901: CMS OVERSIGHT AND ENFORCEMENT OF SAFETY AND QUALITY STANDARDS

HCCA 6TH ANNUAL
HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE

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PRESENTATION OVERVIEW

- Rules Governing Hospital Quality: Medicare Conditions of Participation (CoP), Joint Commission Standards and State statutes and regulations
- Governing Board Responsibilities Under Medicare CoP
- Quality and Patient Experience
  - Quality Assurance and Performance Improvement (QAPI) Programs
- CMS / State Survey Process
- Recent CMS Systems Improvement Agreement (SIA) Actions
- Practical Advice for Governing Boards for Quality and Safety Oversight

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RULES GOVERNING HOSPITAL QUALITY AND SAFETY

Hospitals are governed by a number of rules including: Medicare Conditions of Participation (CoP), Joint Commission standards and State statutes and regulations.

- In order to participate in the Medicare program, hospitals must meet all Medicare Conditions of Participation (CoP).
- Hospitals can be accredited for the Medicare program via a State survey or it can be accredited and deemed to meet Medicare requirements by a CMS-approved Accreditation Organization (AO).
- The Joint Commission (TJC) is a CMS-approved AO and most hospitals in the United States are deemed to meet Medicare requirements through the Joint Commission survey and certification process.
- Although most hospitals are accredited and certified via The Joint Commission triennial accreditation / survey process, all Medicare participating hospitals must at all times also be in compliance with all Medicare Conditions of Participation (CoP).
  - Compliance with Medicare CoP also requires full compliance with the Emergency Treatment and Labor Act (EMTALA), which requires all Medicare hospitals to screen and treat all people presenting at the hospital's emergency room, regardless of ability to pay.
- Additionally, hospitals must also be in compliance at all times with state rules and regulations governing acute care hospitals.
- Even if a hospital has current accreditation, it may be inspected and surveyed at anytime by CMS or a State health agency on behalf of CMS, to determine whether it is still in compliance with all Medicare CoP and State statutes and regulations..

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MEDICARE CONDITIONS OF PARTICIPATION (COP)

Hospitals are required to be in compliance with the federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare / Medicaid payment.

- There are 22 main "conditions of participation." Each "condition" contains several sub-parts or "standards" that further delineate how a hospital is to organize or fulfill a particular condition. *42 CFR §482*

• **Compliance with federal, state and local laws**	• **Utilization Review**
• **Governing Body**	• **Physical Environment**
• **Patient's Rights**	• **Infection Control**
• **Emergency Preparedness**	• **Discharge Planning**
• **Quality Assessment / Performance Improvement (QAPI)**	• **Organ Tissue & Eye Procurement**
• **Medical Staff**	• **Surgical Services**
• **Nursing Services**	• **Anesthesia Services**
• **Medical Record Services**	• **Nuclear Medicine Services**
• **Pharmaceutical Services**	• **Outpatient Services**
• **Radiologic Services**	• **Emergency Services**
• **Laboratory Services**	• **Rehabilitation Services**
• **Food and Dietetic Services**	• **Respiratory Services**

- Hospitals are also required, under Conditions of Participation, to be in full compliance with the Emergency Medical Treatment and Labor Act (EMTALA), which generally requires hospitals to provide screening and necessary emergency treatment to all people who present to a hospital's emergency room for treatment or who are in active labor.

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GOVERNING BOARD RESPONSIBILITIES UNDER MEDICARE COP

The Medicare Conditions of Participation (CoP) views the hospital's Governing Body as being ultimately responsible for the quality and safety of health care services provided at the hospital.

