EXECUTIVE SUMMARY: THE APPLICATION OF THE FRAUD AND ABUSE LAWS AND EMTALA TO PHYSICIAN-OWNED HOSPITALS

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Introduction

The physician-owned hospital industry is heavily regulated. The establishment and operation of a hospital is subject to various federal and state regulations, including laws and regulations governing safety and clinical operations as well as those concerning the kickback, rebate or division of fees between physicians and non-physicians, the receipt or offering of remuneration as an inducement to refer patients, false claims and the manner in which prospective patients may be solicited. This article will briefly describe two key types of laws, including state and federal fraud and abuse laws as well as the Emergency Medical Treatment and Active Labor Act ("EMTLA").

The goals for physician-owned hospitals should be to set and maintain very high standards for compliance with laws and very high standards as to the quality of care.

I. Federal and State Fraud and Abuse Laws

A. The Federal Anti-Kickback Statute

First, under the Medicare and Medicaid programs, the federal and state governments enforce the Anti-Kickback Statute, 42 U.S.C. §1320a-7b, which prohibits the offer, provision, solicitation, or receipt of any sort of remuneration in exchange for the referral of any service potentially reimbursable under Medicare, Medicaid, or other federal health program. The Anti-Kickback Statute is an intent-based statute, meaning that a person must have intent to engage in the prohibited activities in order to be found to have violated the statute. Federal courts have found that an arrangement violates the Anti-Kickback Statute if any one purpose of the arrangement is to refer patients covered by the Medicare or Medicaid programs. The regulations promulgated pursuant to the Anti-Kickback Statute provide for certain “safe harbors.” Compliance with all elements of any safe harbor insures that the arrangement is immune from both criminal prosecution and administrative enforcement by the federal government and will not be deemed in violation of the Anti-Kickback Statute. Failure of an arrangement to fit within a specific safe harbor provision does not in itself mean that the arrangement is illegal. There are several issues that are raised with regard to physician ownership of hospitals under the Anti-Kickback Statute.

There is no safe harbor that provides comfort for the development of physician-owned hospitals. There does exist a safe harbor for certain investment interests in small entities. However, among other requirements, the safe harbor requires that investing physicians own no more than forty percent of the hospital and generate no more than forty percent of the volume of the hospital’s business. Thus, it may not be applicable to many surgical and specialty hospitals. As no safe harbor protection exists for such investments, it is extremely important that the offering of shares in the development of the hospitals be constructed carefully.
utilizing prophylactic guidelines that help demonstrate that the investors are not given special terms or remuneration in exchange for referrals. These guidelines might include:

- Each investor will have an equal opportunity to purchase shares;
- Investors will pay fair market value for shares and will not pay more or less per share based on their ability to generate referrals for the hospital;
- No investor will receive financing from another investor or the hospital for the purchase of shares;
- All returns on investment will be based on ownership of shares and not on the referrals generated by the physician;
- Investors should be required to disclose to patients their ownership in the hospital;
- Physicians should not be expected to make any level of indirect referrals to the hospital;
- The hospital will not discriminate against Medicare or Medicaid or governmental health care program business;
- Services of the entity will be marketed or furnished to all persons in a manner that is the same (i.e., marketing of services will not be different based on who is an owner of the facility);
- The potential ownership group should not be differentiated or based on the volume or value of referrals;
- The hospital will not distribute information relating to referrals from investor owners to place pressure on physicians to increase referrals;
- The real estate lease for the hospital will be consistent with fair market value for the space leased;
- Shares should not be reallocated based on the volume or value of referrals;
- Hospitals should not develop elaborate “target” lists of investor physicians based on revenues or referrals;
- No physician should be offered special remuneration to encourage use of the facility; and
- Physicians should not be pressured to withdraw if they do not generate business for the hospital.

The Department of Health and Human Services’ Office of Inspector General (“OIG”) has expressed concerns in other contexts that should be carefully considered in the context of physician-owned hospitals. First, the OIG has commented negatively on arrangements that may enable investors to derive profits from the provision of indirect referrals. Specifically, in Advisory Opinion 98-12, the OIG outlined its concerns with respect to ambulatory surgery centers (“ASCs”) as follows:
This Office is concerned about the potential for investments in ambulatory surgical centers to serve as vehicles to reward referring physicians indirectly. For example, a primary care physician, who performs little or no services in an ambulatory surgical center in which he has an ownership interest, may refer to surgeons utilizing the ambulatory surgical center, thereby receiving indirect remuneration for the referral through the ambulatory surgical center’s profit distribution. Similarly, an investment by orthopedic surgeons in an ambulatory surgical center that is not equipped for orthopedic surgical procedures, or that is exclusively used by anesthesiologists performing pain management procedures on patients referred by the orthopedic surgeons, would be suspect.

