



## Quality of Care Medical Necessity and Reasonableness of Services

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### Topics for discussion

- Quality is the mission of all healthcare organizations but who is responsible for ensuring quality?
- How do you internally investigate a quality issue and who does it?
- What if your investigation reveals that the standard of care was not met or that procedures were not medically necessary?
- What liability can arise from substandard quality? How would the government approach the issue?
- What can healthcare organizations do to provide quality care and prevent these liabilities?
- What kinds of advice are clients looking for from their lawyers?

## Case study of a quality investigation

Call to the ethics action line:

A nurse calls and reports that a physician is performing medically unnecessary procedures and that the physician caused an unanticipated death. The nurse says that the physician is in the state's impaired physician program for alcohol abuse.

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## Internal investigation of a quality allegation

- What issues were raised?
  - Medical necessity
  - Standard of Care
  - Physician Behavior
- Should these issues be investigated?
- Who is responsible for acting on the results?
  - Medical Staff?
  - Compliance?
  - Legal?
  - The Hospital CEO?
  - Governing Board/Board of Directors?

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## Internal investigation of a quality allegation

- **Who directs the investigation? Who plays a supporting role?**
  - The physician who chairs the Department?
  - The Medical Executive Committee or Peer Review Committee?
  - The Chief Nursing Officer?
  - The Governing Board?
  - A hospital lawyer? External counsel? A lawyer for the Medical Staff?
  - A Nurse Auditor?
  - The Compliance Officer?

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## What facts are needed?

- Clinical review of the medical record referenced by the caller
- Complications by physician
- Volume of procedures by physician
- Sample of cases for chart review
- What safeguards is the hospital following to provide quality care and medically necessary services?
- Details on state program to oversee alcohol abuse
- Credentials file
- Prior peer review actions at the facility
- National Practitioner Data Bank reports showing peer review actions by other facilities
- Malpractice history
- Interviews with staff
- Current licensure status
- Prior complaints and incident reports (patients, staff, Ethics calls, other sources) and responses
- Media search

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## What standards should be used to analyze these facts?

- For standard of care issues, review charts using objective professional society criteria (where available)
  - American College of Cardiology and American Heart Association criteria for cardiac interventions; American College of Obstetrics and Gynecology standards for OB cases etc.
  - Use a clinical expert to help you decide what objective criteria are available
- For medical necessity issues, do chart review but also compare volume to national data
  - How many standard deviations from the mean? Why?

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## What not to do

- Fail to protect patients while the investigation is underway
- Usurp the authority of the hospital's peer review body
- Approach the investigation like defending a medical malpractice case
- Overlook reputational risks and False Claims Act risks
- Rely on the state to protect patients
- Rely on the patient consent form
- Conduct the investigation exclusively through interviews

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If you confirm the standard of care was not met

- Did you bill the payer?
- Has the peer review body taken appropriate action against the physician? What if they don't act?
- Did you report the matter to the state or other agencies? Did you report the physician or other caregivers to the state licensing bodies? Did you report to the data bank?
- Did you disclose to the patient?

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What theories of liability might be used by the government?

- Civil or criminal?
- Standard of care
  - Implied certification
  - Worthless services
- Medically unnecessary
  - Medicare coverage requirements
- OIG permissive exclusion authority
  - Failure to meet professionally recognized standards of care
- OIG mandatory exclusion authority
  - Convictions for patient abuse or neglect

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## How to prevent these issues from arising

- Develop an effective clinical quality system with strong Board oversight
  - Read the quality of care CIAs
- Train your Board on the OIG/AHCA Resource: *Corporate Responsibility and Healthcare Quality A Resource for Health Care Boards of Directors*
- Structure your Board with a majority of lay members
  - Train the lay members how to oversee quality and credentialing
  - Avoid overwhelming them with charts and graphs
  - Do talk about significant risks
  - Discuss evidence-based medicine/DMS core measures but also discuss unanticipated outcomes and medical necessity
- Develop a team approach – Quality, Compliance, Operations, Legal, Medical Staff