- Medicare CoP provides that: *"There must be an effective governing body that is legally responsible for the conduct of the hospital. 42 CFR §482.12*
- Medicare CoP assigns the Governing Body oversight over:
  - **Medical Staff:** Medical Staff appointments, Medical Staff bylaws, rules and regulations, Medical Staff oversight over quality of patient care, and use of "telemedicine" by the Medical Staff.
  - **CEO:** Appointment of a Chief Executive Officer (CEO).
  - **"Care of Patients":** Ensuring that 1) every patient is under the care of a doctor on the Medical Staff; 2) patients are only admitted upon the recommendation / referral of a qualified member of the Medical Staff; and 3) there is a qualified Medical Staff physician on duty or on call at all times.
  - **Institutional Plan and Budget:** Governing Body must approve a budget and operating plan that is prepared according to generally accepted accounting principles as well as a three-year capital spending plan.
  - **Contracted Services:** The Governing Body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable Conditions of Participation and standards for the contracted services.
  - **Emergency Services:** If the hospital has an emergency department or provides emergency services, the Governing Body must ensure that the hospital is in compliance with all Medicare CoP regulating emergency services. 42 CFR § 482.55.

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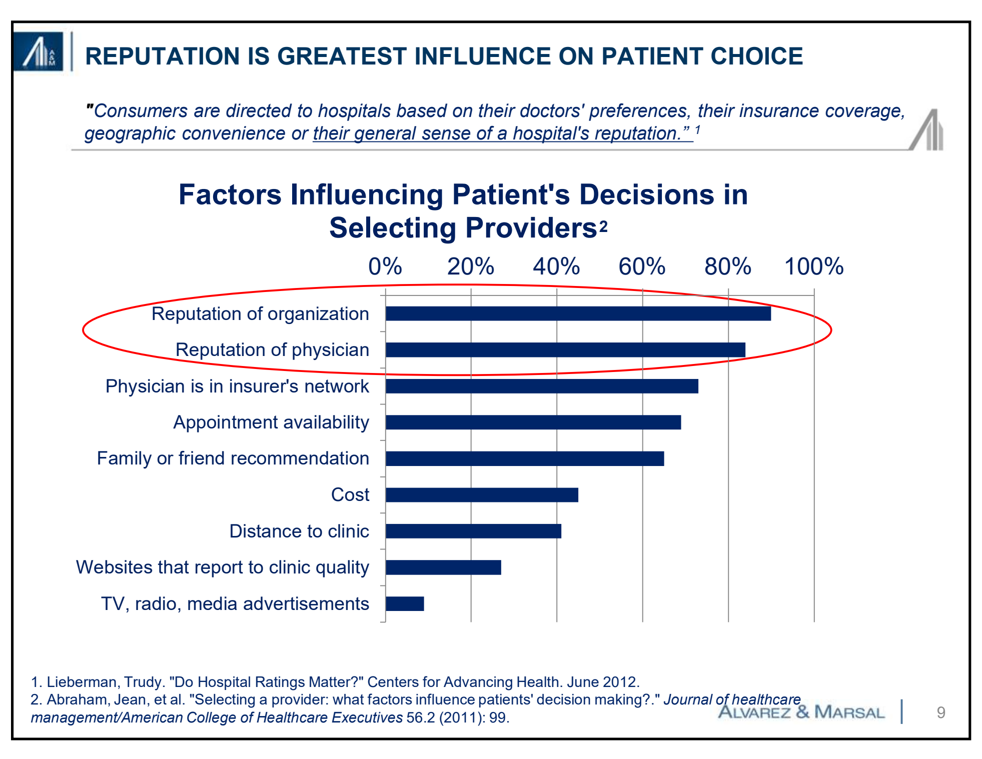

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HOSPITAL GOVERNING BOARD OVERSIGHT OF QUALITY & SAFETY

Quality will continue to drive the agenda of healthcare reform. Healthcare organization leaders must prioritize the quality agenda.

