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Hot Legal Topics

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Negligent Credentialing - Environmental Overview

- Plaintiffs are looking for as many deep pockets as possible in a malpractice action
  - Hospital has the deepest pockets
- Tort reform efforts to place limitations or “caps” on compensatory and punitive damages has increased efforts to add hospitals as a defendant
- Different Theories of Liability are utilized
  - Respondent Superior
    - Find an employee who was negligent
  - Apparent Agency
    - Hospital-based physician, i.e., anesthesiologist, was thought to be a hospital employee and therefore hospital is responsible for physician’s negligence

Negligent Credentialing Environmental Overview (cont'd)

- Doctrine of Corporate Negligence
  - Hospital issued clinical privileges to an unqualified practitioner who provided negligent care

- Emphasis on Pay for Performance ("P4P") and expected or required quality outcomes as determined by public and private payors
- Greater transparency to general public via hospital rankings, published costs and outcomes, accreditation status, state profiling of physicians, etc.

Negligent Credentialing Environmental Overview (cont'd)

- Required focus on evidenced-based guidelines and standards and the six Joint Commission competencies (patient care, medical knowledge, practice based learning and improvement, interpersonal and communication skills, professionalism and systems based practice) and ongoing and focused professional practice evaluation ("OPPE" and "FPPE") as a basis of determining who is currently competent to exercise requested clinical privileges
- The result of all of these evolving developments is an unprecedented focus on how we credential and privilege physicians as well as the volume of information we are requesting and generating as part of this ongoing analysis

Duty - Doctrine of Corporate Negligence

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges. If the hospital knew or should have known that a physician is not qualified and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of this physician
- Doctrine also applies to managed care organizations such as PHOs and IPAs

Duty - Doctrine of Corporate Negligence (cont'd)

- Restatement of this Doctrine and duty is found in:
  - Case law, i.e., Darling v. Charleston Community Hospital
  - State hospital licensing standards
  - Accreditation standards, i.e., Joint Commission and Healthcare Facilities Accreditation Program, NAMSS
  - Medical staff bylaws, rules and regulations, department and hospital policies, corporate bylaws and policies
  - Practice parameters and other standards developed by physician, professional association, i.e., ACOG, ACR

Duty - Doctrine of Corporate Negligence (cont'd)

- Some questions associated with this duty:
  - How are core privileges determined?
  - Based on what criteria does hospital grant more specialized privileges?
  - Are hospital practices and standards consistent with those of peer hospitals?
  - Were any exceptions to criteria made and, if so, on what basis?

Duty - Doctrine of Corporate Negligence (cont'd)

- Were physicians to whom the exemption applied "grandfathered" and, if so, why?
- Did you really scrutinize the privilege card of Dr. Callahan who is up for reappointment but has not actively practiced at the Hospital for the last six years?
- Has each of your department's adopted criteria which they are measuring as part of FPPE or OPPE obligations such as length of stay patterns or morbidity and mortality data?

Breach of Duty

- The hospital breached its duty because:
  - It failed to adopt or follow state licensing requirements
  - It failed to adopt or follow accreditation standards, i.e., FPPE and OPPE
  - It failed to adopt or follow its medical staff bylaws, rules and regulations, policies, core privileging criteria, etc.
  - It reappointed physicians without taking into account their accumulated quality or performance improvement files

Breach of Duty (cont'd)

- It reappointed physicians even though they have not performed any procedures at hospital over the past two years and/or never produced adequate documentation that the procedures were performed successfully elsewhere
- It failed to require physicians to establish that they obtained additional or continuing medical education consistent with requirement to exercise specialized procedures
- It appointed/reappointed physician without any restrictions even though they had a history of malpractice settlements/judgments, disciplinary actions, insurance gaps, licensure problems, pattern of substandard care which has not improved despite medical staff intervention, current history or evidence of impairment, etc.

Breach of Duty (cont'd)

- It failed to grandfather or provide written explanation as to why physician, who did not meet or satisfy credentialing criteria, was otherwise given certain clinical privileges
- It required physician to take ED call even though he clearly was not qualified to exercise certain privileges
- Violated critical pathways, ACOG, ACR standards

Examples of Negligent Credentialing Cases

- Frigo v. Silver Cross Hospital (2007)
  - Frigo involved a lawsuit against a podiatrist and Silver Cross
  - Patient alleged that podiatrist's negligence in performing a bunionectomy on an ulcerated foot resulted in osteomyelitis and the subsequent amputation of the foot in 1998
  - The podiatrist was granted Level II surgical privileges to perform these procedures even though he did not have the required additional post-graduate surgical training required in the Bylaws as evidenced by completion of an approved surgical residency program or board eligibility or certification by the American Board of Podiatric Surgery at the time of his initial appointment in 1992

