REGULATORY & ACCREDITATION: INTERSECTION WITH QUALITY

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March 14, 2024

GREATER NEW YORK HOSPITAL ASSOCIATION & UNITED HOSPITAL FUND

CLINICAL QUALITY FELLOWSHIP PROGRAM

Disclosure Slide

- Dr. Baruch Fertel has no conflicts to report.
- Ms. Hillary Jalon has no conflicts to report.

Session Objectives

- Describe various organizations, including CMS, State Health Departments, and regulatory and accrediting bodies in their involvement in assuring quality at healthcare organizations
- Attempt to demystify the survey process

Agenda

- Setting the Stage
- Survey Types
  - Licensure
  - Complaint Allegation
  - Accreditation
- What Happens after Surveys?
  - Requirements for Improvement/Deficiencies
  - Validation Surveys
- Important Lessons
- **Group Exercise**: Elopements

SETTING THE STAGE

Polling & Open Discussion

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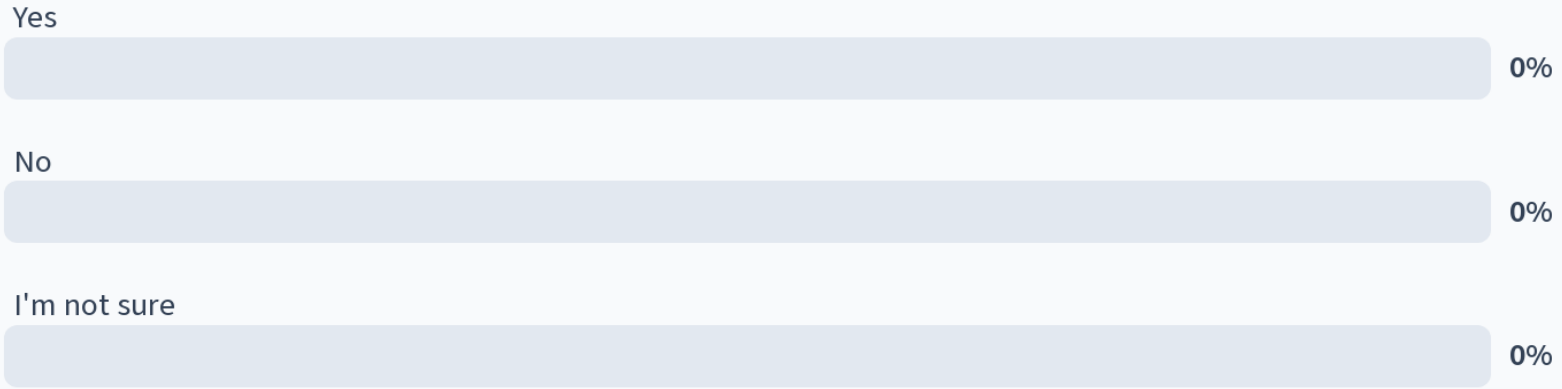
CLINICAL QUALITY FELLOWSHIP PROGRAM

Have you been involved in a regulatory/accreditation survey at your healthcare organization?



Why were the surveyors at your healthcare organization?

Did anyone tell you the findings from the survey?

Yes

0%

No

0%

I'm not sure

0%

Have you been involved in developing corrective actions as a result of a survey?

Yes

0%

No

0%

I'm not sure

0%

Setting the Stage: CMS Role in Oversight, Regulatory Survey Activities

- Maintains oversight for compliance with the Medicare health & safety standards for:
  - Hospitals
  - Nursing Homes
  - Home Health Agencies
  - ESRD Facilities
  - Hospices
  - Any other facility serving Medicare and Medicaid beneficiaries
- Ensures facilities are in compliance with **Conditions of Participation** (CoPs)

Quality, Safety & Oversight - General Information | CMS

Setting the Stage: Sub-set of Functions States Perform for CMS

Conducting surveys

- CoP verification
- Complaint investigations

Certifying and Recertifying

- Certifying and recertifying
- Specifying if entities are qualified to participate in certain certification programs (e.g., stroke center certification)

Quality, Safety & Oversight - General Information | CMS

What is Deemed Status?

