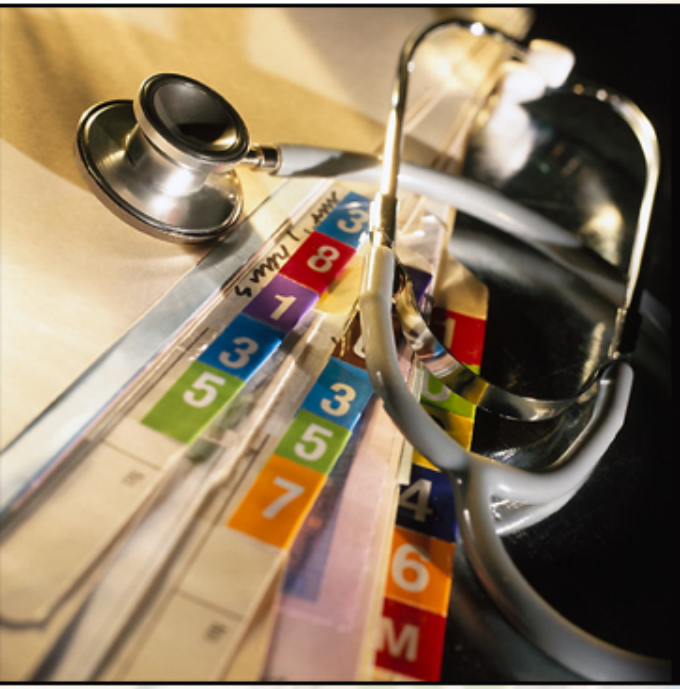

South Carolina Hospital Association
Collaboration + Calamity = C²

Legal Requirements re CMS Survey on Quality of Care Complaints: How to Best Protect Your Healthcare & Hospital Systems

Co-sponsored by SC ASHRM & SCAHQ

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Does this sound familiar?

- A patient comes to the hospital to have an outpatient procedure and was provided with the requisite notice of patient rights
- The patient has a less than optimal encounter.
- The patient's family verbally complains to the nurse taking care of the patient:
  - The surgeon was late getting to the OR;
  - Surgery resulted in unanticipated complications resulting in an inpatient admission;
  - My family wasn't told what was going on;
  - We had to wait 20 minutes for pain medication;
  - The food wasn't what we ordered and came late, and cold;
  - The room wasn't clean;
  - Etc. Etc. Etc.

Does this sound familiar?

- The nurse relays the complaint to the charge nurse.
- The charge nurse speaks with the patient and family, but the patient and family are not satisfied with the charge nurse's intervention.
- The charge nurse reports the complaint to the supervising nurse who also speaks with the patient and family who are still not satisfied.
- The supervising nurse contacts the patient liaison who is responsible for resolving complaints and implementing the hospital's grievance policy/procedure.
- The liaison spoke with the patient about their complaint and information about how to file a grievance (included in the notice of patient rights) was reviewed with the patient.
- The patient files a grievance.

Does this sound familiar?

- The hospital follows its grievance process:
  - The liaison documents the complaint on the hospital grievance form and reports the complaint to the Risk Manager/Quality Director;
  - A letter is sent to the patient/patient's family acknowledging receipt of the grievance;
  - The grievance is investigated (determined not to involve an allegation of immediate or imminent danger);
  - The investigation is completed within the appropriate time frame;
  - The grievance committee (delegated the responsibility by the governing board of the hospital) receives the complaint and investigation;

Does this sound familiar?

- The grievance committee makes a recommendation for resolution;
- The Director provides the patient notice of the grievance committee's recommendation advising the patient:
  - To contact the Director with any questions regarding the resolution;
  - The steps taken on behalf of the patient to investigate the grievance;
  - The results of the grievance process; and
  - The date of completion of the process.
- The Director provides the information from the grievance to the hospital's Performance Improvement Program.
- The patient is still not satisfied with the hospital's actions.

Liability Protection #1

- Be sure that your Grievance Policy/Procedure complies with the standard at 42 C.F.R. § 482.13(a)(2).
- Review the Interpretive Guidelines: When does a concern / complaint rise to the level of a grievance?
  - A “patient grievance” is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient’s representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital CoPs, or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489.
  - But . . .

