The passing of the Patient Protection and Affordable Care Act (PPACA), as amended, and proposed use of Accountable Care Organizations (ACOs) signify an important shift in the healthcare system paradigm. This new national focus emphasizes the value of cooperation among providers, increased efficiency and quality patient outcomes, improved use of existing resources, and limitations on increasing healthcare costs. While the enthusiasm of this movement impacts many different healthcare providers, physicians have been experimenting for many years with methods to combine resources with other physicians to conserve resources, improve quality, and reduce costs. Although physician practices may affiliate in a variety of ways, this article focuses on one such approach: the shared diagnostic facility.

The Basic Shared Facility Structure

Under a shared facility approach, multiple medical practices located in the same building share in the ownership and/or leasing of diagnostic equipment (e.g., MRI, CT, PET) and space where the diagnostic testing is provided (e.g., office condo). A separate legal entity is not used for ownership of the space and equipment; rather, the multiple practices are equal “co-tenants” in their ownership/rent of the space and equipment. In turn, the participating practices have equal access to use the shared facility space and equipment for diagnostic testing on their patients as an extension of each participating physician’s practice. Referrals for diagnostic testing to the shared facility by a participating physician are considered self-referrals to such physician’s respective practice. The shared facility cooperative itself is not intended to be a vehicle to generate income for physicians. It is simply a mechanism whereby multiple practices share both in the costs of operating a diagnostic facility and the benefits and quality of on-site diagnostic testing services.
Regulatory Issues

A shared facility must be carefully structured to comply with relevant healthcare regulations. It is important to conduct a thorough review of the shared facility arrangement to ensure that each shared facility participant is operating its independent medical practice in compliance with relevant law and that each practice's involvement with the proposed shared facility is equally compliant. Failure to conduct an appropriate analysis of the potential regulatory impact at the outset can mean a lack of success for the shared facility, as well as federal and/or state regulatory implications for each participating physician practice.

Although there are multiple laws and regulations impacting a shared facility, of paramount concern are the Stark Law, Anti-Kickback Statute, and Independent Diagnostic Testing Facility (IDTF) regulations.

The Stark Law

The Stark Law generally prohibits the referral of Medicare patients for Designated Health Services (DHS) to an entity with which the referring physician (or family member) has a financial arrangement, unless an exception applies. Given that a shared facility is not a separate legal entity, referrals for diagnostic testing to the shared facility by the participating medical practices are actually self-referrals to each referring physician's respective practice. As the physicians participating in the shared facility each have an ownership interest or other financial relationship with their own practice, the Stark Law is implicated by this self-referral.

The applicable exception to the Stark Law that applies to the shared facility model is the In-Office Ancillary Services (IOAS) exception. The Centers for Medicare & Medicaid Services (CMS), the agency that currently regulates and enforces the Stark Law, has maintained, through multiple iterations of the Stark Law, that shared facility arrangements can be properly structured to comply with Stark Law regulations by meeting the IOAS exception. In response to a comment concerning solo practitioners who proposed to establish a shared clinical laboratory located in the same building, CMS indicated that “[S]olo practitioners may own and operate shared DHS facilities as long as they fit in the [IOAS] exception.” Accordingly, CMS indicated that structuring shared facility arrangements to meet the IOAS exception would permit use of non-abusive shared facility arrangements.

The IOAS exception allows a physician to lawfully make an otherwise-prohibited referral to the physician's own medical practice without violating the Stark Law. To meet the IOAS exception, each practice with two or more members must be deemed a group practice under the Stark Law. Any practice with more than two members not meeting the group practice definition may not qualify for the IOAS exception, and thus, may not participate in the shared facility. Once it is established that all practices with two or more members are group practices under the Stark Law definition, each participating practice must meet the remaining requirements of the IOAS exception, commonly referred to as the: (1) supervision; (2) location; and (3) billing components.

Supervision

Diagnostic testing at the shared facility generally will be conducted by a non-physician technician. To meet the IOAS exception, the testing must be supervised by a physician in the group practice, which includes physician employees or independent contractors of the practice. This means that each practice should enter into a contractual relationship with a physician (typically a radiologist) who will act as an independent contractor or employee to the practice when a patient of such practice obtains services at the shared facility. The supervising radiologist should identify himself or herself as a contractor or employee of the referring practice. Although it is not required that all medical practices participating in a shared facility use the same supervising radiologist(s), it is a simpler approach. The participating practices should provide the radiologist with the referring physician’s particular preferences or instructions, if any, regarding the diagnostic services provided to his or her patients. In the event that a participating physician practice contracts with a radiology group, it is essential that each radiologist providing services through that radiology group at the shared facility also execute the agreement between the radiology group and the practice participating in the shared facility. This is to ensure that a direct contractual relationship exists between the physician supervising the shared facility services and that participating practice, as required under the IOAS exception.

Location

To meet this prong of the IOAS exception, the shared facility must be located in the same building as each participating practice. Each practice must maintain a presence in the same building as the shared facility at all times while it participates in the shared facility and satisfy one of the Stark building tests related to number of hours the practice office is open in the building and provides services unrelated to the provision of DHS.

Billing

To meet the billing requirement of the IOAS exception, diagnostic tests conducted in the shared facility must be billed under the billing number assigned to the supervising radiologist's group practice. This means that services provided to patients of a particular practice must be billed under a number assigned to that group (i.e., the independent contractor or employee supervising the test is deemed part of the practice to which it provides services).

In addition to meeting the IOAS exception, physicians who refer patients for MRI, CT, or PET imaging services pursuant to the IOAS exception must provide patients with written financial disclosure of the financial interest at the time any referral is made for such imaging service. The written disclosure must inform the patient that he or she may obtain the test from other suppliers. The disclosure also must provide the patient with a written list of at least five suppliers who furnish the same testing service within a twenty-five-mile radius of the physician's office location at the time of referral. If a test is ordered for a patient over the phone, verbal notification must be made and written notification must immediately follow either by mail, fax, or email. There also may be specific state law
issues that apply to patient notifications. It is further recommended that such notice be practice-specific, with the name of the referring practice and physician included on the form.

