The Health Law Guide to
HOSPITAL OPERATIONS

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ATTORNEYS AT LAW

Introduction

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 in this guide, the importance of a comprehensive and effective compliance program is demonstrated throughout this guide within the topics covered in the articles. This guide should supplement a hospital's compliance program and related compliance plans, policies, procedures, training, and internal compliance audit functions.

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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 strong and effective internal compliance program has taken on added significance in the past few years. The Centers for Medicare and Medicaid Services and the Office of Inspector General 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, which says that 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. The various government agencies that oversee and enforce government health care program integrity and compliance provide many valuable resources online. As you utilize the resources provided in this guide, we encourage you to review the available online resources as well, some of which are listed below.

- 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 can be a hospital's most valuable tool in planning for, preventing, and handling 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 part of the team is critical to ensure quality and effectiveness of processes within your organization to address compliance related issues, including many of those covered in this guide.

HOSPITAL - PHYSICIAN PEER REVIEW HEARINGS

Legal, Fair, and Safe for Everyone Involved

By: Steve Shaber

Every hospital and medical staff will occasionally have to conduct a professional review concerning one of its physicians, and sometimes that review will lead to a hearing. Happily, no hospital does this very often, but, consequently, no hospital does it often enough to be really familiar with the process.

Most of the hearing process should be described in the Medical Staff Bylaws or related document with a name such as Fair Hearing Plan. This should include all time limits, notice instructions, and other details – the recipe for holding the hearing. Behind all that lies a federal law that sets the standards for a fair hearing and protects the people who abide by them.

The federal Health Care Quality Improvement Act, 42 U.S.C. § 11101, et seq., protects medical staff members and hospital administrators who participate in a professional review action involving another physician's clinical privileges or membership on the hospital medical staff – provided they do it correctly.

In simplest terms, the Act is in two parts. The first describes how a professional review action, which includes a medical staff fair hearing, should be conducted. According to the Act there must be:

1. A reasonable effort by the medical staff to get the facts;
2. Adequate notice to the physician who is the subject of the hearing;
3. Fair, adequate hearing procedures (with due regard to all the circumstances);
4. A reasonable belief that the facts known, after adequate notice and a fair hearing, warrant whatever action is taken; and
5. A reasonable belief that the action taken furthers quality health care.

Adequate notice means giving the physician:

1. Notice that professional review action is proposed;
2. Notice of reasons for the proposed action;
3. Notice of physician's right to request a hearing;
4. Notice of any deadline for requesting a hearing;
5. If hearing is requested, at least 30 days notice of the hearing date; and
6. If hearing is requested, a list of witnesses against the physician.

An adequate hearing means giving the physician:

1. An impartial arbitrator, hearing officer, or hearing panel (i.e., one that is not in direct economic competition with physician);
2. The right to be represented by counsel or another person;
3. The right to a transcript of the hearing, at reasonable cost;
4. The right to call, examine, and cross-examine witnesses;
5. The right to submit evidence, unfettered by the strict rules of evidence; and
6. The right to submit a written statement at the end of the hearing.

An adequate hearing also leads to a written recommendation by the arbitrator, hearing officer, or hearing panel and a written decision by the ultimate decision maker. Each writing needs to state the basis for its recommendation or decision. (However, these procedures may be skipped or reduced in the case of a short (14-day) summary suspension or in the case of an emergency.)

The second part of the Act protects the following people from liability for damages, provided the action they have participated in meets the standards summarized above:

1. The professional review body itself;
2. Any person acting as a member of or as staff to the review body;
3. Any person under contract to the body; and
4. Any person who participates with or assists the body with respect to the action.

Most of the requirements and standards in the Act are straight-forward. Most can be followed without much trouble. A few do cause problems from time to time. In order to protect the members of the medical staff and the hospital administration, which also participates or assists in the hearing, it is essential to ensure the action bears a reasonable relation to quality health care, not just to business, and certainly not to personal interests. It is equally important that the investigation and hearing procedures follow the law closely.

CONFIDENTIALITY AND PRIVILEGE OF PEER REVIEW RECORDS: *What This is and How to Protect It*

By: Steve Shaber

State law purports to make the proceedings of a medical review or quality assurance committee confidential and privileged. This protection applies to the materials the committee reviews, the records it produces, and the recollections of the people who were at its meetings. N.C. Gen. Stat. § 90-21.22A(c); N.C. Gen. Stat. § 131E-95(b). However, the protection is not as solid as you might imagine.

First of all, many documents originate outside of peer review and quality assurance, where they are not privileged, and these original source documents cannot be turned into privileged secrets just because they were considered during peer review. For example, an operative note in a patient's chart remains part of that chart, and must be copied for the patient upon a proper request, or produced at a deposition through the proper process, even though a review committee has used it during meetings or attached it to its report. But the review committee should not have to produce its particular copy of the operative note, explain how it used the note in its work, and state the conclusions it drew from the note.