There is no specific safe harbor for physician-owned hospitals that invokes the extension of practice concept that exists in the ASC safe harbor. Certain parties have viewed physician-owned hospitals as providing an opportunity for the involvement of primary care physicians as owners in such hospitals. However, one should be aware of the OIG’s concerns regarding arrangements in which physicians who are indirect referral sources are brought in as owners. For example, most recently in Advisory Opinion No. 07-13 (October 19, 2007), the OIG stated that owners of an ASC could be sanctioned for violations of the Anti-Kickback Statute if the proposed ownership included (in addition to a hospital and ophthalmologists who would perform surgeries at the ASC) nine non-surgeon optometrists. The OIG acknowledged that failure to meet the requirements of the specific ASC ownership safe harbor provided in the Anti-Kickback Statute does not necessarily mean an arrangement violates the Anti-Kickback Statute and that the intent of the parties must be examined to ultimately determine whether the arrangement is a violation, but it did note concerns that without proper safeguards the non-surgeon optometrists could be passive referral sources with ownership used as an inducement to generate referrals to the ASC. Although this advisory opinion was issued in a non-hospital context, it reaffirms the OIG’s historical position that joint ventures involving physicians or other referral sources for at least some health care services to be reimbursed by a government program should be structured as extensions of the physicians’ medical practices to avoid an inducement to passive referral sources to increase referrals to a provider due to ownership in the provider. Thus physician owned hospitals should ideally be structured to avoid the appearance of such inducements. Any physicians not providing services at the hospital should be allowed to invest, for example, because they make a capital investment to the hospital and not to induce or encourage referrals.

B. The Federal Stark Law
Hospitals and the physicians who refer patients to the hospitals are also subject to the Ethics in Patient Referrals Act of 1989 known as the “Stark Law.” The Stark Law prohibits the referral of a Medicaid or Medicare patient to any healthcare provider with which he or she has a financial relationship (an investment or compensation relationship) for certain designated services (including hospital services) as well as prevents the healthcare provider from accepting such prohibited referral and billing for its services. Unlike the Anti-Kickback Statute in which an activity may fall outside a safe harbor and still not violate the Anti-Kickback Statute, a referral under the Stark Law that does not fall within one of its enumerated exceptions is strictly prohibited. The Stark Law contains an exception for a physician’s ownership in a hospital. 42 U.S.C. §1395nn(d)(3). Among other requirements, in order to satisfy the “whole hospital” exception, the physician must be authorized to perform services at the hospital (i.e., the physician must have medical staff privileges and such privileges should be real in practice) and the physician’s ownership must be in the whole hospital and not merely a division or department of the hospital. The Stark Act has continuously been reviewed as to whether amendments should be made which might further restrict physician ownership.

C. Other Federal Laws and State Laws

There are a number of other federal laws governing healthcare providers, including those dealing with disclosure of physician ownership to patients and availability of physicians on site. In August 2007, a new rule was finalized that requires that patients be given written notice, at the beginning of such patient’s stay or outpatient visit, that a hospital is physician-owned in order to assist the patients in making informed decisions about their care. The notice must disclose the fact that the hospital meets the federal definition of a physician-owned hospital and that a list of the physician owners is available upon request.

Many states also have laws addressing the disclosure of physician-ownership or entities to which they refer and otherwise limiting such referrals. These state laws are often similar to but not identical to the federal counterpart, and each physician-owned hospital should closely examine its own state laws and structure their relationship and operation consistent with those laws. A sample disclosure notice that some hospitals have found useful and that can be posted in a waiting area or included with the information packet that patients receive is attached as Exhibit A.

Also in August 2007, further guidance was issued with respect to the government’s expectation of hospitals regarding the appraisal, initial treatment and referral, when appropriate, of patients with medical emergencies. The new

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1 42 C.F.R. § 489.20(u). For purposes of the regulation, a hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service. Commentary relating to this regulation is set forth at 72 FR 47385 (Aug. 22, 2007).
rule provides that hospitals must furnish written notice to all patients, at the beginning of their hospital stay or outpatient visit, if a physician is not present in the hospital 24 hours per day, 7 days a week. The notice must indicate how the hospital will meet the medical needs of any patient who develops an emergency condition at the time when there is no physician present in the hospital. A sample emergency response plan that some hospitals have found useful is attached as Exhibit B. Certain states also have laws specific to this issue and each physician-owned hospital should examine its own state laws.