An issue of particular debate with regard to shared facilities is whether each practice must “block-lease” the use of the shared facility. A block-lease is a mechanism whereby practices lease the shared facility for a specific period of time during which no other practice participants use the shared facility. This issue was raised in Phase III commentary to the Stark Law, where CMS specifically addressed the use of shared facilities in response to a question regarding whether physicians providing DHS in shared space (i.e., a shared facility) “could use simultaneously the facilities . . . and simply share the costs and administration of the DHS without having to separately lease the facilities for specific blocks of time.” In response, CMS indicated that physicians sharing a diagnostic testing facility in the same building must meet the Stark Law IOAS exception and control the facility and staffing at the time DHS is furnished to their patients, which, “[a]s a practical matter, . . . likely necessitates a block lease arrangement for the space and equipment used to provide the [DHS].”

On its face, CMS’ response could suggest that each shared facility participant must block-lease a specific period of time during which it may refer patients to the shared facility for diagnostic testing, although, notably, CMS did not elect to use language that mandated block leases for a shared facility model to be used. CMS’ reluctance to take a hard-line approach on requiring block leases appears to be even more evident in a response published on January 31, 2008, by CMS to an inquiry questioning CMS’ Phase III commentary. The requestor asked whether the Stark Law would be satisfied if, outside of a block-lease approach, “a group practice provide[s] and bill[s] for ancillary services provided in shared office space using shared equipment [and] if the supervision requirement for the particular service is satisfied by a ‘member’ of the group and the arrangement otherwise complies with Medicare coverage and reimbursement regulations.” In what arguably appears to be more evidence that CMS does not desire to mandate block leases, CMS answered this question in the affirmative, noting the requestor’s non-block lease approach was acceptable as long as the IOAS exception was met. CMS again did not expressly mandate a block-lease requirement.

Based on CMS’ comments, it would appear that while a block-lease approach is one acceptable structure to use in a shared facility model, a simultaneous-use approach, where all shared facility participants may use the shared facility at any time, also may be lawful if the referring practice controls the shared facility when its patients receive diagnostic services and all other IOAS exception requirements are strictly satisfied. How such control can be demonstrated, whether through signage, patient interaction, or other methodologies is unclear.

**Anti-Kickback Statute**

The Anti-Kickback Statute (AKS) generally is implicated by the payment of remuneration in exchange for referrals or other business payable under a federal healthcare program. Under a shared facility model, the participating physicians self-refer to their own practices and are not induced to do so by the payment of any remuneration. This conclusion is further reinforced by each practice’s compliance with the “group practice” definition under the Stark Law, which specifically prohibits a physician from receiving remuneration for referrals made. As the shared facility is not an independent entity, the participating physicians neither hold an investment interest nor garner any profits as a participant in the shared facility. Accordingly, the shared facility model is not prohibited by AKS.

**IDTF Regulations**

It is important to distinguish a shared facility from an IDTF. An IDTF is a Medicare-enrolled entity that provides diagnostic testing, which is billed under a specific IDTF provider number. IDTFs must meet strict operational and credentialing requirements. As a general rule, a physician practice is not required to enroll as an IDTF unless a “substantial portion” of the practice’s business involves the performance of diagnostic tests. As a guide, a practice historically is not deemed to be providing a substantial portion of its business in the performance of diagnostic tests if no more than 30% of patients receiving diagnostic testing from the practice are coming from referrals from physicians outside the
practice, although there is no firm published rule on this issue. To avoid any suggestion that the shared facility is operating as an IDTF, and therefore must enroll as an IDTF and meet the associated regulatory requirements, each practice should limit use of the shared facility to its own patients.

Memorializing the Shared Facility Arrangement
To comply with the aforementioned regulations, and to ensure each participant understands their shared facility obligations and general management, it is essential to memorialize all facets of the shared facility relationship. Minimally, the following agreements should be executed.

Regulatory Opinion
Counsel should conduct a thorough analysis of the shared facility model under applicable state and federal law. The regulatory opinion should contain all facts relevant to the particular shared facility, including the method by which the participating practices will share expenses.

Co-Tenancy Agreement
Similar to a shareholder’s agreement, the co-tenancy agreement reflects the understanding among all participating practices regarding their rights and responsibilities with respect to the shared facility. The co-tenancy agreement should detail such terms as:

- Sharing of expenses. Generally, if five practices participate in a shared facility, each is responsible for one-fifth of equipment and space costs;
- Sharing of associated expenses, such as utilities, taxes (if applicable), maintenance, etc. With respect to per-test cost of consumables (e.g., contrast media, films, etc.), the participants may choose to establish a per-test, fixed fee schedule based on the cost of supplies for a particular test, with each practice incurring the cost of consumables for its patients;
- Terms for leaving the shared facility;
- Process for admitting a new shared facility participant;
- Process for removing a shared facility participant;
- Terms for expanding diagnostic testing services; and
- Terms for dissolving the shared facility;

Equipment Lease/Purchase Agreement
Each practice will enter into a lease or purchase agreement for the diagnostic testing equipment to be used as part of the shared facility.

Shared Facility Space Lease/Purchasing Agreement
Each practice will enter into a lease or purchase agreement to lease or purchase space in the same building to locate the shared facility.

Practice Space Lease/Purchasing Agreement
A separate agreement for each participating practice to lease (or purchase) its office space in the same building as the shared facility.

Management Agreement
An agreement between each practice and the shared facility manager, if applicable, setting forth the management services to be provided. The manager may conduct the day-to-day management of the shared facility, including supply and/or management of personnel, supplies, and equipment. The manager also should be experienced in all facility licensing issues and other federal, state, and payor credentialing standards. As an independent contractor of each practice, the manager will provide concurrent services to all participants. Arguably, this approach further works to meet CMS’ directive that the referring practice control the facility at the time its patients receive services (i.e., the referring practice is controlling facility operations through its contracted manager). The manager also can expand services to include billing for testing on behalf of the participating practices and managing all financial aspects of the shared facility, including sharing of expenses by participating practices and administration of equipment and space leases and/or loans.