Or so it might seem. Actually, the statutes are applied strictly, not only to documents that are used in the review process, but to documents that originate with the process as well. Courts generally believe that they and the parties to a lawsuit should know as much about the case as possible, and if the review documents are germane to the case, the courts can find lots of technical reasons to decide that the records lie outside the privilege.

In order to protect the privilege as best they can, hospitals and physicians need to do several things:

1. From the beginning of a review, carefully identify each request for documents as a request that is being made in the course of medical review or quality assurance.

2. Clearly identify the person making the request as a member of, or an agent for, a medical review or quality assurance committee.

3. Always identify the documents being produced as documents that are being given to a medical review or quality assurance committee for review purposes.

4. Be careful to identify any correspondence and materials that are sent to or received from outside review organizations assisting the hospital with peer review or quality assurance functions as being sent or received specifically as part of a peer review or QA process.

5. Do not rely on your labels. Instead, document the specific review purpose of the request, and document how the committee used the materials for review purposes.

6. Finally, when resisting a request for privileged information, prepare a detailed response that shows why – in fact – the materials are privileged.

The burden is on the person who is using the privilege to resist what would otherwise potentially be a proper request for information, so that person needs to do everything possible to show the privilege applies to each document being requested.

WHEN THE GOVERNMENT COMES KNOCKING
False Claims Act Investigations

By: Chris Brewer

The primary federal and state enforcement agencies handling Criminal or Civil False Claims Act government investigations 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), the Department of Defense (Tricare Health Program), the United States Postal Inspection Services, 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.

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 and have the opportunity to be present or review the legal document or request presented to the hospital to provide advice and assistance.

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 or has been pursuing a criminal investigation. There may also be allegations that a facility's records may be destroyed or altered. A hospital's compliance program should provide the process and guidance for ensuring appropriate cooperation with government agents, while protecting the rights of the hospital to the fullest extent possible. The following information should be included.

- 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 (the required supporting affidavit may be under seal and not available). Contact the hospital's attorney immediately and send a copy of the warrant. Ask the government agent to 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 government investigation. Search warrants are for documents and do not authorize interviews. You do not have to tell them 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 made 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 providing non-corporate or personnel records unless specifically identified within the scope of the search warrant. Inform the agents of documents that may be subject to attorney/client-privilege and insist 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.

- Accept a copy of the inventory but decline to sign the inventory unless 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, including grand jury subpoenas, civil investigative demands, HIPAA subpoenas, and agency administrative subpoenas (HHS/OIG, for example).
- The hospital should accept service of a subpoena 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.
- HIPAA privacy rules generally prohibit the hospital from disclosing protected health information. HIPAA contains exceptions for responding to subpoenas, but the rules differ depending upon the type of subpoena issued. There are also protections for attorney/client privileged and work product documents.

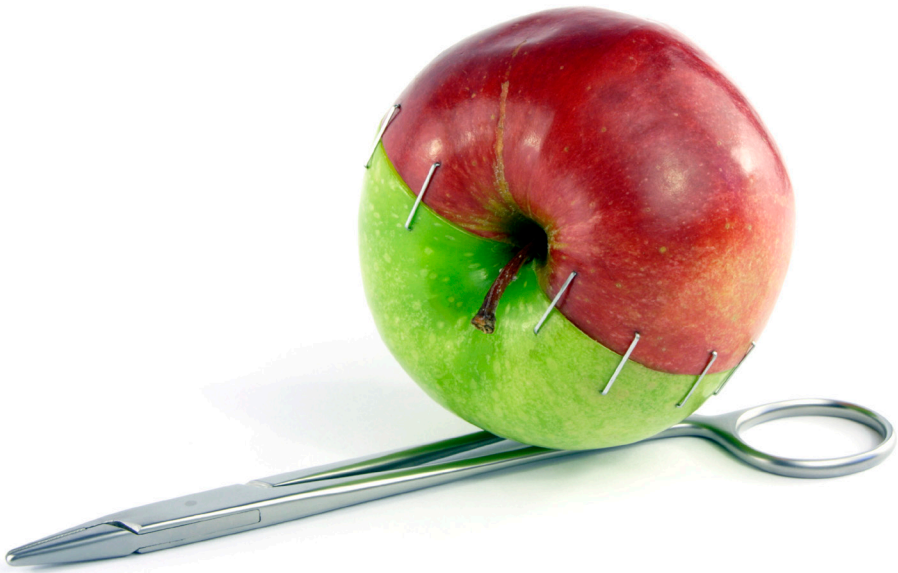
Internal Investigations

Government enforcement actions and investigations require a hospital to immediately conduct its own internal compliance investigation. The hospital's compliance program should describe how the internal investigation will be conducted and steps to take when it is completed. Several important points are discussed below that may assist in obtaining a more favorable outcome or mitigate penalties and collateral consequences.

