The SIA: Overcoming Organizational Fear of Closure

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Objectives

- Using the Systems Improvement Agreement as a means to recover when your hospital is on a termination track following deficient CMS surveys.
- Learn from a case study: How to engage leadership in the quest for quality improvement.
- Discuss the use of subject matter experts to accelerate organizational adoption of best industry practices that comply with CMS Conditions of Participation.

The Scenario

CEO to CFO: I just received a letter that says we are going to lose our Medicare Payments. That will not matter will it?
CFO to CEO: We receive over 400 million in payments from them each year.
CEO to CFO: I probably should speak to the Governing Board about a process call a Systems Improvement Agreement.
The Systems Improvement Agreement

- A voluntary agreement between a provider and the Centers for Medicare & Medicaid Services (CMS).
- The provider is not meeting the Conditions of Participation (CoPs) for Medicare.
- Substantial improvement is needed for continued federal funding.
- A letter of termination has been sent or is imminent.
- An SIA suspends the termination process.

The Systems Improvement Agreement

- During the SIA, the hospital’s provider agreement remains in effect.
- A full validation survey is conducted at end of a timeline.
- If the hospital is found to be in substantial compliance with all CoPs, the SIA ends and the provider agreement remains in effect.
- If not, the termination process resumes.
- Appeals process.

The Systems Improvement Agreement

- SIAs are rare for hospital Medicare provider agreements.
- Each situation has unique elements.
- Contracts are customized.
- The SIA is legally binding.
- SIAs are administered at the CMS regional level.
  - 10 CMS regions
  - Division of Certification and Survey Operations
  - CQISCO (National Consortia for QI, Certification, and Survey Ops.)
Letter of Termination:
Provider of Hospital Services

Example of contents:
- The Medicare certification number.
- The date of the deficient survey.
- A list of Conditions that are not met.
- A position statement:
  - Previously identified systemic problems persist
  - Lack of governance
  - Threats to patient safety
  - Lack of capacity to provide adequate care
- Specific supporting details may be presented.
- The Statement of Deficiencies (2567).

Letter of Termination:
Provider of Hospital Services

Example of contents
- The date of decertification
  - Immediate jeopardy is 23 days
  - Normal termination is 90 days
- Payment for patients in-house on termination date.
- That a public notice will be published in the press
  - Required for provider of emergency services
- Process to apply for recertification following termination
- Appeal process
  - Prior to termination date
  - Refute findings in writing
  - Request in-person hearing before an administrative law judge of the Department of Health and Human Services

The Systems Improvement Agreement

Most hospitals have some survey deficiencies. What is different about a hospital that is in jeopardy?

The hospital is not meeting Medicare participation requirements
- Progressive decline in CMS survey results.
  - Condition-level deficiencies
  - Immediate jeopardy to patient safety
  - Repeated deficiencies
  - Plans of Correction not fully implemented
- Hospital is not meeting EMTALA obligations.
  - Complaint investigations
  - Self reported events
  - Restraint or seclusion deaths
The Systems Improvement Agreement

- What is different about a hospital that is in jeopardy?
- The hospital is underperforming on publicly reported quality measures
  - A wealth of quality data is available to regulators
  - Published benchmarks.
  - Patient experience survey: HCAPS
  - Healthcare-acquired infections: NHSN data
  - Claims data (administrative and abstracted)
  - Reimbursement-linked quality measures
    - Value-based purchasing
    - Hospital-acquired condition program
    - EHR meaningful use

Common Early Warning Signs

- Multiple complaint surveys with repeated findings
- High number of immediate jeopardies
- Inability to implement, measure and monitor corrective actions plans
- Minimal oversight of QAPI and service contracts by the Governing Board
- Insufficient credentialing and privileging for medical staff
- Unstable workforce - high use of traveler and agency nurses
- New building expansions
- Compliance with the Conditions of Participation not a high management priority

What is an Immediate Jeopardy

- 42 CFR §489.3 defines immediate jeopardy as “a situation in which the provider’s non-compliance with one or more of the requirements of participation has caused or is likely to cause, serious injury, harm, impairment, or death ...”
- Hospitals have only 23 days between the end of the survey and Medicare termination
- If the immediate jeopardy is not abated within that time, the hospital’s participation in Medicare is terminated.
The Systems Improvement Agreement

- Quality improvement is needed
  - Reported in the literature

Conclusion: Compared with hospitals in the U.S. states, hospitals in the U.S. territories have significantly higher 30-day mortality rates and lower performance on every core process measure for patients discharged after AMI, APP, and PFH. Eliminating the substantial quality gap in the U.S. territories should be a national priority.