- Public policy now mandates transparency and increased accountability regarding safety and quality of patient care in hospitals.
- Standard measures, benchmarks and reporting tools are widely available to assist hospitals in the development, tracking and continuous improvement of care quality and safety at every point in the delivery system.
- CMS expects all hospitals to have a fully functioning Quality Assessment and Performance Improvement (QAPI) program to serve a "self-policing" and "self-improvement" role for patient protection and regulatory compliance.
- A hospital's QAPI program must be hospital-wide, data-driven, and designed to increase patient safety and continually improve the quality of care provided within the organization. 42 C.F.R § 482.21
- The hospital's governing body must ensure that the QAPI program reflects the complexity of the hospital's organization and services, that it involves all hospital departments and services (including services under contract or arrangement) and that the program focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

Medicare CoP requires that a hospital's QAPI program meet the following five (5) elements:

- ***Scope:*** Must include an ongoing program that shows measurable improvement in evidence-based indicators that will improve health outcomes and identify and reduce medical errors. The QAPI must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.
- ***QAPI Data:*** Must incorporate quality indicator data including patient care data and must use the data collected to: (i) monitor the effectiveness and safety of services and quality of care; and (ii) identify opportunities for improvement and changes that will lead to improvement. Frequency and detail of data collection must be specified by the hospital's governing body.
- ***QAPI Activities:*** Must set priorities for QAPI performance improvement activities that: (i) focus on high-risk, high-volume, or problem-prone areas; (ii) considers the incidence, prevalence, and severity of problems in those areas; and (iii) affect health outcomes, patient safety, and quality of care. QAPI program performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital. A hospital must take actions aimed at performance improvement and, after implementing those actions the hospital must measure its success, and track performance to ensure that improvements are sustained.
- ***QAPI Performance Improvement Projects:*** As part of its QAPI program, a hospital must conduct performance improvement projects. The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.
- ***Executive Ownership of QAPI:*** The hospital's governing body must ensure that: (i) a QAPI program is established and maintained; (ii) the hospital's priorities for improved quality of care and patient safety are met; (iii) clear safety expectations are established; and, (iv) adequate resources are allocated to the QAPI.

BOARD OVERSIGHT OVER QUALITY AND SAFETY METRICS

Hospital boards and quality committees should track key quality indicators much in the same way that they track key financial indicators .

House-wide / Organization-wide Metrics

- Volume
- Finance
- Operations
- Governing Board / Governing Body
- Transfusions
- Dietary Performance
- Employee / Staffing
- Environmental Services
- HIM / Medical Records
- Case Management
- Medical Staff Services
- HIM Medical Records
- Infection Prevention
- Medical Staff Services
- Nursing Performance
- Patient Satisfaction / Patient Rights
- Patient Safety Indicators
- Pharmacy Performance
- Utilization Review / Management

Department / Service Line Level Metrics

- Anesthesia Performance
- Cancer / Oncology
- Cardiology / Heart Surgery / Cardiac Procedures
- Dermatology Performance
- Emergency Department Performance
- Gynecology Performance
- Medicine Services Performance
- Medicine Services Critical Care Performance
- Obstetrics Performance
- Pathology Performance
- Pediatrics Performance
- Physical Medicine & Rehab Performance
- Psychiatry / Behavioral Services Performance
- Radiology Performance
- Respiratory Therapy
- Surgery / Peri-Operative Services (Inpatient / Outpatient)

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QUALITY DASHBOARDS AND BALANCED SCORECARDS

Hospital boards and quality committee should track key quality indicators much in the same way that they track key financial indicators.

Sample Board Dashboard	Below Target	Meeting Target	Exceeds Target			
CULTURE	**Benchmark**	**FY Target**	**FY 06 QTR 1**	**FY 06 QTR 2**	**FY 06 QTR 3**	**FY 06 QTR 4**
Employee Turnover Rate (Annual)	.5%/month	2.50%	2.41%	2.84%	2.79%	3.00%
RN Vacancy Rate	1.00%	8%	18.00%	10.00%	5.00%	7.00%
PREVENTING HARM (Safety)	**Benchmark**	**FY Target**				
Falls with injury **(Quarterly)**	0	5 TO 10	15	18	10	3
Medication Errors (ADEs) Category E-I	.025/1000 doses	2/1000 doses	3.5	5.0	4.0	1
Central Line Infections Rate (Critical Care Units)	0	3 TO 5	2	6	0	0
Ventilator Associated Pneumonia	0	1 case per quarter	0	1	5	1
Pressure Ulcers	0	10 to 15	40	30	15	12
CLINICAL QUALITY	**Benchmark**	**FY Target**				
EVIDENCE-BASED CARE % OF PATIENTS RECEIVING ALL REQUIRED ELEMENTS						
Acute MI	100%	90-95	98%	98%	97%	95%
Pneumonia	100%	80-90	89%	88%	82%	79%
Congestive Heart Failure	100%	90-95	98%	93%	94%	97%
Surgical Infection Prevention Protocol	100%	100	96%	98%	98%	98%
Mortality Rate (HSMR)	40	80 to 85	101	84	84	60
FINANCIAL HEALTH	**Benchmark**	**FY Target**				
Cost/discharge	$4,200	$5,500	$4,900	$5,100	$7,000	$6,000
Days Cash On Hand	180 days	80-90	91	80	67	82