- Immediate efforts must be undertaken to gather and preserve materials relevant to the fraud investigation. Failure to preserve relevant documents or electronic information may be viewed as obstruction of the investigation and result in penalties or other sanctions.
- Document retention and litigation hold policies should be in place that preserve relevant materials, especially electronically stored information. Employees should be immediately notified when the hospital implements a litigation hold and informed of its scope.
- Appropriate legal representation should be in place for both the hospital and its personnel who may need legal advice. Hospital counsel will decide and

advise whether independent legal counsel will be provided by the hospital for employees. Any contact with the hospital or its employees should be made only through counsel for the hospital. A decision should also be made early on whether to hire independent consultants to assist hospital counsel.

- Conducting the internal investigation requires cooperation from hospital staff under difficult circumstances. The hospital's compliance program should guide the scope, method, accountability, and reporting between the attorneys directing the investigation, the consultants conducting the investigation, and the hospital authorizing the internal investigation.
- If the internal investigation confirms the existence of misconduct, improper billing, or related non-compliance, corrective action should be taken and documented to stop any improper practices. Employees who engaged in misconduct should be appropriately disciplined.



REGULATORY REQUIREMENTS FOR NONPROFIT HOSPITALS IN FINANCIAL ASSISTANCE AND DEBT COLLECTION

By: David Broyles

Roughly 60% of hospitals nationwide have either obtained or are seeking tax-exempt status under the Internal Revenue Code (Code) and applicable rules. Rules adopted by the Treasury Department and the IRS impose upon nonprofit hospitals (referred to in the Federal Register as charitable hospitals) a number of additional requirements when attempting to collect debts owed for patient care and have imposed additional mandates related to financial assistance policies (FAP) and qualification of low-income patients for financial assistance.

The Patient Protection and Affordable Care Act of 2010 added Section 501(r) to the Code (26 U.S.C. §501(r)), imposing four additional requirements on charitable hospitals to maintain tax-exempt status. Charitable hospital organizations must meet each separately for every facility they operate. The final rules clarified the following requirements:

1. Conduct a community health needs assessment (CHN Assessment) at least once every three years and adopt an implementation strategy to meet those community health needs, or be subject to a $50,000 tax penalty.

2. Establish a written FAP that describes the eligibility criteria for assistance, how patients apply for assistance, and how they are charged for care under the policy; and a written emergency medical care policy requiring emergency care to individuals regardless of their eligibility for financial assistance.

3. Limit the use of gross charges and the amounts charged to those patients who qualify for financial assistance for emergency or other medically necessary care to not more than the amounts generally billed to individuals who have insurance covering such cases.

4. Make reasonable efforts to determine whether an individual is eligible for assistance under the financial assistance policy before engaging in extraordinary collection actions (ECA).

Potential areas of focus for regulators in their review and enforcement actions against charitable hospitals include:

- CHN Assessment process requires careful documentation of the multiple levels of need assessment, community input and collaboration, and a hospital's plan and implementation to address the need.

- A hospital's FAP must describe all eligibility criteria, all financial assistance and discounts available, and how to apply for financial assistance, as well as actions that must be taken in the event of nonpayment by eligible patients.

- Hospitals must continue to make the FAP, the FAP's application form and a plain language summary of the FAP available upon request, available in certain areas of the hospital for visitors and patients, available on a website, and available to members of the community served.

- Certain written notices with FAP information, a summary of the FAP application process and contact information for FAP-related documents must be provided to patients against whom a hospital intends to engage in ECA.
- Hospitals must limit the costs for any care for which FAP-eligible individuals will be personally responsible to not more than amounts generally billed (AGB), and define in the FAP how AGB is calculated.
- Reasonable efforts must be followed and documented during each step of an ECA assessment application, including notification and further billing and collection communication(s) with FAP-eligible individuals. ECA is defined clearly in the rules.

The full text of the rules related to the additional requirements on charitable hospitals contain specific regulatory changes and other nuances not touched on in the points mentioned above, and can be found at http://www.gpo.gov/fdsys/pkg/FR-2014-12-31/pdf/2014-30525.pdf.

On June 26, 2015, IRS Notice 2015-46 was issued to provide clarification to certain requirements in the new 501(r). The notice clarified requirements under 501(r)-4(b)(1)(iii)(F), which mandate that a hospital list in its FAP health care providers providing emergency or other medically necessary care in the facility who are covered and are not covered by the FAP. The notice provided hospitals the flexibility to, among other things, list a group practice vs. each individual physician, or all physicians vs. none, where applicable. Hospitals also can 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.

These rules should be reviewed in tandem with other state and federal fair debt collection practices laws, the FTC's Red Flag Rules requiring a written Identity Theft Protection Program, and other billing and collection requirements. Hospital leadership and experienced legal counsel should closely review all related policies, procedures, and facility practices to ensure full compliance with these laws.

