Healthcare Outsourcing Overview: Staying Focused in Uncertain Times

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What's In With Healthcare Outsourcing

With change occurring all around them, teaching hospitals are taking steps to focus their business on their core competency—the delivery of healthcare services. While citizens will always need healthcare, teaching hospitals are not recession-proof. They are exposed to the negative economy and are vulnerable to declining government reimbursement for their services and increased costs associated with the changing laws and regulations that govern the delivery and billing of healthcare services, a trend that will accelerate with healthcare reform. In this uncertain economic and regulatory environment, many teaching hospitals and academic medical centers (AMCs) are exploring outsourcing as a way to deal with these challenges.

Teaching hospitals are outsourcing ancillary tasks to sharpen their focus on the resilient core of delivering healthcare services. Outsourcing arrangements can improve financial results by reducing administrative costs and increasing revenues, efficiency, and service quality. Areas that are strong candidates for outsourcing include any function outside the direct delivery of healthcare that is either underperforming, requires specialized skills, or requires substantial infrastructure or other resources. Outsourcing such functions allows teaching hospitals to focus on treating patients and generally results in increased savings and operational efficiency. There are myriad outsourcing vendors and options, but some of the most common tasks outsourced by healthcare providers include revenue cycle services, human resources (HR), benefits administration, information technology, laundry, housekeeping, food services, and, in some cases, clinical services that the provider is not well-equipped to provide without the assistance of a third party, or that a third party is able to provide at a higher quality and/or at a lower cost than the provider could do by itself.

Revenue Cycle Services

A focus on avoiding errors and maintaining consistency permeates teaching hospitals’ objectives. Mistakes in areas such as billing directly impact healthcare providers’ bottom line. For example, estimates have shown that billing errors can...
result in a near 10% loss of a physician practice group's revenue.¹ In addition to the financial impact, the increasing complexity of coding adds to the risk that a hospital will be found to be noncompliant and subject to government investigations and fines. In this environment, getting billing right is a high priority. Because electronic systems and data now drive billing, it should be no surprise that many hospitals are outsourcing billing functions to healthcare technology companies that specialize in billing. In addition, hospitals are also outsourcing other parts of their revenue cycle such as the admissions process, coding, billing, collections, and everything in between. These processes are exceedingly complex and constantly subject to changes in technology and regulations. Therefore, it makes sense to leverage a specialist's expertise and capabilities. Healthcare providers have recognized this situation and are increasingly looking to third-party outsourcing providers to handle revenue cycle services. For example, in 2009 Memorial Health University Medical Center, an AMC in Savannah, GA, outsourced its revenue cycle management to McKesson Corporation.²

Information Technology

Outsourcing information technology functions continues to be the dominate form of outsourcing in every area of business, including the healthcare industry. Healthcare delivery is increasingly data driven. Healthcare providers must electronically track medical records, billing codes, electronic monitoring systems, and other data related to patient care and billing. These electronically based administrative activities create an increased need for information technology infrastructure and devices such as servers, desktops, networks, wireless networks, PDAs, and laptops.

Maintaining such infrastructure and devices is increasingly challenging and requires specialized expertise. Having an external outsourcing provider maintain such infrastructure, device, and systems can have many benefits for healthcare institutions. For example, technology outsourcing companies are generally better at attracting and retaining qualified information technology providers. The performance of top talent results in a higher level of technology service delivery. In addition, healthcare institutions are able to decrease or eliminate capital expenditures on technology infrastructure by leveraging the outsourcing provider's infrastructure and only paying for technology services on an as-needed basis. Such outsourcing converts a fixed cost into a variable cost, which can be beneficial during a recession.³ Outsourcing information technology services is a mature offering that continues to be popular with healthcare providers, allowing them to save money, modernize, and become more efficient. Last year, Mercy Hospital & Medical Center, Chicago’s first teaching hospital, was recognized by the Healthcare Information Management and Systems Society for modernizing its medical information systems by outsourcing various healthcare information systems to Cerner. Through the implementation of the Cerner systems, Mercy Hospital & Medical Center moved into the top 0.5% of hospitals in the United States for its use of electronic medical records.⁴

Laundry, Housekeeping, and Food Services

Contracting with companies that provide essential services such as laundry, housekeeping, or dining services can be cost effective and can substantially benefit healthcare providers. For example, utilizing outside suppliers for laundry has been and continues to be a successful option for hospitals. Before the economy took a downturn, 74% of top hospitals outsourced support services that included laundry assistance.⁵ Because of the continued monetary incentives for outsourcing such a service, the number of hospitals outsourcing laundry services has grown in the last two years.⁶ Such services are generally commoditized and have only a tangential relationship to patient care. So, healthcare providers have little incentive to provide these services in-house. This combined with the cost benefits leads many healthcare providers to outsource such services.
Clinical Services

While teaching hospitals generally outsource functions that are not directly related to patient care, certain services that are squarely within patient care are being outsourced out of financial necessity or due to a lack of resources. Declining reimbursement from Medicare, Medicaid, and private insurance companies have made it difficult for hospitals to maintain their historical profit margins for certain clinical services, such as imaging tests. In addition, a lack of capital funds has resulted in the inability of health systems to purchase new and advanced models of imaging equipment. As a result, third-party providers are filling the gap by offering medical scanning services. Third-party outsourcing providers are also offering related services such as interpretation of imaging results or transcription of physician case notes, often from less expensive, overseas locations. Such services offer a cost-effective and efficient alternative to having in-house employees perform these services. Also, because of the difference in time zones, such services can be performed overnight and the results can be ready for the physician in the morning, thus improving the quality of care for patients.

Developing an Outsourcing Relationship

Establishing a successful outsourcing arrangement involves a number of steps, most of which, when done correctly, require a high level of expertise and can take a significant amount of time. At a high level, the typical outsourcing process involves: (1) building an outsourcing team of internal and external experts; (2) identifying the functions to be outsourced; (3) developing the request for proposal (RFP); (4) requesting potential outsourcing vendors to respond to the RFP; (5) evaluating the outsourcing vendors’ proposals; (6) building and negotiating the outsourcing agreement; (7) transitioning the services from the company to the outsourcing provider; and (8) executing an effective contract agreement; (7) transitioning the services from the company to the outsourcing provider; and (8) executing an effective contract management and governance structure.

Building an Outsourcing Team

Because outsourcing can touch many areas of an organization and involves both business and legal issues, AMCs and teaching hospitals looking to outsource should first build an appropriate team of experts to drive the outsourcing process. Outsourcing a portion of any organization can be seen as operationally risky and, like any dramatic organizational change, can be viewed with skepticism. Outsourcing can also be politically charged both inside and outside the organization. Because of these factors, the most successful outsourcing initiatives start with a high-level business executive (chief executive officer, chief financial officer, chief operating officer, chief information officer) who is committed to outsourcing, if it is the right financial or operational decision for the organization. This executive often appoints a leader who “owns” the outsourcing evaluation and execution process. This leader then builds a team of relevant experts: (1) subject matter experts in the potential scope of services to be outsourced; (2) sourcing/procurement professionals; (3) financial analysts; (4) HR; (5) security; (6) risk management; (7) internal audit; (8) tax; and (9) legal. In an AMC setting, the team may need to include representatives from the medical school and the teaching hospital. The majority of significant outsourcing projects also include external advisors who are experts in outsourcing. These external advisers include experienced outsourcing attorneys and technical advisers. Because organizations only form outsourcing arrangements on a sporadic basis, these external advisers bring valuable market knowledge and help level the playing field between healthcare providers and the outsourcing providers that negotiate such deals on a regular basis. Such advisers’ experience can also help tailor the contract to the healthcare environment, addressing the often significant regulatory issues. Outsourcing transactions involve many unique and complex issues that are not typically addressed in other corporate transactions. Just like not all doctors can perform heart surgery, not all transactional lawyers can effectively advise on outsourcing transactions. Therefore, hospitals looking to outsource should hire outside legal counsel that are experts in healthcare outsourcing.

