Responding to Licensing and Certification Deficiencies

CHA Webinar
May 21, 2014

Welcome

Liz Mekjavich
California Hospital Association
Program Overview and Introductions

Lois Richardson
California Hospital Association

Faculty: Claire E. Castles

Claire Castles, JD, is an associate for Jones Day advising clients across the health care industry on compliance strategies and regulatory issues, and in proceedings before federal and state government agencies. Her areas of practice include licensing and certification, payment and reimbursement, health privacy, Emergency Medical Treatment and Active Labor Act (EMTALA), Medicare Conditions of Participation, contracting and transactional matters, internal investigations, and government investigations and audits.
Accreditation and Medicare Deemed Status

Deemed Status

- A hospital that has voluntarily applied for and has been accredited by a national accreditation program approved by CMS
  - For example, The Joint Commission
- Accredited hospitals are deemed to meet Medicare Conditions of Participation
  - 42 U.S.C. 1395bb; 42 CFR 488.7
Deemed Status

An accredited hospital will be deemed to meet Medicare Conditions of Participation if the hospital:

- Authorizes the accreditation organization to release to CMS and the state survey agency a copy of the current accreditation survey with any related information;
- Permits validation surveys; and
- Authorizes the state survey agency to monitor correction of any deficiencies found during a validation survey.

Different Types of Surveys

- Certification/Recertification Survey
- Complaint/Allegation Survey
- Validation Survey
Certification/Recertification

Comprehensive survey to confirm compliance with all Medicare requirements

Certification:
- Conducted following submission of the application

Recertification:
- Cyclical basis to confirm provider continues to meet Medicare requirements

Complaint/Allegation

- Conducted following a complaint that is determined to be a “credible allegation” of a Condition-level deficiency
- Surveys to Conditions related to the complaint
  - CMS or state agency may expand the scope
- If survey supports finding of a deficiency in a Condition, CMS will authorize a full Medicare survey
Validation

- May be comprehensive or focused in scope
- Significant deficiencies may result in removal of the “deemed” status as to compliance with the Conditions of Participation
- Selection for Validation Survey
  - Random sample
  - Substantial allegation of noncompliance

Refusal to Cooperate with the Survey

- A hospital that does not cooperate with the survey (e.g., by denying the surveyors access to parts of the hospital, medical records or other documents or hospital employees) may have its deemed status removed and may be subject to termination of its Medicare and Medicaid provider agreements
  42 CFR 488.7(c)
- The OIG may exclude the hospital from participation in all federal health care programs
General Survey Process

- Surveyors will conduct observations, interviews and document review
- Guiding principals from State Operations Manual (SOM):
  - Focus attention on actual and potential patient outcomes (and required processes);
  - Assess the care and services (appropriateness and within context of regulations);
  - Visit patient care settings;
  - Observe actual provision of care to individual patients;
  - Use Interpretative Guidelines and other CMS guidance
  - Use Appendix Q (of SOM) for a suspected Immediate Jeopardy (IJ)

Survey Outcomes

- Standard-level Deficiency(ies)
- Condition-level Deficiency(ies)
- 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”
CMS can impose an enforcement action against an accredited hospital only if it has Condition-level deficiencies.

If no such deficiencies exist, CMS Regional Office will issue a notice that the hospital is in compliance with all Medicare-deemed conditions.

The CMS Regional Office will remove the hospital’s deemed status and will issue the hospital a notice of termination and request a Plan of Correction (POC).

The notice will provide an effective date for the termination.

Hospitals should immediately:
- Establish communication with state survey agency (SSA) and CMS Regional Office; and
- Take immediate action to abate the IJ.
THE CMS REGIONAL OFFICE.WILL REMOVE THE HOSPITAL’S DEEMED STATUS AND WILL ISSUE THE HOSPITAL A NOTICE OF TERMINATION AND REQUEST A POC.

- The notice will provide an effective date for termination.
- If the validation survey found IJ and a revisit found the IJ abated, but Condition-level deficiencies continued, the termination timing may change.

**Condition-Level Deficiency Without Immediate Jeopardy**

- The CMS Regional Office will remove the hospital’s deemed status and will issue the hospital a notice of termination and request a POC.
- The notice will provide an effective date for termination.
- If the validation survey found IJ and a revisit found the IJ abated, but Condition-level deficiencies continued, the termination timing may change.