Radiology Agreement
Agreement between each practice and a radiologist/radiology group for supervision of diagnostic services.
Service Agreements

Depending on the needs of the facility, it may be necessary to draft employment or independent contractor agreements for ancillary service providers, such as nurses or radiology technicians. Unless otherwise employed or engaged by the shared facility manager, each participating practice should enter into an agreement engaging all personnel who will provide services at the shared facility.

As applicable, these agreements should be drafted to meet the appropriate Stark Law exception (e.g., rental of office space and equipment, personal service arrangements) and the AKS safe harbor provision (space and equipment rental, personal services, and management contracts).

Conclusion

For many physician practices, a shared facility may be a practical and more affordable method to provide necessary and higher-quality diagnostic services to patients. For the solo or small physician practice, it may be the only manner by which it can compete with larger, more resourceful groups. Physicians considering participating in a shared facility must proceed cautiously, taking great care to comply with all regulatory requirements and establishing a workable framework for shared facility operations. It is also important for physicians to carefully select their co-participants. A practice's creditworthiness, financial solvency, size, and enthusiasm for the venture should all be considered when structuring a shared facility. While the shared facility model itself is not new, it continues to be an effective and efficient approach for healthcare providers looking to meet new challenges and expectations of the healthcare system. With implementation of ACOs just around the corner, the shared facility model may prove a valuable resource for a competitive and successful ACO.

2 In its most basic sense, an ACO is an organization of hospitals and other healthcare providers established to provide quality and efficient patient care based on financial incentives for collaborative treatment and reduced healthcare costs. For the proposed ACO regulations, see 76 Fed. Reg. 19528, (Apr. 7, 2011).
3 An analysis of all regulations potentially impacting a shared facility approach is beyond this article's scope. To this end, an analysis of state law (e.g., state self-referral and/or anti-kickback regulations) and additional federal regulations should be conducted.
4 42 U.S.C. § 1395m, et seq.
5 42 U.S.C. § 1320a-7b et seq.
6 42 C.F.R. § 410.33(15)(g).
7 The Stark Law only applies to the referral of Medicare patients. Similar state self-referral laws may impact the shared facility structure, as well as the specific payment and participation requirements of individual insurers.
8 “Designated Health Services” are specifically listed by CPT code in the Stark regulations and are updated annually in the Physician Fee Schedule. The CPT codes that are listed generally include “Radiology services, including magnetic resonance imaging, computerized axial tomography scans and ultrasound services.” See definition of “designated health services” at 42 C.F.R. § 411.351.
10 The Healthcare Financing Administration was initially responsible for early Stark Law regulations. For ease of understanding, CMS will be used exclusively throughout this article.
There is no doubt that healthcare attorneys who represent physician groups are currently busy with sales of physician practices to hospitals or large healthcare systems. According to the Medical Group Management Association (MGMA), in 2005 more than two-thirds of all medical practices were physician owned. By 2008, that share dropped below 50%, MGMA reported. Physician groups are currently selling their groups to hospitals en masse.

Some of us who experienced the previous cycle of practice sales to hospital systems in the late 1990s, though, wonder if the trend will reverse itself. The sales trend in the 1990s boomeranged in the first years of this millennium, when we saw a lot of unwinds. Will the current trend follow the same course?

If history repeats itself, then as we draft current deals, we need to maintain an eye toward protecting our clients in the event of a future unwind. I want to use this Chair’s Column to share some thoughts on considerations when drafting a purchase and sale agreement in 2011 so that physician group clients have a viable opportunity to unwind if the new relationship with the purchaser does not work out.

• **Electronic Medical Records**—Unlike the sell-unwind cycle that occurred in the late 1990s and early 2000s, most practices today have to deal with some sort of electronic medical records system (EMR). If the selling practice has an EMR in place at the time of sale, will the practice be able to continue to use its EMR? With many systems buying practices with the aim of forming an accountable care organization or similar, fully integrated operation, the systems typically want any purchased practices to be on—or eventually get on—the same EMR system. If that happens, how will records from the practice's EMR be transferred into the hospital system's EMR? Or will they? If they are not, who pays to maintain the license fees and equipment on the old equipment? Who pays for necessary interfaces? And the same questions apply, perhaps twofold, in the event of an unwind. Does the physician group have to license the EMR from the hospital in order to continue to have patient records after the unwind?

• **Real Estate**—If a long-term lease of the building that is owned by the physician group upon the sale is leased to the hospital system, be mindful to allow termination of the lease in the event of an unwind.

• **Non-compete**—Also, if there is any non-compete, carve out the practice's existing location so that in the event of an unwind, the physician group can maintain its practice in its old/current space. Similarly, make sure non-solicitation provisions do not prohibit the group from being able to retain the staff it has at the time of an unwind.

• **Price**—As we learned during the last sale-unwind cycle, a high sales price may be great to the physicians at the time of the sale, but a high valuation can come back to bite them if they want to buy back their assets in an unwind. When setting a price for the sales of assets (which must, of course, be defensible as fair market value), be mindful of what the price will be if they want to buy back the assets in a few years. How is the valuator or appraiser chosen in the event of an unwind? Is there a way to characterize some of the money exchanging hands at the time of the sale to the hospital as something other than payment for the assets?

• **Forced sell-back?** Any employment agreement and/or asset purchase agreement with the hospital system should address whether the selling physician group can force the hospital system to sell back their assets in the event of an unwind. Sometimes hospital systems are happy to allow the physician group to unwind, perhaps after a few years, because if the relationship remains good, the hospital system may continue to secure their hospital business and (compliant) patient and ancillary referrals.
• **Location control and autonomy**—One of the more difficult issues to negotiate, particularly if the group is selling and becoming only employees of a larger, already-established system (as opposed to retaining its own corporation that is perhaps partly or wholly owned by the system), is to allow the continuation of decision-making locally (at the practice site). The lower the degree of local autonomy (and the higher the degree of power given to the system), the harder it is to achieve the practicalities of fluidly and without interruption operating a practice post-unwind. Consider negotiating into the agreement the right of the practice to appoint a chief of that location, who can enter into contracts up to a certain dollar amount, has veto power or the right to hire and fire staff, and determine staffing levels and salaries.

