

CORRIDORS

News for North Carolina Hospitals
from the Health Law Attorneys of Poyner Spruill LLP



When the Government Comes Knocking

by Chris Brewer

This article will provide an outline of some of the most significant points for hospitals to use when confronted with a formal government investigation under the Criminal or Civil False Claims Act. As noted below, you should refer to your compliance program, which should provide more detailed guidance in these situations. Audits or reviews by government health care programs or state Medicaid program contractors require a less immediate response by the hospital.

Federal and state enforcement agencies include the U.S. Department of Justice (DOJ), the Federal Bureau of Investigation (FBI), the Office of Inspector General for the U.S. Department of Health & Human Services (OIG), Department of Defense (Tricare Health Program), United States Postal Inspection Services, Drug Enforcement Administration, State Medicaid Fraud Control Units, and task forces comprised from these agencies.

Government investigators have the authority and tools to gather information relating to an investigation using many methods, including search warrants, subpoenas, electronic surveillance, and interviews. Investigations come from a wide variety of sources. The government may try to avoid alerting a health care organization that it is under investigation, and the provider often becomes aware of the investigation from the investigative tools used by the government. The particular tools used significantly affect how the provider should respond.

As part of an effective compliance program, a hospital should develop a process and written policy to prepare for situations where a government agent presents a search warrant, subpoena,

civil investigative demand, authorized investigative demand, or other legal document, or attempts to conduct interviews of hospital management or employees. Outside legal counsel should be notified of the contact at the earliest possible time. The hospital should make every effort to allow counsel the opportunity to review the legal document or request presented to the hospital, to provide advice and assistance, and to be present when the government agent conducts interviews or has other direct contact with hospital personnel.

SEARCH WARRANTS

- A search warrant is issued by a court to grant law enforcement agents the right to search a location and seize certain items. A search warrant indicates that the government is pursuing a criminal investigation. There may be allegations that a facility's records may have been destroyed or altered. It may be used to initiate an investigation or result from extensive investigative activities already conducted. A hospital should follow the process and guidance in its compliance program for how to respond if served with a search warrant. The compliance policy should cover appropriate cooperation with government agents, while protecting the rights of the hospital to the fullest extent possible.
- The hospital compliance program should designate a point person and response team for the hospital. Request a copy of the search warrant and review it carefully to determine its scope (note that the affidavit may be under seal and not available).

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Contact the hospital's attorney immediately and send a copy of the warrant. Request that the government agent wait for the hospital attorney to arrive before searching or until the hospital may consult with its attorney by telephone.

- Find out the name of each agency and agent participating in the search. Request to see and copy credentials of each agent and ask for business cards.
- You are not required to assist the agents during their search, but hospital personnel should not obstruct or interfere with a government investigation. Search warrants are for documents and do not authorize interviews. You do not have to tell agents where the documents are located, nor do you have any obligation to answer questions about the content or meaning of the documents they are examining and seizing. However, any statements you make should be true and accurate.
- A search warrant authorizes seizure of original records. Ask the agents to accept copies of records that are essential to operations. Request permission to make a copy of all documents seized or arrange for a copy to be provided as soon as possible.
- Object to any demand for noncorporate or personal records unless specifically identified within the scope of the search warrant. Inform the agents of documents which may be subject to attorney/client privilege and insist that appropriate procedures be followed to protect that privilege.
- Request that a designated representative of the hospital accompany the agent to any location to be searched. Make a detailed list of the areas searched, the documents or types of documents seized, and any questions asked or information provided.
- Accept a copy of the inventory but decline to sign the inventory unless you are certain it is detailed and accurate. Tell the agent you do not have authority to sign any document until it has been reviewed by your attorney. After the search, conduct interviews with the employees who monitored the agents and document as much information as possible about what occurred during the search.

SUBPOENAS

- A subpoena is a court or administrative order that requires a health care provider to testify or produce documents or other items, or both, at a specified time and place.
- Subpoenas may be issued by a federal or state court or enforcement agency with jurisdiction over the provider.