Liability Protection #1

- The interpretive guidelines provide:
- “[t]he expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response.” SOP, Appendix A, A-0118.

Liability Protection #1

- Focus on providing high quality, safe patient care starting with governing body buy-in;
- Resolve complaints before they become grievances;
- Have specific policies/procedures in place to address complaints/grievances however they arise;
- Assure that the appropriate patient's rights notices are provided;
- Specify individuals whose roles are to intervene;
- Carefully determine time frames for notifications, investigations and reporting;
- Carefully craft your acknowledgment letters and resolution letters;
- Educate staff so they know who to call and when to call to avert complaints/grievances.

Liability Protection # 1

- Structure meetings with patient/family to comply with protections of the South Carolina Unanticipated Medical Outcome Reconciliation Act. S.C. Code Ann. 19-1-190
- Any statements, affirmations, gestures, activities, or conduct expressing benevolence, regret, apology, sympathy, commiseration, condolence, compassion, mistake, error, or a general sense of benevolence made by a healthcare provider (employee, agent or institution) at a designated meeting to discuss an unanticipated outcome shall be inadmissible.

If a patient wants to file a quality of care complaint against a provider . . .

- Search “quality of care complaint” and you will get:
- http://www.medicare.gov/claims-and-appeals/file-a-complaint/quality-of-care/complaints-about-quality-of-care-.html
- Tabs at the website:
  - Claims and appeals
  - File a Complaint
  - Complaints about quality of care
- Patients are provided with examples of what Medicare considers quality of care complaints as follows . . .

Examples of Quality of Care Complaints

- Complaints about drug errors
  - Like being given the wrong drug or being given drugs that interact in a negative way.
- Complaints about unnecessary or inappropriate surgery
  - Like being operated on for a condition that could've been effectively treated with drugs or physical therapy.
- Complaints about unnecessary or inappropriate treatment
  - Like being given the wrong treatment or treatment you didn't need.
- Complaints about not getting treatment after your condition changed
  - Like not getting treatment after abnormal test results or when you developed a complication.

Examples of Quality of Care Complaints

- Complaints about getting discharged from the hospital too soon
  - Like being sent home when you're still in severe pain.
- Complaints about incomplete discharge instructions and/or arrangements
  - Like being sent home from the hospital without instructions for the changes that were made in your daily medicine.
- Complaints about customer service
  - For example, you think the customer service hours for your plan should be different.
- Complaints about access to specialists
  - For example, you don't think there are enough specialists in the plan to meet your needs.

Where/How does a patient file a complaint?

- On the same page, patients are provided with the roadmap to where to file a complaint based on the type of complaint as follows . . .
- Complaints about your health or drug plan
  - Use the Medicare Complaint Form or follow the instructions in your plan membership materials to submit a complaint about your Medicare health or prescription drug plan.
- Complaints about improper care or unsafe conditions
  - To file a complaint about improper care (like claims of abuse to a person in a nursing home) or unsafe conditions (like water damage or fire safety concerns) in a hospital, home health agency, hospice, or nursing home contact your State Survey Agency (usually part of your State's department of health services).

Where/How does a patient file a complaint?

- Complaints about hospital conditions
  - To file a complaint about conditions at a hospital (like rooms being too hot or cold, cold food, or poor housekeeping) contact your State department of health services.
- Complaints about your doctor
  - To file a complaint about your doctor (like unprofessional conduct, incompetent practice, or licensing questions) contact your State medical board.

Where/How does a patient file a complaint?

- Complaints about home health agencies
  - If you have a complaint about the quality of care you're getting from a home health agency, call the home health agency and ask to speak to the administrator. If you don't believe your complaint has been resolved, call your state home health hotline. Your home health agency should give you this number when you start getting home health services.
- Complaints about kidney care
  - Find out how to file a complaint (grievance) about your dialysis or kidney care.

Where/How does a patient file a complaint?

- Under the “find someone to talk to” tab for South Carolina the patient finds:
  - How to contact the CMS Regional Office to report a complaint directly to CMS: Local: (404) 562-7500 or a link to the website.
  - How to contact the South Carolina QIO (Carolina Center for Medical Excellence): Toll Free: (800) 922-3089 Local: (803) 251-2215 or a link to the website.
  - Surprisingly, SCDHEC is not on the list – under “State Health Departments” SC DHHS listed.