Identifying the Functions to Be Outsourced

Selecting the proper scope of services to be outsourced is the first and sometimes one of the most difficult decisions for the outsourcing team. This decision involves many different considerations. What is the goal of the outsourcing arrangement? What are the risks? Is the function to be outsourced more of a commodity? Are there experienced outsourcing providers that can effectively provide the service? Does the function give the organization a competitive advantage? How much cost savings can be achieved? How much internal expertise will need to be retained to effectively manage the outsourced service? Will the decision to outsource a function have sufficient buy-in from impacted stakeholders? Are there legal restrictions to outsourcing
the function? These and other questions will need to be asked and answered before selecting the scope of services to be outsourced.

**Outsourcing Vendor Selection Process**

Once the scope of the potential outsourcing is determined, the teaching hospital should create a detailed RFP that is clear about the project’s scope, expected levels of service, and the organization’s objectives and goals. Many times, the RFP contains a draft of the outsourcing agreement that the outsourcing vendors will be required to sign if they are selected.

A clearly articulated RFP allows an outsourcing service provider to tailor its response to the healthcare entity’s specific needs. An organization submits the RFP to all potential outsourcing providers. The potential outsourcing providers will then provide comprehensive written proposals responding to the RFP. The teaching hospital will evaluate these proposals and will often ask the outsourcing vendors to orally present their proposed solution to the hospital outsourcing team. The team will then perform due diligence on the potential outsourcing providers, including checking customer references. The hospital outsourcing team will then “down select” the vendors who will move into the negotiating phase.

Teaching hospitals often move multiple potential outsourcing providers into the negotiation phase. In other instances, organizations “sole source” the project—negotiating with only one outsourcing vendor who is particularly well positioned to offer the service. In sole-sourcing negotiations, the outsourcing provider can sometimes have a disproportionate amount of bargaining power. In contrast, competitive bidding among multiple outsourcing vendors often results in more favorable terms for the hospital.

**Building and Negotiating the Outsourcing Agreement**

Preparing the outsourcing agreement is a multi-step process involving members of the teaching hospital’s outsourcing team and other parties. As stated above, the RFP often contains a draft of the outsourcing agreement. Therefore, it is important to get all knowledgeable parties necessary to create the master terms and key exhibits involved prior to the RFP process. The outsourcing agreement generally consists of master legal terms and various business, financial, operational, and service-specific exhibits. A few of the typical exhibits include: fees, service descriptions, transition plan, service levels, reports, governance, technology and security policies, approved subcontracts, disengagement assistance, and HR terms.

Negotiating an outsourcing deal is often a multi-track process. The lawyers and key business leaders will generally negotiate the master terms and other key financial and legal exhibits (e.g., fees and HRs). The operational teams and other subject matter experts from both parties will often, in parallel, negotiate the technical exhibits (e.g., service description, reports, and transition plan). Some exhibits, such as service levels, have operational and financial components requiring input from both tracks. In addition, certain issues negotiated in the master terms need to flow into the exhibits and vice versa. Therefore, both tracks need to constantly communicate.

While there is no typical timeframe, negotiating an outsourcing deal often takes three to six months. Larger, more complex deals can take nine to twelve months to negotiate.

One of the most important exhibits in the outsourcing agreement is the service description. A common source of conflicts in outsourcing relationships are disputes centered around which party is responsible to perform a task. In other words, the parties have a different view regarding what is “in scope” under the outsourcing agreement. Such disputes can be minimized with a comprehensive and thoughtful service description. Creating such a service description takes sufficient preparation and planning, allowing the hospital to define the precise functions that the outsourcing provider should perform. A proper service description will help avoid misunderstandings and unexpected expenses.

Outsourcing agreements should also include adequately defined service levels. Service levels are the outsourcing provider’s service performance guarantees, measuring service delivery and results. The service levels are continually monitored by the outsourcing vendor and are periodically reported to the hospital, generally on a monthly basis. If the service provider fails to reach a service level, then the hospital typically receives a credit that can be used to reduce the fees...
owed to the outsourcing vendor. Traditionally, parties to an outsourcing agreement have a large number of service levels. However, utilizing fewer but more-focused service levels can make enforcement and compliance with the service levels easier on both parties. Using fewer service levels—perhaps no more than two dozen—allows the parties to focus on the issues that are most important to the hospital's business. For example, a hospital entity that outsources its billing functions may use a service level addressing the average days to submit completed claims. This is a service level that has a direct and measurable result on the hospital's cash flow.

There are many ways to price the services offered in an outsourcing deal. When crafting and negotiating the fee structure, hospitals should, when possible, establish pricing mechanisms that track the hospital's business volumes and revenues. For example, a hospital that decides to outsource its information technology services can help align interests by tying the fees under the outsourcing agreement to the hospital's monthly patient count (rather than the number of maintained computers). The idea is that the patient count is a representative proxy for the activity level of the hospital, and thus the information technology infrastructure needed to support such activity level. If the hospital is able to get such a fees structure, when business is up, the hospital will pay more. When business is down, the hospital will pay less. This type of structure helps keep expenses in line with revenue and adds needed flexibility in an unpredictable economy.

**Service Transition**

The next step in the outsourcing process is the transfer of the services from the hospital to the outsourcing provider. This may or may not involve the transfer of employees from the hospital to the outsourcing provider—often called “rebadging.” (One day the employee has a badge with the hospital’s name, the next day the employee has a badge with the outsourcing provider’s name.) Often these transitioned employees continue performing the same job functions that they performed prior to the transition, only now they are being paid by and taking direction from the outsourcing provider. If the transition does not involve the transfer of employees, there will often be a knowledge transfer process whereby the employees performing the function to be outsourced will provide all necessary technical and process information to the outsourcing provider. The outsourcing provider’s personnel may also “shadow” the hospital employees, watching them perform their job functions for a period of time.

After the knowledge transfer phase is completed, the outsourcing provider will set up all necessary systems and execute the transition of the outsourced services in accordance with the transition plan set forth in the outsourcing agreement. Depending on the complexity of the services, the operational transition can sometimes be nearly instantaneous (e.g. laundry services) or may have multiple phases occurring over several months (e.g. transition of billing services).

**Establishing and Executing an Effective Governance Structure**

After the contract is completed and services have been transitioned to the outsourcing vendor, then the real work begins. Establishing and executing an appropriate governance structure between the parties is the only way to ensure the long-term success of an outsourcing arrangement. Successful governance structures account for change, allow for flexibility, facilitate communication, align interests, and quickly escalate potential problems. To effectively implement appropriate governance, a hospital must devote sufficient and knowledgeable resources to diligently managing the outsourcing relationship.

To survive in today’s economy and regulatory environment, AMCs and teaching hospitals must make savvy business decisions. Outsourcing certain business functions can be the right business decision for many healthcare providers. Implementing a successful outsourcing strategy takes time and requires careful planning and skilled advisors. But once they are implemented, outsourcing arrangements can decrease costs, increase flexibility, and allow teaching hospitals to focus on their core competency of delivering quality patient care.

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HITECH and Your Business Associate Agreements . . . To Amend or Not to Amend?

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Teaching Hospitals and Academic Medical Centers (TH/AMCs), like other Covered Entities (CEs), are now undergoing the task of reviewing and, if necessary, revising their business associate agreements (BAAs). As a consequence of the diverse nature of work done by TH/AMCs (education, research, and patient care), they are likely to handle both a high volume and a diverse base of BAAs, further complicating the analysis and determination of the full impact to the organization once changes called for under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009, are operationalized.

This article explores how BAs being held directly accountable under the new regulations alters the relationship with CEs, and may affect compliance activities. TH/AMCs that decide not to amend BAAs, based on the belief that an amendment is not legally required to implement the changes under the HITECH Act, may want to re-think that decision.

Under the new regulations, BAs are “on the hook” to comply with many Health Insurance Portability and Accountability Act (HIPAA) requirements for the first time. The associated effect is that BAs are now in the driver’s seat in some areas of HIPAA-related decision-making that previously rested exclusively with the CE. An amendment to the BAA is the key mechanism through which a CE can contractually maintain control over HIPAA compliance activities related to the CEs protected health information (PHI).

