

FRAUD & ABUSE

PROPOSED REGULATORY CHANGES THREATEN MANY COMMON HOSPITAL-PHYSICIAN COLLABORATION ARRANGEMENTS

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As health care attorneys and their clients have become more comfortable with the parameters of the federal prohibition on physician self-referrals, commonly referred to as the Stark Law, new variations of financial arrangements between hospitals and physicians have become commonplace.¹

These arrangements, which have been created by enterprising health care attorneys and their clients, are specifically tailored to comply with an exception or loophole to, or quirk of, the Stark Law and its implementing regulations.² The objective of these relatively new and now fairly common collaboration arrangements is to remove the arrangement to the greatest extent possible from the Stark Law's basic prohibition on a physician real-

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1. 42 U.S.C. § 1395nn.

2. The regulations implementing the Stark Law are set forth at 42 C.F.R. § 411.351 *et seq.* The regulatory history of the Stark Law is rather tortuous. Final regulations for the original version of the Stark Law, commonly referred to as Stark I, which only prohibited a physician's referrals for clinical laboratory services to an entity with which the physician had a financial relationship, were published in 1995. However, in 1993, Congress expanded the Stark Law's prohibition from referrals for clinical laboratory services to referrals for a number of "designated health services." This expansion is commonly referred to as Stark II. Although the Centers for Medicare & Medicaid Services (CMS) issued proposed regulations for Stark II in 1998, final regulations were not issued until 2001. Further, CMS issued these regulations in phases with Phase I being issued in 2001, Medicare & Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule, 66 Fed. Reg. 856 (Jan. 4, 2001) (hereinafter, the "Phase I Regulations"), and Phase II being issued in 2004, Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Final Rule, 69 Fed. Reg. 16,054 (Mar. 26, 2004) (hereinafter, the "Phase II Regulations"). CMS was supposed to issue Phase III of the Stark II final regulations in March of 2007; however, these regulations were just released by CMS. Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III); Final Rule, 72 Fed. Reg. 51,012 (Sept. 5, 2007) (hereinafter, the "Phase III Regulations").

izing a financial gain from his or her referrals to an entity with which he or she has a financial relationship.

Even if they can be structured to be minimally impacted by the Stark Law, such arrangements are not without statutory and regulatory oversight. To the extent that such arrangements involve Federal health care program beneficiaries (e.g., Medicare and/or Medicaid program beneficiaries), they implicate the Federal Anti-Kickback Statute, which generally prohibits any person or entity from paying, receiving, soliciting or offering to pay any remuneration, directly or indirectly, to any person in exchange for referrals for items or services reimbursable by a Federal health care program.³ Further, to the extent that the hospital is exempt from federal income tax, the arrangement is also subject to a number of prohibitions designed to prohibit charitable assets from unjustly enriching private persons or entities.⁴ Additionally, such arrangements are typically subject to a number of structural safeguards or mandates imposed by the particular Medicare reimbursement scheme implicated by the arrangement.⁵ Finally, such arrangements are typically subject to a number of state laws that may range from state licensure and certificate of need requirements to state prohibitions on kickbacks, fee-splitting, and self-referrals.⁶

Nonetheless, compliance with the Stark Law is of primary importance in structuring hospital-physician financial collaborations in that the failure to comply with an exception to the Stark Law results in the automatic prohibition of physician self-referrals. Further, the submission of a claim for a designated health service that is the result of a self-referral prohibited by the Stark Law results in the automatic imposition of penalties under the Stark Law regardless of the medical necessity of the services, the unavailability of alternative service providers, or the intent of the parties.⁷ In other words, the Stark Law generally creates a strict liability standard for physician self-referrals.

3. 42 U.S.C. § 1320a-7b(b). Violators of the Anti-Kickback Statute are subject to civil and criminal penalties, as well as exclusion from participation in any Federal health care program. *Id.* (criminal); 42 U.S.C. § 1320a-7a(a)(7) (CMP authority); 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion authority).

4. For general tax-exempt principles applicable to hospital-physician financial relationships, see Bernadette M. Broccoli & Kathleen Nilles, *Tax-Exempt Status of Health Care Organizations* (BNA'S HEALTH L. & BUS. SERVICES NO. 1900), § .04 (1997).