Medicare Conditions of Participation

- Regulatory Standards
  - Rarely Change
- State Operations Manual – Interpretative Guidelines
  - Updated as Needed
  - Used by State agencies that are under contract to perform surveys and process the Plan of Correction.

Medicare Conditions of Participation: SOM

Appendix A - Hospitals

<table>
<thead>
<tr>
<th>Condition of Participation</th>
<th>Tag numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>§482.11 Condition of Participation: Compliance with Federal,</td>
<td>A-0020 through A-0023</td>
</tr>
<tr>
<td>State, and Local Laws</td>
<td></td>
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<tr>
<td>§482.12 Condition of Participation: Governing Body</td>
<td>A-0031 through A-0034</td>
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<tr>
<td>§482.13 Condition of Participation: Patient’s Rights</td>
<td>A-0115 through A-0122</td>
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<tr>
<td>§482.21 Condition of Participation: Quality Assessment</td>
<td>A-0263 through A-0315</td>
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<tr>
<td>and Performance Improvement Program</td>
<td></td>
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<tr>
<td>§482.22 Condition of Participation: Medical Staff</td>
<td>A-0338 through A-0364</td>
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<tr>
<td>§482.23 Condition of Participation: Nursing Services</td>
<td>A-0385 through A-0402</td>
</tr>
<tr>
<td>§482.24 Condition of Participation: Medical Record Services</td>
<td>A-0431 through A-0460</td>
</tr>
<tr>
<td>§482.25 Condition of Participation: Pharmaceutical Services</td>
<td>A-0480 through A-0511</td>
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</table>
### Medicare Conditions of Participation: SOM EMTALA

**Appendix V - Responsibilities of Medicare Participating Hospitals in Emergency Cases**

<table>
<thead>
<tr>
<th>Regulations</th>
<th>Interpretive Guideline</th>
<th>Tag numbers</th>
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<tbody>
<tr>
<td>§482.20, §482.29 (3)(m)(4), (1)</td>
<td>A-2436 through A-2442</td>
<td></td>
</tr>
</tbody>
</table>

- Complaint-driven process
- Investigation
- Civil monetary penalties are possible
- Includes all patients (not just federally-funded care)
The CMS 2567

- A Statement of Deficiencies from a CMS Survey
- Samples:
  - The Governing Body did not ensure all services offered and provided met the Medicare Conditions of Participation. Areas of noncompliance identified included: Patient Rights and Quality Assessment and Performance Improvement (QAPI).
  - Based on observation, document review and interview, the hospital governing body failed to ensure that contracted services were provided in a safe and effective manner.
  - Based on record review and interview the facility governing body failed to ensure that individuals providing patient care services were appointed members of the medical staff with approved, specific privileges.

Medicare Conditions of Participation

Most Frequently Cited Standards - Hospitals (Short Stay)

<table>
<thead>
<tr>
<th>Standard Tag</th>
<th>Tag numbers</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESTRAINT OR SECLUSION</td>
<td>A-0159 through A-0208</td>
<td>Patient Rights</td>
</tr>
<tr>
<td>IN SUPERVISION OF NURSING CARE</td>
<td>A-0395</td>
<td>Nursing Services</td>
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<tr>
<td>RESTRICTED CARE / SAFE SETTINGS</td>
<td>A-0444</td>
<td>Patient's Rights</td>
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<tr>
<td>EMPLOYEES WITH PRIVILEGES</td>
<td>A-0731</td>
<td>EMTUJA</td>
</tr>
<tr>
<td>PHYSICAL ADMINISTRATION</td>
<td>A-0742</td>
<td>EMTUJA</td>
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<td>NURSING SERVICES</td>
<td>A-0741</td>
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<td>PATIENT SAFETY</td>
<td>A-0746</td>
<td>Nursing Services</td>
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<tr>
<td>ADMINISTRATION OF DRUGS</td>
<td>A-0940</td>
<td>Nursing Services</td>
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<tr>
<td>INFECTION CONTROL PROGRAM</td>
<td>A-0949</td>
<td>Infectious Control</td>
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<tr>
<td>EMERGENCY SERVICES</td>
<td>A-1286</td>
<td>QA Program</td>
</tr>
<tr>
<td>NOTICE OF GRIEVANCE DECISION</td>
<td>A-0123</td>
<td>Patient’s Rights</td>
</tr>
</tbody>
</table>