- To participate in Medicare or Medicaid
  - Compliance with the health and safety requirements
    - CoPs
    - Federal regulations
- Survey Based
  - State agency on behalf of the federal government
  - National accrediting organization (e.g., The Joint Commission)
  - Recognized by CMS (process called “deeming”)
  - Standards meet or exceed Medicare’s requirements

Examples of Conditions of Participation (CoPs): Hospitals (partial list)*

- Governing Body
- Patient's Rights
- Quality Assessment/Performance Improvement
- Medical Staff Services
- Nursing Services
- Surgical Services
- Anesthesia Services
- Infection Control and Prevention and Antimicrobial Stewardship
- Organ, Tissue, and Eye Procurement
- Emergency Preparedness
- And many more…
- *Of note*: The Joint Commission's standards align with the CMS CoPs

*Full listing of CoPs for Hospitals can be found through the Code of Federal Regulations (CFR) here:
eCFR :: 42 CFR Part 482 -- Conditions of Participation for Hospitals

Spotlight: Elopements

Hospital A+ is a 410-bed acute care hospital serving a diverse community in an urban, economically disadvantaged location. There are approximately 165,000 emergency department (ED) visits annually. Patient elopements are a common challenge. On October 1, a 25 year old cognitively impaired female with moderate intellectual disability and schizoaffective disorder arrived at the ED with a sitter from her group home to be seen for exacerbation of asthma. While waiting, the sitter left at 8pm, leaving the patient alone. The patient eloped from the hospital. Upon recognition that she left, the nurse immediately let other clinicians and the Administrator on Duty know. After attempting to find the patient in the surrounding areas, including involving NYPD, they couldn't find her. About 10 hours later on October 2, the patient was found by NYPD 15 minutes away from Hospital A+, unconscious. It was discovered she was killed by a motor vehicle. Some of Hospital A+ staff & clinicians heard about this on the news and they realized it was her.

- What would you do immediately if you were leadership involved in this situation at Hospital A+?

Some Immediate Steps after Serious Elopement

- Ensure other patients are safe and being cared for
- Make sure staff involved are okay
- Contact Risk Management as soon as possible
- Escalate notification per your hospital's notification pathway, for example:
  - Department Leadership
  - Hospital/Facility Leadership
  - System Leadership if applicable
- Submit occurrence report
- Confirm that disclosure to family or caregiver occurs

Elopements: Adverse Event Reporting

- 405 Minimum Standards for Hospitals: Ensure hospitals meet criteria related to patient care, safety, & other essential aspects
- Report event: in NYS, Section 405.8 outlines adverse events to be reported include but not limited to:
  - Patient elopements resulting in death or serious injury
- Root Cause Analysis to be conducted: You'll learn much more about this **later** in CQFP! (outside the scope of today's session)
- Notify your accreditation agency about event

Title: Section 405.8 - Adverse Event Reporting | New York Codes, Rules and Regulations (ny.gov)

LET'S TALK ABOUT TYPES OF SURVEYS NOW…

We'll come back to our elopement case soon.

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CLINICAL QUALITY FELLOWSHIP PROGRAM

But first…here's where we should be: Continuous Readiness

- Preoccupation with failure
- Tracers (more described later)
  - Focused vs. General
- Rounds
- Mock Surveys
- Everyone engaged

- A survey can occur at ANY time, unannounced!

Snapshot: Types of Surveys
Licensure

Licensure

- State

Complaint Allegation

- CMS authorizes on-site investigations
- DOH acts on behalf of CMS
- OSHA & PESH: workplace safety/health inspections
- TJC: complaint investigation

Accreditation and Certification

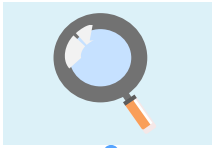
- TJC Triennials
- Disease Specific Certifications (e.g., Stroke)
- Specialty certifications (e.g., Trauma)

Validation

- CMS sends surveyors to validate findings
- Occur up to 60 days after a TJC survey
- Other complaint validation surveys can occur up to 90 days after initial survey

Licensure: Article 28 Certification & Recertification Survey

Why does survey happen?