5. For example, CMS imposes a number of requirements on entities seeking provider-based status (i.e., in the hospital context, an entity seeking to bill under Medicare's Hospital Outpatient Prospective Payment System (HOPPS), including where such entities may be located, on when and how such entities may be managed by a third party, and how and when such arrangements may be joint ventured.) 42 C.F.R. § 413.65.

6. For an overview of state laws generally applicable to health care joint ventures, see THOMAS E. BARTRUM, *DIAGNOSTIC IMAGING CENTERS: LEGAL AND REGULATORY ISSUES*, (2ND EDITION), CH. VII (2006).

7. Technically, this statement is no longer completely accurate in that the Phase II Regulations provided an exception to the Stark law's denial of payment penalty for an entity that submits a claim for designated health services when the entity did not have

Of course, the limited applicability of the Stark Law is not the sole reason for the widespread embrace of these new models of hospital-physician collaboration. The fact is that any particular hospital-physician collaboration is the result of many factors. Further, many of these factors may be legitimate in that they are not intended to compensate physicians for referrals, but rather to address the business and clinical needs of the hospital. For instance, a hospital that is interested in developing a stereotactic radiosurgery service may determine that it makes good business sense to share the cost of acquisition of such expensive, new technology with a business partner. Further, since the service can only be offered to the community if a core of dedicated physicians will commit themselves to becoming proficient in the new technology, it makes sense to look to physicians who will utilize the equipment in choosing a business partner. Such a strategy may also prevent the duplication of expensive equipment in the hospital's market. Besides avoiding a potential arms race of new and expensive equipment, the increased utilization resulting from a jointly-owned piece of equipment may also result in the delivery of higher quality services, as numerous studies have indicated that there is a positive correlation between the quality of health care services and the number of such services performed by a particular provider of services.⁸

Nonetheless, it appears that the Centers for Medicare & Medicaid Services (CMS), in both its capacity as enforcement agency for the Stark Law and as Medicare payment policy-setting agency, is poised to either prohibit many of these new collaborative models or ensure that such models are no longer financially viable. CMS proposed significant amendments to the Stark Law, Medicare's reassignment prohibition⁹ and Medicare's purchased diagnostics rule¹⁰ in its Medicare physician payment update for fiscal year 2007 that would have prohibited or limited the availability of certain of the hospital-physician collaboration models discussed herein. Although most of these proposed changes were ultimately abandoned in fiscal year 2007, this summer CMS issued a number of additional regulatory changes, most significantly changes to the Stark Law and Medicare's purchased diagnostics rule, intended to specifically curtail many of the hospital-physician collaboration models discussed

actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the referring physician. 42 C.F.R. § 411.353(e).

8. See generally Ethan A. Halm, et al., *Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature*, 137 ANN. OF INTERNAL MED., 511-520 (2002). Further, duplication of equipment in a given market may actually increase pressure on the owners of the equipment to inappropriately utilize the equipment in order to cover the costs of the equipment.

9. 42 U.S.C. § 1395u(b)(6) (reassignment prohibition for suppliers and physicians); 42 U.S.C. § 1395g(c) (reassignment prohibition for providers); and 42 U.S.C. § 1396a(a)(32) (reassignment prohibition for Medicaid).

10. 42 U.S.C. § 1395u(n)(1); 42 C.F.R. § 414.50.

herein.¹¹ If these changes are adopted by CMS in the final rule as proposed, it will be necessary for hospitals and physicians to unwind many of these arrangements before January 1, 2008.

CURRENT MODELS

There are currently a number of possible hospital-physician collaboration models that can be structured in a manner so as to comply with the Stark Law.¹² Such collaborations may rely upon true exceptions to the Stark Law such as the whole-hospital or rural provider exception, or such collaborations may technically be exempt from the scope of the Stark Law because the physician-owner does not make “referrals,” the joint venture entity does not furnish designated health services, the joint venture entity does not constitute an “entity” for purposes of the Stark Law, or the joint venture entity does not bill the Medicare program for referrals of designated health services from physician-owners of the joint venture.