Medicare Conditions of Participation: SOM Updates

- The CMS website - updated SOM
- SOM Appendix A Hospitals
- Review Transmittals located at the end of the document
- Recent changes are in red text
- Hospital must comply with the SOM that is in effect at the time of the validation survey.
### Medicare Conditions of Participation: SOM

**Example of an Update**

<table>
<thead>
<tr>
<th>Box #</th>
<th>Issue Date</th>
<th>Subject</th>
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</thead>
<tbody>
<tr>
<td>R1228/04</td>
<td>09-26-2014</td>
<td>Revisions to State Operations Manual (SOM), Appendix A. Survey, Protocol, Regulations and Interpreting Guidelines for Hospitals</td>
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### Medicare Conditions of Participation: SOM

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### Medicare Conditions of Participation: SOM

- State Operations Manual – Interpretative Guidelines
- References standards and guidelines from other federal agencies as well as professional organizations
  - Association of periOperative RNs (AORN)
  - Facilities Guidelines Institute (FGI)
  - Institute for Safe Medication Practices (ISMP)
  - Food and Drug Administration (FDA)
  - Agency for Healthcare Research and Quality (AHRQ)
Medicare Conditions of Participation: SOM
Life Safety Code

- Complete the appropriate Fire Safety Survey Report (Form CMS-2786);
- Use only qualified fire safety inspectors in the performance of these surveys.

Medicare Conditions of Participation: SOM
Life Safety Code

- Use only qualified fire inspectors.
- Complete the Fire Safety Survey Report
  - Form CMS-2786;

Medicare Conditions of Participation: SOM
Life Safety Code Waivers

- Categorical Waivers
  - August 2013 Categorical Waiver Letter
  - Unreasonable hardship on a large number of providers
  - Must:
    - Formally elect waiver and document decision
    - Notify Survey Team at entrance conference
    - Conform to requirements of waiver
    - CMS regional office approval is not required
System Improvement Agreement (SIA)

► What is it?
  ■ An SIA is a time-limited contractual arrangement between a Medicare-accredited healthcare organization and CMS.
► Why enter into?
  ■ Provides more time to fix deficiencies
  ■ Loss of Medicare payment would force most hospitals to close
► How long does it last?
  ■ An SIA typically lasts from 6 months to 1 year

Corporate Integrity Agreement (CIA)

► What is it?
  ■ The Corporate Integrity Agreement (CIA) is an enforcement tool used by the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS), to improve the quality of health care and to promote compliance to health care regulations.
► Why enter into it?
  ■ A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG’s agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs.
► How long does it last?
  ■ The average time frame for a CIA is typically 5 years
The Systems Improvement Agreement

- Can be initiated by CMS or the Hospital
- Must be executed before the termination date of the hospital's provider agreement.
- Will list the deficient Conditions of Participation per the termination letter.
- Will require the hospital to contract with a healthcare consulting firm that is acceptable to the CMS RO.
- Will describe the required expertise and reporting requirements of the external consultants.
- Will describe a timeline until the re-survey.

Requirements of an Integrity Agreement

**SIA**

- Obtain an independent consultant
- Submit the names and curriculum vitae for approval
- Acquire expertise in the development and implementation of an effective quality assessment and improvement program

**CIA**

- Hire a compliance officer/appoint a compliance committee
- Retain an independent review organization to conduct annual reviews
- Quality of Care CIA
  - OIG requires that the provider retain an independent quality monitor.