- There are many different types of subpoenas that may be used by the government in conducting health care fraud investigations. These include grand jury subpoenas, civil investigative demands, HIPAA subpoenas, and agency administrative subpoenas issued, for example, by HHS or OIG.
- The hospital should accept service of a subpoena issued seeking documents or testimony by hospital or staff, and immediately provide a copy of the subpoena to its corporate counsel. Documents or interviews should not be provided at the time of service, as the subpoena will always have a future return date for either documents or testimony sought by the government.
- Subpoenas cannot require you to create documents to produce, unless there is agreement to do so as part of discussions with government counsel in responding to the subpoena.
- The HIPAA privacy rules generally prohibit the hospital from disclosing protected health information. HIPAA contains exceptions for responding to subpoenas, but the rules differ depending on the type of subpoena issued. There are also protections for documents considered attorney/client privileged or work product prepared on behalf of your attorney.

INTERNAL INVESTIGATIONS

Government enforcement actions and investigations make it necessary for a hospital to conduct its own internal compliance investigations. In response to receiving notice of a government enforcement action, the hospital's compliance program should require an immediate internal investigation. The policy should address in detail how to conduct an internal investigation and the steps to be taken when that investigation is completed. Several important points are discussed below.

- Immediate efforts must be undertaken to gather and preserve materials relevant to the fraud or other allegations that are the subject of the investigation, even if the government has not yet requested materials or documents.
- Document retention and litigation hold policies should be in place to preserve relevant materials, especially electronically stored information. Failure to preserve relevant documents or electronic information may be viewed as obstruction of the investigation and result in penalties or other sanctions. Employees must be notified immediately when the hospital implements a litigation hold and informed of its scope.
- Hospital personnel may also have potential individual exposure in the investigation. Appropriate legal representation for these individuals, separate from hospital counsel, should be in place.

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Government attorneys should be informed that any contact with the hospital or its employees should be made only through counsel for the hospital. Hospital counsel will advise you regarding legal fees for independent legal counsel for employees. The hospital may decide to enter into a joint defense agreement with these attorneys to participate in the internal investigation. A decision should also be made early on as to whether to hire independent consultants to assist hospital counsel.

- The scope, method, accountability, and reporting between the attorneys directing the investigation, the consultants conducting the investigation, and the hospital authorizing the internal investigation should be clearly understood. The scope of the internal investigation should also define the subject matter and issues to be reviewed, and to whom within the hospital the law firm and investigative team will be accountable.

- Conducting the internal investigation requires interacting with members of the hospital staff and may result in negative findings concerning the hospital or certain staff members. If the internal investigation confirms the existence of misconduct, improper billing, or noncompliance, corrective action should be taken and documented to stop any improper practices. Employees who engaged in misconduct should be appropriately disciplined. These steps may assist in obtaining a more favorable outcome and/or mitigating potential penalties.

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IRS Issues Further Clarification Concerning Section 501(r)

by David Broyles

Our spring 2015 edition of *Corridors* featured an article on the additional burdens nonprofit hospitals face in the areas of financial assistance and debt collection under the new Section 501(r) of the Internal Revenue Code. This statute was enacted as a part of the Patient Protection and Affordable Care Act and imposes additional requirements on a charitable hospital organization to maintain its tax-exempt status.

IRS Notice 2015-46, issued on June 26, 2015, provided clarification concerning certain requirements in the new Section 501(r). The notice clarified requirements under 501(r)-4(b)(1)(iii)(F), which mandates that a hospital in its financial assistance policy (FAP) must identify all those health care providers providing emergency or other medically necessary care in the facility, whether or not they are employed or contracted with the hospital (or a substantially related entity) and thus covered by the FAP. The notice provides hospitals with the flexibility, among other things, to list an independent group practice as opposed to listing each individual physician member if all the physicians in the group are included in a hospital's FAP. Hospitals may also use an appendix to the FAP, since the physician list will often be fluid. The full text of the notice and clarifications therein can be found at <http://www.irs.gov/pub/irs-drop/n-15-46.pdf>.