SELF-REFERRAL AND ANTI-KICKBACK STATUTES 101 FOR HOSPITALS

By: Wilson Hayman

Hospital decision makers must understand the basics of the federal self-referral and anti-kickback statutes in structuring business arrangements with physicians and others in a position to refer, including medical director and other physician contracts, service agreements with other parties who generate referrals, management contracts, and joint ventures.

Federal Physician Self-Referral Stark Law. The federal Stark statute prohibits, unless an exception applies, (1) a physician (including dentists, podiatrists, optometrists and chiropractors) from making a referral to an entity to furnish any one of 11 designated health services payable by the Medicare or Medicaid program, 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 designated health service. 42 U.S.C. § 1395nn(a). The designated health services covered by the Stark statute, which Congress has deemed to be at high risk for inappropriate utilization and abuse, are limited to: clinical laboratory services; physical therapy; occupational therapy; radiology (including MRI, CAT scans and ultrasound); radiation therapy; DME; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. A financial relationship under the Stark law includes both compensation arrangements and the physician's ownership or investment interest in an entity.

Stark establishes a bright line rule, and referrals between parties with a financial relationship that do not fall within a statutory or regulatory exception to the statute still violate the law even if the parties have no bad intent. Civil sanctions for violators of this statute include:

1. Denial of payment;

2. The requirement to refund any claims collected in violation of the law;

3. A civil money penalty of up to $15,000 for each bill or claim that a person knew or should have known was a service for which payment may not be made; and

4. A civil money penalty of up to $100,000 for each arrangement or scheme which has a principal purpose of assuring referrals that, if directly made, would be in violation of the law.

The Stark prohibition does not apply to a physician's referral of designated health services provided personally by the referring physician himself. However, Stark does cover a physician's referral of designated health services furnished by another individual, including an individual supervised by the physician.

Exceptions. The Stark law's exceptions for contractual financial relationships generally require fair market compensation set in advance that does not reflect the volume or value of any referrals or business generated between the physician and entity. These exceptions, among others, include the following:

1. The lease of space to the entity for one year or more, as long as the space rented is reasonable and necessary for legitimate business purposes;

2. The provision of personal services by the referring physician, if the arrangement is for a term of at least one year and covers all services to be furnished by the physician to the entity, and the aggregate services do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement; and

3. Any other items or services provided for fair market value by the referring physician if the arrangement is commercially reasonable and the terms generally meet the requirements outlined above.

Anti-Kickback Statute. The Medicare and Medicaid Anti-Kickback Statute makes it a criminal offense for anyone (not only physicians) to knowingly and willfully offer, pay, solicit or receive any remuneration intended to induce the referral, purchase, lease, order, or arranging for any good, facility service, or item paid by a federal health care program. Criminal penalties are punishable by fines up to $25,000 per offense and imprisonment up to five years, exclusion from the Medicare and Medicaid programs, as well as administrative civil money penalties. 42 U.S.C. § 1320a-7b(b). In addition to several statutory exceptions, the Office of Inspector General of the Department of Health and Human Services (OIG) has promulgated regulations describing payment practices or "safe harbors" that, although potentially technical violations of

the statute, are not subject to criminal and civil penalties. While an arrangement must meet all elements of a safe harbor to be protected from prosecution, failure to comply with terms of a safe harbor does not necessarily mean the statute has been violated. Whether there has been a violation depends on all facts and circumstances of the particular case.

Safe Harbors. Compensation to bona fide employees is not subject to the Anti-Kickback Statute, but payments to independent contractors are covered. Safe harbors protect, if all elements of the applicable safe harbor are met, such common activities as rental of space or equipment, sale of a practice, and physician or other practitioner recruitment, warranties, discounts, group purchasing organizations, coinsurance waivers, risk sharing arrangements, electronic prescription systems, and certain investment interests, among others. The safe harbor for personal and management services requires, without limitation, that the aggregate compensation paid to the agent or contractor be set in advance and consistent with fair market value, and that compensation not be determined in a manner that takes into account the volume or value of any referrals of business generated between the parties for which payment may be made by a federal health care program.

Ambulatory Surgery Center Joint Ventures. Safe harbor regulations have also been promulgated for wholly physician-owned ambulatory surgery centers (ASC or ASCs), as well as ACSs jointly owned by a hospital and physicians. The safe harbor for surgeon-owned ASCs specifically requires that all the investors must be either:

1. General surgeons or surgeons engaged in the same surgical specialty who are in a position to refer patients directly to the entity and perform surgery on such referred patients;

2. Surgical group practices composed exclusively of such surgeons; or

3. Investors who are not employed by the entity or any investor, and are not in a position to provide items or services to the entity or its investors or to make or influence referrals to the entity or any of its investors.