- Regulatory assessment conducted under Article 28 of NYS Public Health Law for certification or recertification
- Licensure and operations of healthcare facilities, ensuring they comply with state regulations
- Evaluates full cadre of services

Survey Example

- Nursing home had unannounced Article 28 recertification survey
- 6 surveyors (including 2 sanitarians) over 6 days
- Survey performance resulted in a decrease in their CMS 5-star health inspection rating to 2-stars based on the most recent survey

Licensure: Article 28 Recertification Survey (continued)

Sample Documents Requested

- Bylaws
- Minutes of various committees
- Equipment maintenance records
- Specific policies and procedures
- Fire safety protocol
- Educational components (e.g., domestic violence education)
- Staff/clinicians' HR files
- Documentation of training, education, & orientation of various staff members

Sample of Common Activities

- Rounding, observing practices
- Speaking with front line clinicians
- Reviewing documents & policies
- Reviewing Medical Records
- Assessing if policies are in compliance with standards
  - Asking staff about practices compared to policies
- Analyzing/inspecting environment of care
- Conducing interviews with HR about staff files/competencies

Snapshot: Types of Surveys Complaint Allegation

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Complaint Allegation: Federal Title 18 Allegation Survey*

Why does survey happen?

- State conducts unannounced survey on behalf of CMS
- Prompted by complaint allegation
- Focused survey to find evidence of compliance (or lack thereof) with 1 or more CMS Condition of Participation
- Being proactive helps with these surveys!

Survey Example

- **Back to our case example:** Patient with cognitive impairment eloped from hospital and was found deceased 15 minutes from the hospital in October. A few weeks later, this prompted investigation into CoP, Patient's Rights; 4 surveyors present, and initial investigation lasted 8 days.

(This hypothetical survey will be the focus of our exercise later!)

**Note*: This is a federal survey that is conducted on behalf of CMS by a State agency; in NYS, NYSDOH conducts these surveys. There are also smaller-scale, state complaint surveys conducted by NYSDOH called Code 405 State Complaint Surveys.

Complaint Allegation: Title 18 Allegation Surveys (continued)

- Opening Session, specifies: How long, COP(s), How many surveyors
- Sometimes you can piece together the index case(s) based on document list provided

- **Common Activities:**
  - Rounding
  - Observing practices
  - Reviewing environment of care
  - Reviewing & questioning documents
  - Analyzing medical record documentation
  - Interviewing staff/clinicians
  - Survey can and often does expand beyond index case(s)

Sample Documents Requested:

Documents Requested by NYSDOH:

Focus on Patient Rights

1. Patient Complaint & Grievance Log x12 months
2. Incidents/Accidents/Occurrence Log x12 months
3. Safety & Security Committee Minutes x12 months
4. Facility Investigations for Reportable Events x12 months
5. Organizational Charts (names & hospital titles), include emergency department
6. List of all staff & clinicians in Emergency Department
7. 2023 Executive Quality Assurance/Performance Improvement and Patient Safety Plan
8. Quality Assurance/Performance Improvement Quality Indicators
9. Policy & Procedures (Nursing) Content: Index Page
10. Medical Staff Bylaws
11. Policy: Medical Clearance
12. Policy: Elopements and Against Medical Advice
13. Policy: Levels of Patient Observation
14. Policy: Medical Record Access
15. Policy: Medical Record Release Information
16. Policy: Complaints & Grievances Process
17. Policy: Incident Reporting
18. Policy: Representative/Prompt Notice
19. Staff personnel files & education files: physician & practitioner credential sample of files to be requested
20. Medical Records to be requested
21. Morbidity & Mortality Reviews from last 6 months
22. Complaints & Grievances: Emergency Department from the last 12 months
23. Morbidity & Mortality Committee Minutes
24. Census during each day of survey
25. List of patient services and locations in the facility

Norma Ray, xxxxxx@xxxx.gov, NYSDOH Team Coordinator

Complaint Allegation: TJC

- Media Scan
- Patient Complaints: TJC Office of Quality & Patient Safety complaint allegation surveys
- Serious Safety Event via CMS

- Hint: Be proactive
  - Inform TJC and share your POC
  - Can avoid a visit

Snapshot: Types of Surveys

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*Note: there are other accreditation organizations besides TJC (e.g., DNV)

Accreditation: The Joint Commission (TJC)

Why does survey happen?