D. **Compliance Plans and Codes of Conduct**

A physician-owned hospital should adopt a basic compliance plan to help encourage compliance in a systematic manner and to inform its employees and members of legal concerns. It is equally important to follow and periodically update this compliance plan. Additionally, a Code of Conduct can be a useful tool for ensuring owners and staff are adhering to the hospital’s compliance requirements. A sample Code of Conduct incorporating some key concepts that some hospitals have found useful is attached as Exhibit C.

Each hospital is encouraged to consult with their own legal counsel as to issues arising under the Anti-Kickback Statute.

II. **EMTALA**

Over the past few years, increasing attention has been paid to the issue of how the provisions of EMTALA (Emergency Medical Treatment and Labor Act) apply to physician-owned hospitals. Two recent incidents at physician-owned hospitals have further thrust the issue into the spotlight. On January 10, 2008, the Office of Inspector General (“OIG”) released its report on physician-owned hospitals’ ability to manage medical emergencies. This section summarizes recent activity relating to EMTALA and physician-owned hospitals and the significant provisions and requirements of EMTALA as applied to hospitals, including physician-owned hospitals whether general hospitals or specialty or limited service hospitals.

A. **Background**

Congress enacted EMTALA in 1986 “amid growing concern over the availability of emergency health care services to the poor and uninsured. The statute was designed principally to address the problem of ‘patient dumping,’ whereby hospital emergency rooms deny uninsured patients the same treatment provided paying patients, either by refusing care outright or by transferring

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2 42 CFR § 489.20(v).
uninsured patients to other facilities.” Congress desired to ensure that individuals with emergency medical conditions were not denied lifesaving services because of a perceived inability to pay. Accordingly, EMTALA imposes certain duties upon hospitals to provide for appropriate medical screening upon request and stabilization in cases where the patient presents with an emergency medical condition.

The focus on physician-owned hospitals and their relation to EMTALA is not new. In 2003, a Technical Advisory Group (referred to as “EMTALA TAG”) was established to advise on issues related to the regulations and implementation of EMTALA and to solicit comments from hospitals, physicians and the public regarding the implementation of the EMTALA regulations. Composed of nineteen individuals, including the administrator of CMS and the Inspector General of the Department of Health and Human Services, EMTALA TAG has convened seven times since its establishment, most recently on September 17 and 18, 2007.

In 2005, EMTALA TAG solicited comments on the intersection of EMTALA and specialty hospitals and asked three questions: (1) whether there should be a federal requirement for specialty hospitals to maintain an emergency department; (2) whether specialty hospitals are subject to the EMTALA requirement under which Medicare participating hospitals with specialized capabilities or facilities may not refuse to accept an appropriate transfer of an individual who requires such capabilities or facilities if the hospital has the capacity to treat the patient; and (3) whether additional or different on-call requirements should be established for specialty hospitals.

Several national associations commented on the issue. For example, the Federation of American Hospitals (the “Federation”) submitted testimony stating that (a) the Federation did not support a federal requirement that specialty hospitals maintain an emergency department, (b) that all EMTALA transfer requirements pertaining to receiving facilities be uniformly applied to specialty hospitals, regardless of whether they have to operate an emergency department, and (c) that CMS impose special requirements under EMTALA to ensure that physicians practicing in specialty hospitals are available to provide on-call services to emergency patients in their communities.

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5 71 FR 24116 (April 25, 2006).
6 Cleland v. Bronson Health Care Group, Inc., 917 F.2d 266, 268 (6th Cir. 1990)
7 Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
8 70 FR 55903 (Sept. 23, 2005).
In an earlier letter to EMTALA TAG, the American Medical Association ("AMA") expressed its "concerns about EMTALA's expanding scope,"\(^{10}\) stating specifically with respect to specialty hospitals:

The AMA believes that specialty hospitals without dedicated emergency departments should not be subject to EMTALA requirements. Problems with the provision of on-call services began long before general hospitals became concerned about specialty hospitals...Some general hospitals have actually exacerbated the on-call problem through their own economic credentialing policies. If hospital management was more receptive to a meaningful role for medical staffs in hospital governance, then hospitals and their medical staff could work cooperatively to address the issues of emergency department overcrowding, ambulance diversions, and physician on-call coverage.\(^{11}\)

These deliberations, and the comments solicited in response, were considered by CMS in its 2006 proposed modification to the EMTALA regulations. In its final rule, CMS ultimately decided not to recommend to Congress that it should require all hospitals to have an emergency department or require as a condition of Medicare participation that all hospitals have an emergency department, taking into account EMTALA TAG's deliberations and public comments. In addition, CMS did not propose any statutory or regulatory changes regarding on-call requirements. However, the final rule did modify the regulations (42 CFR § 489.24) to clarify that any hospital participating in Medicare with specialized capabilities or facilities, even if it does not have a dedicated emergency department, may not refuse to accept an appropriate transfer if the hospital has the capability to treat the individual.\(^{12}\) Commenters requested additional guidance on the definition of "specialized capabilities or facilities." The commentary accompanying the final rule noted that these facilities, include but are not limited to "burn units, shock-trauma units, neonatal intensive care units and certain referral centers..." and noted that it would include "physician-owned limited service facilities with special capabilities."\(^{13}\)