Institute for Healthcare Improvement 2007 Funded by the Office of Rural Health and Washington's Department of Health

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POTENTIAL METRICS - MONTHLY QUALITY DASHBOARD

Dashboard metrics should emphasize those measures that can drive quality improvements.

Anesthesia

- Anesthesia events / complications / deaths

Blood Transfusion

- Transfusion reactions

Emergency Department

- Volume by date / hour
- Conversion rate to admission
- ED LWOBS (Left without being seen) / LWOBT (Left without beginning treatment) / Left AMA
- Wait Times / Patient boarding times

Infection Control / Prevention

- SSI / CAUTI / CLASBI / HAI / Nosocomial / BSI MDROs
- Reportable Diseases
- Surveillance Activities
- Hospital Staff Immunizations

Laboratory

- Lab Errors / Critical Values Reporting
- Infectious Blood Reporting

Labor & Delivery / NNICU

- Volume and ADC / C-Section Rate / C-Section Infections / VBAC Rate

Medical Staff

- Current staff breakdown (Active / Associate / Courtesy / House, etc.)
- Appointments / Re-Appointments
- OPPE/FPPE (Ongoing/Focused Professional Practice Evaluation) statistics
- Sanctions Issued – Number and Description

Patient Safety

- Mandatory and Voluntary Cases Reported to State / CMS / Joint Commission
- “Never Events” / Sentinel Events
- Patient Grievances – Volume and Type
- Patient Restraints – Number and Type

POTENTIAL METRICS - MONTHLY QUALITY DASHBOARD (CONT’D)

Dashboard metrics should emphasize those measures that can drive quality improvements.

Medical Records

- Completion Rates
- Accuracy Reviews
- History & Physical (H&P)
- Operative Notes
- Discharge Notes Completion
- Nursing
- Staffing data
- Patient Acuity
- Average Daily Census (ADC) by Major Units
- Verbal Orders – Number and Type

Peri-Op / Surgical

- Surgical Volumes (Inpatient and Outpatient)
- Surgical Deaths & Complications
- Surgical Infection Rates

Pharmacy

- Medication Errors
- Prescriptions Issued / Administered
- Near Misses / Medication Management – Interaction Issues