As TH/AMCs look to update their HIPAA BAAs, it is important to keep in mind changes that are not technically “required” by the HITECH Act or implementing regulations, but are critical to reserve a reasonable amount of flexibility for the organization in complying with the new regulations.

A Proactive Approach—Examples:

Reserve the Exclusive Right to Make the “Risk Assessment” Determination of Whether or Not an Unauthorized Activity Constitutes a “Breach,” as HITECH Defines That Breach

Under HITECH, portions of the HIPAA regulations become directly applicable to the BA, including the obligations to terminate the business arrangement or report to the U.S. Department of Health and Human Services (HHS) Secretary if the BA becomes aware of a violation by the CE.

At the same time the breach notification regulations define what a “breach” is in two parts:

1. the impermissible unauthorized access, use or disclosure of unsecured PHI; and

2. which unauthorized activity comprises the security or privacy of PHI in a manner that ‘poses a significant risk for financial, reputational, or other harm to the individuals.’

The BAs direct accountability, coupled with the risk-of-harm threshold in the breach definition, make it imperative that the BAA requires the BA to notify the CE of all incidences of unauthorized activity. At the same time, the BAA should exclusively reserve for the CE the right to make the harm determination of whether the unauthorized activity constitutes a “breach,” and whether any exclusion available under the HITECH Act applies.

Absent this protection in the BAA, the CE may find its BAs reporting the organization to the HHS Secretary, sending out mass breach notifications, or terminating business arrangements without first affording the organization the opportunity to determine if a breach has occurred under the two-part test, or if an exclusion applies, such that no further action/notification to affected individuals, or the HHS Secretary is required.

Sample language:

To the extent that Business Associate accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses “unsecured PHI” as defined in the HITECH Act, Business Associate shall, as soon as possible but not later than ten days following the discovery of any impermissible unauthorized access, use, or disclosure of such information, notify Covered Entity of such unauthorized activity. Unsecured PHI is defined as PHI that is not secured through the use of a technology or methodology that renders the information “unusable, unreadable, or indecipherable” to unauthorized individuals. Business Associate shall be considered to have discovered such impermissible activity as of the first day on which the unauthorized activity is known or by exercising reasonable diligence would have been known to the Business Associate. Such notice shall include identification of each individual whose unsecured PHI has been or is reasonably believed by the Business Associate to have been accessed, acquired, or disclosed during such unauthorized activity. Covered Entity, at its sole discretion, shall make the determination of whether or not the definition of “Breach,” as that term is set forth in the HITECH Act, 45 CFR § 164.402, has been met, which shall include the determination of whether:

(i) the unauthorized activity “poses a significant risk for financial, reputational, or other harm to the individuals”; and

(ii) a regulatory exclusion applies (e.g. inadvertent disclosure by authorized person to another authorized person).
If Covered Entity determines the unauthorized activity by Business Associate qualifies as a Breach that triggers the HITECH breach notification requirements, then Business Associate will reimburse Covered Entity for all costs related to notifying individuals of said Breach of unsecured PHI maintained or otherwise held by Business Associate.

Establish BA Independent Contractor Status in BAA
Under the regulations, the date that the BA discovers or should have discovered the breach is imputed to the CE, if the BA is acting as the CE's agent, thereby starting the clock on the “sixty calendar day” maximum to make the notifications potentially way before the organization is made aware of the breach. If the BA is acting as an independent contractor, however, the CE is not considered to have discovered the breach until it is notified by the BA.

Based on the above, it is critical to establish within the BAA that the BA acts as an independent contractor, not an agent of the CE. Make independent contractor status the “standard” in your BAA, but take care to delete that representation if there are situations where the BA is in fact acting as your agent.

Sample language:

Independent Contractors
Both parties expressly intend that with regard to the provisions of this Agreement, said parties are independent contractors. Further, it is the express intent of the parties hereto that no agent, servant, contractor, or employee assigned by Business Associate to perform the Business Associate obligations described herein shall be deemed an agent, servant, contractor, or employee of Covered Entity.

Expressly Obligate BAs to Comply with National Institute of Standards and Technology (NIST) Standards for Encryption

Sample language:

Business Associate shall, among other requirements:

Implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of such EPHI, including but not limited to the encryption safeguards set forth in the HITECH Act and its implementing regulations.

Include Some General “Catch All” Language Regarding the New Requirements Put into Effect by the HITECH Act

Sample language:

Overview
The Health Information Technology for Economic and Clinical Health Act Title XIII of Division A and Title IV of Division B, including Subtitle D of Division A of the HITECH Act entitled “Privacy” (HITECH Act), and its implementing regulations impose new requirements on BAs with respect to privacy, security, and breach notification. The HITECH Act requirements set forth in this Agreement shall apply commencing on the date of enactment, or such other date as may be specified in the applicable regulations, whichever is later (Applicable Effective Date).

Business Associate agrees to comply with all aspects of the HITECH Act. Business Associate and the Covered Entity further agree that the provisions of HIPAA and the HITECH Act that now apply directly to BAs and that are required to be incorporated by reference in a business associate agreement are incorporated into this Agreement between Business Associate and Covered Entity, as if set forth in this Agreement in their entirety and effective as of the Applicable Effective Date.

Include Some Language to Educate Your BAs About the New Requirements for Securing Data. Expressly Obligate Your Business Associate to Comply with Them

Sample language:

Standards to Secure Data
The HITECH Act imposes on entities covered by the Health Insurance Portability and Accountability Act (HIPAA) and their BAs federal breach notification requirements when “unsecured” PHI is acquired by an unauthorized party. The breach notification requirements will apply to PHI in any form. PHI may be vulnerable in any of the following commonly recognized data states:

(a) “Data in motion”: Data that is moving through a wired or wireless network;

(b) “Data at rest”: Data that resides in databases, files, or in storage;

(c) “Data in use”: Data that is in the process of being created, maintained, updated, or destroyed; or

(d) “Data disposed”: Data that has been discarded or recycled.

PHI in each of these data states, with the possible exception of “data in use,” may be secured using one or more methods:

(a) Encryption (which will apply only to electronic information): Encryption of “data at rest” must satisfy NIST Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices. Valid encryption processes for “data in motion” must comply with the requirements of Federal Information Processing Standards (FIPS) 140-2. These include, as appropriate, standards described in NIST Special Publications 800-52; Guidelines for the Selection and Use of Transport Layer Security (TLS)
A Few More Things to Think About

First, if your organization has a lengthier BAA, which also served as an educational tool for your BAs when HIPAA Privacy Standards first went into effect, consider simplifying terms of the prior BAA that have now become well-established practice in the industry (i.e. reference regulatory section generally, rather than writing out the specifics of what that section required).

Second, although enforcement has been delayed once again by the FTC to June 2010, the Red Flags Rule should be addressed in the agreements entered into between the parties to set forth the terms of the business arrangement between the parties. Often this is incorporated into a general regulatory compliance clause. You can also address in the BAA, provided the clause is appropriately limited to when applicable.

Sample language:

If Business Associate provides services with respect to patient accounts of CE, BA shall develop and implement appropriate procedures to protect against identity theft in accordance with the “Red Flags Rule,” as set forth in 16 C.F.R. § 681, et seq., and any other applicable law, rule, or regulation relating to identity theft. BA shall maintain and implement reasonable policies and procedures designed to detect, prevent, and mitigate the risk of identity theft or Red Flags, as defined in the Red Flags Rule. Upon discovery of a Red Flag, BA shall promptly notify CE of same and take appropriate steps to prevent or mitigate identity theft.

Third, check to ensure that prior sections referencing the various requirements are updated to also reference the HITECH Act.

Sample language:

Definitions
All capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in HIPAA, the Privacy Standards, the Security Standards, and HITECH Act (as defined herein).