The hospital-physician collaboration models discussed herein rely upon the fact that the legal entity in which the physicians have an ownership interest does not constitute an “entity” furnishing designated health services for purposes of the Stark Law. The Stark Law currently defines an “entity” as “the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient’s behalf.”¹³ Hence, so long as the joint venture entity does not bill Medicare for designated health services, it is not necessary that the physician’s direct ownership interests in the joint venture entity be structured to fit within an ownership or investment interest exception to the Stark Law.¹⁴

These collaboration models, often referred to as “non-provider models” because the joint venture entity does not bill for designated health services in its own right, are not free from scrutiny under the Stark Law because such arrangements may create indirect financial arrangements among the various joint venturers. For instance, a hospital and a group of surgeons may form a joint venture entity to manage the hospital’s surgi-

11. Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule, 72 Fed. Reg. 38,122 (July 12, 2007) (hereinafter, the “2008 Proposed Physician Payment Update”).

12. By necessity, this article has to simplify many complicated health care regulatory issues. Also, our focus here is changes in the Stark law so we will be concentrating on compliance with the Stark law even though many of the hospital-physician collaboration models may raise significant issues under other health care statutory and regulatory schemes such as the Anti-Kickback Statute.

13. 42 C.F.R. § 411.351. One exception to this definition is that, if the person or entity has reassigned right of payment to either an employer or a healthcare delivery system, then the entity receiving the reassigned payment (with certain exceptions) will be the “entity” furnishing designated health services for Stark law purposes. *Id.*

14. The Stark law exceptions are generally categorized as: exceptions applicable to all financial arrangements, 42 C.F.R. § 411.355; exceptions applicable only to ownership or investment interests, 42 C.F.R. § 411.356; and exceptions applicable only to compensation arrangements, 42 C.F.R. § 411.357.

cal service. Although the joint venture entity would not result in a direct ownership in an entity for purposes of the Stark Law, the parties would want to assure themselves that any indirect financial relationships created as a result of the arrangement complies with the so that the surgeons may continue to utilize the hospital.¹⁵

Anecdotal evidence suggests that the most popular of this new breed of non-provider, hospital-physician collaboration model is the “under arrangement” model. This model arises from the fact that Medicare allows hospitals (as well as certain other providers) to obtain certain services that it furnishes to Federal health care program beneficiaries “under arrangement.”¹⁶ That is, instead of the furnishing the service directly, the hospital can contractually obtain the service from another service provider. The service, however, is billed and paid as if the service was furnished directly by the hospital.¹⁷ In essence, an “under arrangement” relationship is no more than a means by which a hospital can purchase particular services from another entity and offer such services to its patients as its own.

For instance, a hospital may choose to obtain magnetic resonance angiography (MRA) services under arrangement from a joint venture entity as opposed to furnishing the service directly. In such an arrangement, the hospital and a cardiology group might create a separate joint venture entity to furnish the equipment, services, supplies, and personnel necessary to furnish the technical component of MRA services to the hospital’s patients. The hospital would enter into a written agreement with the joint venture entity for the provision of such services, the written agreement would typically provide for the joint venture to be paid for each MRA service furnished to the hospital’s patients, and would further provide that Medicare’s payment to the hospital discharges the liability of any person (other than the hospital) to pay the joint venture entity for the services furnished to any Medicare beneficiary. Often times, such arrangements would also include a read agreement between the hospital and the cardiology group whereby the cardiology group furnishes reads (i.e., pro-

15. The Phase II Regulations created three-part tests for the determination as to whether an “indirect compensation arrangement” or “indirect ownership or investment interest” exists and, if so, whether the indirect compensation arrangement complies with the indirect compensation exception. 42 C.F.R. §§ 411.354(b)(5) (defining indirect ownership or investment interests), 411.354(c)(2) (defining indirect compensation arrangement), and 411.357(p) (excepting certain indirect compensation arrangements).

16. 42 U.S.C. § 1395x(w)(1); *see also* 42 C.F.R. § 410.27(a)(1)(i) (providing coverage for hospital outpatient services and supplies furnished incident to physician services if furnished directly or under arrangement); 42 C.F.R. § 410.28(a)(1) (providing that Medicare covers hospital outpatient diagnostic services whether such services are furnished directly or under arrangement); 42 C.F.R. § 410.42 (providing that except for certain exceptions Medicare only pays for hospital outpatient services furnished directly by the Hospital or under arrangement).

17. Medicare Claims Processing Manual (Pub. 100-4), Chapter 1, §10.3. Technically, a service is obtained “under arrangement” only when receipt of payment by the hospital discharges the liability of the beneficiary or any other person to pay for the service.

professional interpretations) for MRA services furnished at the hospital. The read agreement may be either an exclusive arrangement or a non-exclusive arrangement. The hospital would bill for the technical component of the MRA as a hospital outpatient procedure. The cardiology group, or any other supplier of professional reads, would bill the professional component of the service separately under the physician fee schedule.