- Conducted on behalf of CMS
- Deemed Status
- Other accrediting organizations (e.g., DNV)
- Triennial
  - Concurrent
  - Window for Survey
    - Unannounced
    - No more “Avoid dates”

Survey Example

- Hospital Awesome had Triennial survey over 5 days with 7 surveyors including physician, nurse, behavioral health, and life safety
- Survey addressed all aspects of hospital operations & governance (e.g., infection prevention, medication management, patient rights, credentialing, environment of care, etc.)
- Tracers conducted

Accreditation Focus: TJC National Patient Safety Goals (NPSG)

Goal 3

Improve the safety of using medications.

NPSG.03.04.01

Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.
Note: Medication containers include syringes, medicine cups, and basins.

--Rationale for NPSG.03.04.01--

Medications or other solutions in unlabeled containers are unidentifiable. Errors, sometimes tragic, have resulted from medications and other solutions removed from their original containers and placed into unlabeled containers. This unsafe practice neglects basic principles of safe medication management, yet it is routine in many organizations.

The labeling of all medications, medication containers, and other solutions is a risk-reduction activity consistent with safe medication management. This practice addresses a recognized risk point in the administration of medications in perioperative and other procedural settings. Labels for medications and medication containers are also addressed at Standard MM.05.01.09.

Element(s) of Performance for NPSG.03.04.01

1. In perioperative and other procedural settings both on and off the sterile field, label medications and solutions that are not immediately administered. This applies even if there is only one medication being used. R
   Note: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process.
2. In perioperative and other procedural settings both on and off the sterile field, labeling occurs when any medication or solution is transferred from the original packaging to another container. R
3. In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the following: R
   - Medication or solution name

The Joint Commission | Our Websites | Search this site | Login

Standards

- About Our Standards
- Standards Field Reviews
- National Patient Safety Goals +
- Prepublication Standards +
- R3 Report −
  - R3 Report
    - R3 Report Issue 42 Workplace Violence Prevention in Behavioral Health Care and Human Services
    - R3 Report Issue 41 New and Revised Requirements for Infection Prevention and Control for
    - R3 Report Issue 40 New and Revised Emergency Management Standards for Office Based Surgery Programs
    - R3 Report Issue 39 New and Revised Emergency Management Standards for Ambulatory Care Programs
- Standards FAQs
- Universal Protocol
- Patient Safety Systems PS Chapter

R3 Report — Requirement, Rationale, Reference

R3 Reports provide a brief summary of the rationale and references for new Joint Commission requirements.

Search R3 Reports here.

Results 1-10 of 42

DATE PUBLISHED

WEBPAGE

R3 Report Issue 42: Workplace Violence Prevention in Behavioral Health Care and Human Services

Effective July 1, 2024, three new and one revised workplace violence prevention requirements will apply to all Joint Commission–accredited behavioral health care and human services (BHC) organizations.

WEBPAGE

R3 Report Issue 41: New and Revised Requirements for Infection Prevention and Control for Critical Access Hospitals and Hospitals

Accreditation: Tracer Methodology

- Analyze hospitals' organizational systems following a patient's care path
- Methodology: majority of time spent on patient care units speaking with staff
- Roles of physicians, nurses, and leaders during survey
- Start with an ED case and work their way through the patient journey
- Example:
  - ED suicide screening, patient rights, interpreter services, sedation, brief OP note, OR consent, pain scale, med reconciliation

Accreditation: Disputing TJC findings

- Special Issue Resolution Session – SIG (Standards Interpretation Group)
- Always be respectful
- Work with lead surveyor

WHAT HAPPENS AS A RESULT OF SURVEYS?