Examples of Negligent Credentialing Cases (cont'd)

- At the time of his reappointment, the standard was changed to require a completed 12 month podiatric surgical residency training program, successful completion of the written eligibility exam and documentation of having completed 30 Level II operative procedures
- Podiatrist never met these standards and was never grandfathered. In 1998, when the alleged negligence occurred, he had only performed six Level II procedures and none of them at Silver Cross

Examples of Negligent Credentialing Cases (cont'd)

- Frigo argued that because the podiatrist did not meet the required standard, he should have never been given the privileges to perform the surgery
- She further maintained that the granting of privileges to an unqualified practitioner who was never grandfathered was a violation of the hospital's duty to make sure that only qualified physicians are to be given surgical privileges. The hospital's breach of this duty caused her amputation because of podiatrist's negligence

Examples of Negligent Credentialing Cases (cont'd)

- Jury reached a verdict of $7,775,668.02 against Silver Cross
- Podiatrist had previously settled for $900,000.00
- Hospital had argued that its criteria did not establish nor was there an industry-wide standard governing the issuance of surgical privileges to podiatrists
- Hospital also maintained that there were no adverse outcomes or complaints that otherwise would have justified non-reappointment in 1998

Examples of Negligent Credentialing Cases (cont'd)

- Court disagreed and held that the jury acted properly because the hospital's bylaws and the 1992 and 1993 credentialing requirements created an internal standard of care against which the hospital's decision to grant privileges could be measured
- Court noted that Dr. Kirchner had not been grandfathered and that there was sufficient evidence to support a finding that the hospital had breached its own standard, and hence, its duty to the patient
- This finding, coupled with the jury's determination that Dr. Kirchner's negligence in treatment and follow up care of Frigo caused the amputation, supported jury's finding that her injury would not have been caused had the hospital not issued privileges to Dr. Kirchner in violation of its standards

Examples of Negligent Credentialing Cases (cont'd)

Smithey v. Brauweiler (2008)

- Dr. Brauweiler was a family practitioner who applied for and received medical staff privileges at Sandwhich Community Hospital (now Valley West Community Hospital), including obstetrical privileges, in 1991.
- In 1995, he delivered a child by operative vacuum delivery. Delivery was successful but child needed resuscitation. Through no fault of physician, resuscitation was delayed leading to permanent brain damage. Lawsuit was filed in 1997 for alleged negligence against hospital and Dr. Brauweiler.

Examples of Negligent Credentialing Cases (cont'd)

- During deposition, physician testifies that a vacuum extraction would be a deviation of the standard of care if done at +1 station or higher.
- Dr. Brauweiler was reappointed each time with OB privileges, including the specific grant of operative vacuum and operative forceps delivery which were separate privileges in 2000. No adverse results in other vacuum delivery cases.
- In 2001, he delivered a child by vacuum delivery but this time, vacuum extractor was performed 22 times in 33 minutes because it kept popping off. Infant was presenting at +1 the whole time. OB was called and did a C section.

Examples of Negligent Credentialing Cases (cont'd)

Apgars were 2, 3 and 6. Infant diagnosed with hypoxic ischemic encephalopathy. Lawsuit was filed in 2003 against Dr. Brauweiler and amended in 2005 to include the hospital on a negligent credentialing claim.

- In 2002, he withdrew his OB privileges.
- Plaintiff's attorney argued that hospital was negligent in granting OB privileges to Dr. Brauweiler in the first place and especially after the 1995 case even though he was not at fault.
  - Plaintiff contended that the case should at least have called into question the physician's qualifications.

Examples of Negligent Credentialing Cases (cont'd)

- Hospital decided that it did not want to run the risk of losing at trial and settled case for almost $8 million.
- Defense not able to introduce the peer review record of hospital to establish that it met its duty because they were inadmissible under the Medical Studies Act.
- IHA has set up a round table discussion of expert defense and corporate attorneys to discuss how to best defend against these corporate negligence cases in light of more aggressive tactics by plaintiff's attorneys and problems caused by the MSA.

The Kadlec Case

- Trial court had held that a Louisiana hospital and a physician's former group had a duty to report to Kadlec Medical Center in Washington the fact that the applicant anesthesiologist had lost membership and privileges and was fired from the group because he was addicted to Demerol and posed a serious threat to patients.
- The hospital had not responded to any of the questions about the applicant and merely gave the dates of his membership.
- Group described the anesthesiologist as "excellent" and that he would be an asset to any group he joined.