CMS and Congress have again placed renewed focus on the issue of emergency care and physician-owned hospitals. In the FY 2008 IPPS Final Rule\(^{14}\), CMS amended 42 CFR § 489.20(v) to require all hospitals to furnish all patients notice at the beginning of their hospital stay or outpatient stay if a doctor of medicine or osteopathy is not present in the hospital 24 hours per day, 7 days per week and further to describe how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital.

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\(^{10}\) AMA, Statement to the EMTALA Technical Advisory Group, March 30, 2005.

\(^{11}\) Id.

\(^{12}\) 71 FR 48097 (August, 18, 2006)

\(^{13}\) Id.

\(^{14}\) 72 FR 47387 (August 22, 2007)
In addition, the Senate Finance Committee requested the OIG evaluate patient care and safety in physician-owned hospitals. Accordingly, the OIG report focused on hospitals’ emergency departments, staffing patterns, and written policies for managing medical emergencies.

Hospitals, as the OIG report notes, that participate in the Medicare program must meet certain health and safety standards referred to as Conditions of Participation (CoPs). The CoPs require hospitals to have a physician on duty or on call at all times and to provide 24-hour nursing services. The CoPs also require that a hospital have policies and procedures in place to address an emergency care, even if the hospital does not have an emergency department. There is no specific prohibition on a hospital calling 9-1-1 to arrange for the transfer of a patient to another hospital; however, the OIG report notes that according to CMS, a hospital is not in compliance with the CoPs if it relies on 9-1-1 services as a substitute for its own emergency services.

Based on its findings, the OIG made four recommendations to CMS that it felt would improve the ability of physician-owned hospitals to manage emergencies:

1) Develop a system to track physician-owned hospitals.

2) Ensure that the hospital meet the CoPs that require a nurse to be duty 24 hours a day, 7 days a week and a physician to be on call if one is not on-site.

3) Ensure that hospitals have the capabilities to provide for the appraisal and treatment of emergencies and that they are not relying on 9-1-1 as a substitute for their own ability to provide services.

4) Require hospitals to include necessary information in their written policies for managing medical emergencies, such as the use of emergency response equipment and the life-saving protocols to be followed.

The OIG noted that all but the first of these recommendations apply to all hospitals. CMS responded to the OIG’s recommendations by stating that it is adding information to the provider enrollment form so that physician-owned hospitals can be identified. In response to the second recommendation, CMS stated that it measures hospitals’ compliance with the CoPs through routine hospital surveys. In response to the third recommendation, CMS stated that it issued a program memorandum to State Survey Agencies during the time of the OIG’s investigation that reiterates its requirements for hospitals and addresses medical emergency requirements. Finally, CMS stated that it would consider whether regulatory changes to create more specific requirements for equipment and staff would be appropriate.

B. General
Medicare participating hospitals, including physician-owned hospitals, must comply with the EMTALA statute and accompanying regulations in 42 CFR §489.24 and 42 CFR §489.20(l),(m), (q) and (r). EMTALA requires hospitals with emergency departments to provide a medical screening examination (“MSE”) to any individual who “comes to the hospital” (including presenting on the hospital’s campus) and to provide stabilizing medical treatment within its capacity. It also prohibits hospitals with emergency departments from refusing to examine or treat individuals with an emergency medical condition (EMC). The term “hospital” includes specialty hospitals.

A dedicated emergency department is defined as meeting one of the following criteria regardless of whether it is located on or off the main hospital campus. The entity:

1) is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; or

2) is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for EMC on an urgent basis without requiring a previously scheduled appointment; or

3) during the preceding calendar year (i.e., the year immediately preceding the calendar year in which a determination under this section is being made), based on a representative sample of patient visits that occurred during the calendar year, it provides at least one-third of all of its visits for the treatment of EMCs on an urgent basis without requiring a previously scheduled appointment. This includes individuals who may present as unscheduled ambulatory patients to units (such as labor and delivery or psychiatric units of hospitals) where patients are routinely evaluated and treated for EMCs.