Requirements for Improvement/Deficiencies

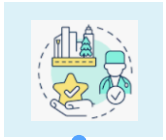
Requirements for Improvement or Deficiencies

- **No Deficiencies**: All requirements have been met

- If requirements have NOT been met:
  - Report developed by regulatory body: Statement of Deficiencies
  - Site develops a Corrective Action Plan to address deficiencies

Types of Deficiencies Identified During State Surveys

Standard Level Deficiencies

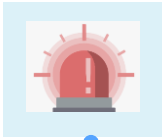


- Non-compliance with CoP of limited consequence
- No significant impact to patient outcomes

Conditional Level Deficiencies

- Non-compliance with CoP, negatively impacting care or outcomes
- Deficiencies must be corrected within 90 days
- **Validation survey** conducted to ensure corrections are made

Immediate Jeopardy (IJ)



- Non-compliance with CoP, causes serious injury, death, or loss of life
- Most serious type of deficiency
- Requires immediate action & correction (IJ removal plan)
- Surveyors won't leave until addressed
- Site gets fined

Deficiencies: IJ Removal Plan

- Immediate action to prevent serious harm from occurring or recurring
- Steps org will take to ensure no recipients are suffering or are likely to suffer serious injury, serious harm, serious impairment or death as a result of noncompliance
- Details how recipients will be kept safe and free from serious harm or death caused by noncompliance
- CMS must accept IJ removal plan

Asheville.com News

Asheville Watchdog: Conditions at Asheville's Mission Hospital Pose 'Immediate Jeopardy to Patients' Health and Safety,' State Investigators Report

MONDAY, JANUARY 15, 2024

Share on Facebook | Share on Twitter

Written by *Andrew R. Jones, Asheville Watchdog.*

Mission Hospital risks losing Medicare and Medicaid funding because of deficiencies in care that were so severe, state inspectors concluded last month, that they "posed immediate jeopardy to patients' health and safety," *Asheville Watchdog* has learned.

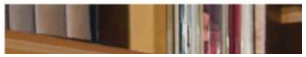
"Immediate jeopardy" is the most serious deficiency possible for a hospital. The North Carolina Department of Health and Human Services has recommended that Mission lose its participation in Medicare unless it quickly corrects the deficiencies, according to a letter obtained Thursday by *The Watchdog.*

OZARKS

Mercy removed from 'immediate jeopardy' status

Alissa Zhu Springfield News-Leader

Published 1:31 p.m. CT Sept. 29, 2017 | Updated 5:33 p



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Termination Notice

Notice is hereby given that on December 27, 2021, the agreement between Galesburg Cottage Hospital, Galesburg, Illinois, and the Secretary of Health and Human Services, as a hospital in the Medicare program, is terminated effective December 27, 2021.

The Centers for Medicare and Medicaid Services has determined that Galesburg Cottage Hospital is not in compliance with the following Medicare Conditions of Participation for hospitals:

42 CFR § 482.12 Governing Body
42 CFR § 482.13 Patient Rights
42 CFR § 482.23 Nursing Services
42 CFR § 482.41 Physical Environment

The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted after the close of December 27, 2021. For patients admitted on December 27, 2021, or earlier, payment may continue for up to 30 calendar days of inpatient hospital services furnished after December 27, 2021.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, MD 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

