct multiple profit-sharing pools (e.g., imaging, PT, infusions, drugs) which are stratified (high, middle, and low) based on historical ordering patterns. Not everyone need participate in all or any sub-pool.

2. Productivity Bonus

The statute and regulations permit a productivity bonus based on services personally performed or incident to such personally performed services. The bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS.³³ Similar to the profit sharing provision, the

²⁹ 42 CFR §411.357(c)

³⁰ 42 CFR §411.352(i)(1)

³¹ 42 CFR §411.352(a)(i)(2)

³² 42 CFR §411.352(h)(i)(2)(ii)

³³ 42 CFR §411.352(i)(3)

regulations offer three safe harbors. (1) The bonus may be based on the physician's total patient encounters or relative value units. (2) The bonus may be based on an allocation of the physician's compensation attributable to services that are not DHS, payable by any federal health care program or private payor. (3) Revenues derived from DHS are less than 5% of the group practice's total revenues and the allocated portion of those revenues to each physician in the group practice constitutes 5% or less of his or her total compensation for the group.

Productivity compensation reflects the fruits of the physician's own labors. Productivity can be calculated as a percentage of revenues. The regulations do not stipulate how expenses must be allocated, but they do permit location based allocation of expenses (e.g., the Maple Street office as opposed to the Elm Street office).³⁴ Going all the way back to 2001, the regulators have explicitly recognized that independent contractor physicians may be paid productivity bonuses.³⁵ The regulators reiterated and clarified these points in their 2004 publication stating that "all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform."³⁶ They explicitly addressed the permissibility of percentage based compensation for personally performed services.

In accordance with the statutory definition, a productivity bonus can include revenues from services that are "incident to" the physician's services. This has been a confounding issue since the publication of the regulations in 2001. Even many lawyers get hung up on the internal contradiction between allowing credit for incident to revenues while prohibiting compensation which directly reflects the volume or value of referrals. In my comments on the proposed Stark regulations, I made the argument that because the long standing definition of incident to services said that they were an "integral although incidental part of the physician's personal professional service to the patient,"³⁷ that by definition they did not meet the standard for being a referral. (That argument was acknowledged in the discussion in the Federal Register but was rejected.³⁸)

In responding to other comments with respect to incident to, the regulators stated that group practice physicians can receive compensation directly related to the physician's personal productivity and to services incident to the physician's personally performed services, provided the "incident to" services comply with the requirements of §1861(s)(2)(A) of the Act and §2050, "Services and Supplies," of the Medicare Carrier's Manual (HCFA Pub. 14-3), Part 3-Claims Process and any subsequent or additional HHS rules or regulations affecting "incident to" billing. Those statements were clear, direct,

³⁴ 66 Fed Reg 910 (Jan 4, 2001)

³⁵ 66 Fed Reg 895 (Jan 4, 2001)

³⁶ 69 Fed Reg 16067 (March 26, 2004)

³⁷ Medicare Benefit Policy Manual Ch. 15 §60.1

³⁸ 66 Fed Reg 909 (Jan 4, 2001)

and unequivocal, particularly to anyone familiar with Medicare reimbursement rules. Apparently, commenters were still confused. In the 2004 comments, the regulators noted that “a number of commenters asked that we clarify that physicians in the group practice can be paid a productivity bonus or profit share based directly on services that are incident to services personally performed by the physician.”³⁹ Those commenters were said to have found the language in the text ambiguous. The regulators reasserted their position and revised the regulations to make clear that profit shares or productivity bonuses can be based directly on services that are incident to the physician’s personally performed services.

Unable to let the matter rest, commenters brought up the subject of incident to services again in the 2007 publication of the regulations. Then the regulators clarified that “incident to” services include both services and supplies (such as drugs) that meet the applicable requirements set forth in the Act.⁴⁰ In the related discussion of what constituted a “referral” under the statute, there was a regulatory kerfuffle over what constituted personally performed services. Reiterating their confirmation that a referral includes services performed by others “incident to” the physician’s services, they addressed such issues as whether a referral occurs when antigens are prepared and furnished by a physician or whether there is a “referral” when a physician refills an implantable pump. The regulators acknowledged that it is possible for a physician to order and personally furnish antigens to a patient and to order a refill for and personally refill, an implantable pump. In such instances, there would be no “referral” for a designated health service and no exception would be needed. They distinguished, however, durable medical equipment and supplies. They stated “There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all the duties of a supplier as set forth in the Supplier Standards in §424.57(c).”⁴¹