• **Contacting patients**—If in the unwind the physician group will continue in the same place, then contacting patients in the event of an unwind may not be a big concern. However, it is essential that the group negotiate the right to maintain the same telephone number upon an unwind, even if they stay at the same location, so that patients can continue to contact them.

• **What is an unwind?** The ultimate issue is how one defines an “unwind.” Is it when all the founding partners of the physician practice decide to leave employment with the hospital system? Or is it when a majority decides to do it? Or when all of the physicians employed by the practice at the time of sale decide they want out?

Perhaps if our clients decide in five or ten years that, in fact, the grass is not greener on the other side, then they will be thankful that we advised them to view the sale as a preparation for a future re-purchase.

*Ann M. Bittinger is chair of the Physician Organizations Practice Group. She practices health law through The Bittinger Law Firm, located in Jacksonville, FL.*

---

**Physician Organizations Practice Group Leadership**

**Ann M. Bittinger, Chair**  
Bittinger Law Firm  
Jacksonville, FL  
(904) 821-9000  
ann@bittingerlaw.com

**Rick L. Hindmand, Vice Chair – Strategic Activities**  
McDonald Hopkins LLC  
Chicago, IL  
(312) 642-2203  
rhindmand@mcdonaldhopkins.com

**David T. Lewis, Vice Chair – Research & Website**  
Husch Blackwell LLP  
Chattanooga, TN  
(423) 757-5935  
david.lewis@huschblackwell.com

**Julie E. Kass, Vice Chair – Membership**  
Ober | Kaler  
Baltimore, MD  
(410) 347-7314  
jekass@ober.com

**Kim Harvey Looney, Vice Chair – Educational Programs**  
Waller Lansden Dortch & Davis LLP  
Nashville, TN  
(615) 850-8722  
kim.looney@wallerlaw.com

**Sidney S. Welch, Vice Chair – Publications**  
Arnall Golden Gregory LLP  
Atlanta, GA  
(404) 873-8182  
sidney.welch@agg.com
Dynamics of the Relationship Between Physicians and Home Health Agencies and Hospices

Douglas M. Wolford, Esquire
Catherine J. B. Sloan, Esquire
Bass Berry & Sims PLC
Nashville, TN

Physicians play many different roles providing medical and administrative services for home health agencies (HHAs) and hospices, and their patients. The Medicare conditions of participation for both hospices and HHAs address certain activities in which a physician is required to either personally perform or participate in conjunction with other employees or contractors. To meet certain of these requirements, HHAs frequently elect to contract with physicians to serve as medical directors, whereas hospices must have a medical director and either contract or employ physicians to fulfill this role. However, because physicians also can be significant referral sources for both HHAs and hospices, these financial relationships may implicate the federal Anti-Kickback Statute (AKS) and the federal physician self-referral statute (Stark Law), and can result in significant liability if not properly structured.

Home Health

The Medicare home health benefit requires physician involvement for Medicare beneficiaries to qualify for an array of services in their homes. To qualify, a physician must certify each patient’s plan of care and the patient must be homebound and require intermittent skilled nursing care or speech or physical therapy. In addition, Medicare requires that an HHA have a group of professional personnel, which must include at least one physician, to establish and review annually the HHA’s policies governing scope of services offered, admission and discharge of patients, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. There is no regulatory mandate to have a formal medical director.

Physicians also must periodically review the plan of care every sixty days and certify any changes. For the HHA and physician, respectively, to receive payment for home health services, a physician must certify that the individual meets the eligibility requirements discussed above as well as certify that the patient’s care will be supervised and periodically reviewed by a physician. This certification must be obtained within either ninety days prior to the start of home healthcare or thirty days after the start of care. Effective for each initial start of care on or after January 1, 2011, the certifying physician must also document that he or she, or a non-physician practitioner working with the physician, had a face-to-face encounter with the patient at the time the plan of care is established. To fulfill the face-to-face requirement, the physician must physically see the patient for a condition that is the primary reason home health services are needed. In addition, the physician must document the encounter with a brief narrative describing the patient’s clinical condition and how the patient’s condition supports homebound status and the need for skilled services. Failure to provide this face-to-face encounter could potentially lead to administrative hassles such as patients walking into the physician’s office unannounced and requesting completion of their face-to-face encounter. In some states, such as Maryland, professional boards may subject physicians to censure for unprofessional conduct if the failure is reported to the state’s medical board. In addition, an HHA that does not meet the face-to-face requirement will not be eligible to receive payment, in part because there will not be a valid certification that a patient qualifies for Medicare home health benefits.

Many HHAs elect to contract with physicians to serve as medical directors to meet the Medicare requirement for physician involvement in providing certain advisory services. These physician arrangements should be carefully scrutinized given that physicians can be a significant referral source for HHAs, and home health services are categorically defined as “designated health services” (DHS) under the Stark Law. Thus, any “referral” from a physician could implicate Stark when a financial arrangement, such as a paid medical director relationship, exists between the referring physician and HHA. A physician is considered to make a “referral” when establishing a plan of care, or certifying a patient for home healthcare, which would include the face-to-face encounter documentation. Therefore, a physician’s financial relationship with an HHA must meet an exception to the Stark Law. The personal services exception to the Stark Law likely would be the most useful Stark exception for medical director arrangements, though other exceptions also may be applicable. There are seven elements to the personal services arrangement exception including that the arrangement be signed and in writing, be for a term of at least one year, specify all of the services to be covered, be reasonable and necessary, and serve a legitimate business purpose, and that the compensation be set in advance and not exceed fair market value or be determined in a manner that takes into account the volume or value of referrals.