Both have the potential to impact your Medicare payments.
The Systems Improvement Agreement

- What are the characteristics of a failing hospital that may be a good candidate for an SIA?
  - Community support – hospital is needed
  - Highly committed governing body
  - Financial support
  - Large investment
  - Insight that change is necessary

The Systems Improvement Agreement

- Stakeholders
  - CMS
  - State Agencies
  - Hospital
    - Governing Body
    - Leaders
    - Medical Staff
    - Employees
  - Community at Large
    - Press
    - Elected Officials
    - Patients
  - Other Local, State, and Federal Regulators
  - Consultant Company

The Systems Improvement Agreement

- Transparency
  - The SIA documents are not available through CMS.
  - Terms may be communicated on the hospital’s website.
  - Reported in the press
  - The Medicare Survey statement of deficiencies is available.
    - Medicare website
    - Association of Health Care Journalists (HospitalInspections.org)
  - Plans of correction may be available online.
    - State agency website
The Systems Improvement Agreement

Transparency
- Hospital Website

The Systems Improvement Agreement

Transparency
- Local Media

The Systems Improvement Agreement

Transparency
- Medicare Survey Report
The Systems Improvement Agreement Case Study

SIA Getting Started

- External consulting firm is selected
  - Experience conducting SIAs
  - Expertise in patient safety and industry best practices
  - Experience in change management
  - Relationships with subject matter experts
  - Independent
  - Ethical
  - Knowledge of Conditions of Participation
Step One: Gap Analysis
Getting Started

- Lead onsite expert selected
  - Project Management
  - On-site visit coordination
  - Report Preparation
  - Document coordination
  - Liaison between hospital and regulators

Step One: Gap Analysis
Getting Started

- Third Party Subject Matter Consultants Selected
  - National Credentials
  - Available
    - Initial review
    - Monthly monitoring
  - Acceptable to Hospital and CMS RO
    - Not a competitor
    - Not a recent employee of hospital
  - Use of teams vs individual experts
  - Use of physician vs nursing experts
  - Knowledge of state regulations is helpful

The Systems Improvement Agreement Timeline
Step One: The Gap Analysis

- Consultants complete a Gap Analysis within 60 days after the hospital signs the third party agreement
  - Compare hospital operations to Medicare Conditions of Participation and best practices.
  - A root cause for each gap is identified.
  - Recommendations are developed to close the gap.
Step One: Gap Analysis
Getting Started

► Experts Requests
  ■ Documents
    ▶ Policies and Procedures
    ▶ Dashboards
    ▶ Previous Surveys
    ▶ Meeting Minutes
  ■ On-Site Schedule Developed
    ■ Interviews
    ■ Observations
    ■ Medical Record Review
    ■ Panel of subject matter experts

Case Study of Gap Analysis: 482.12(a): Medical Staff

► Condition of Participation:
  The governing body must:
  ■ Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;
  ■ Ensure the criteria for selection are individual character, competence, training, experience, and judgment;
  ■ Expert: Credentialing and Privileging

482.12 (a) Medical Staff Survey Findings

► The facility governing body failed to ensure that individuals providing patient care services were appointed members of the medical staff with approved, specific privileges;
► The facility failed to maintain the data in the credentials files that it had considered at reappointment regarding each physician’s recent experience in the requested privileges.
Credentialing and Privileging

Credentialing—the process of obtaining, verifying, and assessing the qualifications of a practitioner to provide care or services in or for a health care organization. Credentials are documented evidence of licensure, education training experience, or other qualifications.

Privileging—the process whereby a specific scope and content of a patient care services (that is clinical privileges) are authorized for a healthcare practitioner by a health care organization, based on an evaluation of the individuals credentials and performance.

