Implementation of a State Law – Mandated Physician Peer Review Process

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Overview

- Session Description:
  In response to the alleged inappropriate stent procedures for which St. Joseph’s in Baltimore entered into a CIA, Maryland’s state legislature enacted revisions to a state law on hospital and freestanding ambulatory care centers that mandates that the credentialing process include practitioner performance evaluation. The law specifically requires review of random cases (not just adverse outcomes) for all physicians and the review of the plan of care particularly in relation to procedures performed. The physician reviewers must be trained in the process and not associated with the case. This session will describe some of the challenges associated with implementation of this law in hospitals.

- Compare TJC Ongoing and Focused Professional Practice Evaluation requirements and the new state-mandated requirements
- Setting the parameters for implementation of revised processes including reporting to compliance committee
- Discussion of spectrum of compliance investigation initiation stemming from involvement in / notification from peer review process
Maryland Impetus

- St Joseph’s Medical Center (SJMC) in Towson, Maryland paid $22 million and entered into a Corporate Integrity Agreement (CIA) effective 11/5/2010
- Allegations resolved in the settlement include
  - Payment of kickbacks to a physician group under the guise of professional services agreements, in return for referrals of cardiovascular procedures, including cardiac surgery and interventional cardiology procedures
  - Above fair market value payments for services not rendered or that were not commercially reasonable relating to 11 professional services agreements with the same physician group
  - Payments received for medically unnecessary stents performed by a partner in physician group (who was later employed by SJMC) from January 2008 to May 2009

St. Joseph CIA Provisions

- Selected provisions that relate to physicians and quality of care / peer review / medical necessity

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<tr>
<th>Area</th>
<th>St Joseph’s Corporate Integrity Agreement Requirements</th>
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<td>Policies and Controls</td>
<td>- Code of Conduct</td>
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<td>- Requires Code of Conduct acknowledgement from all employees and all physicians with a St. Joseph financial relationship</td>
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<td>- Code of Conduct available to all other physicians and best efforts to obtain acknowledgement</td>
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<td>- Policies</td>
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<td>- Stark / Anti-Kickback</td>
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<td>- Medical Record Documentation</td>
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<td>- Quality Assessment and Performance Improvement program</td>
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<td>- Medical Staff Credentialing</td>
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<td>- Oversight of Cardiac Cath Laboratory – includes process for developing criteria for clinical appropriateness, benchmarking, reviewing competence, etc.</td>
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### St Joseph CIA Summary (cont’d.)

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| **Compliance Program Governance** | Maintain a Compliance Officer, Compliance Committee  
- Quarterly reports to the Governing Board  
- Maintain Physician Executive(s) responsible for oversight of medical staff  
  quality of care, including performance improvement, quality assessment,  
  patient safety, utilization review, medical staff peer review, medical staff  
  credentialing and privileging, and medical staff training and discipline  
- Quarterly reports to the Governing Board  
- Medical Director Cardiac Cath Lab  
- Quarterly reports to the Physician Executive and Compliance Officer |
| **Education and Training**  | General Training – two hours for employees and physicians with active staff membership  
- Arrangements Training – two hours for employees involved in negotiating and management of physician relationships  
- Specific Training – two hours for any person performing interventions in Cardiac Cath Lab  
- All training available to all other physicians and best efforts to encourage participation |
| **Monitoring**              | Create and maintain database of all physician arrangements  
- Process requires legal review of new contracts, tracking payments, tracking completion of service logs, monitor use of leased space  
- Quarterly review by Compliance Officer and report to Compliance Committee  
- Disclose suspected violations of Stark Law and repay overpayments |
| **Auditing (by external consultants)** | Peer Review - Initial systems review of medical staff peer review, credentialing and training creating recommendations  
- Annual reports on the implementation of the recommendations  
- Physician Arrangements – annual review of 25 arrangements and required policy adherence, including database, approvals, payments, logs, monitoring of space, and effective response to potential Stark issues  
- Cardiac Cath Procedures – annual review of 50 interventional procedures performed in the Cardiac Cath Lab for medical necessity and appropriateness |
In response to allegations of potentially unnecessary stent placements, Maryland Hospital Association convened the Necessary Care Work Group:

- Charged to identify oversight procedures and systems for monitoring and reviewing physicians’ practices
- Members were several hospital Chief Medical Officers and quality executives
- Reviewed hospital policies and resources from professional societies

January 2011 Published Guidelines to Ensure Appropriateness of Percutaneous Coronary Intervention (PCI) Procedures:

- References American College of Cardiology's Appropriateness Criteria for Coronary Revascularization
- General Guidelines
  - *An ongoing internal performance improvement process that reviews the quality and safety of patient care.*
  - *Participation in efforts to educate the public about the quality, safety and appropriateness of PCI procedures.*
Maryland Hospital Association (cont.)

- **Monthly** –
  - Review of a percentage of each PCI practitioner’s cases by a medical staff member who is credentialed in PCI, or by a designated multidisciplinary review committee with at least one medical staff member who is credentialed in PCI.
  - Appropriateness criteria to include:
    - Proper documentation of the indication for procedure;
    - Proper documentation of the procedure, to include degree and location of any obstruction; and,
    - That the procedure is appropriate to the level of obstruction and the patient's history, in accordance with the Appropriateness Criteria for Coronary Revascularization of the American College of Cardiology.

Maryland Hospital Association (cont.)

- **Quarterly** –
  - Review of overall program data (number of angiograms, procedures, outcomes, etc.), with a comparison to national benchmarks, by the medical director of the program and/or a designated multidisciplinary review committee.