Fourth, address Minimum Necessary. The HITECH Act requires CEs to limit the use, disclosure, or, request of PHI, to the extent practicable, to a limited data set or, if needed, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request.7 In addition, the HITECH Act clarifies that the entity disclosing the PHI (as opposed to the requester) makes the minimum necessary determination.8 The HIPAA Privacy Standards’ exceptions to the minimum necessary standard continue to apply. Although there is more to come on this requirement,1 include some general information on the known changes in your BAA update to avoid the need for yet another revision.

Sample language:

Minimum Necessary
Business Associate shall at all times comply with the “minimum necessary” requirements for use and disclosure of PHI, as defined in the Privacy Standards, Security Standards, HITECH Act, and any implementing regulations. As required by the HITECH Act, the use, disclosure, or request of PHI shall be limited to the extent practicable, to a limited data set or, if needed, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request. In addition, the entity disclosing the PHI (as opposed to the requester) shall make the minimum necessary determination.

Fifth, account for disclosures. The HITECH Act requires that CEs account for all electronic health record (EHR) disclosures for the three years prior to the date an accounting is requested, including
disclosures for purposes of treatment, payment, and healthcare operations. Revise the section of your organization’s BAA on accounting for disclosures to educate your BA about the changes.

Sample language:

Accounting of Disclosures
Business Associate shall make available to University in response to a request from an Individual, information required for an accounting of disclosures of PHI with respect to the Individual, in accordance with 45 CFR § 164.528, incorporating exceptions to such accounting designated under the regulation, and any additional requirements imposed by the HITECH Act and its implementing regulations. For example, under the HITECH Act an accounting is required for all EHR disclosures for the three years prior to the date an accounting is requested, including disclosures for purposes of treatment, payment, and healthcare operations. BA shall provide such information necessary to provide an accounting within forty calendar days of CE’s request.

Sixth, consider helping BAs to be compliant. The HITECH act imposes the same obligation on the BA that previously applied to the CE only, i.e. terminate the agreement, or report to the HHS Secretary, if there is a violation. Include a counterpart to the section that allows the CE to terminate, which allows the BA to terminate for the same reason, but as the CE, provide more time to take corrective action:

Sample language:

If CE is in violation of any provision of the Privacy Standards, Security Standards, or HITECH Act, or applicable federal or state privacy law, or shall fail to observe or perform any material covenant or agreement contained in this Agreement for sixty calendar days after written notice thereof has been given to University by BA, the BA shall have the option to terminate this Agreement, provided that all BAs entered into between the parties for which this Agreement is required are also terminated.

*The statements expressed herein are those of the writer and do not necessarily reflect the policies, practices, or opinions of her employer, its management, trustees, or affiliates.

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**Teaching Hospitals and Academic Medical Centers Practice Group Leadership**

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Conflict-of-Interest Issues for Academic Medical Centers: It’s All Connected

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The term “conflicts of interest” is part of the everyday vocabulary today for tax-exempt organizations, healthcare organizations, and universities. Therefore, it goes without saying that a tax-exempt academic medical center (AMC) hears the term in spades. This article summarizes the development of recommendations and standards for individual and institutional conflict-of-interest disclosure and management, the current National Institutes for Health (NIH) request for comments on how institutional conflicts of interest in research should be addressed, and current initiatives for disclosure of drug and device industry financial relationships.

At one time, hearing the term “conflict of interest” in connection with a university or AMC brought to mind two things: (1) investigators’ interests causing conflicts of interest in research; and (2) conflicts of interest at the board level, where an individual director’s or trustee’s personal interest requires the individual to recuse himself or herself during consideration of a specific matter. However, over the last fifteen years, the government, researchers, associations, and institutions have articulated corresponding concepts of institutional conflicts of interest—where the institution itself may have a conflict—and conflict-management plans. These actors have reviewed the extent to which existing disclosure requirements have been observed and researched the influence that even small interests can exert on behavior. In order to have a coherent and comprehensive conflicts-management system, an AMC needs to consider all the interrelated aspects of operation that interests may affect—from human subjects research, technology commercialization, clinical care, education, purchasing, and fundraising.

This article also describes and compares the three proposals currently pending in Congress for required public disclosure of payments by drug and device companies to physicians. If enacted, such legislation promises to be a game-changer. For the first time, the public, researchers, institutions, and the government will have national, relatively reliable, and comprehensive information on physician-industry relationships with which to validate physician disclosures in other contexts.

Chronology of Events

The federal government has regulated financial conflicts of interest in clinical research since 1995 for federally sponsored research through the Public Health Service (PHS) and since 1999 for clinical research supporting marketing applications to the U.S. Food and Drug Administration (FDA). These regulations addressed only individual researcher interests, although the concept of an institutional conflict of interest—one created by the financial interests of the institution itself or those controlling the institution—has been discussed in the literature at least since 1995. Since the initial regulations, the conflict-of-interest focus has moved from concentrating only on research to encompassing a variety of institutional functions, from looking at the individual’s interests to looking at the institution’s as well, and from allowing the reporting individual to determine whether an interest creates a conflict to more-objective reporting of interests.

A chronological list of selected actions and reports is as follows.

- July 1995: PHS issues regulations, “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.” These rules govern NIH grants but address individual conflicts of interest only, not institutional conflicts of interest.
- February 1999: The FDA issues regulations, “Financial Disclosure by Clinical Investigators.” These rules apply to clinical investigators whose clinical studies are submitted in support of marketing applications for human drugs, biological products, or medical devices. The regulations do not address institutional conflicts of interest.
• July 2002: NIH reviews conflict-of-interest policies and releases report, *Financial Conflict of Interest: Objectivity in Research—NIH Review of Institutional Conflict of Interest Policies.* The study observes that policies are diffuse, vague, and confused.


• February 2007: NIH Office of Extramural Research releases *Observations from NIH’s FY 2006 Targeted Site Reviews on Financial Conflict of Interest.* This study revealed that some of the institutions’ interpretations of who was covered by NIH regulations were inconsistent with and narrower than NIHs interpretation.


• April 2009: Institute of Medicine releases consensus report, *Conflict Of Interest In Medical Research, Education, And Practice,* which examines the evidence and practices concerning individual and institutional conflicts across the spectrum of research, education, medical practice, and clinical practice guideline development and makes recommendations, including standardization of disclosures.

• May 2009: NIH issues Advance Notice of Proposed Rulemaking (ANPR) requesting comments on “Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors; Request for Comments.”

• June 2009: AAMC and AAU submit joint comments to NIH in response to ANPR.


Before plunging into a comprehensive conflicts-management program, one might ask whether, aside from appearance, financial interests actually make a difference in behavior. A number of studies over the past decade suggest that they do. Further, disclosure of interests may not present a full solution. In June 2007, the AAMC convened a Symposium on the Scientific Basis of Influence and Reciprocity designed to explore the challenges to objectivity that are presented by gifts, favors, and influence. The symposium’s report concluded, “The neurobiological and behavioral evidence presented at the symposium suggests that traditional mechanisms for addressing conflicts of interest and ensuring objectivity [i.e., disclosure] may not adequately take into account the biological and psychological processes operating in the human brain that can influence judgment and decision making.”

**Conflicts of Interest in Research**

Understandably, because of the significant risk for harm to patients and skewing of research results, clinical research has garnered the most conflicts attention and is the subject of many of the aforementioned reports and publications. The work done in identifying and addressing research conflicts of interest has served as the base for expansion and refinement.

*Guidance for Human Subject Protection,* issued by HHS in 2004, recommends the following questions be considered in the implementation of conflicts-of-interest systems for research. These questions lay out the basic approach for identifying and managing potential conflicts in all areas.

• Does the research involve financial relationships that could create potential or actual conflicts of interest?
  – How is the research supported or financed?
  – Where and by whom was the study designed?
  – Where and by whom will the resulting data be analyzed?