The brouhaha had been created by a couple of law firms that had sent out newsletters indicating that if a physician handed a continuous positive airway pressure (CPAP) machine to a patient that it would qualify as a personally performed service for which the physician could be given productivity credit. In completely rejecting the argument, the regulators stated “We believe that it is highly unlikely that a referring physician would meet the criteria for personally performed services when dispensing CPAP or other DME equipment. í We note that CPAP equipment is DME that does not qualify for the in office ancillary services exception.”⁴² This is as distinct from prosthetics and orthotics, which can meet the standard for in office ancillary services. (See below.) To qualify as personally performed DME (a strange notion unto itself since DME is not a service, but

³⁹ 69 Fed Reg 16080 (March 26, 2004)

⁴⁰ 72 Fed Reg 51016 (Sept. 5, 2007)

⁴¹ 72 Fed Reg 51019 (Sept. 5, 2007)

⁴² 72 Fed Reg 51020 (Sept. 5, 2007)

at best could be "incident to" the physician as a supply) would include but not be limited to the following: personally fit the item for the beneficiary; provide necessary information and instructions concerning use of the DME; advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME; explain the purchase option for capped rental DME; explain all warranties; usually deliver the DME to the beneficiary at home; and explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.⁴³

It was in the same publication that turning 180 degrees from the way diagnostic testing had been billed throughout the history of the Medicare program, they took the position that only those services that do not have their own separate and independently listed benefit category may be billed as "incident to" a physician service, except as otherwise expressly permitted by statute (for example, physical therapy services to the extent authorized under §1862(a)(20) of the Act). There, they said "Consequently, diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under §1861(s)(3) of the Act may not be billed as "incident to" services under §1861(s)(2)(A) of the Act."⁴⁴ It is interesting to note that the New York Heart Center settlement was for compensation paid from September 1, 2007 through August 31, 2008, when this neverland provision was not well known.

However, the regulators' new position was another example of the regulators not understanding Medicare reimbursement as well as they might have. Nurse practitioners, physician assistants, and clinical nurse specialists all have their own benefit categories under the Act, yet they can be billed incident to or on their own numbers. Physical therapists can be billed incident to or on their own numbers.⁴⁵ Because the understanding of incident to services and supplies is so critical to what can be done with productivity bonuses, the details of the overarching rules are relevant.

3. "Incident to"

In the first instance, there must be a physician service to which the "incident to" services or supplies are an integral although incidental part. To be billed as "incident to," services and supplies must be those that are commonly furnished in physicians' offices. Supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing for the services or supplies.

There must be direct physician supervision of auxiliary personnel which include any individual acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician, or of the legal entity that employs or contracts with the physician. This represents a

⁴³ 72 Fed Reg 51020 (Sept. 5, 2007)

⁴⁴ 72 Fed Reg 51016 (Sept. 5, 2007)

⁴⁵ Medicare Benefit Policy Manual Ch. 15 §60A and 60.2

change from the earliest versions of "incident to," which required that the services of non-physicians could only be billed "incident to" if they were the W-2 employees and not independent contractors of the physician group.⁴⁶ However, it should be noted that unlike other ancillary personnel who may be billed "incident to," Medicare will only pay to the employer of a physician assistant when that person bills on his or her own number.⁴⁷ Similarly, the physician who is supervising may be an employee, leased employee, or independent contractor of the billing entity. The physician furnishing the services or supplies to which the ancillary personnel are incidental or the physician supervising the ancillary personnel, must have a relationship with the legal entity billing and receiving payment that satisfies the requirements for valid reassignment (See further below).⁴⁸ Direct supervision requires the presence of the physician in the office suite. He must be immediately available to provide assistance and direction throughout the time the aide is performing services.

The physician can bill for "incident to" services even when there is no physician service on the same day. "To be considered "incident to," each occasion of service by auxiliary personnel (with the furnishing of supply) need [not] also always be the occasion of the actual rendition of a personal professional service by the physician."⁴⁹

Although "incident to" services are typically billed in the office, they can be covered during a house call, as an example, if there is direct supervision by the physician. The physician and the nurse would both have to be present. For hospital patients and skilled nursing facility patients who are in a Medicare covered stay, there is no Medicare Part B coverage of the ancillary personnel. As services "incident to" the physician's services in a nursing or convalescent home, the physician and the ancillary personnel must be present together either at the bedside or in a separate office, seeing the patients together. The presence of the physician somewhere in the institution does not constitute direct supervision.