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PROPOSED CHANGES TO STARK RULE WOULD CREATE NEW HOSPITAL EXCEPTIONS AND LESSEN BURDEN OF SELF-DISCLOSURES

by *Wilson Hayman*

In a development that is limited in scope but still welcomed by hospitals, the proposed 2016 Physician Fee Schedule proposes a number of new exceptions to the physician self-referral or Stark law and other refinements that should lessen the burden of technical Stark violations leading to self-disclosure. The proposed rule would create new exceptions under the Stark law for hospital payments to physicians to recruit mid-level practitioners and timeshare arrangements with physicians. The rule clarifies that certain Stark exceptions requiring the terms of the financial arrangement to be set out in writing need not be documented in a formal contract and permits further flexibility in cases of temporary noncompliance with signature requirements. The Centers for Medicare & Medicaid Services (CMS) released the proposed rule on July 8, which was published in the Federal Register on July 15 (80 Fed. Reg. 41,685), and has invited public comment. CMS' large backlog of Stark self-disclosures, many for technical violations of Stark that do not pose a substantial risk of overutilization of Medicare services, has apparently convinced CMS that this enforcement burden should be reduced.

The Stark law prohibits, unless an exception applies, (1) a physician from making a referral to an entity to furnish any one of 11 designated health services (DHS) payable by Medicare, if the physician or his immediate family member has a financial relationship with the entity, and (2) the entity from presenting a claim for reimbursement for such a DHS. Because Stark establishes a "bright line" rule with strict liability, referrals between parties with a financial relationship that do not fall within an exception violate the law even in the absence of bad intent by the parties. In addition to a host of statutory exceptions, the Secretary has the authority to promulgate additional exceptions by rule. Many of the changes to these regulatory exceptions proposed by CMS in the 2016 Physician Fee Schedule will be discussed below. The Voluntary Self-Referral Disclosure Protocol was developed and released by CMS in 2010 per the Patient Protection and Affordable Care Act to provide a mechanism for providers to self-disclose actual or potential violations of the Stark law.

NEW HOSPITAL RECRUITMENT EXCEPTION. Recognizing changes to health care delivery and payment systems, as well as shortages of primary care physicians particularly in rural areas, CMS proposes a new Stark exception to be codified at 42 CFR § 411.357(x) to allow payments by a hospital (or a federally qualified health center or rural health clinic) to a physician who will employ a physician assistant, nurse practitioner, clinical nurse specialist or certified nurse-midwife (Nonphysician Practitioner) to provide primary care services to patients of the physician's practice. 80 Fed. Reg. at 41957. The amount of the payments may not exceed the lower of either (1) 50 percent of all compensation and benefits paid by physician to the Nonphysician Practitioner, or (2) an amount equaling the actual compensation and benefits paid to the practitioner by the physician less the sum of all receipts attributable to the Nonphysician Practitioner's services for the same period. Both of these tests must be calculated for a period not to exceed the first two consecutive years of employment. The Nonphysician Practitioner must not have practiced in the hospital's geographic service area or been employed or engaged to provide patient care elsewhere by a physician organization which has a medical practice site in the hospital's service area. Among other additional requirements, the Nonphysician Practitioner's total compensation paid by the physician may not exceed the fair market value of the patient services furnished by the practitioner to the practice's patients. CMS also proposed to revise the existing Stark exception for physician recruitment by redefining the geographic area from which federally qualified health centers and rural health clinics may recruit physicians.

NEW EXCEPTION FOR TIMESHARE ARRANGEMENTS. The current Stark exception for office lease arrangements does not permit "timeshare" leasing arrangements in which a physician pays the lessor for the periodic right to use office space exclusively on a turnkey basis, including support personnel, waiting area, furnishings, equipment, and supplies. Such arrangements are common in rural areas where a hospital or physician practice makes space and staff available to a visiting physician. This is often structured as the owner's grant of a license or privilege to the visiting physician for use of the property at specified times, without conveying dominion or control over the premises as in a true lease.