- **Annually** –
  - Outside review by an independent expert entity of a percentage of each PCI practitioner's cases.
  - Sharing of these Guidelines with all PCI practitioners and staff working in the cardiac program.
Maryland Hospital Association (cont.)

Post-review:
- Further review of all questionable treatment by a designated multidisciplinary review committee, which determines the course of action to be taken with the individual practitioner (e.g., discussion of case, focused review of all of the practitioner's cases [prospective or retrospective], outside review, etc.).
- Documentation and maintenance of all review outcomes in the program's database, with reporting to the practitioner's medical staff department, as part of the ongoing or focused practitioner performance evaluation.

State Legislative Action – HB 286

- 2011 Legislative Session (January – April) many proposed bills
- House Bill 286 – An Act concerning Hospitals and Freestanding Ambulatory Care Facilities – Practitioner Performance Evaluation
  - condition of licensure,
  - establish a certain practitioner performance evaluation (PPE) process
  - analyze the results of the process
  - require the PPE process to include a review of care;
  - take into account the results of the PPE process for a member of the medical staff in a reappointment process
State Legislative Action – HB 286 (cont.)

- Practitioner Performance Evaluation (PPE) Process
  - Evaluates objectively the performance of each member of the medical staff
  - PPE process will include a review of care provided to patients at the hospital
  - Review of Care includes:
    - Undertaken for cases chosen at random and for cases with unexpected adverse outcomes
    - Based on objective review standards
    - Include a review of the appropriateness of the plan of care for the patient, particularly any procedures

- Review of Care conducted by members of the medical staff or external reviewers who:
  - Are of the same specialty as the member of the medical staff under review
  - Have been trained to perform PPE
  - Are not otherwise associated with the case under review

- Results of Review of Care are taken into account in the reappointment process
State Legislative Action – HB 286 (cont.)

Freestanding Ambulatory Care Facility – differences from hospital portion

- Conducted by [at least two] members of the medical staff
- [As appropriate] Are of the same specialty as the member of the medical staff under review
- Have been trained [in the policies regarding] to perform PPE
- [Review of care for solo practitioner conducted by external reviewer]

[a] indicates additions from previous information
[-a] indicates deletions from previous information

Draft Regulations – Hospital

Definitions

(7) "Medical staff” means:

- (a) A physician; or
- (b) A practitioner:
  - (i) Licensed under the Health Occupations Article; and
  - (ii) Designated as medical staff in the facility's bylaws, policies or procedures.

(9) "Unexpected adverse outcomes” means unanticipated negative outcome related to a patient's medical treatment and not related to the natural course of the patient’s illness or underlying disease condition.
Draft Regulations – Hospital

❖ Regulations generally mirror law
  ▪ [In conjunction with the standards of The Joint Commission for focused and ongoing professional performance evaluations], the hospital shall establish a practitioner performance evaluation process that objectively evaluates the performance of each member of the medical staff.
  ▪ Be undertaken for cases:
    ▪ (a) Chosen at random;
    ▪ (b) With unexpected adverse outcomes;

Draft Regulations – Freestanding Ambulatory

❖ Differences from hospital regulations
  ▪ [In conjunction with the standards of The Joint Commission for focused and ongoing professional performance evaluations, the administrator shall ensure that the facility] establish [es] a practitioner performance evaluation process that objectively evaluates the performance of each member of the medical staff includes a review of care which shall.
  ▪ Be undertaken for cases:
    ▪ (a) Chosen at random;
    ▪ (b) With unexpected adverse outcomes;
The Joint Commission Requirements

Medical Staff Chapter includes two types of Professional Practice Evaluation (PPE)

- Focused
  - Confirm competence when credentials suggest competence (i.e. initial appointment)
  - When questions arise during Ongoing PPE
  - Multiple methods are allowed
    - chart review,
    - monitoring clinical practice patterns,
    - simulation,
    - proctoring,
    - external peer review,
    - discussion with other individuals involved in the care of each patient

Ongoing PPE

- Continuously evaluate (i.e. more than once per year)
- Identify potential problems as soon as possible
- Fosters evidence-based privilege renewal process
- Multiple methods are allowed
  - Review of operative and other clinical procedure(s) performed and their outcomes
  - Pattern of blood and pharmaceutical usage
  - Requests for tests and procedures
  - Length of stay patterns
  - Morbidity and mortality data
  - Practitioner’s use of consultants
- Acquired through multiple methods including chart review, direct observation, monitoring of techniques used, interviews
Key Challenges

- **Interpretation**
  - In objectively evaluating the performance of “each” member of the medical staff -
    - What to do about low volume providers?
    - Are non-physician practitioners included in medical staff?
  - Review of care
    - How to choose sample size?
    - Do unexpected adverse outcome need to be attributed to a specific member of the medical staff (in order to be “chosen”)?
    - Do objective review standards need to be evidence based?
    - How to rate appropriateness of general plan of care of patient? Could a general scale of Standard of Care was met suffice?
    - For each procedure, is research for evidence based criteria required?

- **Review of care (cont.)**
  - Does review of care require chart review (v. TJC FPPE process which may not)?
  - Conduct Review of Care
    - If same specialty not present, is external review required?
    - What constitutes training to perform PPE?
    - Differences in review of care (was procedure necessary) versus traditional peer review (was mistake made)
  - Include in reappointment
    - Should all information OPPE, FPPE and new reviews of care be part of reappointment process?
Key Challenges

- Interaction between Compliance and the PPE Process
  - Is the entire PPE process included in the peer review privilege?
  - Should compliance have access to peer review privileged information?
  - If a potential issue arises during PPE, should compliance officer be notified? If so, when?
  - How to differentiate Attorney – client privilege for a compliance-related investigation v. Peer review privilege

Questions

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