Radiology

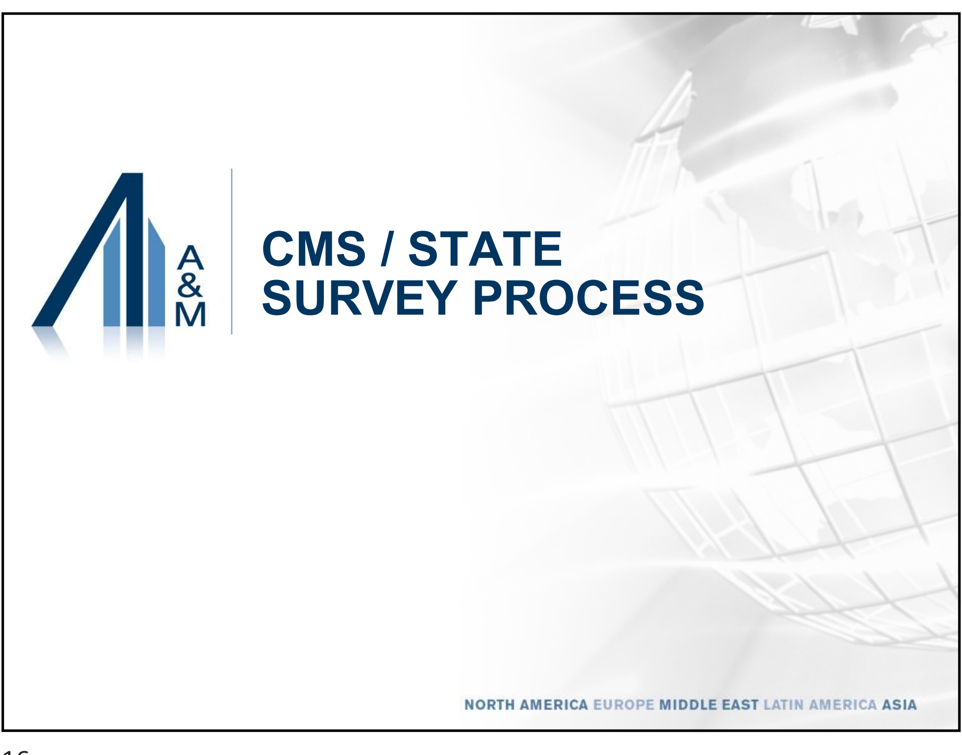
- Safety inspections
- Over-reads
- Staff radiation exposure

Utilization Review / Management

- Length of Stay (LOS)
- One Day Stays / Observation Stays
- Discharge Planning
- Re-Admissions

Contract Services

- Contract Quality Indicators



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CMS / STATE SURVEY PROCESS

CMS and State regulatory agencies do periodic and unannounced, on-site surveys of hospitals to validate a hospital's compliance with Medicare Conditions of Participation (CoP)

- Hospital surveys are used by CMS to assess a hospital's compliance with federal and state health, safety, and quality standards. These standards, such as the CoP are designed to ensure that all patients receive safe, quality care and services.
- All hospital surveys are unannounced.
- There are four types of CMS / State surveys:
  - Initial Certification
  - Recertification
  - Substantial Allegation (Complaint)
  - Revisit/Follow-Up Surveys
  - Sample Validation.
- Medicare participating hospitals are also subject to complaint surveys in response to substantial allegations of noncompliance.
  - For example, a patient complaint to CMS or in Texas DSHS about the care received by the patient (e.g., quality of nursing care, whether the hospital's emergency room provided proper screening and treatment) may trigger a complaint survey.
- If a hospital is found to be NOT in compliance with all Medicare CoP, CMS can initiate decertification proceedings to remove the hospital from the Medicare program.

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3 TYPES OF CMS SURVEY FINDINGS

There are generally three levels – from most severe to least severe – of CMS / State survey findings: Immediate Jeopardy, Condition Level and Standard Level.

- **There are generally three types of CMS survey findings:**
  - Immediate Jeopardy
  - Condition Level
  - Standard Level.
- **"Immediate Jeopardy"**
  - 42 CFR 489.3 defines immediate jeopardy (IJ) as *"a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death"* to a patient or resident.
- **Condition Level**
  - There is a single requirement out of compliance which is of such magnitude as to result in noncompliance with the entire Condition (degree). Many of the requirements and / or standards within the Condition are found out of compliance (manner).
- **Standard Level**
  - Any noncompliance with any requirement / tag within a standard, is standard level noncompliance.

"IMMEDIATE JEOPARDY" FINDINGS

A CMS / State survey finding of "Immediate Jeopardy" can put a hospital on a "fast-track", 23 day termination process to remove the hospital from the Medicare program.