• What interests are created by the financial relationships involved in the situation?
  – Do individuals or institutions receive any compensation that may be affected by the study outcome?
  – Do individuals or institutions involved in the research:
    » Have any proprietary interests in the product, including patents, trademarks, copyrights, or licensing agreements?
    » Have an equity interest in the research sponsor and, if so, is the sponsor a publicly held company or non-publicly held company?
    » Receive significant payments of other sorts? (e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, or honoraria)
    » Receive payment per participant or incentive payments, and are those payments reasonable?

• Given the financial relationships involved, is the institution an appropriate site for the research?

• How should financial relationships that potentially create a conflict of interest be managed?

• Would the rights and welfare of human subjects be better protected by any or a combination of the following:
Teaching Hospitals

Teaching Hospitals

The OIG reviewed clinical investigators’ financial interests reported to the FDA relating to federal fiscal year (FY) 2007 approved marketing applications and assessed the FDA’s oversight of this information. The report explained that sponsors of marketing applications—usually pharma and device companies—are required to collect information on conflicts from investigators before clinical trials begin, but are required to submit this information to the FDA only when the marketing application is submitted, not before clinical trials are conducted. The sponsor is to submit information disclosing financial interests for each investigator with a financial interest, along with what steps were taken to minimize the conflict. The OIG found that the FDA could not determine whether sponsors had submitted required information for all investigators because the FDA did not have a complete list of investigators. About 1% of the reporting investigators reported financial interests. Forty-two percent of marketing applications had missing certification or information forms or indicated that the sponsor had used due diligence to obtain required information but was not successful, or both. Of the marketing applications with disclosed financial interests, no documented action was taken either by the FDA or the sponsor to minimize the effect of conflicts on the research. The OIG recommended that financial information be submitted during the pre-trial application process so that the FDA could be sure that required information was collected.

Second, in late 2009, the OIG released a review of 184 investigator financial conflicts of interest provided to NIH by grantees during federal FY 2006, including how the grantee institutions managed, reduced, or eliminated the conflict. The most frequently reported conflict was equity ownership, including stock and stock options. Disclosure, rather than elimination of the interest, was by far the most common management technique. The OIG found that 90% of the institutions reviewed left the determination of whether an interest created a conflict up to the researcher’s discretion, and institutions did not routinely verify information submitted by researchers. The OIG made a number of recommendations, including that institutions be required to collect information on all significant interests, whether or not the researcher believes that they affect research (echoing the AAMC-AAU Report), that the conflict review and management process be better documented, and that regulations be developed to address institutional financial conflicts of interest.

- Reduction of the financial interest?
- Disclosure of the financial interest to prospective subjects?
- Separation of responsibilities for financial decisions and research decisions?
- Additional oversight or monitoring of the research?
- An independent data and safety monitoring committee or similar monitoring body?
- Modification of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent or a change of investigator?
- Elimination of the financial interest?

These questions informed the AAMC-AAU 2008 report, Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research (AAMC-AAU Report). The AAMC-AAU recommends that comprehensive conflicts-of-interest programs in human subjects research be fully implemented. Some specific recommendations are:

- Individuals should be required to report all outside financial interests related to their professional responsibilities, regardless of amount and regardless of whether the individual believes these financial interests might reasonably appear to be affected by the individual's research. An institution may wish to consider exempting certain clearly defined types of consulting and fees from its definition of reportable financial interests, i.e., fees for serving on grant review committees and fees given as honoraria by another academic institution for an academic activity, such as a seminar or grand rounds presentation.

- The institution should have a rebuttable presumption that a researcher with a financial interest has a conflict, whereby some compelling circumstances may rebut that presumption. The conflicted investigator's role should be restricted according to the level of anticipated risk. Possible roles to be restricted are subject recruitment, subject selection, subject consent, and clinical evaluation of subjects, including adverse event evaluation and reporting.

- While conflict-management plans should be developed and implemented in the case of a conflict, there should not be prescribed standards for such plans.

Although the guidance described above was issued in 2004 and the AAMC-AAU Report recommendations were issued in 2008, immediate progress was not apparent. In 2009, the OIG released two studies, one relating to conflicts information submitted to the FDA and one relating to NIH grantees, criticizing the agencies and institutions involved. First, in early 2009, the OIG released a review of the FDA’s use of clinical researcher conflicts-of-interest information. The OIG reviewed clinical investigators’ financial interests reported to the FDA relating to federal fiscal year (FY) 2006, including how the grantee institutions managed, reduced, or eliminated the conflict. The most frequently reported conflict was equity ownership, including stock and stock options. Disclosure, rather than elimination of the interest, was by far the most common management technique. The OIG found that 90% of the institutions reviewed left the determination of whether an interest created a conflict up to the researcher’s discretion, and institutions did not routinely verify information submitted by researchers. The OIG made a number of recommendations, including that institutions be required to collect information on all significant interests, whether or not the researcher believes that they affect research (echoing the AAMC-AAU Report), that the conflict review and management process be better documented, and that regulations be developed to address institutional financial conflicts of interest.
Admittedly, the OIG reports were based on older data (from federal FYs 2006 and 2007), but still were not encouraging. The NIH took action, actually before the OIG report concerning NIH grantees was issued, by asking for suggestions in an ANPR in May 2009.24 The ANPR indicates that NIH intends to review its policies but that grantees, such as universities, rather than NIH, would remain primarily responsible for researchers’ activities. The ANPR states that NIH will consider strengthening regulations on researchers’ financial conflicts to reduce financial conflicts of interest in scientific research, including addressing institutional conflicts of interest. The ANPR provided for a sixty-day comment period. Approximately 130 comments were received; they can be viewed at www.regulations.gov.25

Institutional Conflicts to the Fore

The NIH ANPR asks for comments on how institutional conflicts should be defined and handled. Concern about institutional conflicts of interest is not new. A 2001 GAO report26 expressed concern about institutional financial conflicts of interest in research, particularly in the technology transfer context. The concern is that if the institution has a financial interest in a startup company, for example, it may act to maximize the value of its investment rather than purely in the research’s best interests. The GAO reviewed the interaction between research and technology transfer functions at five academic institutions with medical schools and found that the institutions’ policies on technology transfer and investment in startups varied considerably. The report noted that HHS guidance did not provide detailed information concerning management of institutional conflicts and recommended that HHS develop specific guidance or regulations to address institutional financial conflicts of interest.

This concern is not merely theoretical. A 2003 analysis of studies published between 1980-2002 on management of financial conflicts of interest found that about two-thirds of academic institutions in the data set held equity in startup companies that sponsored research conducted at the institution.27 A 2006 survey of U.S. medical schools concerning their conflict-of-interest policies28 indicated that only 38% of the respondents’ policies addressed interests held by the institution itself, although a much higher percentage of respondents had policies addressing interests held by institutional officials.

The 2008 AAMC-AAU Report provided a useful template for institutional conflicts of interest and definitions of such terms as “institutional officials.” The template policy describes institutional conflicts of interest as follows:

Institutional conflict of interest can also arise when the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the education, clinical care, business transactions, or other activities of the institution . . . . Relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the institution’s primary missions, including the safety and integrity of its research, education, and clinical care.29

The policy indicated that potential institutional financial and fiduciary interests needing review include: 30

- Royalties: The institution has the potential to receive significant milestone payments or royalties from the sales of an investigational product that is the subject of the research; and
- Equity interests: The institution has obtained an equity interest, or options or warrants, in a company that sponsors research at the institution or manufactures a product to be studied in research at the institution. This may be an interest in a non-publicly traded company or a significant amount of interest in a publicly traded company.

The AAMC-AAU Report makes a recommendation that research and financial decision-making processes and agents be separated to prevent or manage institutional conflicts. This is already being done in many cases. For example, in a 2006 survey of medical schools,31 a majority of the respondents had adopted organizational structures that separated research responsibility from investment management and from technology transfer responsibility.