The Manual's interpretation of the provision pertaining to personnel that have their own benefit adds to the general confusion between the Stark regulators and the reimbursement regulators. The Manual specifically addresses non-physician practitioners, who are licensed by the state to assist or act in the place of a physician, including, for example, certified nurse midwives, clinical psychologists, clinical social workers, physician assistants, nurse practitioners, and clinical nurse specialists.⁵⁰ Services performed by these non-physician practitioners (NPPs) "incident to" a physician's service include not only services ordinarily rendered by a physician's office staff person, such as taking

⁴⁶ Downtown Medical Center v. Bowen, 944 F 2d 756 (10th Circuit 1991)

⁴⁷ Medicare Benefit Policy Manual Ch. 15 §190D

⁴⁸ Medicare Benefit Policy Manual Ch. 15 §60.1A

⁴⁹ Medicare Benefit Policy Manual Ch.15 §60.2B

⁵⁰ Medicare Benefit Policy Manual Ch. 15 §60.2

blood pressures and temperatures, giving injections, and changing dressings, but also services ordinarily performed by the physician, such as minor surgery, setting casts or simple fractures, reading x-rays, and other activities that involve evaluation or treatment of a patient's condition. These same services can be billed on the NPP's own number, but in certain instances such as PAs and nurse practitioners, will be paid at 85% of the fee schedule. The other practitioners are paid at 100% of the fee schedule. All of the other requirements for "incident to" billing must be met, including that there is a physician service to which the NPP services are incidental, as well as on premises direct physician supervision.

In a group practice, the physician supervising need not be the physician to whom the services are incidental. The Manual addresses the issue of "physician directed clinics." A physician directed clinic is one where (1) a physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open; (2) each patient is under the care of a clinic physician; and (3) the non-physician services are under medical supervision.⁵¹ Direct supervision is still required. When the ordering physician is directly supervising the service, the signature of the ordering physician is entered in Item 31 of the CMS1500. When the ordering physician is not supervising, the signature of the supervising physician goes in Item 31.⁵² The fact that a different physician supervises does not undermine the fact that the services are "incident to" the ordering physician.

Because there must be a physician service to which the ancillary services are incidental, ancillary personnel may not be billed "incident to" on an initial visit by a new patient to the physician, because until the physician has seen the patient, there is no service to which the ancillary services can be incidental. That said, it is entirely appropriate for a physician and ancillary personnel to share a visit in the office where both contribute to the creation of what is billed. The ancillary personnel are always invisible on the claim form when "incident to" services are billed, since they are billed as if the physician rendered the service himself.

It should be noted that in the documentation standards for Medicare visits, while ancillary personnel can function as scribes, contemporaneously writing what the physician says, the physician must record the service. Only the review of systems and past family and social history may be recorded by someone other than the physician.⁵³

Once the course of treatment or plan of care has been established, the "incident to" personnel may continue to treat the patient. However, the physician must see the patient with sufficient frequency to demonstrate he remains involved in the delivery of care.

⁵¹ Medicare Benefit Policy Manual Ch. 15 §60.3

⁵² Medicare Claims Processing Manual Ch. 26 §10.4

⁵³ Med Learning Network, "Evaluation and Management Services Guide," http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/eval_mgmt_serv_guide-ICN006764.pdf at p. 13

Some Medicare Administrative Contractors are relatively restrictive in their approach to this. “Changes in the plan, including changing a drug or the dosage of the same drug, constitute a new plan of care.”⁵⁴ Others take the position that a new symptom, no matter how minor, requires physician intervention to establish a new course of treatment. Cahaba Government Benefit Administrators says that in an FAQ.⁵⁵ Noridian Services says, contrary to the Manual, that ancillary personnel must be the employees or leased employees of the physicians.⁵⁶ Novitas Solutions is silent on the symptom issue as well as the employment issue, although they do say an initial visit billed incident to will be denied.⁵⁷ It is absurd that the agencies administering this national health insurance are inconsistent in their guidance.

Astonishingly, although it cannot be found in regulations, informal guidance allows a physician to be billed “incident to” another physician, although it is described as a very rare circumstance. A physician with an NPI number that is not yet attached to the group under reassignment could, conceivably, be billed in this manner. Given all of the emphasis on strict enrollment criteria,⁵⁸ this seems contrary to fundamental enrollment policy. Yet, in 2001 in a tussle over billing for physical therapy, citing their regulation at 42 CFR §410.26(a)(1), the regulators said “We deliberately used the term ‘any individual’ so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant.”⁵⁹ They have not only not walked away from that position, they have reiterated it upon inquiry.