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ACCESS TO EMPLOYEE BENEFIT RECORDS – TAKE ACTION NOW TO AVOID ISSUES LATER

by Nancy Brower

In today's world, many records relating to employee benefits reside with the vendors who administer those employee benefit plans (including forms mandated by statute and regulations, participant phone call center recordings and notes, benefit elections, benefit calculations, compensation data, and other historical data). Employers are sometimes surprised to find that their vendors (or former vendors) are not able to produce the records they need in order to respond to a participant or government audit or inquiry or that those records and forms are insufficient to meet compliance standards. The following are steps you can take to lessen the risk that this will happen to your company.

CHECK YOUR VENDOR AGREEMENT. Confirm your rights to your retirement plan data. Make sure you have full access to call center recordings, as the actual transcript of a participant call may vary in important ways from the call summary the vendor provides you.

AUDIT YOUR VENDOR'S PROCEDURES, FORMS, AND RETENTION OF ADMINISTRATIVE DOCUMENTS. The government will hold your company, not the vendor, liable for failing to comply with the terms of your plan documents or failing to be able to produce proper documentation supporting various plan transactions. In particular, the IRS has identified issues with the manner in which some vendors document hardship distributions. You should periodically obtain copies of the forms, records and procedures your vendor uses to administer your plan to confirm compliance. You may wish to take this step soon after changing vendors so that you catch errors early, which will save your company both time and money.

PROTECT YOUR HISTORICAL PLAN DATA ON VENDOR CONVERSION. While a vendor may agree to retain your data for a period of time, it is more difficult to get timely data retrieval from them when you are a former client, and should they experience a systems change, your data may not be available. Relying on a vendor to comply with its contractual obligations for an extended period of time is not the best practice. In particular, for defined benefit plans, make sure that you have access to all benefit calculations performed by the vendor.

PROTECT YOUR PAYROLL DATA. This is a crucial step when any payroll system change occurs. You may need to access information regarding compensation and hours worked from the point a participant entered the plan (yes, that includes time worked over 35 years ago). Therefore, you should consider supplementing electronic records with images that your company will be able to access in the future regardless of technology and system changes.

RETAIN EXECUTED COPIES OF RETIREMENT PLAN DOCUMENTS UNTIL PLAN IS TERMINATED AND BEYOND. You should retain executed copies of all retirement plan documentation (including determination letters and determination letter applications) until at least seven years after the plan has been terminated and all benefits have been distributed. If you are on a prototype document, make sure you have a full copy of the base plan document that accompanies the adoption agreement, as well as the opinion letter on the prototype plan. Prototype sponsors are not always able to provide the base document years later, especially when the prototype sponsor has been subject to a merger and acquisition. Most vendors do not take responsibility for keeping copies of your executed retirement plan documents.

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HOSPITAL COMPLIANCE PROGRAM OVERVIEW

by Chris Brewer and David Broyles

In the constantly evolving climate of health care enforcement, maintaining a comprehensive and effective internal compliance program has taken on added significance, especially in the past few years. While detailed coverage of the elements, drafting, and implementation of a hospital compliance program cannot be provided by this article, this overview serves as a broad summary of what hospital leadership and compliance teams should be focusing on as we see the advent of mandatory compliance programs. The resources referenced in this article, along with the assistance of experienced legal counsel, should assist your facility in its review and development of a robust compliance program and related compliance plans, policies, procedures, training, and internal compliance audit functions.

The Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) of the U.S. Department of Health & Human Services, along with various other federal and state enforcement agencies, have increasingly focused on self-regulation of health care providers' compliance as one of their top priorities. That increased focus is underscored by Section 6401 of the Patient Protection and Affordable Care Act (ACA), which provides that the implementation of compliance programs by hospitals will soon be mandatory as a condition of enrollment in Medicare, Medicaid and the Children's Health Insurance Program (CHIP). As often is the case, CMS has not yet been able to provide a firm date when the implementation of hospital compliance programs will be mandatory. However, a review of the OIG's annual work plans and its sentencing commission guidelines over the years arguably show that the OIG essentially views compliance programs as already mandatory for hospitals, independent of the conditions of participation in the ACA referenced above.

