Session #13:

CMS Surveys: Immediate Jeopardy Findings, Condition Level Deficiencies and Other Surprises Every Board Should Understand

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Sponsored by:
Susan Kratz, J.D.

Susan Kratz is a shareholder at Minneapolis law firm Nilan Johnson Lewis and is chair of the firm’s health care practice group. Susan is known for her loyal collaborations with both clients and colleagues. Her genuine interest in her clients’ industries makes her an excellent partner with clients, who appreciate her drive towards resolution, creativity when solving problems, and ability to understand the bigger picture and not get distracted by superfluous issues. Susan has a knack for seeing the best traits in others, and is lauded by her colleagues for being able to put together the perfect team so that each matter is staffed efficiently and effectively.

Elizabeth Winchell, J.D.

Elizabeth Winchell is an attorney at Nilan Johnson Lewis. As someone who has worked directly with patients and clients in a variety of health care settings, Elizabeth loves supporting the critically important efforts of health care providers, plans, and others active in the health care sector. She views her work as an opportunity to facilitate health care delivery in a completely different way. Elizabeth fully grasps the issues that are important to her clients and uses her knowledge to help them navigate the complexity of health care regulations. She ably translates opaque legal and regulatory requirements, creating clarity for clients to understand and to operationalize successfully.
CMS Surveys:
Immediate Jeopardy Findings, Condition Level Deficiencies and Other Surprises Every Board Should Understand

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Outline

I. Introduction
II. Key Terms and Concepts
III. Survey Protocol
IV. Advanced Considerations
V. Conclusion and Questions
Key Terms and Concepts: Survey Basics

- Accreditation and Medicare Deemed Status
  - Hospitals must be certified as meeting Medicare Conditions of Participation (COPs) to be paid by Medicare.
  - Certification alternative to CMS (or state agency on behalf of CMS) survey
  - The Joint Commission (TJC) is a commonly used accrediting organization approved by CMS as having standards and survey process that meet or exceed Medicare’s requirements
  - Achieving accreditation through TJC means health care organization is deemed to meet or exceed Medicare COPs.
Key Terms and Concepts: Survey Basics

• Types of Surveys
  – Certification/Recertification (routine) and Validation
  – Complaint/Allegation

• Certification/Recertification Survey (routine)
  – Hospital may choose to be certified by CMS and not accredited by TJC or others and in “deemed” status
  – Unannounced

• Validation Survey
  – CMS has right to do its own survey of “deemed” status hospital
  – Random
  – Could be as a result of deficiencies identified in TJC survey
  – Unannounced
Key Terms and Concepts: Survey Basics

• Complaint/Allegation Survey
  – Complaint = allegation of noncompliance with COPs
  – Allegation = assertion of improper care that could result in citation of deficiency with COPs
  – Can come to the attention of CMS (or state agency surveyors) from any source, including media

Key Terms and Concepts: Survey Basics

• Complaint/Allegation Survey (continued)
  – Unannounced
  – If “immediate jeopardy” may be present, survey will occur within 2 working days of receipt of complaint (or for deemed providers, within 2 working days of authorization of CMS regional office)
Key Terms and Concepts: Survey Basics

• Surveyors
  – In Minnesota, performed by the Minnesota Department of Health
  – Team with a lead surveyor

Key Terms and Concepts: Survey Violations

• Standard Level Deficiencies
  – Noncompliance with any single requirement or several requirements within a particular standard
  – Doesn’t substantially limit a facility’s capacity to furnish adequate care, or doesn’t jeopardize the health or safety of patients if the deficient practice recurred.