ASC safe harbors for multi-specialty ASCs and hospital/physician ASCs also require, among other things, that at least one-third of those procedures capable of being furnished in the ASO performed by the physician investor must be done at the ASC.

BEST PRACTICES FOR DEALING WITH DIFFICULT DISCHARGES

By: Ken Burgess and David Broyles

Fortunately, most people think of hospitals as places to go for treatment and healing, and then cannot wait to go home. Now and then, however, a hospital encounters the patient who just won't leave, despite being medically able to do so. Imagine this scenario - a patient with recurring abdominal pain has presented to the hospital emergency department numerous times, often requiring a short term inpatient admission to stabilize and treat his or her acute medical need. Most recently, the patient presented to the ED, was admitted, and has been an inpatient in the hospital for over 50 days. The clinical determination is that the patient is medically stable and only in need of home or outpatient care, and inpatient acute care is no longer medically necessary. However, the patient refuses to leave the hospital and utilize other options for medically appropriate care. What should be done in this scenario?

North Carolina statutes provide hospitals with a tool for dealing with such situations. Keeping in mind that legal proceedings should be initiated as a last resort, the exception could be a situation where a patient simply refuses to leave the hospital after discharge, or is not able to participate in the decisions related to the discharge process.

- If a patient refuses to leave the hospital after all required notices have been given to the patient and any post-discharge caregiver(s), a hospital can initiate action in North Carolina for trespass against the patient.
    - Under N.C. Gen. Stat. §131E-90 if a patient is discharged by the attending physician, and then refuses to leave the hospital, upon having his or her case reviewed by two physicians licensed in North Carolina who find that inpatient acute care is not medically necessary, and final authorization for the discharge is given by the hospital administrator, the patient is guilty of a Class III misdemeanor and subject to arrest.
    - This option is, of course, drastic and may raise public relations issues including bad press coverage. Hospital administration, care management teams and legal counsel should ensure all required legal and regulatory steps are taken prior to initiating a trespass action, and a discharge plan is in place to assure the patient will be in a safe environment with the appropriate level of care necessary for his or her medical needs.
- If a patient is not able to participate in discharge planning due to cognitive issues or some other disability, care management and discharge planning staff should attempt to identify early on in the admission if a guardian will be needed so hospital counsel can be engaged to expedite the guardianship process.

While North Carolina law provides hospitals with a strong tool to address the difficult discharge patient, hospitals should carefully follow all state and federal legal and regulatory requirements, along with any health plan requirements, where applicable. These requirements include:

- Medicare and Medicaid requirements for discharge planning, beneficiary rights and beneficiary appeals processes;
- State licensing laws for hospitals related to discharge planning;
- The Joint Commission requirements for discharge planning; and
- Health plan provider and member contracts, including any National Committee for Quality Assurance requirements.

Hospitals should also establish strong relationships with downstream providers, social services agencies and other community-based programs that can offer or assist with post-discharge planning and care. Interdisciplinary teams and communication processes should be defined and put into place to handle potential and actual difficult discharges, and should include representatives from case management, medical staff, finance, public relations, administration, and legal counsel. These best practices will enable a hospital to triage and mediate difficult discharge situations internally, and help achieve the goal of great results for the patient and the hospital.

Honoring Patients End of Life Wishes: *Avoiding the Pitfalls of Advance Directives*

By: Ken Burgess

All patients have the right to direct the course of their medical care. This includes the right to decline care, even life sustaining care. So says the United States Supreme Court, the U.S. Congress and the N.C. General Assembly. Through an array of Supreme Court decisions and federal and state laws, patients are guaranteed the right to create advance directives, such as living wills and health care powers of attorney, that either describe the care they want, or name a third party to make such decisions, when the patient is no longer able to make or communicate their own health care decisions. Federal law also requires that hospitals educate patients at admission about their right to create advance directives; create policies and procedures addressing how they implement and honor advance directives; educate staff about those policies; inquire whether patients have advance directives; and document patients' medical records accordingly.

Sounds simple. In reality, the implementation of patients' end-of-life wishes, consistent with a written advance directive or the directives of a legally-authorized third party surrogate, remains one of the more challenging aspects of medical care for hospitals, and a number of major North Carolina hospital systems now have entire departments dedicated to end-of-life health care planning, including patient, community and staff training; ethics and implementation functions.

Implementing patients' end-of-life wishes is also a huge risk management area for hospitals. Providing unwanted life-sustaining care, inconsistent with a patient's advance directive or third party surrogate's instructions, can result in lawsuits for assault and battery and medical negligence, with damages for medical expenses, pain and suffering and in extreme cases punitive damages. Withholding life-sustaining care inconsistent with a patient's advance directive or third-party surrogate directives can lead to suits for wrongful death.

