

HCNCC: Compliance Seminar

May 1, 2008

San Francisco

-
- Coordinating the Roles
 - of the
 - Hospital and the Medical Staff
 - for
 - Quality of Care Issues

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State of California Quality Enforcement: Current Issues

- **Health & Safety Code § 1280.1
Administrative Penalties**
 - **Applies to general acute hospitals,
psychiatric hospitals, special
hospitals**
 - **Triggered by:**
 - **Adverse event**
 - **Licensing survey**
 - **“Complaint”**

State of California Quality Enforcement: Current Issues (cont'd)

- **Applies if hospital receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient**
- **If the hospital is required to submit a plan of correction**
- **The department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars (\$25,000) per violation.**

State of California Quality Enforcement: Current Issues (cont'd)

- **"[I]mmediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.**

State of California Quality Enforcement: Current Issues (cont'd)

- **Adverse event reporting, 1279.1**
 - **Requires California hospitals (general acute, psych, special) to report the occurrence of any one of 27 "adverse events."**
 - **Within 5 days of detection (24 hours if ongoing)**
 - **Creates a mechanism for others to report such events when a hospital fails to do so.**

State of California Quality Enforcement: Current Issues (cont'd)

- **“Adverse event” defined by listings**
 - **Surgical events**
 - **Product or device events**
 - **Patient protection events**
 - **Care management events**
 - **Environmental events**
 - **Criminal events**
 - **Event or events “that cause the death or serious disability of a patient, personnel, or visitor”**

State of California Quality Enforcement: Current Issues (cont'd)

- **Following receipt of a report, the department is obligated to investigate the event and publicize its findings.**
- **Hospitals failing to report an adverse event are subject to a fine not to exceed \$100 for each day the event was unreported.**

State of California Quality Enforcement: Current Issues (cont'd)

- **Beginning January 1, 2009, the department is charged with making available to the public reports of substantiated adverse events, as well as any subsequent investigations or inspections. This information must be posted on the Department's internet website by January 1, 2015.**
- **[The Patient Safety and Quality Improvement Act of 2005 created a federal system for voluntary reporting.]**

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Medicare "Never" events rules**
 - **No "higher rate" payments for identified hospital-acquired conditions, beginning October 1, 2008,**
 - **Unless acquired "pre-admission"**
 - **Expansion of covered conditions expected**

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Covered conditions, e.g.**
 - **Object inadvertently left in after surgery**
 - **Blood incompatibility**
 - **Certain types of falls and trauma**

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Medicare Quality reporting**
 - **See Social Security Act § 1886(b)(3)(B)(viii)**
 - **“Voluntary” reporting of medical information**
 - **Hospital payment reduced if it does not participate**

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Begun with 10 quality measures, 27 measures covering six areas for fiscal 2008, such as:**
 - **Heart attack**
 - **Example quality indicator; were heart attack patient given aspirin upon arrival?**
 - **Pneumonia**
 - **Example quality indicator; were antibiotics given?**
- **<http://www.hospitalcompare.hhs.gov>**

Example Quality/False Claims Enforcement Actions

- Redding Medical Center
 - \$54 million paid to resolve allegations that doctors conducted unnecessary heart procedures and operations on hundreds of patients
 - Alleged billing government health programs for tests and treatments that were not “necessary and reasonable”
 - Did NOT resolve the many private malpractice cases

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Our Lady of Lourdes Regional Medical Center**
 - **04/08: Lafayette General Medical Center pays \$1.8 million to settle \approx 100 malpractice cases filed by patients of a cardiologist alleged to have performed unnecessary procedures**
 - **Total of \approx \$15 million paid by Lafayette and Our Lady of Lourdes Regional Medical Center**
 - **Cardiologist scheduled for trial 08/08 for billing governmental and private insurers for more than \$2 million in unnecessary heart procedures. 76 patients, mainly angioplasties and stents.**

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Alleged:**

“LGMC knew – from reports of hospital employees and from reports generated by its own internal review processes – that a physician was performing unnecessary procedures at its hospital yet deliberately failed to address the problem.”

Federal Quality Improvement Measures: Current Issues (cont'd)

- **Enforcement action follows from a whistle-blower suite filed by a cardiologist who alleged that “another cardiologist was routinely endangering the health and safety of patients by subjecting them to unnecessary and inappropriate medical procedures”**

Potential Enforcement Consequences

- **Non-payment/recoupment**
- **Conditions of Participation deficiencies**
- **Exclusion from Federal payment programs**
- **Civil Penalties**
- **Criminal Penalties**

Potential Enforcement Consequences (cont'd)

- **State Licensing action**
- **Joint Commission action**
- **Private action**
 - **Non-payment**
 - **Cancellation of private provider agreements**
 - **Malpractice actions**
- **Effect on good will, reputation, professional recruitment**

Sources of Adverse Information

- **Incident reports**
- **Sentinel event reports**
- **Medical Staff Quality Review/
Focus Review**
- **Rumor**
- **Hospital Quality Data reporting**
- **Payment data review**

Sources of Adverse Information (cont'd)

- **Recovery Audit Contractor reviews**
- **Self-reported payment correction**
- ***Qui tam* actions**
- **Incident to investigations/
audits/surveys**
- **Self-disclosure**
- **Public web site postings**

Enforcement Trigger points

- **Abnormally high utilization**
- **Abnormally high number of incident reports/malpractice events**
- **Dips/atypical lows in quality indicators**

Hospital/Medical Staff Interface

- California Senate Bill 1325
- **The Legislature finds and declares that providing quality medical care in hospitals depends on the mutual accountability, interdependence, and responsibility of the medical staff and the hospital governing board for the proper performance of their respective obligations.**
- **The ... governing board of a hospital must act to protect the quality of medical care provided and the competency of its medical staff, and to ensure the responsible governance of the hospital in the event that the medical staff fails in any of its substantive duties or responsibilities. ... [T]hat final authority may only be exercised with a reasonable and good faith belief that the medical staff has failed to fulfill a substantive duty or responsibility in matters pertaining to the quality of patient care.**

Hospital/Medical Staff Interface

- Balancing Hospital obligations with Medical Staff obligations and protections
 - Medical staff has the professional resources and initial responsibility for quality of care issues
 - Hospital has its own institutional responsibilities
 - Medical staff peer review function has confidentiality privileges/obligations under law, Evidence Code §1157

Hospital/Medical Staff Interface: Example Scenarios

- Medical Director of rehab unit accused of admitting patients who do not meet rehab criteria and failing to see that patients are seen by their physicians on a regular basis.

Hospital/Medical Staff Interface: Example Scenarios (cont'd)

- Employee complaints of a physician's harassing behavior

Hospital/Medical Staff Interface: Example Scenarios (cont'd)

- Physician failure to document pre-existing conditions relating to “Never” events

Hospital/Medical Staff Interface: Example Scenarios (cont'd)

- Disclosure to patient of unanticipated outcomes

Hospital/Medical Staff Interface: Example Scenarios (cont'd)

- Physician who is rumored to not see patients on a regular basis (seen on unit, not directly meeting with patient, notes entered in medical record)(potential false claims in billing)

Thank you.

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