• Condition Level Deficiencies
  – Noncompliance with requirements in a single standard or several standards within the condition
  – Representing a severe or critical health or safety breach
  – 90 calendar day termination track
Key Terms and Concepts: Survey Violations

- **Immediate Jeopardy (IJ)**
  - “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.” (See 42 CFR Part 489.3.)
  - Harm does not actually have to occurred
  - Does not have to be related to incident triggering complaint survey
  - Generally issued orally during survey

(continued)

- **Immediate Jeopardy (IJ) (continued)**
  - Difficult, if not impossible, to have surveyors or CMS remove IJ finding once cited
    - See Command Center concept later in presentation for proactive approach
  - CMS needs to confirm, but significant deference given to surveyors
  - Puts hospital on **23 calendar day termination track** if not corrected before surveyors leave
  - If corrected before surveyors leave, IJ citation will be noted in Form CMS-2567 as given but abated; Will receive Condition Level deficiency citation
Key Terms and Concepts: Conditions of Participation

- Overview of CoPs
  - Specific requirements that providers must meet in order to participate in the Medicare program
  - Minimum standard that will ensure the provision of safe quality care to beneficiaries of services
  - Purpose is to protect patient’s health and safety and to ensure quality care provided to all patients
  - Deficiencies can result in payment and may lead to exclusion from Medicare if not corrected

Key Terms and Concepts: Conditions of Participation

- Overview of CoPs
  - Requirements vary based on type of entity
  - Found in Social Security Act, regulations, subregulatory guidance
    - CMS publishes State Operations Manual (SOM) for state survey agency use
    - SOM contains the regulatory language of the CoPs + interpretive guidelines and survey procedures
  - Subject to change
Key Terms and Concepts: Conditions of Participation

- **Overview of CoPs**
  - Best practices include:
    - Educate and train administration, providers, and staff about changes
    - Collaborate with key stakeholders when changing policies, including medical staff bylaws and hospital operating procedures
    - To keep up to date on the CoPs, visit the CMS website weekly and consider subscribing to a CMS email list, such as [http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospitals.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospitals.html)

Key Terms and Concepts: Conditions of Participation

- **Governing Body**
  - There must be an effective governing body that is legally responsible for the conduct of the hospital.
  - Standards:
    - Medical staff
    - Chief executive officer
    - Care of patients
    - Institutional plan and budget
    - Contracted services
    - Emergency services
Key Terms and Concepts: Conditions of Participation

• Quality Assessment and Performance Improvement (QAPI) Program
  – The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven QAPI program.
  – The hospital's governing body must ensure that the program:
    • reflects the complexity of the hospital's organization and services;
    • involves all hospital departments and services (including services furnished under contract or arrangement); and
    • focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.
  – The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

Key Terms and Concepts: Conditions of Participation

• Patient’s Rights
  – A hospital must protect and promote each patient's rights.
  – Standards:
    • Notice of rights
    • Exercise of rights
    • Privacy and safety
    • Confidentiality of patient records
    • Restraint and seclusion (including staff training and death reporting)
    • Patient visitation rights
Key Terms and Concepts: Conditions of Participation

- Medical Staff
- Nursing Services
- Infection Control
- Discharge Planning
- Food and Dietetic Services
- Surgical Services
- Anesthesia Services

SURVEY PROTOCOL
Survey Protocol: Before surveyors arrive

• Compile documents surveyors may request upon arrival (see list next slide)
• Surveyors will expect these documents as soon as possible, and no later than 3 hours after the request is made
• Failure to give surveyors access to facilities or documents may result in Medicare participation termination

Survey Protocol: Before surveyors arrive

• List of current inpatients, with each patient’s name, room number, diagnosis(es), admission date, age, attending physician, and “other significant information as it applies to that patient”;  
• List of department heads with their locations and telephone numbers;  
• Copy of the facility’s organizational chart;  
• Names and addresses of all off-site locations operating under the same provider number;  
• Hospital’s infection control plan;  
• List of employees;  
• Medical staff bylaws and rules and regulations;  
• List of contracted services; and  
• Copy of the facility’s floor plan, indicating the location of patient care and treatment areas.
Survey Protocol: Before surveyors arrive

- Additional steps:
  - Identify key personnel/define survey response team
  - Provide training/readiness tips to all staff
  - Ensure that monitoring data/internal audit results are reviewed
  - Effectively solve known hospital issues
  - Be aware of CMS/state survey focus areas
  - Review SOM