The Kadlec Case cont'd

- Kadlec hired the anesthesiologist who later, while impaired, failed to observe that the patient was in respiratory distress.
- Patient suffered permanent brain damage and brought malpractice case against Kadlec which settled for over $7 million.
- Kadlec turned around and sued Louisiana Hospital and group and received an $8 million verdict which was upheld by a trial court which ruled that there was a duty to disclose based on a hospital's "special relationship" with other hospitals and the importance of sharing information that obviously would have affected Kadlec's hiring decision. Group's conduct was seen as an outright misrepresentation, if not fraudulent.

The Kadlec Case cont'd

- On appeal, the Circuit Court of Appeals reversed as to the Louisiana Hospital but affirmed the verdict against the group.
- Court said that unless there was a contractual or fiduciary relationship between the hospitals, there is no duty to disclose, If a hospital does respond, however, it may not mislead or create a misapprehension through its response.
- Here, the Louisiana Hospital merely gave the physician's dates of service, nothing more. No misrepresentation or misleading information was provided about his

The Kadlec Case cont'd

competency or if he was impaired, unlike the group whose conduct essentially was fraudulent. Therefore, hospital was not liable.

- Duty in Illinois?
  - No duty to disclose
  - Like Louisiana, there is no duty to disclose between unaffiliated hospitals unless there is fiduciary or confidential relationship, such as between hospitals in a multi-hospital system or in some kind of joint venture, such as a PHO.
  - A hospital can be liable for negligent misrepresentation or fraudulent misrepresentation.

The Kadlec Case cont'd

- Negligent misrepresentation is when a hospital makes a representation it believes to be true but, in fact, is false and the hospital reasonably should have known it was false.
- Fraudulent misrepresentation is where the hospital makes an affirmative representation it knows to be false or is made with reckless disregard as to whether it was true or false.
- See attached client advisory.

The Poliner Case

- Jury awarded $366 million dollars to a cardiologist who was summarily suspended by “agreeing” to not exercise certain privileges pending an investigation.
- Judge and jury determined that request abeyance was not voluntary because the physician was not allowed to consult with his attorney, was only given three hours to decide whether to agree and was told that if he did not voluntarily agree to the abeyance, he would be summarily suspended.
- Court also noted that the Department Chair who demanded the abeyance testified that there was no imminent threat to patients which was the bylaws standard for both the abeyance and a suspension.

The Poliner Case cont'd

- Although the court reduced the jury verdict to $22.5 million, the decision was viewed as having a significant chilling effect on the medical staff's willingness to participate in peer review activities.
- On July 23rd, the 5th Circuit Court of Appeals reversed and held that all defendants were immune from liability under the Health Care Quality Improvement Act ("HCQIA"). In so ruling, the court made the following findings and comments.
  - Court spent considerable time detailing the quality of care issues that were identified, some of which were acknowledged by Dr. Poliner.

The Poliner Case cont'd

- Court affirmed the use of the objective versus subjective standard in determining whether the physicians acted reasonably.
- Failure to follow bylaws and policies does not necessarily mean that a hospital and medical staff will lose its HCQIA immunity protections.
- The fact that the decision to extend the suspension was later overturned does not mean that that action was not reasonable at the time the decision was made.
- Good or bad faith of the reviewer or decision maker, by itself, is irrelevant. Must look to totality of the circumstances.

The Poliner Case cont'd

- HCQIA does not require that the actions taken have to improve the quality of health care or that the reviewers were in fact correct.
- There was nothing in the record which indicated that the information relied on when making the decision was either "facially flawed" or "so obviously defiant" as to make defendant's reliance unreasonable.
- Poliner was entitled to a reasonable effort to investigate the facts not a perfect effort.
- Congress understood that in its efforts to protect and encourage robust peer review to root out incompetent physicians and protect patients that some harsh outcomes to physician could result.

The Poliner Case cont'd

- The ability under HCQIA to impose an immediate summary suspension when there is "an imminent danger to the health of any individual" does not require that the physician be impaired or grossly incompetent.
- Court also stated that the intent of HCQIA was to reinforce the pre-existing reluctance of courts to substitute their judgment for that of medical staffs and governing boards acting within their expertise.

The Poliner Case cont'd

- Lessons Learned
  - Do your bylaws comply with Joint Commission standards, HCQIA, Hospital Licensing Act?
  - Follow your bylaws
  - Have clear documentation on quality of care issues before acting
  - Make sure your procedures allow for interaction with and a response by the physician before taking action

The Poliner Case cont'd

- Summary suspensions are almost never necessary and no one person should have the authority to impose a suspension.
- You should consider other remedial actions first and document why they are not good alternatives if you decide to suspend anyway.
- Bylaws should include clauses that state that physician waives any right to sue over disciplinary action and if suit is brought, physician is obligated to pay hospital's legal expenses if he loses.