4. Shared Visits

A concept related to “incident to” but entirely separate is the concept of shared visits, which was created in 2002. Prior to that date, the Health Care Financing Administration and CMS had routinely and for many years, emphatically rejected the idea of ancillary

⁵⁴ Berra and Krupa, “Incident To Services” Documentation and Correct Billing, WPS Medicare (July 23, 2013)

⁵⁵ <http://www.cahabagba.com/faqs/are-incident-to-services-allowed-when-an-established-patient-is-being-seen-based-on-an-established-treatment-plan-but-during-the-course-of-the-visit-the-patient-indicates-a-new-illness-or-problem-in-w/>

⁵⁶ <https://med.noridianmedicare.com/web/jeb/topics/incident-to-services>

⁵⁷ http://www.novitas-solutions.com/webcenter/faces/oracle/webcenter/page/scopedMD/sad78b265_6797_4ed0_a02f_816279_13bc78/Page49.jsp?wc.contextURL=%2Fspaces%2FMedicareJH&wc.originURL=%2Fspaces%2FMedicareJH%2Fpage%2Fpagebyid&contentId=00004947&_afLoop=1291938512835000#%40%3F_afLoop%3D1291938512835000%26wc.originURL%3D%252Fspaces%252FMedicareJH%252Fpage%252Fpagebyid%26contentId%3D00004947%26wc.contextURL%3D%252Fspaces%252FMedicareJH%26adf.ctrl-state%3Dkjlbd3fiq_297

⁵⁸ See Shay, “Halt! Who Goes There?” Coping with the Continuing Crackdown on Medicare Enrollment, HEALTH LAW HANDBOOK (2011 ed) WestGroup, pp. 71-102

⁵⁹ 66 Fed Reg 55268 (Nov 1, 2001)

personnel functioning incident to a physician in the hospital. With Transmittal 1776, they did yet another about face and, only applicable for hospital inpatient, outpatient, or emergency department visits, allowed a visit to be shared between a physician and an NPP from the same group practice. Under those circumstances, if the physician provided any face to face portion of the encounter with the patient, the service could be billed under the physician's number. This would permit an NPP, leased to or employed by the physician group, to round on a hospital inpatient in the morning. Later in the day, if the physician followed, performing any portion of the visit in a face-to-face encounter with the patient, either could report the visit; but it would be folly not to report under the physician's number to get 100% of the fee schedule payment.

For Stark purposes, the services billed in this manner, like incident to services, would have the ancillary personnel invisible on the claim form and would qualify the service as personally performed for reporting purposes. However, that analysis is not even necessary, since these visits are not DHS even though they occur in an inpatient or outpatient hospital setting. The DHS referenced by inpatient and outpatient hospital services are the services of the hospital itself and not a physician merely recording the place of service as "hospital." A similar confusion arises over the allocation of revenues from visits billed by NPPs in the office when those visits are billed under the NPP's own number and at 85% of the fee schedule. Those are not DHS either and can be allocated directly to the physician who shares the care of the patient. If the NPPs perform diagnostic services that qualify as DHS, then those profits would have to be allocated in a profit sharing formula.

Exception: Referral to a Physician

The very first statutory exception provides that the prohibition on referrals will not apply in the case of physician services (as defined in §1861(q)) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) as the referring physician).⁶⁰ The confounding elements of this language, short as it is, are remarkable. How can services be physician services when they are performed under the personal supervision of a physician? The personal supervision of a physician would require that both physicians be in the same room under Medicare reimbursement rules. The regulators took this nonsense and refined it to mean that physician services may be furnished personally by another physician who is a member of the physician's group practice or is a physician in the same group practice as the referring physician.⁶¹

Physician in the group practice means members of the group practice (partners, shareholders, or employees), as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group

⁶⁰ 42 USC §1395nn(b)(1)

⁶¹ 42 CFR §411.355(a)(1)(i)

practice, to provide services to the group practice's patients in the group practice's facilities.⁶² The definition goes on to say that the contract must contain the same restrictions on compensation that apply to members of the group or it must satisfy the requirements of the personal services arrangements exception and the independent contractor's arrangement with the group practice must comply with the reassignment rules that otherwise pertain under Medicare. The reference to the group's "facilities" is intriguing. That is not a term typically associated with Medicare physician billing. "Incident to" rules reference "on premises and in the office suite." As we will see later, the in office ancillary services exception references the group's "offices" or "shared facilities," which means shared with another group. "Facilities" are nowhere defined.

The regulation further says that physician services may be those that are "under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services." So there is no reference to personal supervision in the regulatory definition. The regulation provides further still that for purposes of referring for physician services, those physician services include "incident to" services.⁶³ It is still impossible to understand, other than for "incident to" services, how supervised services of any type meet the statutory and regulatory definitions of "physician services" in Medicare generally.