There are many hospitals that do not have emergency departments. A hospital that does not have a dedicated emergency department, as defined by 42 CFR §489.24(b), generally does not have an EMTALA obligation to provide screening and treatment, and is not required to be staffed to handle potential EMC. Nevertheless, pursuant to the Medicare Conditions of Participation for hospitals, the hospital’s governing body to assure that the medical staff has written policies and procedures for the appraisal of emergencies, initial treatment (within its capability and capacity, and makes an appropriate referral to a hospital that is capable of providing the necessary emergency services. Such a facility must have policies and procedures in place for handling patients in need of immediate care. For example, the facility policy may direct the staff to contact the emergency medical services/911 (EMS) to take the patient to an emergency department or provide the necessary care if it is within the hospital’s capability.
A hospital without an emergency department should review the bylaws, rules and regulations of the medical staff to determine if they reflect EMTALA requirements.

C. Requirements for Hospitals With Emergency Departments

Hospitals with dedicated emergency departments are required to take the following measures:

- Adopt and enforce policies and procedures to comply with the requirements of 42 CFR §489.24;
- Post signs in the dedicated ED specifying the rights of individuals with EMCs and women in labor who come to the dedicated ED for health care services, and indicate on the signs whether the hospital participates in the Medicaid program;
- Maintain medical and other records related to individuals transferred to and from the hospital for a period of five years from the date of transfer;
- Maintain a list of physicians who are on call to provide further evaluation and/or treatment necessary to stabilize an individual with an EMC;
- Maintain a central log of individuals who come to the dedicated ED seeking treatment and indicate whether these individuals:
  - Were refused treatment;
  - Were denied treatment;
  - Were treated, admitted, stabilized and/or transferred or were discharged,
- Provide for an appropriate MSE;
- Provide necessary stabilizing treatment for EMCs and labor within the hospital’s capability and capacity;
- Provide an appropriate transfer of an unstabilized individual to another medical facility, but only if:
  - The individual (or person acting on his or her behalf) after being informed of the risks and the hospital’s obligations requests a transfer;
  - A physician has signed the certification that the benefits of the transfer of the patient to another facility outweigh the risks or
  - A qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed the certification after a physician, in consultation with that qualified medical person, has made the determination that the benefits of the transfer outweigh the risks and the physician countersigns in a timely manner the certification. (This last criterion applies if the responsible physician is not physically present in the emergency department at the time the individual is transferred.)
Additionally, prior to, and as part of the transfer, the transferring hospital must:

- Provide treatment to minimize the risks of transfer;
- Send all pertinent records to the receiving hospital;
- Obtain the consent of the receiving hospital to accept the transfer;
- Ensure that the transfer of an unstabilized individual is effected through qualified personnel and transportation equipment, including the use of medically appropriate life support measures; and
- Provide the name and address of any on-call physician who refused or failed within a reasonable time to provide necessary stabilizing treatment.

- Not delay in the MSE and/or stabilizing treatment in order to inquire about payment status;
- Accept appropriate transfer of individuals with an EMC if the hospital has specialized capabilities or facilities and has the capacity to treat those individuals; and
- Not penalize or take adverse action against a physician or a qualified medical person because the physician or qualified medical person refuses to authorize the transfer of an individual with an EMC that has not been stabilized or against any hospital employee who reports a violation of these requirements.

In light of the many requirements imposed upon hospitals with emergency departments, this section briefly focuses on requirements relating to (1) signage, (2) screening and stabilizing, (3) call coverage, (4) specialists, and (5) central logs.

### 1. Hospital Signage Requirements

Hospital signage must at a minimum:

- Specify the rights of individuals with EMCS and women in labor who come to the emergency department for health care services; and
- Indicate whether the facility participates in the Medicaid program.

Signs must also be clear and use simple terms and language that are understandable by the population served by the hospital. Furthermore, the signs must be posted in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment (e.g., entrance, admitting area, waiting room, treatment area).
2. **Screening and Stabilization**

A hospital must screen individuals to determine if an EMC exists. CMS has expressly stated that it is not appropriate to merely “log in” an individual and not provide a MSE. Individuals coming to the emergency department must be provided a MSE beyond initial triaging. Triaging is not equivalent to a MSE. Triage merely determines the “order” in which individuals will be seen, not the presence or absence of an EMC.

A MSE is the process required to reach with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist.

A hospital, regardless of size or patient mix, must provide screening and stabilizing treatment within the scope of its abilities, as needed, to the individuals with EMCs who come to the hospital for examination and treatment.

3. **Call Responsibilities**

Hospitals, as a requirement for participation in the Medicare program, that have an emergency department must maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. The on call list identifies and ensures that the emergency department is prospectively aware of which physicians, including specialists and sub-specialists are available to provide care. Hospitals have an EMTALA obligation to provide on call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual.