When these requirements are not met, liability under the Stark Law can arise. As an example, in February 2007, a federal court in United States ex rel. Roberts v. Aging Care Home Health, Inc. found an HHA and its owners violated both the Stark Law and the federal False Claims Act (FCA) due to the improper financial relationship between the HHA and five medical directors. The HHA and its owners were ordered to pay nearly $4.7 million in penalties and fines as a result of both substantive and technical violations of the Stark Law, as well as FCA. The HHA in the Aging Care case ran afoul of the Stark Law due to its contractual arrangements with multiple medical directors in which the physicians performed little or no actual services, but were paid $25 to $50 an hour. Despite the fact that the medical director...
physicians all had signed written agreements with the HHA in which the physicians were required to perform specific services;\textsuperscript{27} the court found the HHA's agreements with all five physicians did not meet the Stark exception because the parties “failed to specify the services actually performed, the physicians were compensated for performing unnecessary services at rates that exceeded fair market value, and the [the] 1999 agreements failed to include terms of at least one year or more.”\textsuperscript{28} One of the physician's records did “indicate that he performed clinical record reviews, agency policy reviews, agency education, and annual agency evaluations for approximately fifteen hours”; however, the court held the personal services exception for this physician still would not have been met given that the physician's medical director agreement with the HHA did not include a term of at least one year.\textsuperscript{29} Although the physicians were not named in this lawsuit, physicians could potentially face exposure for similar arrangements that violate the Stark Law.\textsuperscript{30} The Aging Care case serves as a reminder that physician services memorialized in a medical director agreement must be appropriate and commercially reasonable, substantively provided and documented, and the agreement also must meet each element of any applicable Stark exception.

In addition to Stark, arrangements between HHAs and physicians can run afoul of the AKS.\textsuperscript{31} Problematic practices include an HHA providing administrative services for free or below fair market value to physicians, or providing any remuneration to a physician for a plan of care certification, re-certification, or face-to-face encounter.\textsuperscript{32} A July 1997 U.S. Department of Health and Human Services Office of Inspector General (OIG) audit report concluded that physicians “did not always review or actively participate in developing the plans of care they signed, especially for less complex cases.”\textsuperscript{33} The report further found physicians “relied heavily on HHAs to make determinations as to homebound status, as well as to develop the plans of care for home health services.”\textsuperscript{34} This lack of physician involvement likely could result in non-covered services for the HHA and the physician, as well as AKS and FCA liability.\textsuperscript{35} Furthermore, any home health services for which a physician is compensated independently by Medicare, such as certification of a plan of care, generally should not be included in the hours or duties for which a physician is compensated by an HHA as a medical director. Therefore, it is advisable that HHAs and physicians properly understand their respective roles when a physician is providing medical director services, as well as when establishing and certifying an appropriate plan of care for medically necessary services.

**Hospice**

Medicare-certified hospices must offer a comprehensive set of palliative care services to terminally ill patients as set forth in an individualized plan of care created and coordinated by an interdisciplinary group (IDG) of the hospice.\textsuperscript{36} Physicians must be members of the hospice's IDG, and unlike HHAs, hospices must have medical directors who must be physicians.\textsuperscript{37} In addition, the hospice must indentify a physician to assume the responsibility and obligations of the medical director when the medical director is not available (Physician Designee). The hospice may either employ an individual physician to serve as a medical director or contract\textsuperscript{38} with an individual physician or a physician group to fulfill the medical director role for the hospice.\textsuperscript{39}

The specific duties of the hospice medical director include reviewing the clinical information for each hospice patient and providing written certification that the patient's life expectancy is anticipated to be six months or less if the illness runs its normal course.\textsuperscript{40} Further, the medical director, or physician member of the IDG, also must provide written certification (or recertification) for each subsequent ninety-day election period.\textsuperscript{41} For recertification of a hospice patient whose total stay across all hospices is anticipated to reach the third ninety-day benefit period,\textsuperscript{42} the medical director must have a face-to-face encounter with that patient to gather clinical findings, determine continued eligibility, and attest that such a visit took place.\textsuperscript{43} In addition, the medical director (or physician member of the IDG) must be involved in the formulation and updating of a comprehensive assessment of the hospice patient and an individualized plan of care,\textsuperscript{44} meet patient needs that are not met by the patient's attending physician,\textsuperscript{45} and also actively participate in a hospice's quality assessment and performance improvement program.\textsuperscript{46}
Although hospices must employ or contract with physicians, OIG recommends that hospices and physicians “still tailor such agreements to avoid violation of the Anti-Kickback statute . . . and to comply with applicable Medicare conditions of participation.” Notably, Medicare-covered hospice services that are reimbursed under the hospice composite rate are specifically excluded from the reach of the Stark Law. It is always advisable to memorialize compensation arrangements with potential referral sources in writing in a manner that complies with an AKS safe harbor if possible, to aid in establishing that the parties have the requisite intent under AKS. The “personal services and management” safe harbor is likely the most applicable. There are seven elements to this safe harbor, which are similar to the elements found in the Stark personal services exception, and all of the elements must be met to qualify for immunity from liability. Thus, it is imperative that there be a signed, written agreement evidencing the arrangement that sets forth clear duties that are actually provided by the physician. The services also must be reasonably necessary and therefore should be grounded in the Medicare hospice conditions of participation. Further, compensation must be set in advance and based on fair market value, and not determined in a manner that takes referrals into account.

OIG has listed among the examples of arrangements that may run afoul of AKS practices in which a hospice pays a fee to a physician for each certification of terminal illness, when the physician bills for services that are duplicative of the care that the hospice is required to provide its patients, or instances where a hospice provides nursing, administrative, and other services for free or below fair market value to physicians, with the intent to influence referrals. Other risk factors to consider under the AKS include contracting with a physician medical director with no palliative care experience who also is in a position to be a significant referral source, contracting with multiple medical directors whose combined aggregate services are unnecessary, or contracting with a medical director who also is a nursing home medical director in a position to generate significant referrals.

Physicians can play many different roles when providing services to HHAs and hospices and their patients. Physicians, HHAs, and hospices should ensure that they consider how such arrangements fit within the Stark Law and AKS. In addition, proposed arrangements should be structured to comply with the requirements of any applicable state anti-kickback, physician self-referral, or fee-splitting laws, as they may apply more broadly than federal fraud and abuse laws. All parties should be aware of their respective responsibilities in each aspect of care and ensure their respective services and compensation are appropriate.