Because of the way in which the referral to a physician exception is structured, it is abundantly clear that referral for a professional component is just as implicated under the Stark statute as a referral for a technical component. The statutory definition of physician services means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls.⁶⁴ The provision is further interpreted in the Medicare manuals as follows: "Physician services are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight."⁶⁵ As we have seen previously, the ability to visualize some aspect of the patient's condition permits billing for interpretations only. These services are physician services within the definition of the statute, and therefore the physician services for which referrals are implicated by Stark when the physician service is part of a designated health service. The statute defines a physician as (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state in which he performs such function or action; (2) a dentist; (3) a podiatrist; (4) an optometrist; (5) a chiropractor; and no one else. Even though in Medicare non-physicians such as nurse practitioners, physician's assistants, and clinical nurse specialists are authorized to do services within their scope of license that would otherwise be paid for if

⁶² 42 CFR §411.351

⁶³ 42 CFR 411.355(a)(2)

⁶⁴ 1861(q) of the Social Security Act

⁶⁵ Medicare Benefit Policy Manual Ch. 15 §30A

a physician did them, they do not count as physicians under the reimbursement rules or the Stark statute and regulations.⁶⁶

Exception: In Office Ancillary Services

In a truly unfathomable drafting lapse, the second exception in the statute references services “(other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies))”⁶⁷ in the definition of what qualifies as in office ancillary services. Most remarkable is the fact that despite the double parenthetical, which makes the provision opaque in the extreme, none of the items mentioned is, in fact, a service. They are “items.” The provision then goes on to address (1) who may render the service, (2) where it may be rendered, and (3) how it will be billed.

The durable medical equipment which is covered by the in office ancillary services exception, by regulation, means canes, crutches, walkers, and folding manual wheelchairs, and blood glucose monitors that meet the following conditions: the item has to be something that a patient requires for the purpose of ambulating or uses in order to depart from the physician’s office or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than one hundred of each). The item has to be furnished in a building that meets the same building requirements that otherwise apply to the in office ancillary exception. The item has to be furnished personally by the physician who ordered the DME, by another physician in the group practice or by an employee of the physician or the group practice. Where any DME is provided, even including canes, walkers, wheelchairs, and the rest, the physician practice has to meet the DME supplier standards set forth in 42 CFR §424.57(c).⁶⁸ Recalling the CPAP kerfuffle regarding personally performed services, here, the physician need not himself literally hand the DME to the patient, but may have an employee do so.

1. Who can provide in office ancillary services?

In office ancillary services qualify for the exception if they are furnished personally by the referring physician, a physician who is a member of the same group practice, or an individual who is supervised by the referring physician or by another physician in the group practice, provided that the supervision meets the other applicable coverage rules.⁶⁹ Interestingly, the statute states that the individuals who are not physicians must be “directly supervised” and the regulations, following the earlier discussion, take the position that the supervision that is required is that which otherwise pertains for the Medicare services. There had been some confusion over whether independent

⁶⁶ They are referred to as “practitioners” or “non-physician practitioners” (NPPs).

⁶⁷ 42 USC §1395nn(b)(2)

⁶⁸ 42 CFR §411.355(b)(4)

⁶⁹ 42 CFR §411.355(b)(1)

contractors who are not members of the group can supervise in office ancillary services, but the reference to supervision by a physician in the group practice makes it clear that independent contractors can be supervisors for in office ancillary services.

In office ancillary services can consist of such things as physical therapy, infusions, radiation therapy, clinical laboratory services, the technical components of radiology services, and the provision of prosthetics, orthotics, and prosthetic devices and supplies. Under general Medicare reimbursement rules, any personnel providing these kinds of services must first meet state law requirements. Some states are more prescriptive than others with regard to who can provide certain kinds of services. For example, a licensed physical therapy assistant in Pennsylvania may only be supervised by a physical therapist and not a physician.⁷⁰ In the state of Washington, testing that includes ionizing radiation may be restricted to being performed only by registered or licensed radiology technicians.⁷¹ In West Virginia, recent law establishes that certain imaging services may only be supervised by a board certified radiologist.⁷² In Pennsylvania, prosthetics and orthotics may now only be fitted by a licensed prosthetist or orthotist. Incidentally, because the Medicare Administrative Contractors who administer the durable medical equipment and prosthetics and orthotics supplies benefit do both together, many people confound the Stark treatment of DME and POS. In fact, as described above, physician practices can get a durable medical equipment supplier number and may dispense the very limited items recognized in the regulations, but otherwise may not provide durable medical equipment to their own Medicare and Medicaid patients. They can serve the patients of other physicians if they have a DME number. Prosthetics and orthotics are not excluded from the definition of in office ancillary services and may be provided within a group practice by those who are authorized to do so.