Gap Analysis: 482.12(a): Medical Staff

Document Request
- Medical Staff Bylaws
- Medical Staff Rules and Regulations
- Recent 2567
- Recent Accreditation Survey
- Minutes
  - Governing Board
  - Medical Executive Committee
  - Credentials Committee
  - Peer Review Committee
  - Professional Review Committee
  - Departments of Medical Staff

Office of Inspector General Work Plan 2015

Oversight of hospital privileging
We will determine how hospitals assess medical staff candidates before granting initial privileges including verification of credentials and review of the National Practitioner Databank. Hospitals that participate in Medicare must have an organized medical staff that operates under bylaws approved by a governing body. (42 CFR § 482.22). A hospital’s governing body must ensure that the members of the medical staff, including physicians and other licensed independent practitioners, are accountable for the quality of care provided to patients. Robust hospital privileging programs contribute to patient safety. (OE; 06-13-00410; expected issue date: FY 2016)
Gap Analysis: 482.12(a): Medical Staff

On-Site Process
- Interviews
  - President and President-Elect of the Medical Staff
  - Chairs of the following committees:
    - Credentials
    - Peer Review
    - Professional Review
    - Chief Medical Officer
    - Chair of Governing Board

Documents
- Credentials Files
  - Random selection
  - Most recent approved

Identified Gaps: 482.12(a): Medical Staff
1. Nurse Mid-wife file contained no evidence of training to perform in the role of first assist but privilege was granted.
2. A provider's file lacked evidence that is required on the privilege sheet for continuation of privileges.
3. Physician's credential file contained at least five investigations regarding behavior yet re-appointment sheet indicated outstanding in the interpersonal skills category.
4. Re-appointment did not happen in the required time frame.
5. The medical staff peer review process is untimely and not comprehensive.

Identified Root Cause: 482.12(a): Medical Staff
1. Lack of reliable and consistent method to process new medical staff applications.
2. Lack of consistent process to review files for requested privileges at time of appointment and reappointment.
3. Process not monitored by leadership – hospital and medical staff.
4. Insufficient medical staff office resources
   1. Electronic system
   2. Qualified staff
5. No system in place to ensure peer review timeframes met targeted goal.
6. Governing board is unaware of problematic medical staff.
Recommendations: 482.12(a): Medical Staff

1. Ensure that the appointment and re-appointment contain the requirements for appointment is complete prior to credentials committee.
2. For re-appointment identify a mechanism to collect verification that provider performed required amount of requested privilege.
3. For files noted to have deficiencies work with Credentials Chair and appropriate Department Chair to develop an action plan.
4. Educate leadership, including board, on appointment and reappointment process and their responsibilities.
5. Include peer review timeliness as quality goal.

The Systems Improvement Agreement Timeline

Step One: The Gap Analysis

- Gap Analysis is approved by CMS Regional Office
- Consultants present Gap Analysis in an oral briefing to CMS and hospital
  - Highlights
  - Hospital has opportunity to challenge or accept.
  - Once accepted becomes foundation for the action plan

Step Two: The Action Plan

- Consultants complete a Action Plan within 60 days after the Regional Office approves the Gap Analysis
  - Recommendations to close the gap are specified
    - Stepwise
    - Concrete
    - Reflect industry practices and interpretive guidelines
    - Achievable within timeframe of SIA
    - Measurable
    - Milestones
  - The action plan is not an assessment of the capabilities of current leadership
    - Recommendations about specific individuals are not made
    - Insufficient resources made be identified as a root cause
The Systems Improvement Agreement Timeline
Step Two: The Action Plan

- Action Plan is approved by CMS Regional Office
- Consultants may present Action Plan in an oral briefing to CMS and hospital
  - Highlights
  - Hospital has opportunity to challenge or accept.
    - Once accepted becomes hospital’s implementation plan

Action Plan: 482.12(a): Medical Staff

Recommendations:
- Ensure the appointment and re-appointment process requirements for appointment is completed prior to credentials committee.
- For re-appointment clarify the mechanism to collect verification that provider performed work at amount of requested privileges.
- For those that have deficiencies work with the services Chair and appropriate Department Chair to develop an action plan.
- Educate leadership, including board, on appointment and re-appointment process.

Action:
- Develop a checklist that contains all the requirements for appointment and re-appointment.
- Develop a mechanism to collect verification such as procedure codes.
- Consider shorter timeframes for re-appointment.
- Denial of privileges.
- Educate department chairs on how to receive a file for appointment or re-appointment.