Obligations of Health Care Practitioners and Providers of Health Care Services

- 42 U.S.C. § 1320c-5(a): It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or persons to beneficiaries and recipients under this Act:
  - (1) will be provided economically and only when, and to the extent, medically necessary;
  - (2) **will be of quality which meets professionally recognized standards of health care**; and
  - (3) **will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing QIO in the exercise of its duties and responsibilities.**

QIO Quality of Care Reviews: Beneficiary Complaints

- Medicare has delegated the review of beneficiary quality of care complaints to the Quality Improvement Organizations (“QIO”S).
- The SC Medicare QIO: Carolina Center for Medical Excellence.
- DHHS substantially revised the QIO processes for quality of care complaints in November 2012 (most of the revisions became effective January 2013) to “better meet the needs of the beneficiaries.”
- The QIOs conduct (among other things) quality of care reviews that include beneficiary complaint reviews.
- QIOs determine whether the quality of the services meets professionally recognized standards of health care, as determined through the resolution of oral beneficiary complaints (§ 476.110), written beneficiary complaints (§ 476.120), or the completion of general quality of care reviews (§ 476.160). § 476.71

QIO Quality of Care Reviews: Verbal Beneficiary Complaints

- § 476.110 Use of immediate advocacy to resolve oral beneficiary complaints:
  - (1) The complaint is received not later than 6 months from the date on which the care giving rise to the complaint occurred.
  - (2) After initial screening of the complaint, the QIO makes a preliminary determination that--
    - (i) The complaint is unrelated to the clinical quality of health care itself but relates to items or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider; or
    - (ii) The complaint, while related to the clinical quality of health care received by the beneficiary does not rise to the level of being a **gross and flagrant**, **substantial, or significant quality of care concern**.

QIO Quality of Care Reviews: Verbal Beneficiary Complaints

  - (3) The beneficiary agrees to the disclosure of his or her name to the involved Provider and/or Practitioner.
  - (4) All parties orally consent to the use of immediate advocacy.
  - (5) All parties agree to the limitations on redisclosure set forth in § 480.107.
- Immediate advocacy can be discontinued at any time by the QIO or either party.
- All communications are confidential and must not be redisclosed without the consent of all parties.

QIO Quality of Care Reviews: Verbal Beneficiary Complaints

- **Gross and flagrant violation** means a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or wellbeing of a program patient or places the program patient unnecessarily in high-risk situations.
- **Significant quality of care concern** means a determination by the QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

QIO Quality of Care Reviews: Verbal Beneficiary Complaints

- **Substantial violation** in a substantial number of cases means a pattern of providing care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

Quality of Care Reviews: Written QIO Beneficiary Complaints

- §476.120: Submission of Written Beneficiary Complaints:
- QIO will conduct a review of any written beneficiary compliant about the quality of health care if the compliant is received not later than 3 years from the date on which the care giving rise to the compliant occurred.
  - Written complaint includes electronically submitted complaints.
  - If the beneficiary contacts the QIO but declines to make the complaint in writing and immediate advocacy has not been offered, the QIO may complete a general quality of care review (§476.160) if the QIO determines that the complaint involves potential gross and flagrant, substantial or significant quality of care concern.
  - New concerns raised during the review will be treated as new complaints.

Quality of Care Reviews: Beneficiary Complaint Review Processes

- §476.130:
- (a) Scope of Review: QIO will review information provided by the Beneficiary and the Provider.
  - (1) QIO focuses on the episode of care from which the complaint arose and address the specific concerns raised and any concerns identified by the QIO.
  - (2) QIO will use evidence based standards of care to the maximum extent practicable. If none exist, then QIO will use available norms, best practices and established guidelines.
  - The determination regarding the standard used is NOT appealable.