2. Where must the services be provided?

The statute itself provides that the in office ancillary services must be provided either in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice for the provision of some or all of the group's clinical laboratory services or for the centralized provision of the group's designated health services (other than clinical laboratory services).⁷³ In their first regulations in 2001, the regulators went so far as to define a building to be "a structure or combination of structures that share, a single street address as assigned by the U.S. Postal Service. For purposes of this rule, the "same building" does not include

⁷⁰ 28 PA Code §40.173

⁷¹ RCW 18.84.010 (WA)

⁷² 9:11-9-2e (W VA)

⁷³ 42 USC §1395nn(b)(2)(A)(ii)

exterior spaces such as courtyards, lawns, driveways, or parking lots or interior parking garages.⁷⁴

Where the statute required that the in office ancillary services could be in the same building with the practice, the regulators required that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building substantial physicians' services unrelated to the furnishing of federal or private pay DHS. They went further to say that the unrelated physicians' services furnished in the building must represent substantially the full range of physicians' services unrelated to the furnishing of DHS that the physician routinely provides.⁷⁵ In addition, the patient's visit could not be for the primary purpose of receiving DHS. With respect to the "centralized building," they specifically permitted multiple centralized locations and established further that the exception may only be used when the space that is centralized is used exclusively by the group on a 24 hours per day, 7 days per week basis. They explicitly excluded part-time "centralized" DHS arrangements. Again, the definition of a building was reconsidered and further expanded to say "a building will be considered as one building for all suites or room numbers located inside that are required by the U.S. Postal Service to use the same street address, regardless of the suite number."⁷⁶ The regulation was roundly criticized for the vagueness of the "substantial" and "substantially all" tests.

In their 2004 publication, the regulators created three alternative tests to satisfy the "same building" requirement. They replaced the prior regulations with its reference to substantial and substantially all and primary purpose. In the first test,⁷⁷ the designated health service is considered to be furnished in the same building if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 35 hours per week and the referring physician or one or more members of his or her group regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week. Some of the services must be unrelated to the furnishing of DHS, whether federal or private pay, although the unrelated physician services may lead to the ordering of DHS. The purpose was to address some concerns expressed by radiologists, oncologists, and others whose practices primarily consist of furnishing DHS. As far as the regulators are concerned, "Conceptually, this test generally describes buildings that are the principal place of practice for physicians or their groups."⁷⁸

⁷⁴ 66 Fed Reg 888 (Jan 4, 2001)

⁷⁵ Id.

⁷⁶ 66 Fed Reg 889 (Jan 4, 2001)

⁷⁷ 42 CFR §411.355(b)(2)(i)(A)

⁷⁸ 69 Fed Reg 16073 (March 26, 2004)

Under the second test,⁷⁹ the building qualifies as the same building if the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week and the referring physician regularly practices medicine and furnishes physician services to his or her patients in that office at least 6 hours per week, including some services unrelated to the furnishing of DHS. The regulators pointed out that “in this test, services provided by members of the referring physician’s group practice do not count toward the 6 hour threshold.”⁸⁰ Conceptually, this test generally describes a building where a referring physician practices at least one day a week, but then they go on to say, “and that is the principal place in which the physician’s patients receive physician services.”

The third test⁸¹ says the same building test is met if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week and the referring physician or a member of his or her group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week in that office. This third test is qualified by an additional condition that states that the referring physician must be present and order the DHS in connection with a patient visit during the time the office is open, in the building where the referring physician or a member of his group must be present while the DHS is furnished during the time the office is open in the building. The test requires presence in the building but not necessarily in the same space or part of the building. Here, the regulators distinguish from the other two tests by saying that, “Conceptually, this test generally describes buildings in which referring physicians or group practice members provide physician services to patients at least one day per week and the DHS are offered during a patient visit or the physicians are present during the furnishing of the designated health service.” The regulators explained that while the time tests must be met, the standard is regularly and not uniformly, so vacation time and other failures to meet the hourly test in some instances are not fatal. In its discussion of these new requirements, the regulators reasserted the legitimacy of using the post office address as the touchstone for a building and also emphasized that the rules did not intend to preclude physicians from purchasing the technical components of other studies.

Under these revised rules, block time leasing of an MRI, CT, or a physical therapy space would be entirely legitimate to meet the in office ancillary services exception, provided that the time commitments were met. Some analysts, in viewing the new rules, thought that they eliminated the opportunity, which had been published as early as 2001, allowing physicians who are of separate practices but in the same medical office building to jointly share a designated health service by virtue of being on the same lease for the space in the same building, as well as by sharing by joint ownership or jointly leasing the equipment to be utilized. As long as each practice can meet the relevant requirements for the type of in office ancillary services rendered, block time leasing is not necessary since they both,

⁷⁹ 42 CFR §411.355(b)(2)(i)(B)

⁸⁰ 69 Fed Reg 16073 (March 26, 2004)

⁸¹ 42 CFR §411.355(b)(2)(i)(C)

in effect, hold the designated health service "by the entirety." "Shared facilities in the same building are permitted to the extent they comply with the supervision, location, and billing requirements of the in office ancillary services exception."⁸²