However, in 2001 the GAO questioned whether a traditional “firewall” between academic affairs and investment management through the use of professional investment managers was effective in addressing equity investments in startup companies.32 In its 2001 report, the AAU explained why a firewall between endowment management and research did not suffice:

[M]ost universities have long-standing ‘firewall’ arrangements governing the management of these funds and their separation from the campus’s research enterprise. Such firewalls are provided when the equity is part of an institution’s general endowment or investment portfolio, is managed in accordance with standard institutional investment policies, with no special restrictions or considerations, and is overseen by an appropriate oversight or board of trustee finance and investment committee that exercises no control over university programs and operations. Such firewalls are vital, and need to be carefully designed, but they are of less immediate concern here than the policies and procedures that must be developed to address the newer sort of equity holdings [e.g., venture funds and incubator programs] and royalty income derived from technology transfer.33

No consensus has yet developed about whether and how institutional conflicts created by interests in startup companies can best be managed.

Easier Said than Done: Implementing a Comprehensive Conflicts Program

While this article is not a “how-to” on implementing a comprehensive conflicts program, we should acknowledge the difficult position AMCs face when trying to do so. It is difficult enough for a university or medical school to identify and address conflicts in research. The GAO observed in its 2001 study that the necessary information could be located in different places within a
university: financial disclosures might be with the conflict-of-interest committee; the grants office might keep information on funding sources; and the technology transfer office might keep information about faculty relationships with industry. Frequently the AMC is frequently one step removed. Even though research may be taking place within its facility and publications refer to the AMC, research funding, accounting, and royalty payments to faculty may be administered through another entity that may or may not be under common control with the AMC. Nonetheless, the regulators and the public look to the AMC to identify and address conflicts that may arise from research, education, patient care, and other functions.

Federal Initiatives for Disclosure of Industry Payments to Physicians

The AAMC-AAU 2008 report recommended broad disclosure of financial interests related to human subjects research and pointed out that these disclosures would for the first time provide academic institutions with a tool to audit conflicts-of-interest reporting forms.\textsuperscript{34} Some AMCs have begun disclosing their physicians’ interests on their websites.\textsuperscript{35} Several states have either enacted\textsuperscript{36} or are considering\textsuperscript{37} proposals that would require drug and/or device companies to disclose payments to physicians. In addition, a number of settlements between device manufacturers and the government have resulted in public disclosure of payments to physicians on the companies’ websites. The audits of conflicts reporting forms have accordingly begun. For example, a comparison of disclosures made by orthopedic surgeons participating in a 2008 American Academic of Orthopaedic Surgeons meeting with disclosures made by device manufacturers indicated that only 79% of directly related payments and 50% of indirectly related payments were disclosed.\textsuperscript{38}

Provisions to impose uniform disclosures across the country were included in both the House\textsuperscript{39} and Senate\textsuperscript{40} healthcare reform bills and were also introduced by Senators Herb Kohl (D-WI) and Charles Grassley (R-IA) in the Physician Payments Sunshine Act of 2009.\textsuperscript{41}

All three proposals regarding reporting of physician payments have the following features in common; differences between the bills are described in the attached table. Required reports regarding payments by manufacturers to physicians must be submitted on an annual basis to HHS (by March 31 for the previous calendar year). The manufacturer must make the information publicly available on a website, in electronic and easily manipulable form, by June 30 for the previous calendar year.

- Every manufacturer, marketer, or distributor of a drug, device, biological, or medical supply covered by Medicare or Medicaid, and certain subsidiaries and affiliates thereof, would be required to report. Some group purchasing organizations (GPOs) owned by physicians would also be required to report.
- Payments to physicians, whether in the form of cash or cash equivalent, in-kind items or services, stock, stock options, or other ownership interest or return on investment, would be reportable.
- Indirect payments (payments to an entity or individual at the request of or designated on behalf of a recipient to whom payments are covered) would also have to be reported in the covered recipient’s name.
- Payments for the following items would be reportable: research; grants; consulting fees; other compensation for services; honoraria; gifts; entertainment; food; travel; education funding; royalties or licenses; and current or prospective ownership or investment interests.
- Payments consisting of the following items would not have to be reported: loan of a device for evaluation; discounts and rebates; and in-kind items used for the provision of charity care.
- Payments below a minimal threshold would not have to be reported. These thresholds vary across bills.
- The following information must be reported: the name and business address of the recipient; if the recipient is a physician, the physician’s specialty; a description of payments, as well as their value and dates of payment; and, if a payment is related to a specific drug, device, biological, or medical supply item, the name of the item.
- The penalty for failure to report is a civil monetary penalty (CMP) of between $1,000 and $10,000 for each payment not reported, with the total annual penalty not to exceed $150,000. If there was a knowing failure to report, the CMP is increased to between $10,000 and $100,000 for each payment not reported, with the total annual penalty not to exceed $1 million.
- The legislation preempts state laws except for those that require additional disclosure or reporting.
- In addition, if a physician or physician’s family member has an ownership interest in a manufacturer or GPO (other than an interest in a publicly traded security or mutual fund), the manufacturer or GPO must report the following with respect to the investment by the physician or family member: dollar amount invested; value and terms of investment; and any payment to a physician holding such an ownership or investment interest.

The attached table highlights features that vary between the bills.

Conclusion

The conflicts spotlight will stay on AMCs, both for individual and institutional interests. Heightened attention to governance and conflicts in the tax-exempt sector, as well as increased publicly available information on physicians’ financial relationships with drug and device companies, will keep it focused there. To avoid reporting or acting on incomplete or inaccurate information—or information inconsistent with what is available to the public—AMCs need to continue to pursue enterprise-wide conflicts detection and management across operational lines, with the added feature of cross-checks against publicly disclosed information.
## Differences Between Physician Payment Disclosure Proposals

<table>
<thead>
<tr>
<th></th>
<th>Physician Payments Sunshine Act (S. 301)</th>
<th>House Healthcare Reform Bill (HR 3962, Section 1451)</th>
<th>Senate Healthcare Reform Bill (HR 3590, Section 6002)</th>
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</thead>
<tbody>
<tr>
<td><strong>Recipients to whom payment must be reported</strong></td>
<td>Physician medical practice or physician group practice</td>
<td>Physician group practice; pharmacy; pharmacist; entity offering health benefits plan and its employees; pharmacy benefits manager; hospital; medical school; sponsor of CME program; patient advocacy or disease specific group; organization of healthcare professionals; biomedical researcher; or GPO</td>
<td>Teaching hospital</td>
</tr>
<tr>
<td><strong>Other types of payments that must be reported</strong></td>
<td>Charitable contribution</td>
<td>Speaking fee; dividend; or profit distribution</td>
<td>Charitable contribution</td>
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<tr>
<td><strong>Dollar threshold for reporting</strong></td>
<td>$100 in aggregate per calendar year</td>
<td>Transfers over $5</td>
<td>$10 per transfer unless aggregate payments to that recipient by that manufacturer exceed $100 per calendar year; dollar amounts to be indexed over time</td>
</tr>
<tr>
<td><strong>Payments that need not be reported</strong></td>
<td>Product samples; educational materials for patient use</td>
<td>Payments by self-insured health plan</td>
<td>Product samples; educational materials for patient use; payments for health services to manufacturer's employees under self-insured plan; payments to physicians for services with respect to civil or criminal action or administrative proceeding</td>
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<tr>
<td><strong>Delayed reporting</strong></td>
<td>If payments are for development of new item or for clinical investigation, reporting can be delayed for two years or date of FDA approval, whichever is earlier; total must be reported in year paid and simply indicated as clinical research</td>
<td>If payments are for development of new item, reporting can be delayed for two calendar years or date of FDA approval, whichever is earlier; if payments are for clinical investigation, reporting can be delayed for two calendar years or date clinical investigation is registered on website, whichever is earlier; total must be reported in year paid and simply indicated as clinical research</td>
<td>If payments are for development of new item or for clinical investigation, reporting can be delayed for four years or date of FDA approval, whichever is earlier; total must be reported in year paid and simply indicated as clinical research</td>
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<tr>
<td>Other aspects of payment that must be reported</td>
<td>Physician Payments Sunshine Act (S. 301)</td>
<td>House Healthcare Reform Bill (HR 3962, Section 1451)</td>
<td>Senate Healthcare Reform Bill (HR 3590, Section 6002)</td>
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<tr>
<td>If payment is to physician, Medicare billing number</td>
<td>If payment is to physician, National Provider Identifier (NPI not to be disclosed to public but may be made available for researchers or business use). With respect to each drug sample: name, number, date, and dosage units (this information is not made available to public but may be made available for researchers or business use).</td>
<td>If payment is to physician, NPI (NPI not to be disclosed to public)</td>
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| Penalties for failure to report | Total annual penalty for knowing failure to report is not to exceed the greater of $1 million or 0.1% of total annual revenues of reporting entity. A state attorney general may enforce reporting requirements. | |

| Other reporting | Hospitals and other healthcare providers must also report physician ownership interests |

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4. Available at www.hhs.gov/ohrp/nhrpac/mtg12-00/finguid.htm.
21. Id. at 2.