---

**Exit Interview**

“The provider has a right to disagree with the findings and present arguments to refute them. Surveyors should be receptive to such disagreements. If the provider presents information to negate any of the findings, surveyors should indicate their willingness to reevaluate the findings before leaving the facility. The survey team’s reasonableness demonstrates their fairness and professionalism. The degree of receptivity displayed by providers during the exit conference often depends upon the attitudes and survey style of the survey team.”

- SOM

Surveyors are directed that Tag numbers should not be identified and no discussion as to whether deficiencies are Condition- or Standard-level.

Surveyors are to see that “all findings are discussed.” - SOM
Post-Survey

- Consolidate all notes/information gathered during survey
- Develop Plans of Correction
- Begin taking action steps
- Education and monitoring
- Prepare resource binder
- Oversight of implementation

Plans of Correction

For each deficiency cited:

- Identify immediate corrective action steps (and dates);
- Identify permanent corrective action steps (and dates);
- Identify monitoring procedures to prevent reoccurrence; and
- Identify person(s) ultimately responsible for corrective action steps
Points of Practice

- Don’t panic
- Don’t argue
- Maintain an ongoing dialogue
- Begin working to correct any deficiency when you learn the surveyors are considering a citation
- If surveyors find IJ, work quickly to address it and endeavor to abate the IJ before the surveyors complete the survey and leave

Points of Practice

- Identify team to prepare and implement PoC
- Involve counsel and/or consultants, if indicated
- Be prepared for press
- Balance confidentiality with communication
- Engage governing body
- Don’t waste time
Thank you

Claire Castles  
(213) 243-2629  
ccastles@jonesday.com

Responding to CDPH and CMS Licensing and Certification Deficiencies

Ann Sparkman  
University of California, San Francisco
**Faculty: Ann Sparkman**

**Ann Sparkman, JD**, has served for eight years as the deputy campus counsel for Health Affairs for the University of California, San Francisco (UCSF). Ms. Sparkman has extensive health care experience and was appointed to serve on the Marin Healthcare District Board in November, 2011. Prior to joining UCSF, she held the position of in-house counsel for Kaiser Permanente and was a partner in healthcare law at Hassard Bonnington.

---

**The Mechanics of the Survey**

- Applies whether the survey is a complaint survey, focused survey or full validation survey
- The survey is always unannounced – surveyors often show up at 0730
- Often hold a entrance conference, yet CMS surveyors have been known to begin survey interviews without entrance conference. See *State Operations Manual (SOM), Appendix A (Entrance Activities, Information Gathering/Investigation)*
Practical Pointers

- Develop a phone tree/other process for ensuring that departments are alerted immediately upon surveyor arrival
- Include command center members along with roles and responsibilities, including escorts and runners
- Have available hospital policies and procedures, and departmental policies for Title 22 requirements and CoPs that are typically surveyed (Nursing, Pharmacy, Dietary, Infection Control, Patient Rights – Privacy, QAPI, Governance)

Practical Pointers

- Escorts are essential to accompany surveyors – serve several roles
- Witness for rebuttal and appeal
- Guide with difficulty in answering questions
- Defusing tension should surveyor become intimidating or threatening
- Scribe
  - Record the identity of surveyor, staff, patient, date and start/stop time, and requested documents
  - Best to do so immediately after survey to retain identities of staff and patients while fresh in mind
  - CMS typically declines requests for staff/patient lists
- Runners are essential to retrieve documents
The Mechanics of the Survey – Areas of CDPH/CMS Scrutiny

- Infection Control
- Nursing Services
- Pharmaceutical Services
- Food & Dietary Services
- Governance
- Patient Rights — Privacy
- Patient Safety and Quality
- Life Safety
- Grievances

Mechanics of Survey – Immediate Jeopardy

- Immediate Jeopardy – Definitions:
  - A situation in which the provider’s non-compliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident (CMS in SOM)
  - An immediate jeopardy (IJ) is a situation in which the hospital’s noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient (CA HSC §§ 1280.1 & 1280.3)
- To be limited to non-compliance that is immediate and serious
- The threat must be present when the surveyor is on-site, and of such magnitude to seriously jeopardize a patient’s health/safety
- Not to be used to expedite compliance on routine deficiencies
- CDPH/CMS declaring more IJs. L&C attorneys & Deputy Director need to approve before it is declared
- CDPH often attempts to impose a “retrospective” IJ
Practical Pointers with an IJ