Status of MS.1.20

- Joint Commission has proposed a significant change to its Medical Staff standards in July, 2007 that would have the following results:
  - Require that substantive provisions dealing with appointment, reappointment, credentialing, peer review and hearings must be in the medical staff bylaws rather than a manual, rule, regulation policy or procedure.
  - Bylaws must contain a procedure that discusses how MEC members are elected/appointed and how they can be removed.
  - Bylaws must spell out how the stated authority of the MEC can be reduced or eliminated.

Status of MS.1.20 cont'd

  - Bylaws must spell out and specifically give authority to the "organized medical staff" to bypass the MEC and to propose amendments to bylaws, rules and regulations and policies directly to the board of directors.
- This "final rule", which was a last minute standard prepared by the AMA, created an uproar in the industry and eventually was opposed by the AHA, FAH, NAMSS and other groups.
- JC relented and appointed a Task Force of physician and hospital representatives to try and address the major concerns expressed by both sides.

Status of MS.1.20 cont'd

- Task Force is at an impasse. Revised rules that would have given hospitals and medical staffs the right to decide what has to be in the bylaws and what can be in a policy, as well as requiring some type of dispute resolution process between the organized medical staff and MEC before it could be bypassed or its authority reversed, was rejected by the AMA reps.
- Effective date of January, 2009 was pushed back and will probably be pushed back again.

Joint Commission Leadership Standards

- Standard LD.01.01.01

  The [organization] has a leadership structure.

  – Rationale for LD.01.01.01

    Every [organization] has a leadership structure to support operations and the provision of care. In many [organization]s this structure is formed by three leadership groups; the governing body, senior managers, and the organized medical staff.

Joint Commission Leadership Standards
cont'd

- Standard LD.01.02.01

` The [organization] identifies the responsibilities of its leaders.

  – Elements of Performance

    - 1. Senior managers and leaders of the organized medical staff work with the governing body to define their shared and unique responsibilities and accountabilities. (See also NR.01.01.01, EPs 2 and 3)
    - 2. The governing body establishes a process for making decisions when a leadership group fails to fulfill its responsibilities and/or accountabilities.

Joint Commission Leadership Standards
cont'd

- Standard LD.01.03.01

  The governing body is ultimately accountable for the safety and quality of care, treatment, and services.

  - Elements of Performance
    - 7. The governing body provides a system for resolving conflicts among individuals working in the hospital.
    - 8. The governing body provides the organized medical staff with the opportunity to participate in governance.
    - 9. The governing body provides the organized medical staff with the opportunity to be represented at governing body meetings (through attendance and voice) by one or more of its members, as selected by the organized medical staff.
    - 10. Organized medical staff members are eligible for full membership in the hospital's governing body, unless legally prohibited.

Joint Commission Leadership Standards
cont'd

- Standard LD.01.05.01

  The [organization] has an organized medical staff that is accountable to the governing body.

- Standard LD.02.01.01

  The mission, vision, and goals of the [organization] support the safety and quality of care, treatment, and services.

  - Elements of Performance
    - 1. The governing body, senior managers, and leaders of the organized medical staff work together to create the hospital's mission, vision, and goals. (See also NR.01.01.01, EP 2)

Joint Commission Leadership Standards
cont'd

- Standard LD.02.02.01

  The governing body, senior managers and leaders of the organized medical staff address any conflict of interest involving leaders that affect or could affect the safety or quality of care, treatment and services.

  – Rationale for LD.02.02.01

    Conflicts of interest can occur in many circumstances and may involve professional or business relationships. Leaders create policies that provide for the oversight and control of these situations. Together, leaders address actual and potential conflicts of interest that could interfere with the [organization]'s responsibility to the community it serves.

Joint Commission Leadership Standards
cont'd

- Elements of Performance
  - 1. D The governing body, senior managers, and leaders of the organized medical staff work together to define in writing conflicts of interest involving leaders that could affect safety and quality of care, treatment, and services.
  - 2. D The governing body, senior managers, and leaders of the organized medical staff work together to develop a written policy that defines how conflict of interest involving leaders will be addressed.
  - 3. Conflicts of interest involving leaders are disclosed as defined by the hospital.

Joint Commission Leadership Standards
cont'd

- Standard LD.02.04.01

  The [organization] manages conflict between leadership groups to protect the quality and safety of care.