Quality of Care Reviews: Beneficiary Complaint Review Processes

- (b) Medical information requests:
  - All medical information must be produced within 14 calendar days of the request.
  - QIO may request sooner if the complaint involves potential gross and flagrant, substantial or significant quality of care concern AND circumstances warrant earlier receipt.
  - Failure to comply = QIO issues denial determinations for the claims it was unable to review, make the determination that financial liability will be assigned and may report to the HHS Inspector General. (Practice tip = don't fail to comply)
  - QIO must inform the Provider that the medical information is being requested in response to the beneficiary complaint, explain the Provider's right to discuss the QIO's interim initial determination and request the name of a contact person.

Quality of Care Reviews: Beneficiary Complaint Review Processes

- (c) Interim initial determination:
  - Provider will be notified of the interim initial determination within 10 days of the QIO's receipt of all medical information.
  - If there is a determination that the quality of services does not meet professionally recognized standards of care for any concern in the complaint, the Provider will be notified of an opportunity for a discussion that must be held no later than 7 calendar days from the date of the initial offer.
  - The interim initial determination becomes final if the discussion does not take place within the 7 calendar days/or the Provider's failure to respond.
  - Written statements may be submitted in lieu of the discussion also within the same 7 days.
  - Extensions will rarely be made.

Quality of Care Reviews: Beneficiary Complaint Review Processes

- (d) Final initial determination: Telephone notification to the Beneficiary and Provider is made:
  - No later than 3 business days after the completion of the review; or
  - No later than 3 business days after the discussion or written submission in lieu of discussion.
- Either party may request reconsideration.
- Written notice of the final initial determination is forwarded to all parties within 5 calendar days after the completion of the review.
- Written notice includes:
  - A statement of each concern that did/did not meet the standard of care;
  - The standard of care used for each concern; and
  - A summary of the facts pertinent to the findings.

Quality of Care Reviews: Beneficiary Complaint Reconsideration Processes

- § 476.140 Reconsideration
  - Beginning with complaints filed after July 31, 2014, a dissatisfied party may request reconsideration.
  - Reconsideration request must be made in writing or by telephone no later than 3 calendar days following initial notification of the QIO's determination.
  - The parties must be available to answer questions.
  - The parties must be provided with the opportunity to provide further information.

Quality of Care Reviews: Beneficiary Complaint Reconsideration Processes

- No more than 5 calendar days after receipt of the request for reconsideration, or, if later, 5 calendar days after receiving any medical or other information needed for reconsideration, QIO must complete the review and notify the parties of its decision.
  - Initial notification of the reconsideration may be by telephone followed by mailing the written notice by noon of the next calendar day that includes:
    - A statement of each concern that did/did not meet the standard of care;
    - The standard of care used for each concern;
    - A summary of the facts pertinent to the findings; and
    - A statement that this is the QIO's final determination and that there is no right to appeal.

After Reconsideration

- The QIO may provide information to the party regarding opportunities for improving the care given to patients based on the specific findings of its review and the development of quality improvement initiatives.
- May have an opportunity to re-open within one year of the final initial determination.
- Re-opening can be extended to four years if:
  - Additional information is received on the patient's condition;
  - Reviewer error occurred in interpretation or application of a Medicare coverage policy or review criteria;
  - There is an error apparent on the face of the evidence upon with the decision was based; or
  - There is a clerical error in the statement of final initial determination.

42 C.F.R. Part 1004 Sanctions :

- If the QIO determines that there has been a violation of services:
  - (1) provided economically and only when, and to the extent, medically necessary;
  - (2) of quality that meets professionally recognized standards of health care; and
  - (3) supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing QIO in the exercise of its duties and responsibilities.
- Then:
  - QIO provides reasonable notice and opportunity for discussion; and, if appropriate
  - A suggested method for corrective action.

42 C.F.R. Part 1004 Sanctions

- QIO submits a report to the OIG after the notice and opportunity is provided and, if appropriate, the opportunity to enter into and complete a corrective action plan ("CAP") if the QIO finds;
  - The Provider has failed substantially to comply with any obligation in a substantial number of admissions; or
  - Grossly or flagrantly violated any obligations in one or more instances.