Other popular non-provider, hospital-physician collaboration models include management companies and lease arrangements. Here again, these arrangements have not historically resulted in the physician having a direct ownership interest in an "entity" for purposes of the Stark Law. Of these collaboration models, lease arrangements are probably more common and raise, in the author's opinion, more interesting health care legal issues.

In the hospital-physician collaboration context, equipment leases typically fall into one of two categories: (i) physicians providing equipment to the hospital for which the hospital bills payors for the services furnished via such equipment or (ii) hospitals providing physicians with access to equipment for which the physicians bill payors for the services furnished via such equipment. In each arrangement, the government's concern arises from the fact that the physician, either as lessor or lessee of the equipment, will potentially realize a financial gain through referrals for services furnished on such equipment.

The classic example of the first type of equipment leasing arrangement is the situation where a hospital leases a lithotripter from a group of urologists so that the hospital can provide lithotripsy services at the hospital. The hospital typically pays the urology group a pre-determined, fixed amount per use (also known as a per click fee) of the equipment. Accordingly, the urologists make money, in the form of the lease payment, when they or any other physician orders lithotripsy services furnished on the equipment. Such arrangements may be structured so that the hospital and the physicians jointly own an equipment leasing company that leases the equipment to the hospital. Although such joint ventures are rare in the context of lithotripsy arrangements, they are quite common in radiation therapy equipment leasing arrangements.

Another variation of equipment leasing arrangements used in hospital-physician collaborations involves the hospital giving the physician or his or her medical group access to equipment to which they might not otherwise have access. For instance, a hospital might find itself in a situation where it has excess capacity on a piece of imaging equipment that is housed in a medical office building. In such a situation, the hospital may consider whether there are any physician tenants in the medical office building that may wish to utilize the imaging equipment on a part-time basis. Assuming that there are such physician tenants, the hospital may seek to structure a lease arrangement whereby the physician tenants lease the equipment, typically on a per block of time basis (as opposed to a per

click basis), for use by the physician-tenant's practice.¹⁸ The physician-tenant would pay a fair market value lease fee for such block of time and would have exclusive right to use the equipment and corresponding space during such blocks of time. Depending upon the structure of the arrangement, the physician-tenant will either bill the services furnished on the equipment as his or her own service, or as a purchased service. In structuring such block lease arrangements, it is essential that the billing physician be able to comply with the Stark Law's in-office ancillary services exception if the service is going to be offered to Medicare beneficiaries.¹⁹

A variation on the block lease arrangement is the so-called shared expense model. Although the shared expense model relies upon the same legal reasoning as the block lease arrangement, this variation allows for greater flexibility with respect to each tenant's utilization of the equipment. For instance, consider the situation where a hospital has a magnetic resonance imaging (MRI) machine housed on the same floor as an orthopedic group and a neurology group, each of whom would like to lease the excess capacity that the hospital currently has on the existing MRI machine. As opposed to structuring two block lease arrangements with the groups, the hospital may consider transferring the equipment to a joint venture entity owned by the hospital, the orthopedic group and the neurology group. The joint venture entity would lease the equipment to each owner on a first scheduled basis and each owner would buy into the joint venture entity based upon its expected utilization of the equipment. The structure would not contemplate value being built in the joint venture entity but instead the entity would be used primarily as a means to share the expense of the operation of the equipment. The joint venture entity would lease the physical space for the equipment from the hospital on a fair market basis, and may consider employing technicians that operate the MRI machine.

PROPOSED STARK LAW CHANGES

In its 2008 Proposed Physician Payment Update, CMS proposed a number of significant amendments to the current Stark Law regulations and sought comments on other changes that it is considering but has not yet proposed.²⁰ These amendments, if adopted in the final physician payment update to be published later in the year, would constitute the most

18. The block lease arrangement is used to assist the physician-tenants in avoiding application of Medicare's purchased diagnostics rule to the arrangement. That is, by being at risk for delivery of the service, the physician-tenant is arguably the "provider" of the service and not the purchaser of the service, and therefore, the physician-tenant may not be subject to the prohibition on a physician marking up the technical component of a purchased diagnostics service.