Proactively focusing on a few systems issues can greatly reduce a hospital's risk exposure in this area. They include:

1. Ensuring that hospital staff who handle or coordinate end of life and advance directives conversations with patients fully inquire into the existence of advance directives or other documents describing end-of-life care a patient does or does not want, and document those conversations.

2. Ensuring that hospital staff who handle or coordinate end of life and advance directives conversations with patients understand the functions of various advance directives, including living wills, health care powers of attorney, and related medical orders such as Portable Do Not Resuscitate Orders and Medical Orders for Scope of Treatment (MOST), including the differences in each type of document and the limitations of each. This includes recognizing conflicting directions in advance directives and/or oral instructions of a legally-authorized surrogate and knowing the hospital's process for resolving such conflicts before a care crisis arises.

3. Creating and maintaining a consistent medical record that contains all of patient's advance directives; identifies any legally-authorized third-party decision maker; and tracks changes in advance directives, such as revocations, substitute agents under health care powers of attorney, and so forth.

4. Ensuring that staff understand when various documents like living wills and health care powers of attorney become effective (when patient lacks capacity to make or communicate health care decisions any longer), and when related health care planning documents like Portable DNR or MOST orders become effective (upon entry of those orders by the applicable physician or physician-extender).

5. Ensuring that hospital staff understand North Carolina's applicable surrogacy laws and, specifically, when a third party is legally authorized to make decisions for an incompetent resident; who is the person authorized to act in that capacity; and what, if any, limitations have been placed upon that surrogate's decision-making authority by the patient. This includes a strong working knowledge of N.C. Gen. Stat. § 91-21.13, which provides a road map for who can give informed consent for medical care for patients unable to speak for

themselves and provides immunity for hospitals that obtain consent pursuant to that hierarchy. Immediately following this article, you will find a summary of that statute, for easy reference.

6. Ensuring that all direct care staff on all shifts can quickly, consistently, access information about a patient's end-of-life wishes, to ensure that proper decisions about life-sustaining care are made quickly and correctly, and without delay or confusion.

7. Ensuring that staff understand the limitations on the making of advance directives, including that: only competent residents can execute advance directives; neither well-meaning family members nor health care providers can do so for patients; and even health care agents under a health care power of attorney cannot do so.

8. Ensuring that staff understand the sometimes subtle, but important, distinctions in advance directives like living wills and health care powers of attorney, and related medical orders such as DNR and MOST orders. The rules governing these documents are different, including the rules for execution or entry of them, and many providers confuse the function, purpose and execution requirements of these documents.

9. Educating staff about various forms of advance directives available in North Carolina. Our statutes contain statutorily-approved forms that are valid and enforceable, but are also optional ways to document end-of-life wishes. Many people find these forms complex and confusing and increasingly, individual hospital systems, hospice providers, and consumer organizations are creating scaled-down, simpler versions of living wills and health care powers of attorney. If properly constructed, these are valid under N.C. law. Hospital staff should have a working knowledge of the basic elements that are required to make one of these optional-form advance directives valid.

10. Finally, having a uniform system for resolving conflicts among family members and hospital staff over a patient's end-of-life wishes. The quarrelling family or quarrelling staff scenario results in delayed decision-making, confusion, stress, and often medical mistakes and risk exposure.

HEALTH CARE DECISIONS FOR PERSONS WHO CANNOT MAKE OR COMMUNICATE THEIR OWN DECISIONS

North Carolina recognizes a person's fundamental right to make health care decisions. Sometimes, however, it is not possible for a patient to make or communicate a health care decision. A patient may be unconscious, comatose, or otherwise incapable of making or communicating a health care decision. In these situations, North Carolina law has clarified who can consent to medical treatment for persons not otherwise able to make or communicate their own health care decisions.

Under that law, the persons listed below can consent to (or withhold or withdraw consent to) medical treatment for a person who is not able to make or communicate his or her own health care decisions (in the order in which they are listed).

1. Health care agent (from a valid health care power of attorney) to the extent authorized by the power of attorney, unless the court has appointed a guardian of the patient's person and suspended the authority of the health care agent to make decisions; if there is no health care agent, then

2. Court-appointed guardian of the patient's person, or general guardian of a person; if there is no court-appointed guardian, then

3. Attorney-in-fact who is granted power over healthcare decisions by a valid power of attorney; if there is no attorney-in-fact authorized to make health care decisions, then

4. Spouse of the patient; if there is no spouse, then

5. A majority of the patient's reasonably available parents and adult children (those 18+ years of age); if there are no reasonably available parents and adult children, then

6. A majority of the patient's reasonably available adult siblings (those 18+ years of age); and if there are no reasonably available adult siblings, then

7. An individual who has an established relationship with the patient, who is acting in good faith on behalf of the patient, and who can reliably convey the patient's wishes.