42 C.F.R. Part 1004 Sanctions

- When the QIO identifies a violation it must:
  - Indicate whether it was gross and flagrant or is a substantial violation in a substantial number of cases; and
  - Send the Provider written notice of the violation containing:
    - The obligations involved;
    - The situation, circumstances or activity that resulted in the violation;
    - The authority and responsibility of the QIO to report violations;
    - A suggested method or correcting the situation and a time period for corrective action, if appropriate;
    - The sanction the QIO could recommend to the OIG;
    - The right of the Provider to submit additional information within 30 days of the receipt of the notice; or

42 C.F.R. Part 1004 Sanctions

- A written request for a meeting with the QIO or both.
- The notice will also state that if a meeting is requested:
  - It will be held within 30 days of receipt of the request (may be extended for good cause);
  - The Provider may have an attorney present who will be allowed to make opening and closing remarks, ask clarifying questions and assist with presenting testimony; and
  - A copy of the material the QIO used to make the finding.

42 C.F.R. Part 1004 Sanctions

- If a meeting is requested and held, after the meeting, the QIO affirms or modifies its finding and may recommend a CAP.
- If the QIO continues to find that a violation exists, then:
  - A report is sent to the OIG
  - Notice is sent to the Provider that a report has been sent to the OIG and the Provider has 30 days to provide additional documentation.
  - Notice is sent to the appropriate licensing board(s).

42 C.F.R. Part 1004 Sanctions

- Sanctions (may include monetary sanctions and exclusion from Federal and State Health Care Programs) are based on consideration of:
  - The type of offense involved;
  - The severity of the offense;
  - The deterrent value;
  - The Provider's or other person's sanction record;
  - The availability of alternative sources of services in the community; and
  - Any other factors that the QIO considers relevant.
- The OIG may accept, reject or modify the sanctions.
- Appeal rights: Very limited.
- QIO Manual: Chapter 5 Quality of Care Review: http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf

Liability Protection #2

- Understand the QIO processes;
- If you receive any notice of a beneficiary complaint, make sure it gets to the right individual(s) in your entity (Risk Management; Compliance; Quality; Performance Improvement; Adminstration);
- Consult with legal counsel to assist you through the process;
- Maintain appropriate documentation;
- Provide the requested information within the requested time frames;
- Cooperate with the process;
- Be prepared for any meeting/discussion of the matter.

CMS/SC DHEC Complaint Survey Processes

- The goal of the Federal complaint/incident process is to establish a system that will assist in promoting and protecting the health, safety, and welfare of residents, patients, and clients receiving health care services. The complaint/incident management system has three objectives:
  - Protective oversight;
  - Prevention;
  - Promote efficiency and quality within the health care delivery system.
- Found at: SOM, Chapter 5 Complaint Procedures:
- http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c05.pdf
- A complaint is an allegation of noncompliance with Federal and/or State requirements.

CMS/SC DHEC Complaint Survey Processes

- CMS/SC DHEC receive complaints from various sources:
  - Patients;
  - Families;
  - Coroner or medical examiner;
  - QIOs;
  - Law enforcement;
  - Ombudsman's office;
  - Adult Protective Services;
  - Media sources; and
  - Etc.
- Typically, the identity of the complainant is kept confidential.
- The receiving agency (SA/RO) provides the complainant with an acknowledgment letter.

CMS/SC DHEC Complaint Survey Processes

- Information obtained from the complainant:
  - Individuals involved and affected;
  - Narrative/specifics of the complainant's concerns including the date, and time of the allegation;
  - The complainant's views about the frequency and pervasiveness of the allegation;
  - Name of the provider/supplier including location (e.g., unit, room, floor) of the allegation, if applicable;
  - How/why the complainant believes the alleged event occurred;
  - Whether the complainant initiated other courses of action, such as reporting to other agencies, discussing issues with the provider, and obtaining a response/resolution; and
  - The complainant's expectation/desire for resolution/remedy, if appropriate.

CMS/SC DHEC Complaint Survey Processes

- Information provided to the complainant:
  - Policies and procedures for handling intakes including the scope of the SA's regulatory authority and any considerations pertaining to confidentiality;
  - The course of action that the SA or RO will take and the anticipated time frames;
  - Information about other appropriate agencies that could provide assistance including the name and telephone number of a contact person, if available; and
  - A SA contact name and number for follow-up by the complainant.
- Deemed providers/suppliers: if the complaint does not rise to a condition level allegation the SA may have the complainant report to the accrediting organization ("AO") or request consent to do so.