- May take around-the-clock work in preparing Plan of Correction (POC) and the necessary documents promised in the POC
  - How will deficiency be fixed (including systemic fixes)
  - New or revised policies and procedures
  - Educational plans — against policies, those in attendance, modalities for education and re-education
  - Audit and monitoring
- Bring all corrective actions to the surveyors’ immediate attention for their review and approval
- Be assertive and persistent in asking that surveyors review and approve the POC

Practical Pointers with an IJ

- Need to document in writing requests for review as surveyors have been known to delay approval
- Clear any IJs before the surveyors leave to avoid:
  - Expedited 23-day termination track with CMS
  - Requirement to submit a separate written response to the 2567 regarding the IJ, in addition to the condition-level and standard-level deficiencies
- Impact of CMS Immediate Jeopardy extends beyond expedited track
  - A CMS (federal) Immediate Jeopardy excludes a hospital from value-based purchasing for the next participation period
**Exit Conference — Practical Pointers**

- Request to audiotape the Exit Conference
  - Provide two tape recorders with recorder for surveyors, and recorder for the hospital
  - Transcribe for immediate post-survey activities
- Ask for identification of Tag Numbers
- Ask for clarification regarding deficiencies
  - If surveyors incorrectly capture the findings, or have missed documentation provided during the survey, offer to clarify on the spot
  - If surveyors have incorrectly cited controlling authority (applicable laws, regulations or professional standards), request basis for citations
  - Hold surveyors accountable for the record – this involves a fine balance so you are not perceived as cross-examining the surveyors

**Post-CDPH/CMS Survey Activities**

Immediately following Exit Conference:

- Meet with leadership, regulatory team, escorts, department managers (owners) to discuss preliminary findings, accuracy, corrective actions and accountabilities in relation to internal deadlines
- Remind participants that in order for CDPH/CMS to accept the POC, that it must contain “credible allegations of compliance”
- Credible allegations of compliance include at minimum:
  - Fixing the deficiency (including an immediate fix, and if indicated, a systemic fix)
  - Education and training (often against the policy, and policies may need to revised to meet the 2567)
  - Monitoring and auditing
Post-Exit Conference Activities

Immediately following Exit Conference:

- Interview those staff and escorts interviewed during the survey to determine what staff and escorts actually said – goes to determining any factual errors made by surveyors and areas of vulnerability
- These interviews will also uncover directors, managers or staff who are problematic with surveyor interviews
- These individuals should be trained in how to improve responses to surveyor interviews
- These interviews also clarify complicated fact-specific issues

Practical Pointers

Communicate survey results to:

- Governing Body – oversight for operation of hospital and quality of care
- Media Affairs – to prepare for any media/public inquiries

As legal counsel, assist in reviewing the draft of the POC to ensure that it addresses all of the deficiencies

- Often there is a lack of appreciation that the POC also may need to address QAPI and Governance
- CDPH/CMS may require supplemental POC
Practical Pointers

Department Managers’/Owners’ responsibilities

- Need to provide robust fixes, education, monitoring and auditing, and confirm that they must carry out what is promised in the POC – this is critical
- Documentation of actions, education and monitoring
- Tie into existing QAPI process
- Governing body oversight of fixes/monitoring

Practical Pointers

Challenges with engagement and accountability

- Medical Staff (physicians), given they are outside the control of the hospital
- Will require strong leadership by Chief Medical Officer and President of the Medical Staff
- Discuss measures to engage Governing Body in oversight of POC

Tie in with Governance and QAPI

- Governance standard is the springboard for Medical Staff involvement — it requires Governing Board oversight — coming up through the pertinent Medical Staff and Executive Medical Committee
- Adverse events leading to survey need to be run up through Medical Staff Committees up to Governing Body as incident-based, rather than as part of aggregate data
Appeals

Timeframe for requesting an appeal/hearing differs for CDPH/CMS

- CDPH: Ten (10) days of receipt of notice of deficiencies/IJ
- CMS: Sixty (60) days of receipt of notice of initial/revised determination

For CDPH – the appeal must dispute

- The determination of the deficiency/failure to correct a deficiency
- Appropriateness of the deadline or correction
- Amount of the penalty

Appeals (cont.)