25 A number of the comments were analyzed in Dawn Crumel and Heidi Sorensen, Be Careful What You Ask For: NIH’s Request for Comments on Conflicts of Interest in Research, 14 AHLA CONNECTIONS 12 (Jan. 2010).


29 AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subject Research, Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research (2008), at Appendix A.

30 Id.

31 Ehringhaus, supra note 28.

32 U.S. Gov’t Accountability Office, supra note 26.


34 Berdahl & Kirch (June 10, 2009), supra note 17.


36 Minnesota is an example (applicable to drug companies only). See Minn. Bd. of Pharmacy, Payments to Practitioners Documents, available at www.phcybrd.state.mn.us/main_pay.htm.


38 Okike, supra note 19.

39 H.R. 3962, 111th Cong.

40 H.R. 3590, 111th Cong.

41 H.R. 3138, 111th Cong.
Avoiding Technical Non-Compliance: The Missing or Nonexistent Written Agreement Problem

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You are about to grab your keys and head out for the day, and you see that familiar red blink on your Blackberry. An email from a hospital client tells you that a sublease of space by the hospital from a physician practice, entered into so that one of the hospital’s employed specialists can follow up with patients who live in an outlying area, expired eight months ago. The hospital’s document management tickler system alerted the legal department of the approaching expiration; although the legal department had timely sent out an amendment and had followed up several times, the overwhelmed practice manager of the physician practice had just not gotten around to reviewing it. The hospital’s specialist has continued to use the space, and the hospital has continued to make payments in accordance with the previous contract.

Or how about a phone call from an academic medical center (AMC) client informing you that one of its faculty members started using a local physician practice’s nurse practitioner four months ago to assist with the faculty member’s research activities, with the promise to reimburse the practice for the salary and benefits costs of the time that the nurse practitioner spent doing the research? The faculty member has just now requested that someone “paper” this arrangement.

The above examples illustrate the common yet potentially daunting scenario where a hospital or AMC finds itself in a financial relationship with a referring physician without a formal, signed, written agreement. Even if the arrangement is legitimate, fair market value is being exchanged between the parties, and there is otherwise no bad intent, a technical deficiency such as lack of a signed agreement can cause enormous exposure for the parties, as this article will discuss.

**Background**

The federal physician self-referral statute (Stark Law)\(^1\) prohibits a physician from referring patients to an entity for the furnishing of certain designated health services\(^2\) (DHS) that are otherwise reimbursable by Medicare and/or Medicaid if the physician (or an immediate family member) has a financial relationship with that entity, unless a specific exception is met. Stark Law violations can result in the application of significant fines, exclusion from the Medicare program, and potential exposure under the federal False Claims Act (FCA).\(^3\) Recent legislative amendments, including under the Patient Protection and Affordable Care Act, enacted March 23, 2010, have expanded the potential FCA liability exposure for failing to comply with the technical components of the Stark Law by now permitting whistleblowers to bring false claims actions against providers who knowingly and improperly retain government funds paid to them in error and by requiring any overpayments be repaid within sixty days of discovery.\(^4\)

The Stark Law is a strict liability statute, meaning that the failure to comply with an exception constitutes a violation of the law regardless of the parties’ intent. Many of the exceptions require, among other things, the presence of a signed, written agreement. As hospitals’ and other providers’ plates become overloaded with new, never-ending, and continually changing regulatory obligations—from quality indicator reporting to “meaningfully” using electronic health records—on top of increasing budgetary constraints, the reality is that providers are struggling to keep up with all of those contracts and to ensure that they and their contracting staff are adequately educated on Stark Law issues. As a result, hospitals and providers may find themselves in situations where they are at risk of a Stark Law technical violation.

**Can the Arrangement Still Meet an Exception?**

An initial consideration is whether the financial relationship between the DHS provider (i.e., hospital or academic medical center) and the potential referring physician (or immediate family member) or physician group can still meet the signed, written agreement requirement in the Stark exception that the arrangement historically met. Some legal commenters have suggested that despite not having a formal, signed, written agreement, you may be able to argue that you have met the signed, written agreement requirement if you have a signed writing or series of writings that could together constitute a signed written agreement under state law. However, the success of this argument is not certain and remains subject to debate.

Presuming the lack of a signed, written agreement, the next consideration is whether the arrangement can still meet an exception to the Stark Law despite the lack of a signed, written agreement. There are several exceptions that may still be able to shelter the arrangement.

**Holdover Provisions**

The space rental, equipment rental, and personal services exceptions to the Stark Law all contain provisions allowing for a six-month holdover immediately following the expiration of a signed, written agreement of at least one year if the arrangement otherwise meets requirements of the applicable exception and continues on the same terms and conditions as the immediately preceding agreement.\(^5\) The Centers for Medicare & Medicaid Services (CMS) believes that the six-month holdover provision “should provide adequate relief to parties to arrangements of these types that would otherwise temporarily fall out of compliance with the physician self-referral law.”\(^6\)

The Stark Law regulations and preamble commentary do not suggest that a holdover provision must be present in the lease in order to take advantage of the six-month holdover provisions. However, if holdover provisions do exist and call for a holdover
The Stark Law contains an exception for certain arrangements involving temporary non-compliance that protects an entity that submits a claim or bill for DHS for ninety consecutive calendar days following the date on which the financial relationship became noncompliant, if:

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception . . . for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the non-compliance; and

(iii) The financial relationship does not violate the anti-kickback statute . . . and the claim or bill otherwise complies with all applicable federal and state laws, rules, and regulations.*

Note that the temporary non-compliance exception may not be used if the arrangement was never in compliance with an exception. Moreover, this exception may be used by an entity only once every three years with respect to the same referring physician, and it may not be used to shelter non-compliance with the non-monetary compensation exception or the medical staff benefits exception.

To rely on this exception, the hospital needs to be able to verify and justify that the reasons for falling out of compliance were beyond its control. CMS has not provided much guidance on what constitutes “reasons beyond the control of the entity” other than saying “a determination of whether such non-compliance was beyond the entity’s control would have to be made on a case-by-case basis.” CMS merely advises DHS entities to maintain adequate and contemporaneous documentation of all financial relationships with referring physicians, including (1) the terms of each arrangement; (2) whether and how an arrangement fell out of compliance with an exception; (3) the reasons for the arrangement falling out of compliance; (4) steps taken to bring the arrangement back into compliance; (5) relevant dates; and (6) similar information.10

Another challenge in relying on the temporary non-compliance exception is ensuring that the hospital adequately verifies that the temporary non-compliance exception has not been used in another arrangement with any of the physicians involved in the last three years. The hospital should flag the related physicians so as to avoid trying to use this exception again in the following three years.