CMS/SC DHEC Complaint Survey Processes

- The SA automatically reports complaints about the following to the RO:
  - Deemed providers/suppliers;
  - Hospital and psychiatric residential treatment facility (PRTF) restraint/seclusion-related deaths;
  - EMTALA complaints;
  - Fires resulting in serious injury or death in a Medicare/Medicaid-certified facility;
  - Federal facilities;
  - Religious Non-medical Health Care Institutions (RNHCIs)(evaluation performed by Region I, Boston, only);
  - CLIA-certified laboratories holding a certificate of accreditation. (See Chapter 6).

CMS/SC DHEC Complaint Survey Processes

- CLIA-exempt laboratory. (See Chapter 6);
- Blood transfusion-related fatalities (See Chapter 6 and Appendix C);
- Over-utilization or inappropriate utilization of services within the QIO's jurisdiction;
- Civil rights violations; or
- Medicare Medicaid fraud

CMS/SC DHEC Complaint Survey Processes

- The complaint is prioritized at the time of intake:
  - High = immediate jeopardy
    - 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/resident.
  - Medium = the alleged noncompliance with one or more requirements or conditions caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical and/or psychosocial status or function.
  - Low = alleged noncompliance with one or more requirements or conditions may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage.

CMS/SC DHEC Complaint Survey Processes

- At times, complaints are referred to other agencies.
- No action may be taken if:
  - There is no allegation of immediate jeopardy;
  - A previous survey investigated the same events;
  - A previous survey evaluated the appropriate individuals, including those identified in the intake; and
  - The situation did not worsen.

Timing of Complaint Surveys

Intake Prioritization				
Provider Type	Immediate Jeopardy (IJ)	Non-IJ High	Non-IJ Medium	Non-IJ Low
Nursing homes	SA must initiate an onsite survey within 2 working days of receipt.	SA must initiate an onsite survey within 10 working days of prioritization.	No timeframe specified, but an onsite survey should be scheduled.	SA should investigate during the next onsite survey.
Non-deemed providers/suppliers, other than nursing homes	SA must initiate an onsite survey within 2 working days of receipt.	N/A	SA must initiate an onsite survey within 45 calendar days of prioritization.	SA should investigate during the next onsite survey.
Deemed providers/suppliers	SA must initiate an onsite survey within 2 working days of receipt of RO authorization.	N/A	SA must initiate an onsite survey within 45 calendar days of receipt of RO authorization.	SA should investigate during the next onsite survey.
CLIA, non-exempt, non-accredited	SA investigates within 2 working days of receipt.	N/A	N/A	N/A
CLIA, exempt	SA notifies RO within 10 calendar days.	N/A	N/A	N/A
CLIA, accredited	SA submits information to RO within 2 calendar days.	N/A	N/A	N/A
EMTALA	SA must complete investigation within 5 days of receipt of RO authorization.	N/A	N/A	N/A
Death related to restraint/seclusion used for behavior management-Hospitals	SA must complete an onsite investigation within 5 working days of telephone authorization from the RO.	N/A	N/A	N/A
Fires resulting in serious injury or death	SA must initiate an onsite survey within 2 working days of receipt.	N/A	N/A	N/A

Complaint Survey/Investigation

- The SA reports poor quality of care or other indications of noncompliance with the CoPs or Conditions for Coverage (CfC) for deemed providers/suppliers to the RO.
- The SA refers to the CMS RO all allegations for deemed providers/suppliers and all EMTALA allegations for Medicare-participating hospitals.
- The RO may authorize the SA to investigate a portion of the EMTALA allegation.
- The SA may not conduct a complaint investigation on a deemed provider without RO authorization.

Complaint Survey/Investigation: Updated 7 & 8/2013

- The SA/RO may find the provider/supplier in:
  - Substantial compliance: If there are no condition level deficiencies.
  - Immediate Jeopardy:
    - Removed while on-site, Form 2567 shows IJ, but abated.
    - Not removed while on-site, the provider/supplier:
      - Is placed on a 23 calendar day termination track;
      - Must submit a plan of correction (“PoC”) in 5 calendar days;
      - A notice is provided to the AO/ deemed status removed.
    - Once an acceptable PoC is submitted, the SA either conducts a full survey or an IJ focused survey at RO’s direction.
    - If no acceptable PoC submitted, then the provider/supplier is terminated and notice is published 15 days prior to termination.