---

1. See 42 C.F.R. § 418, subpt. C.
2. See at 42 C.F.R. § 484.1 et seq.
3. AKS is a federal law that makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration (i.e., anything of value) to induce referrals of items or services for which payment may be made under a federally funded healthcare program. 42 U.S.C. § 1320a-7(b)(6). Civil monetary penalties may be imposed for AKS violations. 42 U.S.C. § 1320a-7(b)(1).
6. The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency’s program, and to assist the agency in maintaining liaison with other healthcare providers in the community and in the agency’s community information program. The meetings are documented by dated minutes. 42 C.F.R. § 484.16(a).
7. The plan of care must be established and authorized in writing by the physician based on an evaluation of the patient’s immediate and long-term needs. HHA staff, and if appropriate, other professional personnel, shall have a substantial role in assessing the patient. The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with the HHA professional personnel, at least every sixty days. Each review of a patient’s plan of care must contain the signature of the physician and the date of review. 42 C.F.R. § 424.22(a)-(b).
8. 42 U.S.C. § 1395(nn); 42 C.F.R. § 424.22.
10. See Medicare Benefit Policy Manual, Ch. 7, § 30.5.1.1(3).
11. 42 U.S.C. § 1395nn(h)(6)(I). The U.S. Department of Health and Human Services Office of Inspector General (OIG) has listed the Stark Law as a “special safe harbor,” which is similar to the elements found in the OIG Compliance Guidance for Home Health Agencies. See 63 Fed Reg. 42410, 42414 (Aug. 7, 1998). Under the Stark physician self-referral law, if a physician (or an immediate family member of such physician) has a financial relationship with an HHA, the physician may not make a referral to the HHA for the furnishing of home health services for which payment may be made under the federal healthcare programs. See 42 U.S.C. § 1395nn.
13. Patients are reportedly receiving pressure from their HHAs to contact their physicians to ensure that the face-to-face encounter requirement is fulfilled.
14. Id.
15. Supra note 8.
16. Supra note 7.
17. 42 U.S.C. § 1395nn(h)(6)(I). The U.S. Department of Health and Human Services Office of Inspector General (OIG) has listed the Stark Law as a “special area of OIG concern” in the OIG Compliance Guidance for Home Health Agencies. See 63 Fed Reg. 42410, 42414 (Aug. 7, 1998). Under the Stark physician self-referral law, if a physician (or an immediate family member of such physician) has a financial relationship with an HHA, the physician may not make a referral to the HHA for the furnishing of home health services for which payment may be made under the federal healthcare programs. See 42 U.S.C. § 1395nn.
The services to be provided pursuant to the medical director agreement included “clinical record review, advisory board attendance, and agency policy and evaluation.” United States ex rel. Roberts v. Aging Care Home Health, Inc., 474 F. Supp. 2d 810, 818 (W.D. La. 2007).

The services to be performed by the physicians included “clinical record review, advisory board attendance, and agency policy and evaluation.” Id.

When contracting for medical director services, the contract must specify the personal who assumes the medical director responsibilities and obligations. According to OIG, allowing numerous personal to submit a claim for services “that [the] person knows or should know are not medically necessary.” 42 U.S.C. § 1395nn(h)(6). However, the Stark Law still might be relevant to the extent that physicians associated with the hospice refer any services that are DHS to the hospice or the clinic, and such services are reimbursable outside of the composite rate.

When an individual makes an election to receive services covered by the Medicare Hospice Benefit, that individual waives the right to receive Medicare reimbursement for any treatment related to his or her terminal illness. Accordingly, a Hospice should ensure it is not involved with a health care provider who the hospice knows submits claims for the following services that are unallowable for reimbursement under the Medicare Hospice Benefit: (3) care from another provider that duplicates care the Hospice is required to furnish. 42 C.F.R. § 418.21(a).

Physician Organizations


See 42 C.F.R. § 418.54. Hospice medical directors are not required to assume total responsibility for updating the comprehensive assessment, although it is expected that a physician member of the IDG be actively involved in all aspects of furnishing care, including updating the comprehensive assessment. 73 Fed. Reg. 32109 (June 5, 2008).

The failure to fit precisely within a safe harbor does not necessarily mean the arrangement violates AKS. See 56 Fed. Reg. 35952 (July 29, 1991). Nonetheless, it is advisable to fit such physician compensation arrangements to meet all the elements within a safe harbor to qualify for safe harbor protection. In addition, if the agreement “is intended to provide for services on a part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals . . . and the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.” 42 C.F.R. § 1001.952(d).

Likewise, it is essential that specific individuals be identified to be the medical director and the physician designee. According to OIG, allowing numerous physicians to furnish the medical director or physician designee role would likely result in inconsistent care and decreased accountability. 42 C.F.R. § 418.3. “Terminally ill” means that the individual has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course. 42 C.F.R. § 418.3; the hospice IDG must include at least the following: a doctor of medicine or osteopathy who is not the patient’s attending physician, a registered nurse; a social worker; and a pastor, clergy, or other spiritual counselor. See 42 C.F.R. § 418.3; 42 C.F.R. § 418.68.

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations. 42 C.F.R. § 418.102.

CMS clarified that the medical director may be an “employee” of the hospice, which includes volunteers. 73 Fed. Reg. 32088, 32138 (June 5, 2008).

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations. 42 C.F.R. § 418.102.

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations. 42 C.F.R. § 418.22(c)(2).

A hospice patient may elect to receive hospice care during one or more of the following election periods: (1) an initial ninety-day period; (2) a subsequent ninety-day period; (3) a subsequent thirty-day period; (4) a subsequent extension period of unlimited duration during the individual’s lifetime. 42 C.F.R. § 418.21(a).

PPACA requires a hospice physician or nurse practitioner to have a face-to-face encounter with a hospice patient no more than thirty calendar days prior to the start of the hospice patient’s third benefit period. The provision applies to recertifications on and after January 1, 2011. A hospice physician (physician who is employed by the hospice or who contracts with the hospice) or hospice-employed nurse practitioner also may perform the face-to-face encounter. Further, the face-to-face encounter must occur no more than thirty calendar days prior to the third benefit period recertification, and no more than thirty calendar days prior to every subsequent recertification thereafter. 42 C.F.R. § 418.22(a)(4).