In addition, the hospital must have written policies and procedures in place (i) to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician’s control; and (ii) to provide that emergency services are available to meet the needs of patients with EMCs if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.\(^\text{15}\)

A hospital can meet its responsibility to provide adequate medical personnel to meet its anticipated emergency needs by using on call physicians either to staff or to augment its emergency department, during which time the capability of its emergency department include the services of its on call physicians.

CMS does not have requirements regarding how frequently on call physicians are expected to be available to provide on call coverage. Nor is there a pre-determined ratio CMS uses to identify how many days a hospital must provide

\(^{15}\) *Id.*
medical staff on call coverage based on the number of physicians on staff for that particular specialty. Instead, each hospital has the discretion to maintain the on call list in a manner that best meet the needs of the hospital’s patients who are receiving services required under EMTALA in accordance with the resources available to the hospital, including the availability of one call physicians.

Call coverage should be provided for within reason depending upon the number of physicians in a specialty. A determination about whether a hospital is in compliance with these regulations must be based on the facts in each individual case. Surveyors will consider all relevant factors including the number of physicians on staff, the number of physicians in a particular specialty, other demands on these physicians, the frequency with which the hospital’s patients typically require services of on call physicians, vacations, conferences, days off and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physician is unable to respond.

The best practice for hospitals, which offer particular services to the public, is that those particular services should be available through on call coverage of the emergency department.

Physician group names are not acceptable for identifying the on call physician. Individual physician names are to be identified on the list. Ultimately, however, the hospital has the responsibility for ensuring adequate on-call coverage and whether a hospital complies with the EMTALA regulations relating to call coverage is a facts and circumstances determination made by the Medicare surveyor.16

A determination as to whether the on call physician must physically assess the patient in the emergency department is the decision of the treating emergency physician. The ER physician’s ability and medical knowledge of managing that particular medical condition will determine whether the on call physician must come to the emergency department.

When a physician is on call for the hospital and seeing patients with scheduled appointments in his private office, it is generally not acceptable to refer emergency cases to his or her office for examination and treatment of an EMC. The physician must come to the hospital to examine the individual if requested by the treating emergency physician. If, however, if it is medically appropriate to do so, the treating emergency physician may send an individual needing the services of the on call physician to the physician’s office if it is part of a hospital-

16 State Operations Manual, Appendix V. Surveyors will consider all relevant factors including the number of physicians on staff, the number of physicians in a particular specialty, other demands on these physicians, the frequency with which the hospital’s patients typically require services of on call physicians, vacations, conferences, days off and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physician is unable to respond.
owned facility (department of the hospital sharing the same Medicare provider number as the hospital) and on the hospital campus.

If a physician who is on call does not come to the hospital when called, but directs the patient to be transferred to another hospital where the physician can treat the individual, the physician may have violated EMTALA.

For physicians taking call simultaneously at more than one hospital, the hospitals must have policies and procedures to follow when the on call physician is not available to respond because he has been called to the other hospital to evaluate an individual. Hospital policies may include, but are not limited to procedures for back up on call physicians, or the implementation of an appropriate EMTALA transfer according to 42 CFR §489.24(e).

Once a patient presents to the emergency room, the on-call physician must determine whether to respond in person or whether a non-physician practitioner (physician assistant, nurse practitioner, orthopedic tech) can be designated as his or her representative, based on the individual’s medical need and the capabilities of the hospital and applicable State scope of practice laws, hospital bylaws, and rules and regulations. The on call physician is ultimately responsible for the individual regardless of who responds to the call.

On call physicians may utilize telemedicine (telehealth) services for individuals in need of further evaluation and/or treatment necessary to stabilize an EMC, as permitted by applicable State scope of practice laws, hospital bylaws, and rules and regulations. Individuals are eligible for telemedicine services only when, because of the individual’s geographic location, it is not possible for the on call physician to physically assess the patient.

Physicians that refuse to be included on a hospital’s on call list but take calls selectively for patients with whom they or a colleague at the hospital have established a doctor-patient relationship while at the same time refusing to see other patients (including those individuals whose ability to pay is questionable) may violate EMTALA. If a hospital permits physicians to take calls selectively while the hospital’s coverage for that particular service is not adequate, the hospital would be in violation of its EMTALA obligation by encouraging disparate treatment.

4. **Specialist Not Available**

The medical staff by-laws or policies and procedures must define the responsibility of the on call physicians to respond, examine and treat patients with an EMC.

Physicians, including specialists and sub-specialists (e.g., neurologists) are not required to be on call at all times or required to be on call in their specialty for emergencies whenever they are visiting their own patients in the hospital. The
hospital must have policies and procedures (including back-up call schedules or the implementation of an appropriate EMTALA transfer) to be followed when a particular specialty is not available or the on call physician cannot respond because of situations beyond his or her control. The hospital is ultimately responsible for providing adequate on call coverage to meet the needs of its patients.