Measurement: 482.12(a): Medical Staff

1. 100% of the credentials checklist for initial appointment will be completed prior to credentials committee for 3 consecutive months by onsite review.
2. Letter is sent 100% of the time when insufficient data is present to grant a privilege by onsite review.
3. 100% of the credentials files will have a department chair signature and date indicated prior to the committee.
4. Board minutes reflect discussion of medical staff appointments before approval.
The Systems Improvement Agreement Timeline

Step Three: Monitoring

- Monthly monitoring until validation survey
- Onsite lead expert
- Subject matter experts
  - Panel of subject matter experts maintain objectivity & independence.
  - Hospital must hire implementation consultants from another source.

Cyclical process
1. On-site visit schedule.
2. Document request.
3. On-site visits performed.
4. Subject matter experts prepare monitoring report.
5. Monitoring report sent to CMS regional office.
6. CMS Regional Office reviews monitoring report.
7. Hospital acts on findings.

Step Four: Validation Survey

- Validation survey is performed
  - Monitoring reports show steady progress.
  - Most of the action plan has been completed.
  - The survey window per the SIA is ending or near.
  - The RO may ask the third party consultants if the hospital is survey-ready.
  - The survey is unannounced per statute.
  - The survey is performed by the state agency
  - The RO approves the survey findings (2567)
  - The survey finds are released to the hospital with the RO’s determination
Group Case Study:

§482.30 Condition of Participation: Utilization Review

- The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.
- A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy.
- The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of:
  - (i) Admissions to the institution;
  - (ii) The duration of stays; and
  - (iii) Professional services furnished including drugs and biologicals.
- Review of admissions may be performed before, at, or after hospital admission.

Why Would a Compliance Officer Care?

- Medicare and Medicaid only cover costs that are reasonable and necessary for the diagnosis or treatment of illness or injury.
- A grand jury indicated a Michigan hospital based on failure to properly investigate medically unnecessary pain management procedures performed by a member of its medical staff.*

* Source: The Health Care Director's Compliance Duties: A Continued Focus on Detection and Enforcement
Survey Findings: §482.30 Condition of Participation: Utilization Review

- Utilization Review Committee has not met according to UR Plan.
- UR Plan has not been evaluated and updated in 2 years.
- Vacancy in Director of Case Management position.
- No consistent dashboard that contains indicators identified in the UR plan.
- No concurrent review of patients in the Emergency Department prior to admission decision.

Step One: Gap Analysis

- What qualifications would you look for in the subject matter expert?
- What documents would you expect the expert to request prior to the on-site visit?
- Who would the expert want to interview?
- What documents would the expert want to review while on-site?
- What gaps will the expert likely find?

Step Two: Action Plan

- What would you recommend as an action plan?
- How would you measure compliance to the action plan?
Tips for Success

Hospital
- Sustain highly committed board
- Maintain financial support
- Oversee SIA process
- Encourage transparency
- Evaluate internal leaders
- Assess resource gaps
- Cautiously use interim directors and managers
- Oversee internal consultants
- Make system changes

Tips for Success

Hospital
- Become a culture of change
- Guide to culture of safety
- Enforce a code of conduct
- Require accountability
- Educate board members about quality and compliance
- Engage medical staff
- Support a learning environment
- Improve teamwork and communication
- Build a stable workforce
- Become resilient

Tips for Success

Hospital
- Keep focus on compliance
- Prioritize needed changes
- Use rapid performance improvement processes
- Institute new structures
- Remove barriers
- Prevent slippage with progress
- Keep to the timeline
- Develop sustainable improvements
Tips for Success

- Prevention is the best strategy
  - Investigate self-reported events promptly
    - Perform root cause analysis
  - Develop action plan
  - Monitor for sustainability

- Recognize patterns of non-compliance
  - Monitor history of regulatory deficiencies
  - Increase intensity of corrective action plans

- Improve publicly reported quality measures
  - Monitor performance compared to benchmarks
  - Adopt strategies to continuously improve

- Adopt patient safety practices accepted by the industry
  - Continuous learning environment

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