Survey Protocol: While surveyors are onsite

- What to Expect
  - All hospital surveys are unannounced.
  - Generally occur during weekday, daytime working hours, but may occur at other times.
  - Size of survey team depends on:
    - Size of the facility to be surveyed;
    - Complexity of services offered, including outpatient services;
    - Type of survey;
    - Whether the facility has special care units or off-site clinics or locations;
    - Whether the facility has a historical pattern of serious deficiencies or complaints; and
    - Whether new surveyors are training.
Survey Protocol: While surveyors are onsite

• What to Expect
  – Entrance conference
  – Additional survey team requests:
    • Location where team can meet privately during survey;
    • Telephone for team communications, preferably in meeting location;
    • Access to photocopier; and
    • Interview with a member of the administrative staff to complete the Medicare Database Worksheet.

Survey Protocol: While surveyors are onsite

• Surveyor Guiding Principles
  – Focus attention on actual and potential patient outcomes, as well as required processes.
  – Assess the care and services provided, including the appropriateness of the care and services within the context of the regulations.
  – Visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc.
  – Observe the actual provision of care and services to patients and the effects of that care, in order to assess whether the care provided meets the needs of the individual patient.
  – Use the interpretive guidelines and other published CMS policy statements to guide the survey.
  – Use SOM Appendix Q for guidance if Immediate Jeopardy is suspected.
Survey Protocol: While surveyors are onsite

- Where will surveyors go?
  - Small hospitals/hospitals with no or a small number of off-campus provider-based locations ⇒ all departments, services, and locations that bill for services under the hospital’s provider number and are considered part of the hospital
  - Hospitals with many provider-based locations ⇒
    - All hospital departments and services at the primary hospital campus and on the campuses of other remote locations of the hospital;
    - All satellite locations of the hospital;
    - All inpatient care locations of the hospital;
    - All out-patient surgery locations of the hospital;
    - All locations where complex out-patient care is provided by the hospital; and
    - A “sample of each type of other services provided at additional provider-based locations.”

Survey Protocol: While surveyors are onsite

- What to Expect
  - Surveyors have discretion whether to allow facility personnel to accompany them during a survey.
  - Surveyors are to maintain open and ongoing dialogue with facility staff throughout survey process.
  - Surveyors are to maintain their role as representatives of a regulatory agency (no consulting).
Survey Protocol: While surveyors are onsite

- What to Expect
  - Patient Review
    - Surveyors select a number of patient records for review based on the facility’s average daily census (at least 10% of the average daily census, but not fewer than 30 inpatient records).
    - In addition to inpatient sample, surveyors “select a sample of outpatients in order to determine compliance in outpatient departments, services, and locations.”
    - Sample size may be expanded as needed to assess hospital compliance.

- What to Expect
  - Patient Review
    - Comprehensive review of care and services received by each patient in a defined sample.
    - Includes observations of care/services provided to the patient, patient and/or family interview(s), staff interview(s), and medical record review.
Survey Protocol: While surveyors are onsite

• What to Expect
  — Certification of hospital compliance with the CoP is accomplished through observations, interviews, and document/record reviews.

• What to Expect
  — Observations
    • Surveyor should have observations verified.
    • Surveyors must not examine patients by themselves, but may have a right to participate in examination of patient in certain circumstances.
    • The health and dignity of the patient is always of paramount concern.
Survey Protocol: While surveyors are onsite

• What to Expect
  – Interviews
    • Interviews with facility staff are supposed to be brief.
    • When interviewing staff, surveyors are to begin interviews with staff that work most closely with the patient.
    • Interviews with patients must be conducted in privacy and with the patient’s prior permission.
    • Surveyors are to validate all information obtained.
    • Telephone interviews may be conducted, but surveyors prefer in-person interviews.

Survey Protocol: While surveyors are onsite

• What to Expect
  – Document/record reviews may include:
    • Open and closed patient records
    • Personnel files
    • Credentialing files
    • Maintenance records
    • Staffing documents
    • Policies and procedures
    • Contracts
Survey Protocol: While surveyors are onsite

• What to Expect
  – Photocopies
    • Surveyors are to make photocopies of all documents needed to support survey findings.
    • If requested by the hospital, the surveyor should make the hospital a copy of all items photocopied.