The various government agencies that oversee and enforce government health care program integrity and compliance provide many valuable resources online. We encourage you to review the available online resources, some of which are listed below, as well as the resources in our recent publication from July 2015, *The Health Law Guide to Hospital Operations*, which can be accessed by following the instructions found on page nine of this issue of *Corridors*.

- OIG Homepage: <http://oig.hhs.gov/>
- OIG Compliance Program Guidance: <http://oig.hhs.gov/compliance/compliance-guidance/>
- OIG Compliance 101: <http://oig.hhs.gov/compliance/101/index.asp>
- OIG Compliance Guidance for Health Care Governing Boards: <http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>
- OIG Advisory Opinions: <http://oig.hhs.gov/compliance/advisory-opinions/index.asp>
- HHS ACA Reference Info: <http://www.hhs.gov/healthcare/rights/law/>
- CMS Homepage: <http://www.cms.gov/>
- CMS HIPAA Resource Page: <http://www.hhs.gov/ocr/privacy/>

An effective compliance program is essential in today's enforcement environment and can be a hospital's most valuable tool in planning for, preventing, and addressing the abundant, and often unpredictable, operational issues confronted each day. As your hospital continues to assess, develop, and ultimately operate its compliance program, the role of legal counsel as a member of the compliance team is critical to ensuring the quality and effectiveness of the processes in place within your organization and addressing compliance-related issues as they arise.

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PROPOSED CHANGES TO STARK RULE ...

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In the 2016 Physician Fee Schedule, CMS proposes a new exception for timeshare arrangements that meet the following criteria: (1) the arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, supplies, and services covered; (2) the licensor is a hospital or physician organization; (3) the licensed premises, equipment, personnel, etc., are used predominantly for evaluation and management services for patients; (4) the licensed equipment is located in the office suite where the evaluation and management services are furnished, is not used to furnish DHS other than those incidental to the evaluation and management services furnished by the physician at the time, and does not include advanced imaging, radiation therapy, or clinical or pathology lab equipment; (5) the arrangement is not conditioned on the licensee's referral of patients; (6) the compensation is set in advance, consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties; (7) the arrangement would be commercially reasonable even in the absence of referrals between the parties; and (8) the arrangement does not violate the Anti-Kickback Statute or any other federal or state law governing billing or claims submission.

WRITING AND SIGNATURE REQUIREMENTS. Many Stark exceptions for various types of compensation arrangements, such as leases of space or equipment and personal service arrangements, require the terms to be set out in writing and signed by the parties. The proposed rule clarifies that while the terms must be sufficiently documented, these exceptions do not require that the arrangement be documented by a single, formal contract or any other particular kind of writing. Therefore CMS has replaced the terms "agreement" and "contract" in those exceptions with "arrangement."

Several compensation arrangement exceptions require the parties' signatures. Currently, a regulatory exception permits the DHS entity to submit a claim and be paid if the signature requirement is temporarily not met, if the arrangement otherwise fully complies with the applicable exception. If an absent required signature is inadvertent, the parties must currently obtain the signatures within 90 days from the date the compensation arrangement became noncompliant. If the parties are aware of the lack of signature, the parties have only 30 days to correct the situation. By the proposed rule, CMS would give the parties 90 days regardless of whether or not their failure to obtain the signatures was inadvertent.

TERM REQUIREMENTS AND HOLDOVER LEASES. Because the exceptions for office space and equipment rental require an agreement with a term of at least one year, many have assumed that a written, formal agreement with a one-year term is required. In the proposed rule, CMS clarifies that an arrangement for the lease of office space or equipment or for personal services, which can be documented to have lasted in fact for at least one year (or which was terminated during the first year and the parties did not enter into a new arrangement for the same space, equipment or service) satisfies the requirement of a one-year term.