**Temporary Non-Compliance With Signature Requirements Special Rule**

The special rule for certain arrangements involving temporary non-compliance with a signature requirement protects an entity that submits a claim or bill (and receives the corresponding payment) for a DHS service if the financial relationship between the entity and the referring physician was a compensation arrangement that fully complied with an applicable exception (except the signature requirement) and the failure to comply with the signature requirement was:

(A) Inadvertent and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant . . . and the compensation arrangement otherwise complies with all criteria of the applicable exception; or

(B) Not inadvertent and the parties obtain the required signature(s) within 30 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant . . . and the compensation arrangement otherwise complies with all criteria of the applicable exception.11

CMS equates a “not inadvertent” failure with a “knowing” failure and instructs parties to attach the ordinary meaning to “inadvertent.” Moreover, as with the general temporary non-compliance exception discussed earlier, the temporary non-compliance with signature requirements special rule may only be used once every three years with respect to the same referring physician, and thus creates the same logistical hurdle discussed above. The hospital must track the physicians with whom the exception has been used previously and must ensure that the exception is not used for the next three years with respect to the physicians involved in the current arrangement at issue.

With this exception, CMS acknowledges that sometimes it is difficult to obtain all signatures and sometimes physicians’ services are needed on very short notice; however, CMS continues to want to incentivize due diligence and believes that:

[Ninety] days after the beginning of an otherwise fully compliant relationship is sufficient time for parties to
exercise diligence and discover whether a signature is missing, and where an entity has knowingly entered into an otherwise fully compliant financial relationship despite a missing signature, 30 days after the beginning of the financial relationship is sufficient time for such entity to procure the signature. CMS specifically declined “to extend the protection afforded [by this exception] to failures to meet compensation requirements (such as the requirement that compensation be at fair market value or not take into account the volume or value of referrals), including failures that result in ‘minor payment errors,’” because CMS is not confident that doing so would not create a risk of program or patient abuse.

Employment Exception

One consideration is whether the financial arrangement at issue could be appropriately considered a bona fide employment relationship. The employment exception protects any amount paid by an employer to a bona fide employed physician (or immediate family member) if: (1) the employment is for identifiable services; (2) the amount of the remuneration is consistent with fair market value of the services and, with the exception of certain productivity bonuses based on personally performed services, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician; and (3) the remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

For example, a physician or a nurse practitioner from a physician group practice who is providing research services under the direction and control of an AMC faculty member could potentially be considered a part-time employee of the AMC rather than an independent contractor or a leased employee. This position could be tenuous, however, because typically employment arrangements involve tax withholdings and benefits. The absence of any such withholdings and benefits would likely cut against any argument that the arrangement constitutes an employment relationship.

Other Possible Exceptions

In addition to the exceptions discussed above, depending on the facts and circumstances, other exceptions may be available to avoid technical non-compliance with the Stark Law including but not limited to the isolated transaction exception, payments by a physician exception, and the exception for remuneration unrelated to DHS. In addition, you may wonder whether you can further limit any liability exposure by making the arrangement retroactively effective (i.e., nunc pro tunc agreements). Although historically it was not uncommon to attempt retroactive compliance through back-dating, CMS has more recently taken a strong stance against such practices by saying, “We believe that the statute does not contemplate that parties have the right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively.” As a result, back-dating, even in an extremely transparent manner (i.e., dating the contract as of the current date to be effective as of some earlier date, and ensuring that the parties signing the contract also date their signatures the date they sign) is now considered more risky. Although some commenters argue that if state contract law recognizes retroactive dating, it might be difficult for CMS to argue that a signed written agreement has not been in place.

CMS suggests “[w]here an entity discovers that it is missing a signature on an agreement, for example, or that too much or too little compensation has been paid, it should take steps to bring its relationship(s) into compliance.” In August 2008, CMS finalized its proposal to clarify the period of time during which a physician could not refer DHS to an entity (and the entity could not bill Medicare) due to a financial relationship between the referring physician and entity that failed to satisfy all the requirements of an exception to the Stark Law (period of disallowance). As finalized, the period of disallowance begins at the time that the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than:

(i) Where the non-compliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;

(ii) Where the non-compliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

(iii) Where the non-compliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.
The period of disallowance is not dependent on self-reporting. The provisions above prescribe an outside limit on the period of disallowance in certain circumstances and, thus, provide assurance that referrals made after a certain date and claims made pursuant thereto will not run afoul of the Stark Law. Parties may still attempt to establish that the period of disallowance ended at some earlier point than those described above. CMS asserts there may be some instances where the period of disallowance that may not end because all the terms of an exception are never met—for example, where the parties are never able to obtain the missing signature on a contract or where excess compensation may never be repaid.

CMS is also clear that taking action to fix the outside date of disallowance does not vitiate a DHS entity's overpayment for any claims submitted during the period of disallowance as the result of prohibited referrals. However, when the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), announced in March 2009 that it would no longer accept through its self-disclosure protocol any self-disclosure of Stark Law violations that do not also involve a “colorable anti-kickback statute violation,” providers lost a clear avenue to self-disclose or otherwise address technical non-compliance issues. The ability to self-disclose Stark Law violations is once again on the horizon. Pursuant to the recently passed Patient Protection and Affordable Care Act, the HHS Secretary (Secretary), in coordination with the OIG, must establish a new self-referral disclosure protocol to enable providers and suppliers to disclose actual or potential violations of the Stark Law by September 23, 2010. Moreover, the Patient Protection and Affordable Care Act expressly authorizes the Secretary to reduce any payment due as a result of Stark Law violations (thereby potentially opening the door for the Secretary to base damages on the amount of the improper Stark compensation, not on the amount of the tainted claims). In establishing the amount due, the Secretary must at a minimum consider: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of self-disclosure; and (3) the cooperation in providing additional information. The Secretary has not yet provided any additional information or guidance regarding how this self-disclosure protocol will be implemented.

In the meantime, given the heightened liability that comes with the recent amendments to the FCA and the new requirement to repay overpayments within sixty days of identification, the prudent course of action is probably to evaluate the number of items and services provided pursuant to referrals stemming from the non-compliant financial relationship during the period of disallowance and to either: (1) not bill for those items and services; or (2) where payments have already been received pursuant to those items and services, reimburse the Medicare Administrative Contractor that handled the claims. Alternatively, you could consider bringing the matter to the attention of your CMS regional office or the U.S. Department of Justice. Note that in any event, you may want to consult legal counsel on how to best approach any repayment.

**Conclusion**

The Stark Law is technically complex and unforgiving with respect to technical non-compliance, even where the arrangement is legitimate, the compensation is at fair market value, and there is no bad intent. The best way to avoid technical Stark Law problems is education on the front end, along with sound policies and procedures designed to identify arrangements that come under the purview of the Stark Law, and flag when such arrangements come up for renewal. Particularly where turnover rates may result in lost knowledge, ongoing education can help to remind personnel of the importance of identifying potential Stark Law relationships and involving the legal department when such relationships arise. In addition, it is important to continually emphasize the organizational message that written, signed contracts must be in place before financial arrangements begin.

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1. 42 U.S.C. § 1395nn
2. Designated health services include, among others, inpatient and outpatient hospital services. 42 C.F.R. § 411.351.
3. Violations of the Stark Law can result in one or more of the following sanctions: (1) denial of payment to an entity furnishing services under a prohibited referral; (2) refunds of billed or collected amounts; (3) assessment of civil monetary penalties of up to $15,000 per prohibited referral (and up to $100,000 for a circumvention scheme); and (4) exclusion from participation in the Medicare program. The sanctions apply to both the referring physician and the entity billing for DHS (i.e., the hospital). 42 U.S.C. § 1395nn. Stark Law violations could also create potential liability under the federal FCA, which is punishable by treble damages (i.e., three times the claim amounts submitted) and up to $11,000 per false claim. 31 U.S.C. §§ 3729-3733.
5. 42 C.F.R. § 411.357(a), (b), (d).
7. Id. at 51045.
8. 42 C.F.R. § 411.353(f).
10. Id.
11. 42 C.F.R. § 411.353(g).
13. Id. at 48707.
14. Id. at 48703.
15. Ser 42 C.F.R. § 411.357 (f), (g), (i).
17. Id.
18. 42 C.F.R. § 411.353(c); 73 Fed. Reg. 48700-48705.
21. Id.
22. Id.
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