For CMS, the appeal must put CMS on notice of all matters in dispute, and enable the ALJ to rule on the relevancy of evidence

- Identify the specific issues, and the findings of fact and conclusions of law with which the hospital disagrees
- Specify the basis for contending that the findings of fact and conclusions of law are incorrect
- Indicate whether facts are at issue, or dispute limited to legal issues in which hearing is not necessary
Appeals (cont.)

Practical considerations with CDPH/CMS

- For CDPH, penalty deferred pending resolution of appeal – important with increased penalty amounts
- For CDPH, important to appeal late-declared IJ notices
- May cause CDPH/CMS to reconsider tenuous positions
- For CMS, filing an appeal early can shorten the period for termination from participation with Medicare
- Ineligibility for Medicare participation triggers a cascade effect
  - Ineligible for Medicaid
  - Basis for termination by commercial payors (requires Medicare certification)
  - Impacts physicians who contract with an excluded provider and provide services to federal beneficiaries
  - Jeopardizes bond financing

Post-Survey Activities

Following submission of Plan of Correction

- Responsible department managers and owners to implement POC
- Requires they prepare and provide binders with evidence of POC – assigning one “keeper” of the binders helps with consistency
- A Steering Committee or Workgroup should be mobilized to oversee these POCs by responsible department managers and owners to ensure accountability
  - Need to report in on fix, education, monitoring and auditing
  - Need for committee to ensure monitoring and auditing – to demonstrate high accuracy, and if not, to take action
  - Internal deadlines vs “completion dates” in POC
Post-Survey Activities

- Prepare binders
- Meet with leadership, regulatory team, escorts, department managers (owners) to discuss preliminary findings, accuracy, corrective actions and accountabilities in relation to internal deadlines
- Remind participants that in order for CMS to accept the POC, it must contain “credible allegations of compliance”
- Consider use of a response “template” that identifies each of these areas in the response to each tag:
  - Corrective Action
  - Education and Training
  - Monitoring and Compliance

Departmental Directors and Managers – Need for Accountability

Given the increased CDPH/CMS scrutiny/penalties:

- Directors and managers should be knowledgeable regarding California state law and Title 22 regulatory requirements, as well as CMS Conditions of Participation and Interpretative Guidelines for their respective departments/services
- Directors/managers should be skilled in handling surveyors, even difficult/offensive surveyors
- Directors and managers should be skilled in monitoring and reporting out
Deadlines and Extensions

CMS State Operations Manual (SOM)
- State agencies are to comply with the SOM, yet often disregard deadlines set forth in SOM
- Unfortunately, hospitals do not have the same discretion in their response timing
- Brief extensions in submission dates may be granted. Any extension does not extend the threatened termination date

Resources

CMS State Operations Manual
- Most important SOM chapters, exhibits and appendices:
  - Chapter 2 – The Certification and Survey Process
  - Chapter 3 – Termination Process (IJ or Condition-Level Non-Compliance)
  - Appendix A – Interpretive Guidelines for each Condition
  - Appendix Q – Guidelines for Determining Immediate Jeopardy
  - Exhibit 7A – Disclaimer advising it is “merely guidance”
    - Interpretive Guidelines (Appendix A) are not law or regulation
    - Interpretive Guidelines are guidance and suggestive of how surveyors may address a finding
Thank you

Ann Sparkman
(415) 476-3000
asparkman@legal.ucsf.edu

Questions

Online questions:
Type your question in the Q & A box, hit enter

Phone questions:
To ask a question hit 14
To remove a question hit 13
Upcoming Programs

• Using ED Overcrowding Assessment Tools to Improve Care and Throughput Webinar
  May 29, Sacramento

• Modern Pricing — Understanding Hospital Pricing Concepts Webinar (Members-Only)
  May 30, Sacramento

• Hospital Finance and Reimbursement Seminars
  June 5 – June 11, three programs

• Disaster Planning for California Hospitals
  September 22 – 24, Sacramento

• Physician Leadership Program
  September – April 2015, seven programs

Thank You and Evaluation

Thank you for participating in today’s program. An online evaluation will be sent to you shortly.

For education questions, contact Liz Mekjavich at (916) 552-7500 or lmekjavich@calhospital.org.