The current Stark exceptions for office space and equipment leases and personal service arrangements permit holdovers for up to six months immediately following the expiration of the lease term, on a month-to-month basis, if the holdover is on the same terms and conditions as the original arrangement. 42 CFR § 411.357(a), (b), (d). CMS has determined that longer holdovers on the same terms do not pose a risk of program or patient abuse. Accordingly, CMS now proposes to permit holdovers for an unlimited period if the arrangements meet the requirements of the applicable exception at the time the arrangement expired and continue to meet applicable requirements and the holdover is on the same terms and conditions as the prior arrangement.

DEFINITION OF REMUNERATION. In *United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009), the Third Circuit Court of Appeals held that Stark was violated when an anesthesia group provided pain management services at an outpatient pain clinic operated by Carlisle Hospital, the physicians submitted claims to Medicare for their services provided at the clinic, and the hospital billed Medicare for the facility and technical component of these visits. The Third Circuit held that the hospital's provision to physicians of free office space, equipment and staff on an exclusive basis constituted remuneration and thus implicated Stark, but the arrangement did not meet the Stark exception for personal service arrangements.

Although CMS has not proposed any regulatory revisions on this issue, it notes in the preamble to the proposed rule that despite the Carlisle HMA decision, split bill arrangements, in which the hospital and physician each bill the appropriate payor only for the resources and services the party provides, do not constitute remuneration under the Stark law. On the other hand, if the physicians had billed a non-Medicare payor globally for both services they performed and hospital resources, that would constitute remuneration from the hospital to the physician and implicate Stark law.

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CONSCIENCE CLAUSES FOR HEALTH CARE PROVIDERS

by *Steve Shaber*

There has been a lot of news lately about a person's right to decline to provide a service to another for reasons of conscience. For example, after the U.S. Supreme Court decision regarding marriage equality, the N.C. General Assembly passed legislation granting magistrates the right to decline to perform marriages for same sex couples. Do health care providers have any similar rights of conscience in North Carolina? In several discrete circumstances, the answer is yes.

END-OF-LIFE CARE. North Carolina law allows for a living will, i.e., a declaration of a desire for a natural death. However, any physician may decline to honor such a declaration if stopping "life-prolonging measures...would violate that physician's conscience or the conscience-based policy of the facility" where the patient is being treated. However, the physician must cooperate with efforts to find a physician or facility that will honor the living will. The N.C. Medical Board's position statement on Advance Care Directives is consistent with this statute.

LAWFUL ABORTIONS. Abortion is legal in North Carolina during the first 20 weeks of pregnancy and also thereafter "if there is substantial risk that continuance of the pregnancy would threaten the life or gravely impair the health of the woman." However, no hospital or institutional provider is required to provide abortion services, and a physician, nurse, or other health care provider who states an objection to abortion on moral, ethical, or religious grounds may refuse to perform or participate in medical procedures which result in an abortion. Moreover, the provider cannot be sued or disciplined for refusing to participate in the abortion.

PHARMACISTS. The North Carolina Board of Pharmacy says that compassionate care and conscientious objection are not mutually exclusive. Pharmacists may object to providing a particular medication for moral or ethical reasons, but those who do have no right to obstruct proper dispensing or delivery, and they should take proactive measures so as not to obstruct a patient's right to obtain such medication. In the specific case of emergency contraception, a pharmacist who objects to the medication on ethical grounds has an obligation to get the patient and the prescription to a pharmacist who will dispense that prescription in a timely manner. N.C. Board of Pharmacy, "Conscience Concerns in Pharmacist Decisions" (Revised, April 2005).

LESSONS TO BE DRAWN. Clinicians in hospitals need to understand in advance what their facilities expect of them and plan to address issues of conscience before they arise. Since these questions often arise when patients are vulnerable, a clinician who cannot conscientiously provide a lawful, medically acceptable procedure upon request must take action to ensure the patient's seamless transfer to a provider who can furnish such treatment.