Complaint Survey/Investigation: Updated 7 & 8/2013

- If the IJ is not removed on the first post IJ revisit survey, then termination is processed:
  - Public notice provided
  - MAC notified
  - AO notified
- If the IJ is removed on the first post IJ revisit survey and substantial compliance is found, then the termination is rescinded.
- If the IJ is removed on the first post IJ revisit survey, but condition level noncompliance remains, then termination continues, but on a 90 day track until substantial compliance is achieved.
  - 2nd post IJ revisit before the 60th day:
    - Substantial compliance (may have standard level deficiencies) – termination rescinded
    - Substantial Noncompliance: termination goes forward.

Complaint Survey/Investigation: Updated 7 & 8/2013

- Condition-level noncompliance: SA or RO either
- Places the provider/supplier on a 90 day termination track; or
- Requires a full survey after the compliant survey
- Determined by:
  - The manner and degree of noncompliance identified as a result of the complaint investigation;
  - The provider's/supplier's compliance history;
  - Recent changes in the provider's/supplier's ownership/management;
  - The length of time since provider/supplier's last accreditation survey;
  - The availability of SA resources at the time required to conduct a full survey; and/or
  - The advantages associated with conducting a more extensive survey compared to the advantages associated with the faster enforcement (and thus a faster potential corrective action) that result when proceeding directly to enforcement action after the complaint survey.

Complaint Survey/Investigation: Updated 7 & 8/2013

- Condition level noncompliance: Provider/supplier on 90 day termination track:
  - PoC required in 10 calendar days
  - If no acceptable PoC submitted within 10 days: termination goes forward.
  - If acceptable PoC submitted:
    - First revisit survey results in substantial compliance, then termination rescinded.
    - First revisit survey results in substantial noncompliance, then RO determines whether a 2nd revisit will occur.
    - Second revisit survey results in substantial compliance, then termination rescinded.
    - Second revisit survey results in substantial noncompliance, then termination goes forward.

Complaint Survey/Investigation: Updated 7 & 8/2013

- Condition level noncompliance: Provider/supplier subject to full survey:
  - First revisit must occur within 60 days.
  - Similar provisions already discussed apply for findings of:
    - Substantial compliance;
    - Immediate Jeopardy;
    - Condition level noncompliance; or
    - Standard level noncompliance.

Complaint Survey/Investigation: Updated 7 & 8/2013

- Special survey provisions apply for complaints:
  - Hospital Restraint/Seclusion Death Reporting;
  - ERSD Services and Suppliers;
  - HIV Infected Individuals
  - EMTALA
  - CLIA

Exit Conference

- Exit Conference:
  - The SA informs the provider/supplier of the survey findings including deficiencies found.
  - The SA informs the provider/supplier that survey findings will be documented on Form CMS-2567, which will be made available to the public under the disclosure of survey information provisions.
  - For deemed providers/suppliers, the SA informs the provider/supplier that the RO will inform of the disposition of the survey investigation.

What the Complainant is Provided

- The SA/RO provides the complainant a written report of the investigation findings as a summary record of the investigation.
- The following is considered in the preparation of the report:
  - Acknowledge the complainant's concern(s);
  - Identify the SA's regulatory authority to investigate the complaint/incident and any statutory or regulatory limits that may bear on the authority to conduct an investigation;
  - Provide a summary of investigation methods (e.g., on-site visit, written correspondence, telephone inquiries, etc.);
  - Provide date(s) of investigation;
  - Provide an explanation of the SA's decision-making process including definitions of terms used (i.e., substantiated or validated, unsubstantiated or not validated, etc.);

What the Complainant is Provided

- Provide a summary of the SA's finding;
  - Anonymity is protected to the extent possible
- Identify follow-up action, if any, to be taken by the agency (i.e., follow-up visit, plan of correction review, no further action, etc.); and
- Identify appropriate referral information (i.e., other agencies that may be involved).

Fall out: Potential Penalties

- Potential Penalties:
- QIO:
  - Termination of the Provider Agreement;
  - Exclusion from the Medicare/Medicaid Programs;
  - Potential monetary penalties.