19. See 42 C.F.R. § 411.355(b).

20. CMS proposes more changes to the Stark Law than discussed herein. See 72 Fed. Reg. at 38,179-187.

sweeping changes to the Stark Law regulations that CMS has yet made outside of the its dedicated Stark Law rulemaking process.

Most significantly, for purposes of the hospital-physician models discussed herein, CMS is proposing to expand the definition of “entity” for purposes of the Stark Law from the current definition, which is limited to persons or entities to which CMS makes payment for designated health services, either directly or upon assignment, to include persons or entities that perform designated health services.²¹ Interestingly, CMS chose not to adopt the proposal put forth by the Medicare Payment Advisory Commission (MedPAC) in 2005, which would have expanded the definition of entity for Stark Law purposes “to include interests in an entity that derives a substantial portion of its revenue from a provider of designated health services.”²²

This proposed change is in response to the perceived proliferation of under arrangement models and CMS’ concern that this trend will further increase upon implementation of the revised Ambulatory Surgery Center (ASC) payment system, which goes into effect on January 1, 2008 and currently provides that ASCs will be paid approximately sixty-five percent of CMS’ payment for the same procedure billed under the Hospital Outpatient Prospective Payment System (HOPPS). That is, given forthcoming payment disparity between surgeries performed in an ASC compared to the same procedure performed in a hospital’s outpatient surgery department, CMS expects more hospital-physician collaborations to restructure their operations as under arrangement joint ventures to capture the higher reimbursement available for hospital outpatient surgeries.

CMS’ proposal leaves unanswered exactly what activity constitutes the performance of designated health services. That is, although it may be clear that an under arrangement provider or staffing company would be deemed to be performing designated health services, does an equipment leasing company “perform designated health services” even if it does not furnish technical personnel to the hospital? One could reasonably argue that the provision of equipment, in and of itself, does not result in the performance of designated health services. Nonetheless, such a result would be surprising because MedPAC had specifically indicated that one of the potentially abusive practices it was concerned about in making its recommendation was physicians leasing equipment to entities furnishing designated health services to which the physicians make referrals for services furnished on such equipment. Further, in explaining its proposed change, CMS repeatedly expresses its concern regarding physician ownership of “leasing, staffing, and similar entities.”²³

21. *Id.* at 38,186-187.

22. MEDPAC, REPORT TO CONGRESS: MEDICARE PAYMENT POLICY (Mar. 2005).

23. 72 Fed. Reg. at 38,187.

The same uncertainty exists with respect to management contracts as to what level of services will constitute the performance of designated health services. Presumably, turn-key management agreements would result in the manager performing designated health services; however, if the manager is not performing clinical services, one could reasonably argue that the manager is not performing designated health services.

CMS is also proposing restructuring the office and equipment rental exceptions to prohibit per click (and other per unit-of-service) lease arrangements to the extent that such charges reflect services provided to patients referred to the lessee by a physician lessor.²⁴ If adopted in the final regulations, this change would prohibit a physician from renting equipment to a hospital on a per click basis when the hospital uses such equipment for services rendered to patients referred to the hospital by the physician thus eliminating most per click lease arrangements. CMS is concerned that such arrangements are “inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee.”²⁵ Interestingly, the proliferation of per click leasing arrangements can be traced to CMS’ approval of such arrangements in the Phase I Regulations.²⁶

CMS is also soliciting comments as to whether a similar prohibition should be enacted with respect to situations where an entity leases equipment or space on a time-based or per unit-of-service basis to a physician lessee. However, despite the commentary to the proposed rule, which distinguishes between physician and non-physician lessors, the current text of the proposed amendments to the equipment and space lease exceptions does not appear to make such a distinction. This turn of events is interesting because, as mentioned earlier, the position taken by CMS in the Phase I Regulations was the impetus for wide-spread interest in per click lease arrangements. One uncertainty with respect to this position is whether per service arrangements would be allowable when the arrangement includes services bundled with the use of equipment, which is the case in most under arrangement situations.

Despite the fact that in 2004 CMS specifically backed down from its plan to prohibit percentage-based compensation arrangements in the Phase II Final Regulations, in the 2008 Proposed Physician Payment Update, CMS is proposing to restrict the use of percentage-based compensation to only compensating physicians for physician services that they perform.²⁷ Specifically, CMS is concerned that percentage-based compensation arrangements in equipment and office rentals (especially when such percentages are tied to a percentage of revenues raised by the equipment or in the space) are potentially abusive. To effectuate such a prohibition, CMS is proposing that percentage compensation arrange-

24. *Id.* at 38,183.