5. **Central Log**

A central log on each individual who “comes to the emergency department”, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged. The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

**D. Transfers**

As noted above, CMS issued a final rule on August 18, 2006, which clarified the regulations and provided that any participating hospital with specialized capabilities or facilities, even if it does not have a dedicated emergency department, may not refuse to accept an appropriate transfer if it has the capacity to treat the individual. The regulation provides that a participating hospital with specialized capabilities or facilities includes, but is not limited to, facilities such as burn units, shock-trauma units, and neo-natal intensive care units.17 Although there is no further definition, a hospital that furnishes, for example, orthopaedic services, psychiatric services, or women’s services only would be considered a facility with specialized capabilities or facilities. Accordingly, specialty hospitals should be aware of the EMTALA regulations relating to transfers as this will become increasingly important.

Under EMTALA, transfer is permitted if the individual (or a legally responsible person acting on the individual’s behalf) requests the transfer, after being informed of the hospital’s EMTALA obligations and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer.

Transfer is also permitted if a physician has signed a certificate that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based. EMTALA requires an express written certification. Physician certification cannot simply be implied from the findings in the medical record and the fact that the

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17 42 CFR § 489.24(f)
patient was transferred. Rather, the certification must state the reason(s) for transfer. The narrative rationale need not be a lengthy discussion of the individual’s medical condition reiterating facts already contained in the medical record, but it should give a complete picture of the benefits to be expected from appropriate care at the receiving (recipient) facility and the risks associated with the transfer, including the time away from an acute care setting necessary to effect the transfer. The risks and benefits certification should be specific to the condition of the patient upon transfer. This rationale may be on the certification form or in the medical record. Certifications may not be backdated.

Once a transfer has been requested, there are four requirements of an appropriate transfer:

1. If a patient requires treatment, the provision of treatment to minimize the risks of transfer is the first requirement of an appropriate transfer. If the patient requires treatment, it must be sufficient to minimize the risk likely to occur or result from the transfer.

2. The receiving facility must have available space and qualified personnel for the treatment of the individual; and must have agreed to accept transfer of the individual and to provide appropriate medical treatment.

3. The transferring hospital must send to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual’s EMC, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital’s files) must be sent as soon as practicable after transfer.

4. The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.
The Guidance regarding the recipient hospitals provided to date in the State Operations Manual is still instructive despite the recent proposed clarification of the recipient hospital guidelines. The State Operations Manual provides that a recipient hospital has an EMTALA obligation once an individual with an EMC is transferred to its hospital. However, the manual states the following with respect to the obligations of the recipient hospital:

Recipient hospitals only have to accept a patient if the patient requires the specialized capabilities of the hospital in accordance with this section [42 CFR § 489.24(e)] and the hospital has the capacity to treat the individual. If the transferring hospital wants to transfer a patient, but the patient does not require any “specialized” capabilities, the receiving (recipient) hospital is not obligated to accept the patient unless the individual presents at the recipient hospital. If the patient required the specialized capabilities of the intended receiving (recipient) hospital, and the hospital has the capability and capacity to accept the transfer, but refused, this requirement has been violated.  

Therefore, a specialty hospital which is the recipient of a transfer must be sure to familiarize its staff with all aspects of the EMTALA regulations so that the staff can properly accept a transfer and can also properly transfer a patient that should be treated at a different, perhaps more suitable, hospital.

18 Medicare State Operations Manual, Appendix V, Interpretive Guidelines – Responsibilities of Medicare Participating Hospitals in Emergency Cases
DISCLOSURE OF PHYSICIAN OWNERSHIP

NOTICE TO PATIENTS

Please carefully review the information contained in this notice.

1. Certain physicians in this office are owners of and have financial interests in ________________ (the “Hospital”). The Hospital meets the Federal definition of a physician-owned hospital. A list of the physician owners is available upon request.

2. You have the right to choose the provider of your health care services. Therefore, you have the option to use a health care facility other than the Hospital.

3. You will not be treated differently by your physician if you choose to obtain health care services at a facility other than Hospital.

If you have any questions concerning this notice, please feel free to ask your physician or any representative of our office at the Hospital. We welcome you as a patient and value our relationship with you.
DISCLOSURE OF EMERGENCY RESPONSE PLAN

1. _______________ (the “Hospital”) contracts with internal medicine specialists (Hospitalists) to be on-call and immediately available to provide urgent assessment and intervention 24 hours a day, 7 days a week. However, the Hospital cannot guarantee that there will be a physician present in the Hospital at all times.