- CMS:
  - Termination of the Provider Agreement.

Liability Protection # 3

- Comply with the CoPs;
  - SOM, Appendix A Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
  - http: //cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf
  - Keep your policies/procedures updated with changes in the CoPs;
- Comply with Accreditation Standards;
- Understand the CMS complaint survey processes;
- Educate your staff about compliance;
- Have processes in place to assure 24/7 readiness for unannounced complaint surveys;
- Understand what is at stake.

How do we protect information gathered/created/disclosed in responding to complaints?

- Good News!!! (Finally)
- Prior to 2012, there was essentially NO protection for information gathered/created/disclosed in response to complaint surveys.
- All information was discoverable in civil litigation!!
- 2012 Amendments to the SC Peer Review Statute provides BROAD protections for information gathered/created/disclosed in responding to quality of care complaints.

Who is protected?

- All hospital employees and medical staff
- Directors (governing body) and Officers
- Hospital subsidiaries and parent corporations
- Healthcare and Hospital systems (nursing homes; hospice; home health; urgent care; etc.)
- Physician practices owned by hospitals (& the hospital's parent and/or subsidiaries)
- Any committee member of a licensed hospital (standing or ad hoc)
- External reviewers
- Witnesses

What is Confidential?

- All information and proceedings gathered by a committee of a hospital were already protected, but the amended statute expands confidentiality to all proceedings and information relating to:
  - Sentinel event investigations and root cause analyses (document review by TJC, DNV does not waive confidentiality)
  - Investigations into the competence or conduct of hospital employees, agents, or medical staff relating to the quality of patient care, including any related disciplinary proceedings or fair hearings
  - Quality assurance reviews
  - Medical staff credentialing processes
  - Reports by a hospital to its insurance carriers

What is Confidential?

- Reviews or investigations to evaluate the quality of care provided by hospital employees, agents, or members of the hospital's medical staff
- Reports or statements to National Practitioner Data Bank and the SC Board of Medical Examiners providing analysis relating to the quality of care provided by hospital employees, agents, or members of the hospital's medical staff
- Incident or occurrence reports and related investigations
- Reports to DHEC (licensed hospital) not a waiver of confidentiality
- Reports to accrediting bodies not a waiver of confidentiality

But, How Bad Can it Get (When talking about dealing with CMS)??

- Federal False Claims Act: Establishes liability for any person who knowingly presents or causes to be presented a false or fraudulent claim to the U.S. government for payment.
- Quality so deficient that the claim amounts to a false claim.
- Three legal theories:
  - Implied Certification
  - Express Certification
  - Worthless Services

Implied Certification

Medicare Claim Form

- Services medically indicated, necessary and under supervision of billing provider
- Implies that provider certifies compliance with all Medicare statutes and regulations
- Bootstrap Stark and Anti-kickback violations

Express Certification

- Medically necessary care was furnished
- CMS 855 Enrollment Application:
- I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

Worthless Services

9th Circuit

- "Services rendered to resident are so deficient as to be worthless"
- "In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under [the FCA], regardless of any false certification conduct"

2nd Circuit

- "Service must be so deficient as to be equivalent to no performance at all"
- Higher standard

False Claims Act

- Penalties (Civil)
  - Civil Monetary Penalties ranging from $5,500 to $11,000 for each false claim presented
  - Treble damages sustained by Government
  - Exclusion
  - Corporate Integrity Agreement
- Penalties (Criminal)
  - Not greater than 5 years imprisonment (Conspiracy = 10 years)
  - Fine not greater than $250,000

Wrap up

- Look at how you deal with internal complaints/grievances;
- How do you coordinate efforts to respond to complaints among the various hospital departments?
  - Risk Management
  - Quality/Performance Improvement
  - Peer Review
  - Compliance
  - Administration
  - Human Resources
- Share information.
- Understand CMS focus areas on quality:
  - Core measures
  - Never events
  - Meaningful Use
- Use information provided by accrediting bodies (TJC; DNV; AOA) concerning quality measures.
- Use national risk management/quality/safety information, e.g., ASHRM, NAHQ, Leapfrog

Questions?

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