Likewise, it is essential that specific individuals be identified to be the medical director and the physician designee. According to OIG, allowing numerous physicians to furnish the medical director or physician designee role would likely result in inconsistent care and decreased accountability. 42 C.F.R. § 418.3. “Terminally ill” means that the individual has a medical prognosis that his or her life expectancy is six months or less if the illness runs its normal course. 42 C.F.R. § 418.3; the hospice IDG must include at least the following: a doctor of medicine or osteopathy who is not the patient’s attending physician, a registered nurse; a social worker; and a pastor, clergy, or other spiritual counselor. See 42 C.F.R. § 418.3; 42 C.F.R. § 418.68.

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations. 42 C.F.R. § 418.102.

When contracting for medical director services, the contract must specify the physician who assumes the medical director responsibilities and obligations. 42 C.F.R. § 418.102(b). For certification of the initial period, if the patient has an attending physician, that physician also must provide a written certification. See 42 C.F.R. § 418.22(c)(2).

A hospice patient may elect to receive hospice care during one or more of the following election periods: (1) an initial ninety-day period; (2) a subsequent ninety-day period; (3) a subsequent thirty-day period; (4) a subsequent extension period of unlimited duration during the individual’s lifetime. 42 C.F.R. § 418.21(a).
Free Transportation: Recent OIG Opinion Permits in Limited Circumstances—What Does This Mean for ASCs?

Michael F. Schaff, Esquire
Alyson M. Leone, Esquire
Wilentz Goldman & Spitzer PA
Woodbridge, NJ

On March 17, 2011, the U.S. Department of Health and Human Services Office of Inspector General (OIG) once again issued a favorable Advisory Opinion1 to a hospital to provide free transportation for patients unable to transport themselves to the hospital from physician offices located on, or contiguous to the hospital’s campus to receive further treatment. However, OIG has still not issued any guidance to ambulatory surgery centers (ASCs) that wish to provide free transportation to their patients. Therefore, ASCs must carefully consider whether providing transportation at no cost to patients would pass muster under the law.

Law

Complimentary transportation implicates both the Civil Monetary Penalty (CMP) law2 and the federal Anti-Kickback Statute (AKS).3 CMP law provides for a penalty against any person who “offers or transfers remuneration to any individual . . . to influence such individual to order or receive from a particular provider . . . any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].” A violation of the CMP law may result in a penalty of up to $10,000 for each item or service, an assessment of up to three times the amount claimed for each such item or service, and exclusion from participation in Medicare and Medicaid. AKS provides that “whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration . . . to induce such person—to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal healthcare program . . . shall be guilty of a felony, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.”

Legislative history shows Congress did not intend to impose penalties for free local transportation of nominal value. OIG has determined that complimentary transportation that has a value of no more than $10 per trip or $50 per patient in the aggregate annually is of “nominal value” and therefore is not a violation of CMP law.4

Recent Advisory Opinion

A nonprofit, tax-exempt hospital requested an Advisory Opinion from OIG relating to its proposed plan to provide free local transportation to patients and their families that are treated at physician offices located on, or contiguous to the hospital’s campus, require further evaluation and treatment, including admission to the hospital, and are unable to transport themselves. OIG cited several factors in determining that the arrangement would not subject the hospital to administrative sanctions under the CMP law or AKS:

• The selection of patients eligible for the transportation would not be limited to targeted federal healthcare program beneficiaries, but rather determined based on uniform standards.
• The transportation was reasonable, and not a luxury or specialized vehicle.
• Transportation was only offered locally.
• The free transportation would not be marketed or advertised, other than to inform the physicians the transportation is available.
• Public transportation and parking on the hospital’s campus was limited.
• The cost of the transportation would not be claimed on any cost report or claim, or otherwise shifted to any federal healthcare program.
**Previous Guidance**

On November 17, 2000, OIG issued a favorable Advisory Opinion to a hospital that would provide free transportation services to certain patients who were referred to the hospital for extended courses of treatment.

In August 2002, OIG issued a Special Advisory Bulletin on offering gifts and other inducements to beneficiaries wherein the OIG stated it was considering the possibility of a regulatory “safe harbor” exception under the CMP law for complimentary local transportation offered to beneficiaries residing in the provider’s primary service area. Later that year, OIG solicited public comments on the possible development of an exception under the CMP law for complimentary local transportation greater than nominal value.

On December 9, 2002, OIG issued a letter stating free local transportation provided by a hospital that costs no more than $10 per trip and $50 per patient in the aggregate on an annual basis does not violate the CMP law.

On March 6, 2009, OIG issued a favorable Advisory Opinion to a skilled nursing facility proposing to provide free local transportation for friends and families of its residents. Similar to its most recent Advisory Opinion, in concluding the arrangement would not constitute grounds for the imposition of CMPs under the CMP law or administrative sanctions under AKS, OIG cited a number of factors. These factors included that the services are not provided to targeted populations of federal healthcare program beneficiaries, the type of transportation was reasonable, the services would only be offered locally, advertising would only be done locally, public transportation was limited, and the cost of the transportation would not be claimed on any cost report or claim.

**How Does This Affect ASCs?**

This most recent Advisory Opinion does not alter the general rule that free transportation in excess of nominal value potentially implicates the CMP law and AKS. Although on its face it appears that OIG is loosening its standards for when free transportation will be acceptable, in reality free transportation is permitted only in limited circumstances. To date, OIG has not adopted an exception to the law or provided any specific guidance for ASCs. Therefore, free transportation provided by ASCs must be carefully evaluated to determine compliance with the law as well as the factors enumerated by OIG.