  - Elements of Performance
    - 1. Senior management and leaders of the organized medical staff work with the governing body to develop an ongoing process for managing conflict among leadership groups.
    - 2. The governing body approves the process for managing conflict among leadership groups.

Joint Commission Leadership Standards
cont'd

- 3. Individuals who help the hospital implement the process are skilled in conflict management. Note: These individuals may be from either inside or outside the hospital.
- 4. The conflict management process includes the following:
  - Meeting with the involved parties as early as possible to identify the conflict
  - Gathering information regarding the conflict
  - Working with the parties to manage and, when possible, resolve the conflict
  - Protecting the safety and quality of care

Joint Commission Leadership Standards
cont'd

- Standard OD.03.01.01

  Leaders create and maintain a culture of safety and quality throughout the [organization].

  – Rationale for LD.03.01.01

    Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the [organization]. Leaders demonstrate their commitment to quality and set expectations for those who work in the [organization]. Leaders evaluate the culture on a regular basis.

Joint Commission Leadership Standards
cont'd

- Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to [patient] care. Leaders must address disruptive behavior of individuals working at all levels of the [organization], including management, clinical and administrative staff, licensed independent practitioners, and governing body members.
- Elements of Performance
  - 4. [D] The hospital has a code of conduct that defines acceptable, disruptive, and inappropriate behaviors.
  - 5. Leaders create and implement a process for managing disruptive and inappropriate behaviors.

Joint Commission Leadership Standards
cont'd

- Standard LD.03.03.01

  Leaders use [organization]-wide planning to establish structures and processes that focus on safety and quality.

- Standard LD.04.02.01

  The leaders address any conflict of interest involving licensed independent practitioners and/or staff that affects or has the potential to affect the safety or quality of care, treatment, and services.

Joint Commission Leadership Standards
cont'd

- Elements of Performance
  - 1. D The leaders define conflict of interest involving licensed independent practitioners or staff. This definition is in writing.
  - 2. D The leaders develop a written policy that defines how the hospital will address conflicts of interest involving licensed independent practitioners and/or staff
  - 3. Existing or potential conflicts of interest involving licensed independent practitioners and/or staff, as defined by the hospital, are disclosed.

Joint Commission Leadership Standards
cont'd

- 4. The hospital reviews its relationships with other care providers, educational institutions, manufacturers, and payors to determine whether conflicts of interest exist and whether they are within law and regulations.
- 5. Policies, procedures, and information about the relationship between care, treatment, and services and financial incentives are available upon request to all patients, and those individuals who work in the hospital, including staff and licensed independent practitioners.

Patient Safety and Quality Improvement Act of 2005

- Patient Safety Organization
  - Patient Safety Act includes proposed regulations for the creation of Patient Safety Organizations (“PSO”).
  - PSOs are entities which can be profit, not-for-profit, public or private, that would be certified by HHS through the Agency for Healthcare Research and Quality (“AHRQ”) for the purpose of collecting, receiving and offering cumulative advice to providers regarding patient safety events and quality improvement initiatives.

Patient Safety and Quality Improvement Act of 2005 cont'd

- Qualifying information reported to a PSO by a provider and any advice, analysis and reviews conducted by the PSO would be treated as patient safety work product and therefore would be privileged and confidential and state and federal laws would not be subject to discovery and could not be admitted in any judicial or administrative proceeding.
- Final comments on proposed rules have been received and final rules are expected. Not clear whether they will be issued before Bush leaves office.

Patient Safety and Quality Improvement Act of 2005 cont'd

- Many questions still remain about whether current quality assurance and peer review information will be protected but, together with state confidentiality statutes, PSOs could be quite effective in keeping all quality data privileged and confidential. Currently, there is no federal confidentiality protection for this data.

Joint Commission Sentinel Event Alert

- Behaviors That Undermine a Culture of Safety
  - Citing to LD.03.01.01, EP4 and 5, the Joint Commission issued a Sentinel Event Alert which was particularly critical of what it called "intimidating and disruptive behaviors" that cause "medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more professional environments." (Issue 40, July 9, 2008)
  - Although LD.03.01.01 is designed to address behaviors of all hospital personnel, the Alert clearly is more directed toward physicians.

Joint Commission Sentinel Event Alert

cont'd

- Alert contains eleven "suggested actions" including the following:
  - Incorporate zero tolerance standards into medical staff bylaws, employment agreements and administrative policies;
  - Need to adopt non-retaliation policies and standards;
  - Need to discuss how and when to begin disciplinary actions;
  - Develop and implement a reporting/surveillance system
  - Interventional strategies should be progressive in nature.