- **Immediate Jeopardy:** Medicare defines "immediate jeopardy" to mean "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 CFR §489.30.
- There are generally three components that CMS / State looks to in making a finding of "Immediate Jeopardy": Harm, Immediacy and Culpability.
  - **HARM**
    - Actual - Has actual harm occurred? Does the harm meet the definition of immediate jeopardy? Or
    - Potential - Is there likelihood for potential harm? Does the potential harm meet the definition of immediate jeopardy?
  - **IMMEDIACY**
    - Is the actual or potential harm likely to occur in the very near future?
  - **CULPABILITY**
    - Did the entity know or should have known about the situation?
- A finding of "Immediate Jeopardy" puts a hospital on a fast-track, 23 day track to be terminated by the Medicare program unless through a corrective action plan submitted by hospital, which is validated by the State / CMS on resurvey, the hospital can convince CMS / State to remove the IJ finding.

"CONDITION LEVEL" AND "STANDARD LEVEL" DEFICIENCIES

The decision as to whether there is compliance with a particular Medicare CoP depends upon the manner and degree to which the provider satisfies the various standards within each condition.

- **Condition Level or Standard Level Noncompliance:** When a surveyor finds noncompliance with a Medicare CoP the determination of whether a lack of compliance is at the Standard or Condition level depends upon the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the lack of compliance.
- **Condition Level Deficiency:** A deficiency at the Condition level may be due to noncompliance with requirements in a single standard or several standards within the condition, or with requirements of noncompliance with a single part representing a severe or critical health or safety breach. Even a small breach in critical actions or at critical times can cause injury to a patient, and therefore represents a critical or severe threat.
- **Standard Level Deficiency:** A deficiency is at the Standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.
- **Termination:** A Condition Level deficiency, left uncorrected by Plan of Correction (POC) which must be reviewed and accepted by the State / CMS, could still result in the hospital's termination from Medicare within 90 days.

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MOST COMMON CMS "IMMEDIATE JEOPARDY" CITATIONS

Most commonly cited Medicare CoP IJ violations found on surveys involved: violations of: patient rights and unsafe care settings, adequacy of nursing practice, and governing board oversight.

- **Patient Rights, Restraints and Seclusion:** A hospital must protect and promote each patient's rights. Restraints and seclusions of patients are only to be used according to the strict protocols set forth in the Medicare CoP.
- **Nursing Services:** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.
- **Registered Nurses:** A registered nurse must supervise and evaluate the nursing care for each patient.
- **Governing Body:** There must be an effective governing body that is legally responsible for the conduct of the hospital.
- **Environment of Care:** The patient has the right to receive care in a safe setting.
- **Surgical Services:** If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.
- **Pharmacy:** The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

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SYSTEMS IMPROVEMENT AGREEMENTS (SIA)

CMS has recently begun the use of System Improvement Agreements (SIAs) for hospitals.

- In the past, "Immediate Jeopardy" citations led to CMS terminating those hospitals if acceptable corrections weren't in place within 23 days.
- To avoid terminating certain hospitals, particularly essential community providers, CMS has recently increased the use of "System Improvement Agreements" (SIAs) for hospitals. Use of SIAs were typically reserved for skilled nursing, long term care facilities and organ transplant programs, but have increasingly been used in the acute care hospital setting.
- SIAs include a structured approach and timeline for getting provider organizations back into compliance with CoPs, up to and including external oversight.
- SIA's typically entail the retention of a "monitor" to oversee corrective action at the hospital and act as a regulatory liaison between the hospital and CMS.
- The duration of these SIAs has ranged from 12 to 18 months.
- Reasons for imposing the SIAs have included: non-compliance with CoP regarding in emergency services, psychiatric services, telemetry and nursing services.

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PRACTICAL ADVICE FOR GOVERNING BOARDS ON QUALITY / SAFETY

Hospital must adopt a "Culture of Safety and Quality" at all levels. Quality patient care is a value driven from the top of an organization and embraced by all to become culture.