Interestingly, despite all of the emphasis on bricks and mortar, in response to commenters concerned about being able to provide in office ancillary services in a patient's home, the regulators claim that a home care physician meets the same building test if his or her principal medical practice consists of treating patients in their private homes which do not include nursing, long term care, or other facilities, and the physician or staff member accompanying him or her provides a designated health service in a private home contemporaneously with a physician service that is not a designated health service, and the other exception requirements are met, such as employment or personal services.⁸³

3. Who can bill for the services?

The statute sets forth that the billing must be done by "the physician performing or supervising the services, a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice."⁸⁴ In responding to comments on the proposed regulations, with regard to the billing requirements, the regulators noted "the billing requirements set forth in these regulations is for the purpose of determining whether a designated health service fits within the in office ancillary services exception such that, as a threshold matter, a claim or bill for the service may be submitted at all by a physician or group practice. If a claim or bill may be submitted, it must still comply with all applicable Medicare payment and coverage rules (including, for example, the "incident to" rules)."⁸⁵

For a group practice to permit the physician performing or supervising the services to bill under his or her own number flies in the face of the requirement that 75%, on average, of the services by the members of the group through the group is required to meet the definition of a group practice. With respect to a group practice billing under a number that is assigned to the group practice, this implicates all of the reassignment rules.

The Medicare rules for reassignment establish the circumstances under which Medicare will make payment to someone other than the individual who rendered the services to the patient. Under regulations that were originally promulgated in 1973, the principle of restricting reassignment was to prevent factoring of claims, which would mean that Medicare accounts receivable could not be sold as commercial paper. For claims for in office ancillary services to be paid on the basis of a number assigned to a group, the reassignment rules are triggered.

⁸² 66 Fed Reg 888 (Jan 4, 2001)

⁸³ 66 Fed Reg 884 (Jan 4, 2001)

⁸⁴ 42 USC §1395nn (b)(2)

⁸⁵ 60 Fed Reg 16076 (March 26, 2004)

The traditional bases for reassignment included by an employee to his employer, pursuant to a court order, payment to a billing company, payment under reciprocal billing arrangements where physicians cover for each other, billing for locum tenens, and several others.⁸⁶ There had long been a provision on the books which allowed an independent contractor physician to reassign the right to payment to an outpatient clinic, but only for services that were provided on the premises of the clinic.⁸⁷ Finally, in 2004, effective January 1, 2005, Congress enacted a provision that created the most liberal standard for carrier claims only, meaning claims that are submitted under the physician fee schedule primarily. Under this provision of reassignment, a carrier may make payment to an entity (i.e., a person, group, or facility) enrolled in the Medicare program where a physician reassigns the right to payment to any contracted entity, regardless of where the service is furnished. The conditions associated with this rule were that the entity receiving payment and the person furnishing the service would be jointly and separately responsible for any Medicare overpayments, and the person furnishing the service would have unrestricted access to claims submitted by an entity for services provided by that person.⁸⁸

In interpreting the contractual arrangement exception for reassignment, the Stark regulators said, "we interpret this to require that the contractual arrangement be directly between the group practice and the independent contractor physician, and not between the group practice and another entity such as a staffing company."⁸⁹ They implemented this by modifying the definition of a physician in the group practice to state that a "physician in the group practice" qualifies as such as an independent contractor physician during the time he is furnishing patient care services for the group under a contractual arrangement directly with the group practice. The contract must contain the same restrictions on compensation that apply to members of the group practice under 42 CFR §411.352(g), or the contract must satisfy the requirements of the personal services arrangements exception in 42 CFR §411.357(d); and the arrangement must comply with the reassignment rules. The requirement for a direct contractual relationship with the physician is silliness in most instances. First, the actual act of completing the 855R form by which the physician reassigns to the group is a contract in and of itself. If one group leases a part time cardiologist, for example, from another group, both the individual physician who was leased and the group can sign the contract and the standard will be met, since the regulation does not say the agreement may be only between the individual physician and the billing group.

The third entity which can bill for in office ancillary services is an entity which is wholly owned by the group practice. There had been some discussion as to whether the wholly owned entity could be wholly owned by a mirror image of the ownership in the group

⁸⁶ Medicare Claims Processing Manual Ch. 1 §30.2

⁸⁷ See Gosfield, "Slouching Toward the Millennium: False Claims in Medicare Physician Billing," HEALTH LAW HANDBOOK (1997 ed) Clark Boardman Callaghan, p 75