25. *Id.*

26. 66 Fed. Reg. at 876.

27. 72 Fed. Reg. at 38,184.

ments: (i) be used only for paying for personally performed “physician services”²⁸ and (ii) must be based on revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department.

This prohibition would prevent the use of percentage-based compensation in any of the other compensation exceptions that require compensation to be set in advance. For instance, a hospital could not pay a percentage compensation arrangement to an entity owned in part by physicians for management services, equipment leases, and space leases. Further, with respect to independent contractor agreements, the proposed changes would prohibit a hospital from paying a physician for the provision of administrative or management services on a percentage basis. With respect to independent contractor physician arrangements, a hospital would also have to limit itself to paying on a percentage of revenue bases only for physician services covered by Medicare. Hence, if enacted as proposed, a hospital could not pay a physician (or physician owned entity) for management services on a percentage basis even if the percentage was limited to a percentage of the total compensation for achieving certain quality or patient satisfaction standards. Likewise, physicians could not be compensated on the basis of a percentage of collections, a percentage of a fee schedule or other similar methods currently utilized by hospitals and others in the health care industry (i.e., as proposed, a hospital would be limited to percent of revenues only).

CMS is also seeking comments on whether the in-office ancillary services exception should be amended so as to require some type of nexus between the ancillary services protected by the exception and “the diagnosis or treatment that brought the patient to the physician’s office.”²⁹ Such a nexus, according to CMS may curb “the proliferation of in-office laboratories and the migration of sophisticated and expensive imaging or other equipment to physician offices.”³⁰ Any change in the in-office ancillary services exception is likely to negatively impact block lease and shared expense models since both depend upon the physician-tenant being able to bill for such services under the in-office ancillary services exception.

Despite the fact that Congress specifically rejected a more limited in-office ancillary service exception proposed by then President Clinton in 1993, CMS seems determined on limiting the scope of what is arguably, the most important of the Stark Law exceptions.³¹ It should be noted that CMS’ request for comments comes on the heels of CMS’ proposed changes to the in-office ancillary services exception last year, which would have significantly modified the “centralized building” definition. Al-

28. CMS is using the term “physician services” as defined at 42 C.F.R. § 410.20(a). *See* 72 Fed. Reg. at 38,224.

29. 72 Fed. Reg. at 38,181.

30. *Id.*

31. S. 1757, 103rd Cong., 1st Sess., §4042(c)(2)(A) (1993).

though CMS' proposed changes were not ultimately adopted last year, CMS did announce that it is "committed to addressing revenue-driven arrangements that may be facilitating over utilization of diagnostic services" ³² This commitment may explain both CMS' widespread reversal of its previously articulated positions in the 2008 Proposed Physician Payment Update as well as its announcement that it will seek mandatory disclosure from approximately five hundred hospitals (in fifteen states) of existing hospital-physician relationships. ³³

PAYMENT CHANGES IMPACTING CERTAIN HOSPITAL-PHYSICIAN
COLLABORATION MODELS

In addition to the regulatory changes to the Stark Law, CMS also proposes two payment changes that could impact the continued viability of many existing block lease arrangements from both a legal and economic perspective: (1) expanding Medicare's purchased diagnostics rule to cover both the professional technical components of diagnostic tests and (2) adopting a new enrollment standard for Independent Diagnostic Testing Facilities (IDTFs) that would prohibit IDTFs from sharing space, equipment and personnel with, or leasing its operations to, another person or entity.

To understand the proposed changes to the purchased diagnostics rule changes, it is necessary to have some background knowledge of the purchased diagnostics rule. The purchased diagnostics rule currently provides that a physician or medical group that neither performs nor supervises the performance of the technical component of a diagnostic test can nonetheless bill for the technical component of such test, so long as the claim form specifically identifies both the supplier of the test and the amount that the supplier charged for the technical component. ³⁴ Medicare will then pay the lower of the amount charged by the supplier or the Medicare physician fee schedule amount. In other words, the physician is prohibited from realizing a profit on a purchased technical component, because the physician cannot mark-up the test.