Joint Commission Sentinel Event Alert
cont'd

- Must develop a Code of Conduct.
- Although Alert mentions the possibility that behavior could be limited to physical or mental health "pathologies", it does not spend much time discussing or encouraging the use of physician wellness or assistance committees as applied to the Medical Staff.

Medicare Hospital Inpatient Prospective Payment System Final Rule – FY 2009

- On August 19, 2008, CMS published a final rule implementing Hospital IPPS changes for FY 2009 (73 Fed. Reg. 48434 (Aug. 19, 2008))
- Effective October 1, 2008
- In addition to payment changes, the final rule includes various changes and proposed changes of significance to hospitals

Hospital IPPS – Noteworthy Non-Payment Changes

- Hospital-Acquired Conditions
- EMTALA
- Stark Law

Hospital-Acquired Conditions (HACs)

- IOM's 1999 Report "To Err is Human: Building a Safer Health System"
- HAC provision of the Medicare statute is one of several tolls that CMS is using to promote increased quality and efficiency of care
- Tools include measuring performance, using payment incentives publicly reporting payment results, QIO activities
- President's FY 2009 Budget would prohibit hospitals from billing the Medicare program for so-called "never events" and prohibit Medicare payment for the same and require hospitals to report these occurrences

Hospital-Acquired Conditions (HACs)

- Beginning October 1, 2008, Medicare will no longer assign a inpatient hospital discharge to a higher paying DRG if a selected HAC is not present on admission (i.e., the case will be paid as if the secondary diagnosis were not present)
- HACs include: foreign object retained after surgery, air embolism, blood incompatibility, falls and traumas, catheter-associated UTI, pressure ulcers, surgical site infection after coronary artery bypass graft (CABG)

Hospital-Acquired Conditions (HACs)

- Newly proposed HACs include: extreme manifestations of poor glycemic control, surgical site infections following certain types of surgeries (orthopaedic and bariatric), deep vein thrombosis/pulmonary embolism following total knee or hip replacement
- Rejected HACs include: delirium, ventilator-associated pneumonia, staph infection, clostridium difficile associated disease (CDAD), Legionnaires' Disease, iatrogenic pneumothorax, MRSA

EMTALA--Applicability to Inpatients

- CMS has previously stated that the admitting hospital's EMTALA obligations end when the hospital, in good faith, admits an individual with an unstable medical condition as an inpatient.
- Said patient is protected by provisions other than EMTALA (e.g., Hospital CoPs, nondiscrimination obligation)

EMTALA—Applicability to Inpatients

- Open issue/debate with respect to a subsequent specialty "receiving hospital"
  - EMTALA TAG recommended that CMS develop regulations on this issue
  - CMS proposed to add a regulatory provision stating that if an individual covered by EMTALA was admitted as an inpatient and remains unstable with an EMC, then the receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual

EMTALA—Specialty Receiving Hospital

- Proposal was widely criticized—not a clarification, but a significant change in policy from prior bright line test (once admitted as an inpatient, EMTALA no longer applies); promotes patient dumping at hospitals with specialized capabilities
- In response, CMS did NOT finalize the proposed regulatory change and states specifically that:
  - If an individual presents to the admitting hospital that has a dedicated emergency department and is found to have an EMC, and is subsequently admitted as an inpatient in good faith for stabilizing treatment, then the admitting hospital has met its EMTALA obligation, even if that patient remains unstable

EMTALA—Specialty Receiving Hospital

- Further, in such case, a hospital with specialized capabilities does NOT have an EMTALA obligation to accept a transfer of that individual from the referring hospital

EMTALA—On-Call List Obligations

- EMTALA TAG recommendations—annual plan, back-up plan when on-call physician is not available
- Well recognized concerns about on-call coverage, especially by specialty physicians
- Prior attempts to ameliorate by permitting on-call physician to schedule elective surgery while on-call, permitting simultaneous on-call duties, acknowledging no obligation to be on-call at all times, and P&Ps if specialty physician is not available for reasons beyond his control
- EMTALA TAG—Community Call

EMTALA—Community Call

- Acceptable if formal agreements recognized in the their P&Ps and back-up plan
- FY 2009 Hospital IPPS Rule—Hospital may comply with on-call list requirement by participating in a a formal community call plan

EMTALA—Community Call

- Community Call Plan must include the following elements:
  - Clear delineation of on-call responsibilities
  - Definition of the specific geographic areas to which the plan applies
  - Signed by appropriate participating hospital representatives
  - Ensure that applicable EMS system protocol includes information on community on-call arrangements
  - MSE and stabilizing treatment required if patient arrives at a hospital that is not designated as the on-call hospital
  - Annual reassessment