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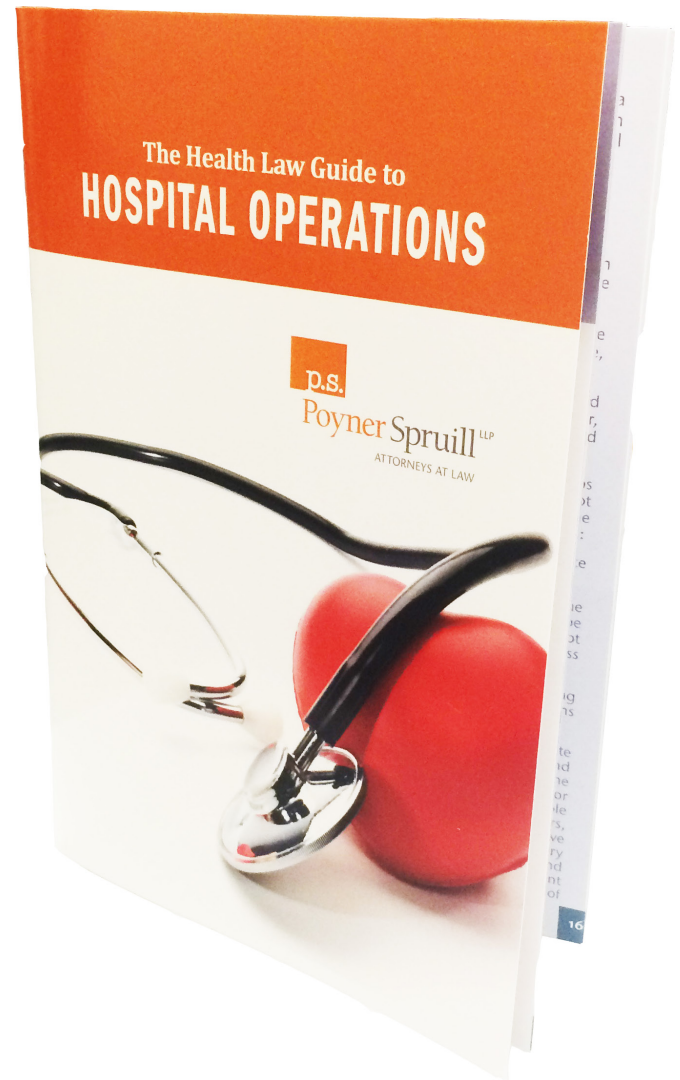
HEALTH LAW GUIDE TO HOSPITAL OPERATIONS

This operations guide provides a brief look at health law issues hospitals deal with on a daily basis. While a detailed coverage of the elements, drafting, implementation, and continued governance of a hospital compliance program is not provided separately, the importance of a comprehensive and effective compliance program is demonstrated throughout this guide within the topics covered in the articles. This should supplement a hospital's compliance program and related compliance plans, policies, procedures, training, and internal compliance audit functions.

Some of the topics included in the guide are:

- Confidentiality and Privilege of Peer Review Records
- Best Practices for Dealing With Difficult Discharges
- Honoring Patients' End-of-Life Wishes

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PROPOSED CHANGES TO STARK RULE ...

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DEFINITION OF STAND IN THE SHOES. The FY 2009 IPPS final rule amended the Stark regulations to treat a physician with an ownership or investment interest in a physician organization as standing in the shoes of the physician organization, and thus having a direct compensation relationship with the entity furnishing DHS, unless the physician's ownership or investment interest is only titular. Other physicians in the group are permitted, but not required, to stand in the shoes of the physician organization. In the proposed rule, CMS proposes to revise this rule to clarify that while only physicians who stand in the shoes of their physician organization are considered parties to the arrangement for signature purposes, all physicians in the physician organization are considered parties to the arrangement for all other purposes, including whether the compensation with the hospital takes into account the volume or value of referrals or other business generated by the physicians. In at least this one proposed change, CMS appears to tighten rather than loosen the requirements of the Stark law by its proposed changes.

CMS will be accepting comments concerning the proposed rule through September 8, 2015. If finalized, many of these provisions will help reduce the burden that Stark imposes on North Carolina hospitals and physicians by removing a number of common, technical violations from the duty to self-report.

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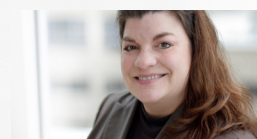
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