• What to do
  – Develop phone tree/other process to alert all departments to presence of surveyors
  – Establish “command center” as gathering place for hospital’s survey response team to confer
  – Assign roles, including escorts, scribes, and runners
  – Maintain an ongoing, open dialogue with surveyors and respond to surveyors requests promptly
  – Ensure command center understands surveyor questions/concerns
Survey Protocol: While surveyors are onsite

• Exit Conference
  – It is the general policy of CMS to conduct an exit conference at the conclusion of each survey.
    • “However, there are some situations that justify refusal to continue or to conduct an exit conference.”
  – The facility determines which hospital staff will attend the exit conference.
  – No surprises (typically)

• Presentation of Findings at Exit Conference
  – Surveyors are to avoid referring to data tag numbers.
  – Surveyors are to present findings of noncompliance, explaining why the findings are a violation.
  – If IJ was identified, surveyors are to explain the significance and the need for immediate correction.
  – Surveyors are to assure that all findings are discussed at the exit conference.
Survey Protocol: While surveyors are onsite

- Recording the Exit Conference
  - Audio taping
    - If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously.
    - The surveyors should take one of the tapes at the conclusion of the conference.
  - Video taping
    - Video taping is also permitted if it is not disruptive to the conference, and a copy is provided at the conclusion of the conference.
    - It is at the sole discretion of the surveyor(s) to determine if video taping is permitted.

Survey Protocol: After surveyors exit

- Statement of deficiencies (Form CMS-2567) mailed within 10 working days to the hospital.
- Written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.
Survey Protocol: After surveyors exit

• Plans of Correction
  – Must be submitted on same Form CMS-2567 received by hospital (which is not electronic!)
  – Will be a public document
  – The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey
  – Signed by provider representative (recommend chief executive officer of hospital)

(continued)

Survey Protocol: After surveyors exit

• Plans of Correction (continued)
  – Must state how the deficiency has been (or will be corrected)
  – Must state date of completion (generally recommend that date should be before Plan of Correction submitted, but exceptions)
  – Should be realistic corrections
  – Should be able to evidence corrections made during re-survey
    • Examples: If training, keep all training materials and logs showing completion. If changes to electronic medical record, keep evidence of change and competency of users.
Survey Protocol: After surveyors exit

- Appeals Process
  - Removal of deemed status does not entitle hospital to reconsideration and hearing rights (i.e., no real appeal rights)
  - ALJ appeal process available if hospital believes determination to terminate not correct, but unlikely to happen prior to termination
  - May need to consider injunction
  - Consider seeking extension from CMS
Survey Protocol: After surveyors exit

- Systems Improvement Agreements
  - Stays termination action and provides an extra window of time during which to correct deficiencies
  - Hospital waives all rights to administrative or judicial challenge to findings described on the CMS-2567
  - Burdensome and likely onerous requirements and therefore not recommended unless no other options

ADVANCED CONSIDERATIONS
Advanced Considerations: Media

- Many ways media may become aware of CMS survey and deficiencies (especially immediate jeopardy findings)
- Hospital should have plan to address media if need arises
- Board should have expectation that it will be apprised by management of survey before media coverage

Advanced Considerations: Role of Counsel and Consultants

- Counsel and consultants important members of command center
- Experienced in understanding nature of surveyor questions
- CMS and surveyors generally will not allow outside counsel to participate in meetings, but exceptions
- Best use of counsel and consultants is:
  - Survey and re-survey readiness
  - Command Center members
  - Assist with Plan of Correction
Advanced Considerations: IJs and Value-Based Purchasing

- VBP Program involves withhold from DRG payments with incentive payments based on quality measure performance
- Hospitals that have multiple IJs in a “performance period” are excluded by VBP Program
- Seems to apply regardless of whether IJ is removed before end of survey
- Subjectivity of IJ citations
- No appeal rights
- May create exclusion for multiple FYs

Advanced Considerations: Fiduciary Duties

- Duty of Care
- In re Caremark
  - “[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.”
QUESTIONS?

Thank you!

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