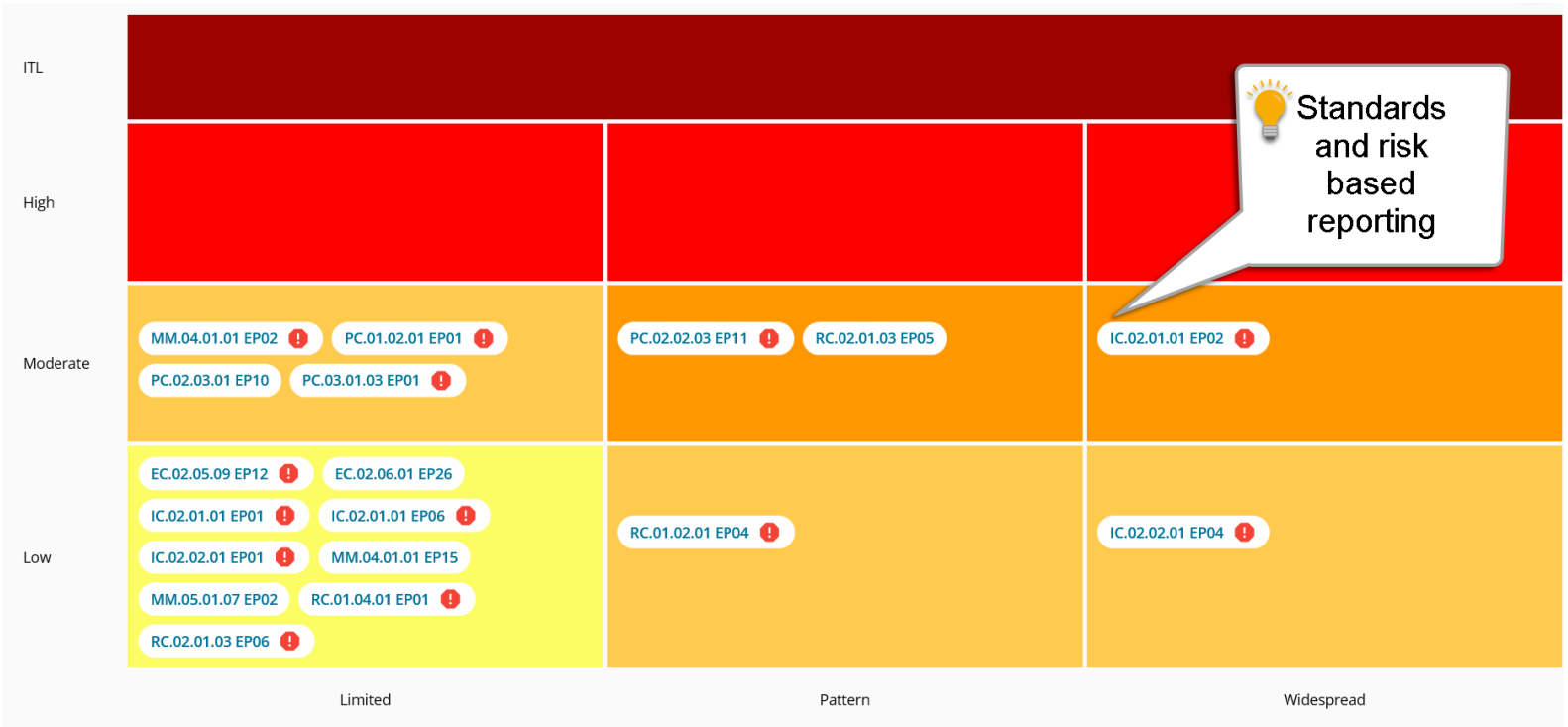
Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Notice to Public of Limitation of CLIA Certificate

Date December 20, 2023
Title Notice to Public of Limitation of CAMPUS HEALTH SERVICES, 03D0057856

The Centers for Medicare & Medicaid Services (CMS) is providing notice that on October 26, 2023, Campus Health Services' (1224 E. Lowell St, Tucson, AZ 85721-0095) CLIA certificate was limited due to a subsequent occurrence of unsuccessful participation in proficiency testing for the subspecialty of bacteriology.