⁸⁸ Medicare Claims Processing Manual Ch.1 §30.2.7

⁸⁹ 72 Fed Reg 51018 (Sept 5, 2007)

practice which was providing in office ancillary services; but in responding to commenters in 2007, the regulators explicitly addressed the issue of whether an entity wholly owned by the group members in their individual capacity to mirror the group practice could qualify. The statute and regulations, they said, require that the group practice must wholly own the billing entity. In other words, it must be a direct subsidiary of a single corporate entity. The mirror image approach described by the commenters would not satisfy this requirement. The regulations make clear that claims submitted by a wholly owned entity must be submitted under a billing number assigned to the entity or a billing number assigned to the physician or group practice.⁹⁰

Anti-Markup Rule

Although quite separate from the Stark statute and regulations, there had long been a Medicare reimbursement rule on the books in the Carrier's Manual at Section 15048 which addressed the markup of a purchased technical component of a diagnostic test. The primary determinant as to whether a technical component had been purchased was who employed the technician performing the service. If the technician was not the physician's own employee, then the physician could only charge to Medicare the amount that was charged to him by the outside supplier providing the technician and/or the equipment.⁹¹ In 2007, published under issues relating to physician self-referral (i.e., Stark), the regulators completely revamped all of the concepts associated with the anti-markup rule.

The anti-markup rule applies to all Medicare diagnostic testing, but only to diagnostic testing. Therefore, it includes all of the Stark DHS diagnostic testing. The anti-markup rule applies when the technical component (TC) or the professional component (PC) is ordered by the billing physician or other supplier (or by a related party) and the physician supervising the TC or performing the PC does not "share a practice with the billing physician."⁹² If the markup is prohibited, the amount that the physician may charge, whether a Stark service or not, is the actual charge where the payment is per transaction, the fee schedule amount, or the "net charge," which is an unfathomable concept offered by the regulators. The anti-markup rule does not affect coverage, but the payment amount. One must meet the Stark standards in order to have a billable claim, but one must analyze the anti-markup rule to determine how much may be submitted on a claim.

To determine whether the physician either performing the PC or supervising the TC shares a practice, there are two tests. The first is that the physician performing the service provides substantially all of his services through the group, which means 75% of his services. Presumably, this count is based on time as it is under the Stark statute, but the regulations do not specify. If that standard cannot be met, and the billing entity has a

⁹⁰ 72 Fed Reg 51035 (Sept 5, 2007)

⁹¹ See Gosfield, "Part B Physician Reimbursement: Developments, Limits, and Pitfalls." 1990 HEALTH LAW HANDBOOK (Clark Boardman Company) pp 281-283

⁹² See 42 CFR §414.50

reasonable belief at the time it submits the claim that the performing physician did perform substantially all of his services with them for the previous 12 months or is expected to, then the site of service is irrelevant. This is similar to the issue that the members of a group practice under the Stark definitions are not restricted with respect to the site of service where they provide services for the group, while an independent contracted physician is only a physician "in the group practice" when he is on the premises of the group.

The second test for whether a markup will be prohibited is based on the site of service. Where the TC is supervised or the PC is performed, the site must be the office of the billing entity, which is the location in which the ordering physician regularly furnishes services and the ordering physician provides the full range of his services. This is more stringent than Stark, which allows the group practice to have an office normally open to patients during limited times. In addition, the requirement to provide the full range of services is not the more liberal "some physician services unrelated to the furnishing of DHS," which applies in the Stark shared facilities context.

The implication is that the supervising or performing physician must reassign his rights to benefits under Medicare. The site of service test requires on premises physician supervision even if the Medicare standard is otherwise general supervision. No vans may be used, even if they are controlled 24 hours, 7 days a week. The physician supervising the TC must be an owner, employee, or independent contractor of the billing entity. The anti-markup rules do not permit a centralized building without co-located offices, unless the performing physician can meet the "shares a practice" test. By contrast, block leases that meet the in office ancillary services requirements can meet the anti-markup standard and shared facilities with two practices in the same building sharing DHS would be legitimate under the anti-markup rules.

Conclusion

The internecine interrelationships between the Stark rules and Medicare's physician reimbursement rules are absurd. Most of the reimbursement requirements are motivated by the now universally regarded as archaic fee for service reimbursement system for physicians, which Medicare has deployed since its inception in 1966. As medical practice has gotten more complex, so have the efforts of the regulators to control, ever more minutely, physician behavior in the hopes of achieving cost containment first and foremost. None of this has worked. Now, as we are beginning to shift to methods of payment which do not focus so much on the individual widgets in the fee schedule that produce reimbursement, and, rather, reward those physicians who achieve better results at lower cost, the complexity of the Medicare reimbursement system should improve. Whether the Stark statute will ever be repealed is another problem. Given congressional gridlock, I would find agreement on Stark repeal to be as elusive as it is on other issues. In the last analysis, it makes for considerable work for lawyers, while it contributes very little to the improvement of healthcare in America.