Stark Law Changes

- "Stand in the Shoes"
- Period of Disallowance
- DHS "Entity" Definitional Changes (Services provided "under arrangement")
- Percentage-Based Compensation and Per-Click Fees

"Stand in the Shoes" Provisions

- Effective October 1, 2008
- Under Phase III, a "physician organization" was defined as a physician, a physician practice or a group practice
- Thus, when determining whether a direct or indirect compensation arrangement existed between a physician and an entity to which the physician refers Medicare beneficiaries for DHS, the referring physician was deemed to "stand in the shoes" of:
  - another physician who employs the referring physician;
  - his or her wholly-owned PC
  - a physician practice that employs or contracts with the referring physician or in which the physician has an ownership interest
  - a group practice in which the referring physician is a member or independent contractor
- Industry concern/reaction as to scope/breadth of proposal on, among others, AMCs and integrated tax-exempt delivery systems

"Stand in the Shoes" Provisions

- Physician owners (other than "titular" owners with no right to dividends or distributions) of physician organizations stand in the shoes of the physician organization
- Stand in the shoes provisions do not apply to arrangements that satisfy the AMC exception
- Did not finalize proposal to have DHS entity "stand in the shoes" of an entity that it owns

Period of Disallowance

- Period of disallowance ends:
  - Where noncompliance is unrelated to compensation, date that financial relationship satisfies all of the applicable requirements of an exception
  - Where noncompliance is due to excess compensation, date that excess compensation is returned AND financial relationship satisfies an exception
  - Where noncompliance is due to inadequate compensation, date that required compensation is paid AND financial relationship satisfies an exception

Services Provided "Under Arrangement"

- "Entity" defined to include person or entity that has performed the DHS or presented a claim or caused a claim to be presented
  - CMS seeks to prohibit physician ownership in joint ventures that typically provide services "under arrangement" with hospitals
  - In CMS's opinion, Congress did not intend to allow physicians to have an ownership interest in a service company when the physician would not have been able to refer patients to the company if it billed Medicare for its services
  - Effective October 1, 2009

Percentage Based Compensation and Per Click Payments

- Prohibit the use of percentage-based compensation formulae in the determination of rental charges for the lease of office space or equipment (effective October 1, 2009)
  - Will continue to review other types of percentage fee arrangements
- Prohibit per-click payments to physician lessors for services rendered to patients who were referred by the physician lessor (effective October 1, 2009)
  - CMS will continue to study the issue of “block time” leasing

HIPAA

- Providence Health & Services
  - First "Resolution Agreement" (July, 2008)
    - Incident arises out of loss of electronic back-up media and laptops containing unencrypted IIHI for over 386,000 patients
  - $100,000 "resolution amount," but no CMPs
  - Corrective Action Plan requirement—revised P&Ps regarding data mobility and access, workforce training, audits

HIPAA

- HHS has proposed to replace the ICD-9 code set with the ICD-10 code set starting October 1, 2011 (73 Fed. Reg. 49796 (Aug. 22, 2008))
  - ICD-9-CM has approximately 13,000 codes
  - ICD-10-CM has approximately 68,000 available codes, which are very specific

IRS Form 990

- Effective for 2008 tax years
- New hospital schedule (Schedule H)
- New compensation schedule (Schedule J)
- Governance/Self-dealing

Recovery Audit Contractors (RACs)

- Medicare Modernization Act of 2003 required RAC demo from March, 2005 through March, 2008
  - Goal was to detect and correct past improper payments and to implement actions to prevent future improper payments
  - California, New York, Florida (May, 2005)
  - Massachusetts, Arizona, South Carolina (Summer, 2007)
  - During the demo, 2007, RACs collected nearly $1 billion in overpayments ($700 million net)
  - CMS paid nearly $200 million in contingency fees to the RACs, reimbursed facilities about $40 million in underpayments and restored about $60 million in determinations that were overturned on appeal or re-review
- Tax Relief and Health Care Act of 2006 required that program be permanent and nationwide no later than January 1, 2010
- National phase-in beginning in fall, 2008, but certain provider trade associations are seeking to delay the roll-out
  - Look back period will be a maximum of 3 years
  - No look back for claims paid prior to October 1, 2007

Gainsharing Stark Law Proposed Exception

- Medicare Physician Fee Schedule Proposed Rule for CY 2009; 73 Fed. Reg. 38502 (July 7, 2008) (42 CFR 411.357(x))
  - Medicare and private payors are increasingly exploring the benefits of various types of gainsharing that use economic incentives to foster high-quality, cost effective healthcare
  - These arrangements implicate the Stark Law