Often in block lease or shared expense arrangements the billing physicians (i.e., the physician lessee) will attempt to make a distinction between purchasing the technical component, which would be subject to the purchased diagnostics rule, and either supervising or performing the service themselves, which would not be subject to the purchased diagnostics rule. That is, in the latter case, the physician would actually be the supplier of the technical service and therefore, not subject to the purchased diagnostics rule. To take advantage of this distinction, diagnostic suppliers have attempted to structure relationships whereby they simply

32. 71 Fed. Reg. at 69,688.

33. 72 Fed. Reg. at 28,056.

34. 42 U.S.C. § 1395u(n)(1); 42 C.F.R. § 414.50. Additional requirements are set forth in the Medicare Claims Processing Manual (Pub. 100-04), Chapter 1, § 30.2.9.

lease equipment and/or personnel to the physician so that the physician is the “supplier” of the service.

As a practical matter, whether a person who leases equipment (and/or personnel) should be treated as the “supplier” or the “purchaser” of the service should depend upon whether the person is at risk for the service. If the person only pays for equipment and/or personnel on a “per click” basis, the person is not at risk for the service and appears to be a mere purchaser of the service. If, however, the person incurs costs associated with the service regardless of utilization, then the person appears to be the supplier of the service. Other factors that may be relevant to the determination include whether the person actually supervises the personnel (i.e., who trains, to whose protocols do the personnel adhere), who is ultimately responsible for the service (i.e., under whose liability insurance), and who is at risk for non-collection. Nonetheless, CMS has warned that “[t]he bona fides of such arrangements may be suspect and could be an attempt to circumvent the prohibition against the mark-up on purchased diagnostic tests.”³⁵

With respect to the purchased diagnostics rule, CMS proposes expanding the scope of the rule so that the anti-mark-up provision covers both the professional and technical components of diagnostic tests billed by a physician or medical group. CMS would also apply the purchased diagnostics rule in both purchased service and reassignment situations. Essentially, this change would prohibit physicians and medical groups from realizing a profit when they purchase or take assignment of either the technical or professional component of a diagnostic test.

Under such an expanded purchased diagnostics rule, CMS would limit payment to physicians and medical groups subject to the purchased diagnostics rule to the lower of: (i) the “supplier’s net charge” to the physician; (ii) the physician’s actual charge; or (iii) the fee schedule amount that would be allowed had the supplier billed the service directly. However, in seeking to prevent gaming of the anti-mark-up provision (i.e., the billing physician or group charging the outside supplier for space or equipment to manufacture a margin on the technical component), CMS has proposed defining the “supplier’s net charge” as excluding any payment made by the supplier to the billing physician or group for equipment or space rental.

CMS further proposes that for purposes of the purchased diagnostic rule, a diagnostic test is performed by an outside supplier whenever it is performed by someone other than a full-time employee of the billing physician or entity. Taken literally, this definition of an “outside supplier” would mean whenever the technical and/or professional component of a diagnostic test is furnished by either an independent contractor (regardless of whether part-time or full-time) or a part-time employee, the ar-

35. Medicare Claims Processing Manual (Pub. 100-04), Chapter 13, § 20.2.4.2.

rangement would be subject to the purchased diagnostics rule's mark-up prohibition.

Although the definition of "outside supplier" seems designed to address block lease arrangements, it is not clear that participants in such arrangements could not simply continue to rely on the argument that since they are bearing the risk for the furnishing the service (and/or furnishing supervision), the purchased diagnostics rule does not apply to such arrangements. In other words, one could argue that in the standard block-lease arrangement, the technical component of the test is neither purchased nor reassigned but instead furnished by the billing physician and therefore, beyond the scope of the purchased diagnostics rule.

However, such uncertainty does not exist with respect to IDTFs participating in such block-lease arrangements, since in the revised IDTF enrollment standards, CMS clearly takes the position that, regardless of the purchased diagnostics rule, IDTFs may not share personnel, equipment or space with another or otherwise lease its operations to another. The uncertainty here is whether an IDTF can enter into part-time arrangements with another and still meet the standard. For instance, under the revised enrollment standards for IDTFs, could an IDTF lease equipment, space and possibly, personnel from a third party on a part-time basis and qualify as an IDTF? That is, is the prohibition only on the IDTF being the lessor or is the prohibition intended to cover situations where the IDTF is also leasing such personnel, equipment and space.