If none of these people are reasonably available, the law authorizes the patient's Attending Physician to provide medical treatment to the patient, in that physician's discretion, without the patient's (or other authorized person's) consent if another physician confirms the patient's condition and the necessity for the medical treatment provided (unless any delay caused by obtaining this confirmation would endanger the patient's life or seriously worsen the patient's condition).

TOP 10 CERTIFICATE OF NEED FAQS

By: Todd Hemphill and Matt Fisher

North Carolina's Certificate of Need Law, codified in N.C. Gen. Stat. Ch. 131E, Article 9, outlines the types of services that require a CON and the requirements for filing, opposing, and ultimately appealing a decision of the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the CON Section) regarding an application. Below is a list of top 10 frequently asked questions that we typically encounter from clients as they navigate this process.

Q: What services and equipment require a CON?

A. Most major services typically provided by hospitals are new institutional health services that require a CON, as does most new medical equipment costing in excess of $750,000. There are exemptions for, among other things, renovations on the main hospital campus and replacement of existing equipment.

Q: When and where do I file a CON application?

A. CON applications are filed with the CON Section on the 15th of the month before a scheduled review start date (unless that date is a weekend or a holiday), and the CON Section's review of an application begins on the first of the following month. The annual State Medical Facilities Plan (SMFP) contains a schedule of the filing dates for different types of service and equipment: http://www.ncdhhs.gov/dhsr/ncsmfp/index.html.

Q: What can I do if the SMFP does not project a need for a service that I want to develop?

A. There are two opportunities each year to petition the State Health Coordinating Council to make changes to the SMFP. Petitions recommending changes that may have a statewide effect must be submitted in early March. Petitions proposing an adjustment to the need determination for a particular geographic area or institution are due in late July.

Q: What is the timetable for obtaining a decision in a CON review?

A. The CON Section's review of an application takes between 90 and 150 days. Assuming a CON application is filed on March 15th, and depending on the length of the review, the following sample timeline would be typical:

- April 1 – Review begins
- April 30 – Written comments filed
- May 15 – Public hearing
- June 30 (90 day review) or August 30 (150 day review) – Decision issued
- July 5 (90 day review) or September 4 (150 day review) – Required State Agency Findings issued
- August 4 (90 day review) or October 4 (150 day review) – CON issued (assuming no contested case appeal is filed)

Q: Should I file written comments if I oppose a CON application's approval?

A. Written comments can be the first introduction a CON analyst has to a project's strength or weakness. If the application is in a competitive review with your application, you definitely should file comments to show why your application is superior. Further, even if you have not filed a competing application, if you see a flaw in a CON application and do not file written comments, that flaw may go unnoticed, resulting in the approval of a non-conforming application. It is much easier to help defend the disapproval of a CON application in litigation than it is to challenge an approval.

Q: If my CON application is disapproved, should I appeal?

A. If your application was unopposed by third parties, you should file a contested case appeal. So long as there are no intervening parties, the CON Section normally will work with the provider to settle the contested case and award the CON. Other factors to consider for any appeal include the bases for the CON Section's decision, the costs of the appeal, and whether there will be additional opportunities to re-apply in the near future.

Q: Should I intervene to support the CON Section decision to deny a competitor's application?

A. If you believe that the service should not be provided or should be changed in some manner, you should intervene. Because the CON Section likely will settle with an applicant if there is no intervenor, intervention typically is the only way to prevent the project or modify it through settlement.

Q: If my application is approved and a third party challenges that approval, should I intervene in the contested case?

A. Yes. The CON Section expects successful applicants to defend their application. Failure to intervene could result in a reversal of the initial approval. As a practical matter, the Assistant Attorneys' General assigned to these cases for the CON Section rely heavily on assistance from the intervenors' private counsel.

Q: What is involved in a CON contested case?

A. The appeal of a decision by the CON Section is made via a Petition for Contested Case Hearing filed with the NC Office of Administrative Hearings. The Petition must be filed within 30 days of the decision. In cases that contest the approval of an application, the petitioner must first file a bond totaling 5% of the total capital cost of the approved project, up to $50,000. A separate bond should be filed for each approved application that is being challenged.

An administrative law judge (ALJ) will be assigned to preside over the case. The ALJ must enter a decision within 270 days from the filing of the Petition, which is much faster than most civil litigation. Otherwise, the litigation process closely resembles a civil case, including written discovery requests, document production, and depositions. There is also a mandatory mediated settlement conference before the contested case hearing. That is when many contested cases are settled.

The conduct of the hearing is similar to a normal non-jury trial. Witnesses are sworn and offer testimony in response to questions from attorneys, and exhibits are admitted by the ALJ. The ALJ then enters his or her decision after the hearing is concluded.

After the ALJ has entered a decision, further appeal may be made to the N.C. Court of Appeals. Appeals of application approvals require a similar appeal bond to be filed. A decision by the Court of Appeals typically takes between 18 to 24 months. Further appeals may be available to the N.C. Supreme Court, which could extend the case another one to two years. A CON is not issued until all appeals are exhausted.