Gainsharing Stark Law Proposed Exception

- Scope
  - Protects only incentive payment and shared savings programs offered by hospitals
  - Cash only programs (i.e., no non-monetary remuneration)

Gainsharing Stark Law Proposed Exception

- Requirements
  - Documented program that must include patient care quality of cost saving measures (or both) supported by objective, independent medical evidence
  - Patient care quality measures to be listed in CMS' Specifications Manual for National Hospital Quality Measures or (alternatively) deemed satisfaction
  - Cost saving measures must use an objective methodology, that is verifiable and supported by credible medical evidence indicating that the measures would not adversely affect patient care, be individually tracked and reasonably related to the services
  - Independently reviewed prior to implementation and at least annually thereafter to ascertain the program's impact on the quality of patient care services

Gainsharing Stark Law Proposed Exception

- Requirements (continued)
  - Participation limited to physicians who are members of the hospital's medical staff at the commencement of the program
    - Participation in pools of five or more participating physicians, among whom the aggregate savings will be shared on a per capita basis
    - Eligibility may not be determined based upon the volume or value of referrals
  - No limit on discretion of a participating physician to make medically appropriate decisions. Hospital must make available to participating physicians the same selection available prior to his/her participation
  - No ability to participate is physician has an ownership or investment interest in or a compensation arrangement the manufacturer or distributor of the item, supply or device
- No shorter than 1 and no longer than 3 years
- Proposed flat 50% limit on the sharing of cost savings; scaled limits for multi-year arrangements

Gainsharing Stark Law Proposed Exception

- Requirements (continued)
  - No intent to reward passive physicians who receive payments but who did not participate in the program; issue—multi-specialty groups

Provena Covenant Medical Center v. Department of Revenue of the State of Illinois

- In a decision dated August 27, 2008, the Illinois Appellate Court issued a decision reversing the circuit court and affirming the Director's original decision
  - The circuit court had reversed the decision of the Director of the Illinois Department of Revenue (Director) and held that Provena Covenant Medical Center (Covenant) was used primarily for charitable and religious purposes and therefore, qualified for exemption from property taxes
  - The Director had originally ruled that Covenant did not qualify for exemption from property taxes, a decision that affirmed the recommendation of the Champaign County Board of Review (but which disagreed with the recommendation of a Department ALJ)

Legal Holding/Standard of Review

- The legal basis for the appellate court's decision was that there was "no clear error in the Director's decision."
- Standard of review was determined to be "clear error." Covenant argued for de novo review
  - Facts were established, rule of law was undisputed, question was whether the rule of law, as applied to the established facts, was or was not violated.
  - Also, this standard of review requires deference to the Director's decision
- Standard of review was a significant basis for appellate court's decision—if there was no evidence in the record to establish that the Director's decision was clearly erroneous, the appellate court deferred to the Director

The Undisputed Facts

- Covenant is a not-for-profit , full-service, general acute-care hospital
- Provena applied for property tax exemption for Covenant on the grounds that it was used primarily for charitable purposes
  - In 2002 (the tax year in question), Covenant devoted 0.7% of its total revenue to charity care
  - In 2002, Covenant had approximately 110,000 admissions. In 2002, Covenant gave free care to 196 patients and discounted care to 106 patients (and hired collection agents to recover the balance from 64 of the 106 patients to whom it had given discounts)

The Director's Decision

- Based upon those facts, the Director denied Covenant's application for exemption.
- Covenant failed to prove, clearly and conclusively, that it was a charitable institution.
- Provision of medical care, in and of itself, is not charitable. Charity does not mean compensated medical care; it means uncompensated care.

The Director's Decision

- Record appears to contain no evidence that, in 2002, Covenant provided charitable care to those who were unable to pay.
- The Director found that Covenant spent only 0.7% of its revenue on charity care in 2002. From that finding, the Director inferred that Covenant did not dispense charity to all who needed it. "We are not left with a definite and firm conviction that he thereby made a mistake."

The Director's Decision

- Covenant had a charity care policy and employed charity care guidelines. Covenant argued that those were mere guidelines. "But the record does not seem to reveal how often Covenant departed from the guidelines of its charity care policy, how often a reassessment was done, what the reassessment considered, and how often a reassessment made any difference."
- Medicare bad debt does not constitute charitable care. Bad debt is an accounting expense not a gift.

Considerations of Public Policy

- Court held that it is the legislature's job, not the court's, to make public policy
- "Until such time as the legislature sees fit to either change or make definite the formula for the determination of the medical/charitable use of real property, Provena cannot, on the record before us here, prevail in its attempt to exempt itself from real estate taxation."