---

1. OIG Advisory Opinion No. 11-02 (Mar. 17, 2011).
2. 42 U.S.C. 1320-7a(a)(5).
3. 42 U.S.C. 1320-7b(b).
5. For a more detailed discussion of previous guidance on free local transportation, please see articles titled “Can ASCs Provide Free Transportation?” published in the June 2006 issue of *Physician Organizations*, and “OIG Provides New Guidance on Free Transportation,” published in the July 2009 issue of *Physician Organizations*.
6. OIG Advisory Opinion No. 00-7 (Nov. 17, 2000).
8. OIG Advisory Opinion No. 09-01 (Mar. 6, 2009).
Physician Organizations

Physician’s Liens: Added Protection for the Bottom Line

Scott K. Penick, Esquire
McGovern Legal Services LLC
North Brunswick, NJ

Marcia was mending her own business as she sat in the park, carefully shading the branches in her newest painting. Meanwhile, Shaun, an employee of the Parks Service, was mowing with headphones on and did not notice the pile of rocks assembled by unknown toddlers earlier that morning. Like a shotgun, the oversized mower shot the rocks in Marcia’s direction, and one rock shattered her tibia. Marcia is a freelance artist. She has no health insurance, but she may have a claim against the state for negligence. And doctors in New Jersey and other states with similar laws have a right to file a physician’s lien if they treat Marcia.1

When Is It Appropriate to File a Physician’s Lien?

In New Jersey, a physician’s lien can only be filed when the patient has “sustained personal injuries in an accident as a result of the negligence or alleged negligence of another person.”2 The point of the physician’s lien law is to provide the healthcare provider with additional protection against non-payment. Without an alternative responsible party, there would be no purpose to the lien, since the patient already has a personal obligation to pay for medical care.

A physician’s lien can provide access to deeper pockets when medical bills go unpaid. Using Marcia’s situation above, instead of only having recourse against the patient, the healthcare providers that treated her can use a physician’s lien to obtain an interest in the proceeds of any judgment obtained, or settlement entered by Marcia with the state.3 Assuming a valid physician’s lien was filed, even if Marcia takes her judgment or settlement proceeds and skips town without paying her medical bills, the state would remain liable to the holder of that lien for a full year after it paid Marcia.4

Of course, patients’ failure to pay is not always a result of being without insurance. For extremely serious accidents, the patient may have inadequate insurance. For example, students often have limited policies offered through their university, which may prove inadequate to cover the total bill for treatment. Furthermore, some health insurance deductibles can exceed $5,000. Coverage may be adequate, but many patients may not have access to $5,000 to cover the deductible, leaving the physician or hospital to absorb the unpaid bills. Filing a physician’s lien in these and similar cases is a simple method to add protection to the bottom line.

It is important to note that New Jersey’s physician’s lien statute does limit the amount of any lien, not to a set dollar amount, but in proportion to the proceeds received for the patient’s injuries. The statute provides that the lien shall not “exceed twenty-five per centum (25%) of the amount of any award, report, decision, judgment or settlement to the injured person.”5 Even with this limitation, some protection is better than no protection.

What Steps Are Required to Ensure That a Physician’s Lien Is Valid?

As with many types of liens, attention to detail is essential when filing a physician’s lien. Miss a deadline and the lien is invalid—no appeals, no reconsiderations. The first clock starts running from the date of the “first treatment, care or maintenance.”6 If the healthcare provider fails to file a notice of lien with the county clerk within ninety days of the first treatment, then he or she has lost the opportunity to enjoy the added protection of the lien. Additionally, the lien must be filed “prior to the payment of any moneys to such injured person or his legal representatives as damages for such injuries.”7 Does this mean that if Shaun pulls a $100 bill out of his wallet and hands it to Marcia saying, “Please don’t tell my boss. I’m really sorry,” that the opportunity for a lien has been blown? It could, but probably not. More troubling is the auto accident where the injured driver accepts compensation before latent injuries surface. In either case, legal counsel should discuss the specific facts with their physician-client.

The New Jersey statute provides a checklist of information that must be included in the lien:

- the name and address of the injured person, the date and location of the accident, the date of the first treatment, care or maintenance, the name and address of the hospital, nursing home, physician or dentist, and, if ascertainable by reasonable diligence, the names and addresses of the persons alleged to be liable for damages sustained by such injured person.8

What constitutes reasonable diligence in attempting to ascertain the names and addresses of the persons who allegedly injured the patient? It depends, of course. The specific factors surrounding the incident that caused the injury will play a significant role in determining reasonableness. In Marcia’s case, not including such identifying information would almost certainly stem from a failure to make any effort to ascertain the information. On the other hand, obtaining this information after a hit-and-run accident that took place at midnight likely would be a much more difficult task.

After the lien is filed, the injured person and the allegedly responsible parties must be served with a copy of the lien within ten days.9 Failure to do so will result in the lien being void.10 Of additional value to the healthcare provider is that the liable party, once put on notice, is likely to keep the provider abreast of any settlement or judgment that may occur. Otherwise, that party could end up being subject to additional liability—essentially paying twice for its negligence.11
Conclusion

A physician's lien clearly can provide extra protection to hospitals, nursing homes, physicians, and dentists, but failure to act quickly can result in the loss of that protection. There is no wiggle room in the New Jersey statute for almost complying or being only a day late. Additional practical considerations also can be taken to protect the healthcare provider's right to payment. Because most injured patients will pursue their claims with the assistance of a personal injury attorney, the healthcare provider who has filed a lien should also serve a copy on the patient's attorney along with a letter of protection. While one might expect the patient to notify his attorney of the lien and any unpaid medical bills, it is always best to take the simple step of providing the notice to the attorney oneself.

2 Id.
3 Id., § 2A: 44-37.
4 Id., § 2A: 44-43.
5 Id., § 2A: 44-39.
6 Id., § 2A: 44-41.
7 Id.
8 Id.
9 Id., § 2A: 44-42.
10 Id.
11 Id., § 2A: 44-43.
Missed a recent webinar? Wish that you could listen to it at your own leisure, on your computer, iPod, or iPhone? Webinar recordings are available in a MP3 format for instant download on the AHLA website.

Practice Group-sponsored webinars are held throughout the year on hot topics with analyses of healthcare law-related issues and cases. Please note that all recordings are accompanied with materials and include a bonus MP4 recording (video format).

For a complete listing and more information about future webinars, please visit our webinar calendar at www.healthlawyers.org/Webinars.

For a complete listing of past webinars and/or to purchase a webinar recording, please visit www.healthlawyers.org/WebinarRecordings.