Deficiencies: TJC SAFER® Matrix*



*SAFER=Survey Analysis For Evaluating Risk ®

Deficiencies: TJC SAFER® Tracer Escalation Process

The SAFER™ Matrix

	Limited (Unique occurrence that is not representative of routine/regular practice)	Pattern (Multiple occurrences with potential to impact few/some patients, visitors, staff and/or settings)	Widespread (Multiple occurrences with potential to impact most/all patients, visitors, staff and/or settings)
ITL (A threat that represents serious risk or potentially may have serious adverse effects on the health of the patient, resident or individual served)	Immediate escalation to Senior Leadership		
High (Harm could happen at any time)	Immediate escalation to Local Leadership	Immediate escalation to Senior Leadership	Immediate escalation to Senior Leadership
Moderate (Harm could happen occasionally)	Local leadership over function	Local leadership over function	Local leadership over function
Low (Harm could happen, but would be rare)	Local Manager via Verge	Local manager via Verge	Local leadership over function via Verge

Scope

Back to Our Snapshot: Types of Surveys

Licensure

- State

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Corrective Actions to Address Deficiencies

In response to each deficiency included in Statement of Deficiencies:

- Healthcare organizations must submit **Corrective Action Plan** within 10 calendar days
  - How and by when finding will be corrected
  - Changes to prevent reoccurrence & monitoring
  - **Plan must be accepted by CMS**

- For surveys with Conditional Level or IJ deficiencies:
  - Remember: IJ deficiencies must be addressed **immediately** before surveyors leave
  - **Validation survey** performed within 60 or 90 days to ensure corrective actions are in place and monitored
  - Must show evidence that all serious deficiencies have been addressed
  - Failure to do so may result in termination from participation in Medicare and Medicaid programs

Some Important Lessons: Interaction with Surveyors

- Be courteous, polite, and welcoming
- Less is more when answering: Answer only the question being asked
- Be Honest: If you don’t know the answer, don’t make something up!
- Do not argue with a surveyor if you disagree with him/her
- If you don’t understand the question, ask the surveyor to rephrase

Some Important Lessons: Command Center During Surveys

- Lead
- Hospital Operations
- Liaisons
- Documents/Policies
- Escorts
- Single source of information (avoid chaos)

GROUP EXERCISE

Small Group Discussions

Back to Our Case: Recap, Elopements

Hospital A+ is a 410-bed acute care hospital serving a diverse community in an urban, economically disadvantaged location. There are approximately 165,000 emergency department (ED) visits annually. Patient elopements are a common challenge. On October 1, a 25-year-old cognitively impaired female with moderate intellectual disability and schizoaffective disorder arrived at the ED with a sitter from her group home to be seen for exacerbation of asthma. While waiting, the sitter left at 8pm, leaving the patient alone. The patient eloped from the hospital. Upon recognition that she left, the nurse immediately let other clinicians and the Administrator on Duty know. After attempting to find the patient in the surrounding areas, including involving NYPD, they couldn't find her. About 10 hours later on October 2, the patient was found by NYPD 15 minutes away from Hospital A+, unconscious. It was discovered she was killed by a motor vehicle. Some of Hospital A+ staff & clinicians heard about this on the news and they realized it was her.

- Several weeks later, we learned that a postmortem toxicology report showed the patient had K2 and alcohol in her system.

Back to our Case: The Aftermath

On October 27, four surveyors from the Department of Health arrived at Hospital A+'s lobby. Hospital Police called the Director of Regulatory & Accreditation to escort the surveyors to a conference room to meet with hospital leadership. At the opening session, the survey team provided a list of requested documents *(see separate attachment)* and told them they were there to investigate Condition of Participation, Patient's Rights. Later that day, they asked for access to 5 patients' records, including the patient that had eloped and died on October 2. Hospital A+'s leadership team originally had a hunch the survey team was there to investigate this case, but now they knew. They felt prepared because they were proactive, and had developed some strong corrective actions.

Instructions

You will review this case in groups. You are Hospital A+'s leadership team. Engage in the following discussion with your group:

- What are some steps you took to make sure clinicians involved in the case are prepared to speak with surveyors?
- On survey day, what documentation do you have available to show evidence to surveyors that Hospital A+ started to proactively address this issue?
- What is 1 example of a corrective action your team implemented to show the survey team you'll make every effort to prevent this from happening again?
  - How have you started to monitor this corrective action?

Thank you!

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