2. The Hospital has taken measures to ensure that qualified and properly trained medical personnel are available to respond to any medical emergency that may arise when a physician is not present in the Hospital. If a medical emergency occurs, physician or non-physician Hospital staff will initiate emergency care. The patient’s surgeon is called and is required to respond immediately. In addition, the Hospitalist on call is called and is required to respond immediately.

3. In the event of an emergency that requires a higher level of care such as admission to an Intensive Care Unit (ICU), the nursing staff arranges ambulance transport by the Fire Department by calling 911. The patient is transferred to _______________. The Hospital also maintains transfer agreements with ________________ and ________________.

4. Every clinical area at the Hospital is equipped with emergency medical equipment and supplies for use with patients who develop complications. This equipment includes an emergency call system, resuscitation equipment, medications, cardiac monitors, oxygen, suction, and defibrillators. All of the nursing staff are trained and certified in Advanced Cardiac Life Support (ACLS), and those nurses working with pediatric patients are certified in Pediatric Advanced Life Support (PALS).

5. If you would like additional information about the Hospital’s capabilities for handling medical emergencies, please contact _________________.

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EXHIBIT C
FORM OF CODE OF CONDUCT

[7] (the “Hospital”) strives to provide quality health care services to the community. The Hospital’s values and goals include the achievement of excellence in the treatment of the patients and the compliance with all laws applicable to the Hospital’s operations. The operation of the Hospital in compliance with all laws shall take precedence at all times over any interest in generating profits. The Hospital, in its business and clinical operations, will strive to abide by the following principles:

1. The Hospital, each owner, and each employee shall use best efforts to protect the confidential information of patients and families of patients.

2. The Hospital, each owner, and each employee will abide by all policies applicable to such person’s positions with the Hospital, as well as all state and federal laws and conditions of participation in health care reimbursement programs.

3. The Hospital, the owners, and the employees will not encourage or participate, directly or indirectly, in activities such as theft, bribery, kickbacks, misappropriation, false statements, submission of false claims, discrimination, boycotts, price fixing, or violations of environmental or workplace safety laws.

4. The Hospital, the owners, and the employees will not make any payment, or offer to make any payment, whether in cash or in kind, to any physician, patient, hospital, facility, or other party in order to induce the referral of patients or other items or services to the Hospital.

5. The Hospital shall not enter into relationships with any person or entity that may refer business to the Hospital unless such arrangements involve compensation for fair market value and the arrangements are fully compliant with all laws. No such arrangement shall take into account the volume or value of referrals by such person.

6. The Hospital will only bill for services in a manner that is legally appropriate. Owners and employees who are involved with billing functions will not submit any claims for amounts other than in accordance with the Hospital’s policies. In the event that any owner or employee discovers any intentional or unintentional improper billing (including the submission of any false claim) practices, such person shall immediately report it to the appropriate Hospital personnel.

7. Owners and employees who refer patients for services to the Hospital will only refer patients for services or procedures that are medically necessary or cosmetic in nature. Services that are neither medically necessary nor cosmetic in nature shall not be performed at the Hospital.
8. The Hospital, each owner, and each employee shall treat all patients (including Medicare, Medicaid, and indigent patients) in a non-discriminatory manner in accordance with Hospital policies regarding acceptance of patients.

9. The Hospital shall not offer shares in exchange for referrals. Shares in the Hospital may only be sold at fair market value, and the sale of more or less shares depending on the referrals generated by such person is strictly prohibited.

10. The Hospital, the owners, and the employees will not pressure any person or entity to refer patients or cases to the Hospital. A physician owner who refers patients to other physicians shall not encourage or require such physicians to utilize the Hospital.

11. All distributions of Hospital earnings shall be based on the number of shares held by the owners and shall in no way be based on the volume or value of referrals to the Hospital.

12. Each owner shall notify patients of his or her financial interest in the Hospital if he or she refers such patients to the Hospital. Each physician owner shall be authorized to perform services at the Hospital in accordance with the federal “Stark Law”. Each physician owner shall not be intended to generate indirect referrals for the Hospital in exchange for ownership in the Hospital. All physician owners who refer patients to the Hospital shall perform services at the Hospital.

13. Each owner and employee shall treat all patients, Hospital personnel, and other members of the community with dignity, respect and compassion.

14. The Hospital, each owner, and each employee will maintain a safe working environment, will fulfill all duties in a safe manner, and will notify the proper Hospital personnel immediately of any hazard, injury, equipment problem, or other potential safety issue.

15. If an owner or employee becomes aware that any Hospital staff or owner or other person providing services to the Hospital has engaged in any of the behavior prohibited above, such person must notify the appropriate Hospital personnel.