- First focus must always be on quality patient care and not margin or financial performance.
  - *You can't financially restructure your way out of a quality / safety problem.*
- Strong leadership matters at all levels throughout an organization.
- Organization must function as a unified whole. Departments and service lines cannot operate as independent silos.
  - "Best practices" must be shared across the organization and organization-wide standardization of quality and safety processes must be pursued.
- Hospitals must have transparency in reporting adverse safety events and quality issues at all levels (senior management, medical staff, governing board, regulators).
- Quality and safety metrics must be comprehensive and timely reported to all stakeholders including governing board.
- Communication must be effective up / down and across the organization.
- Focus on employee engagement to increase patient experience / patient satisfaction.
  - Turnover, high vacancy rates and high use of temporary / traveler personnel must be quickly addressed.
- A culture of complacency, acceptance of "status quo", lack of ownership cannot not be tolerated.

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PRACTICAL ADVICE FOR GOVERNING BOARDS ON QUALITY / SAFETY

Hospital must adopt a "Culture of Safety and Quality" at all levels. Quality patient care is a value driven from the top of an organization and embraced by all to become culture.

- Ask thoughtful questions / appropriately challenge quality data with the same level of scrutiny you would examine financial performance.
- Always be on the lookout for "weak signals."
  - A "weak signal" is an indication of a possible emerging issue.
  - e.g., a recurrent type of safety episode; problems with nurse recruitment and missed shifts; uptick in patient complaints and grievances.
- Monitor a comprehensive set of key operating and quality metrics to identify trends:
  - Increasing turnover rates in personnel which may undermine appropriate level of patient care.
  - Increasing vacancy rates particularly in middle management, nursing and key clinical services which may create gaps in performance, oversight or support of patient care.
  - Declines in patient satisfaction may indicate systemic failures in care.
  - Any shifts in level of medical staff engagement or satisfaction.
  - Decreases in quality indicators – hospital-acquired infection, fall rates.
  - Negative trends in throughput (e.g. dwell times, turnaround times).

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- Peter Urbanowicz is a Managing Director and the Co-Head of Alvarez & Marsal (A&M) Healthcare Industry Group. An experienced corporate officer, board member, presidential appointee, restructuring consultant and attorney, he has built and led highly functioning management teams and improved the financial performance and operations of leading healthcare organizations.
- Mr. Urbanowicz returned to A&M in 2019 after serving as the Chief of Staff to Alex M. Azar II, the Secretary of the United States Department of Health and Human Services (HHS). As HHS Chief of Staff, Mr. Urbanowicz functioned as the department's chief operating officer and was responsible for coordinating all of HHS' agencies and staff divisions. Mr. Urbanowicz also served as HHS Deputy General Counsel during the administration of President George W. Bush where he was part of the team that drafted the historic legislation creating the Medicare Part D drug program and Medicare Advantage plans.
- Mr. Urbanowicz currently assists boards of directors, management, investors and lenders of health care organizations facing regulatory, financial or operating challenges. He has guided organizations through difficult compliance issues and government investigations, while providing support on governance, operations and financial improvement. He served as the federally-approved monitor for Parkland Hospital in Dallas, Texas and directed efforts to reform the safety net hospital's quality and patient safety programs.
- Clients have included healthcare providers, payors and suppliers and engagements have covered: Medicare Advantage plan, Medicare Prescription Drug Plan (PDP) and Medicaid managed care plan acquisitions, operations and compliance; pre and post-acquisition support for private equity funds; corporate governance and board support; health care compliance program organization and support; internal and government investigations; negotiating and structuring government settlements and restructuring debt.
- Earlier in his career, Mr. Urbanowicz served as Executive Vice President, General Counsel and Secretary of Tenet Healthcare Corporation (NYSE: THC). Prior to his service as HHS Deputy General Counsel, Mr. Urbanowicz was a partner in the law firm of Locke, Liddell & Sapp LLP. Prior to his recent HHS service, Mr. Urbanowicz was a Managing Director at A&M and headed the firm's healthcare regulatory practice.
- Mr. Urbanowicz earned his bachelor's and law degrees from Tulane University. He is an elected member of the American Law Institute and is a member of the bars of the District of Columbia, the State of Louisiana and the United States Supreme Court.

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