Q: After I receive the CON, can I change my project or transfer the CON?

A. A CON is valid only for the defined scope, physical location and person named in the application. If an applicant proposes to change any of these three, they need to contact the CON Section to obtain confirmation that the proposed action would be in material compliance with the CON. The section regularly authorizes reasonable changes in location and has allowed a change in the holder of the CON in certain circumstances. A change in the scope of the project (e.g., a significant increase in capital cost or addition of services or equipment not previously proposed) is more likely to require a new CON application.

DOCUMENT RETENTION IN THE HOSPITAL SETTING

By: Wilson Hayman

Every hospital needs a comprehensive and consistently applied record retention policy that covers all forms of hard copy and electronic data. The reasons for adopting and implementing such a policy include, among others, ensuring compliance with statutory and regulatory requirements, maintaining control of records during litigation, improving efficiency in complying with records requests, and avoiding the disclosure of unnecessary or obsolete records.

The following chart provides some general categories and retention periods for hospital records. When a single document falls within two or more categories, the prudent course would be for the hospital to retain the document for the longest applicable retention period. While this chart may serve as a starting point for a record retention policy, these retention periods are for informational purposes only and are not an adequate substitute for legal advice based on your individual business needs and legal requirements.

Type of Record	Suggested Retention Period
Clinical/Medical/Infection Control Records	• Medical records, whether in original, computer media, or microfilm form, should be maintained for a minimum of 11 years following the discharge of an adult patient. • Medical records of a minor patient should be maintained until the patient's 30th birthday. • If a hospital discontinues operation, its management must make known to the Division of Health Service Regulation where its records are stored. Records should be stored in a business offering retrieval services for at least 11 years after the closure date. • A hospital must give public notice prior to destruction of its records, in at least two forms: written notice to the former patient or his/her representative, and display of an advertisement in a newspaper of general circulation in the hospital's area. • The Medicaid Provider Participation Agreement specifies a minimum retention period of 6 years from the date of service for medical records, or longer if specifically required by federal or state statutes, regulations, policies, manuals, bulletins or other controlling authority.
HIPAA-Related Records	HIPAA-related records such as policies, procedures and documentation of required communications must be retained for 6 years from either the date of their creation or the date when the records were last in effect, whichever is later.
Governance (board minutes, bylaws, etc.)	Generally retained permanently.
Quality Assurance, Safety Committee, and Abuse Investigation Records	Generally retained for 5 years.

Type of Record	Suggested Retention Period
Finance/Accounting	• Medicare specifies a retention requirement of at least 4 years. • The Medicaid Provider Participation Agreement specifies a minimum retention period of 6 years from the date of service for fiscal, accounting, and personnel records, or longer if specifically required by federal or state statutes, regulations, policies, manuals, bulletins or other controlling authority. • If a Hospital has been notified that a Medicaid audit or investigation has been initiated, it must retain all original records and supportive materials until the audit or investigation is completed and all issues are resolved if the period of retention extends beyond the minimum required 6-year period. • These records are commonly retained for at least 7 years due to certain tax and financial reporting obligations at the federal level.
Employment Application, Résumé, Hire/Promotion/ Demotion/Transfer Decision, Request for Accommodation, Evaluations, FMLA Records	• Personnel file (application, resume, hire/promotion/ demotion decisions, request for accommodation, test results, evaluations): 4 years after termination • All documents related to Family Medical Leave Act (FMLA) leave: 3 years • Wage and hour information: 5 years after calendar year in which compensation was paid • Employment handbooks, policies & procedures: 4 years after obsolescence of policy or procedures
I-9 Immigration Forms	3 years after hiring or 1 year after termination, whichever is later.
Wage Records (rates of pay, time earning sheets, etc.)	All records of hours and schedule worked, wages paid, deductions from wages, and wage rate tables should be preserved for at least 5 years after calendar year in which compensation was paid.
Most OSHA/Safety Records (including records of inspection/training of equipment)	5 years following end of the calendar year covered by the record (some specific types of OSHA records, such as exposure records and employees' medical files, have much longer retention periods, such as the duration of employment plus 30 years).
Contracts with Vendors/ Suppliers	For contracts valued at $10,000 or more over a 12-month period, Medicare regulations specify a retention period of 4 years after the service(s) furnished under the contract or subcontract; state laws imposing statutes of limitation on contract actions may be as long as 15 years, however.
Tax Records	7 years after taxes at issue were due or paid, whichever is later.
Compliance Records (committee minutes, reports to the board, internal audits, etc.)	10 years appears generally to be the most common retention period for these records.

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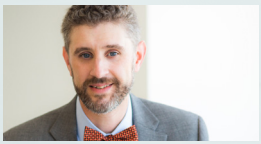

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