

Agency for Health Care Administration

Bureau of Field Operations

Risk Management Survey Process

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I. OVERVIEW

The Agency’s mission of better health care for all Floridians includes and recognizes the need for all stakeholders of hospitals and Ambulatory Surgical Centers (ASC) to collaborate toward a common goal of ensuring quality services and care to patients who receive care. It is the policy of the State that the appropriate and available treatment be used based on the individual needs and best interests of the patient, consistent with optimum clinical practice.

This survey process relates to independent Risk Management surveys for deemed hospitals and the Risk Management surveys done in conjunction with ASC and hospital licensure surveys.

Survey Requirements

Per Florida Statutes 395.0197, “The Agency shall review, as part of its licensure inspection process, the internal risk management program at each licensed facility regulated by this section to determine whether the program meets standards established in statutes and rules, whether the program is being conducted in a manner designed to reduce adverse incidents, and whether the program is appropriately reporting incidents under this section.”

If a full licensure survey is completed in an ASC or hospital (such as a non-deemed provider or a validation of a deemed provider) risk management will always be completed. Other surveys may also include risk management, such as complaints or stand alone risk management surveys.

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Selection of Surveys to be Conducted

Risk management surveys will be conducted with full licensure surveys. They may also be conducted:

1. In conjunction with complaint surveys with allegations suggesting risk management process concerns,
2. As a stand alone process in cases wherein there have been no surveys outside of life safety at the facility for a period of 36 months or more,
3. As a result of concerns with reporting of adverse incidents, including trends of particular incidents or lack of systematic response to incidents,
4. Or in other cases wherein field operations management deems it appropriate.

Reports found at <http://hq3sqlcip/Reports/browse/Adverse%20Incident%20Reports> may assist in making these determinations related to #3 above.

II. HOSPITAL/ASC RISK MANAGEMENT SURVEY

The survey team is expected to follow the survey protocol process for each provider type for the assigned survey.

SURVEY PROCESS

The Risk Management survey is done in conjunction with initial hospital or ASC surveys. It includes a review of policy and procedures to ensure the facility has these in place and mechanisms to ensure patient safety.

If the Risk Management survey is conducted in conjunction with a licensure or complaint survey, the tasks for sampling of incident reports for review, and sampling for staff interviews and training file reviews are reduced. (See sections 4&5 below.)

The goal of the state survey is to determine if the provider is in compliance with the definitions set forth in Chapter 395 and 408, Part II, Florida Statutes (F.S.), and 59A-3 Florida Administrative Code (F.A.C.).

Tasks

1. Off-Site Pre-survey review and preparation
2. Entrance Conference
3. Tours and Floor Visits
4. Sample Selection
5. Information Gathering-Staff/Personnel and Patient/Family interviews/observations and facility record reviews
6. Decision Making and Analysis of Findings
7. Exit Conference

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8. Post-Survey Activities

1. OFF-SITE: PRE-SURVEY PREPARATION

The objective of this task is to analyze information about the provider to determine compliance for the Risk Management Program. The Field Office and/or Team Coordinator will access the Agency Portal/Systems and Resources site to review any Adverse Incident Reports (AIRs) and the Annual Report submitted since the last risk management survey. The Field Office will provide all risk management complaints since the last risk management survey for review and determination of patterns of potential concerns or need for patient sampling.

Note: From the total open complaints, select RM from security class then export to excel and sort by provider:

<http://hq3sqlsip01/Reports/report/LicenseEase%20Reports/TotalOpenComplaints>

Documentation: Risk Management Forms are available electronically on the Health Care Policy & Oversight Portal under the Bureau of Field Operations, Surveyor Tools. The *Risk Management Survey Report and Worksheet* is used to document **all** survey findings, including interviews and observations. Review forms before survey entrance and make a survey folder on desktop for survey documents. **The Team Coordinator is responsible for submitting the final completed *Risk Management Survey Report and Worksheet* to the Field Office.** Additional team members may document on their own **Survey Report and Worksheet** forms and submit as documentation/notes.

Hospitals and Ambulatory Surgical Centers:

- Review survey process.
- Obtain materials required for state licensure/risk management survey, including current risk management and facility forms needed to complete survey.
- Review facility compliance history and determine noncompliance trends.
- Review facility website for price transparency including defined bundles of services or procedures and instructions for financial assistance. (State owned hospitals are exempt from price transparency requirements.)
- Determine team member assignments.
- Prepare for the on-site initial meeting regarding state licensure/risk management survey issues and identified concerns.
- Prepare and notify the team of date, time and location team members will meet to enter the facility.
- Identify potential/anticipated date and time of the exit conference.

Hospitals Only:

- The Risk Management Survey includes a review of the Concern Log items. The Field Office notifies the Team Coordinator of the concerns identified by the Complaint Incident and Management Unit (CIMU) for investigation. The Team Coordinator reviews these concerns with the team for assignment. The investigation of concerns includes interviews, observations, and

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record review to determine compliance and appropriate facility risk management process interventions.

- The Team Coordinator will conduct a review of the hospital website for compliance with price transparency requirements (*State owned facilities are exempt from price transparency requirements.*)

2. ENTRANCE CONFERENCE

The objectives of this task are to explain the survey process to facility management staff and obtain the information needed to conduct the survey.

- Conduct meeting with Hospital/ASC Administration/Risk Manager/Risk Manager Designee.
- Present the Risk Management Entrance Checklist to facility Administration and explain the requested facility documents and information need to be provided as soon as possible.
- Introduce survey team members.
- Explain the purpose and scope of the survey-including Risk Management.
- The team coordinator organizes meetings with facility leadership/staff members. Include appropriate hospital staff related to risk management concerns.
- Request additional information to address facility issues, complaints, and risk management concerns as provided during the off-site preparation.
- Inform administration staff of preliminary date and time for the exit conference.
- **Hospital:** Ask if the hospital has a Patient Safety Organization (PSO). Request the name and date the hospital initiated the PSO. Verify the PSO is a U.S. Department of Health and Human Services federally listed organization. The list is on the Agency for Healthcare Research and Quality (AHRQ) website (<https://psa.ahrq.gov/listed>).

NOTE: The surveyor **must not** ask to see information that was developed by the facility for reporting to a **Patient Safety Organization**, or legal deliberations or root cause analysis.

3. TOURS AND FLOOR VISITS

This brief tour/floor visit focuses on areas of identified concerns from the off-site preparation. Interviews and observations focus on concerns identified on the concern log or complaint allegations. If a hospital has more than one premise, a brief tour is done ONLY if there are identified concerns for that premise.

The objective of this task is to visit the floors of the hospital or ASC facility where areas of concern have been identified to determine compliance with the Risk Management regulations. Conduct **brief** observations and interviews related to the identified concerns during this tour.

The list of observations, staff and patient interviews provided in the Information Gathering section of this protocol may be used as a guideline for this task.

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4. SAMPLE SELECTION

ASC: Select 10 incident/adverse reports to review.

Note: If conducted in conjunction with a recertification, relicensure survey or complaint survey, select 3 incident/adverse reports to review. (May expand if any concerns.)

Hospital: For hospitals with less than 100 beds, complete 10 incident reviews. For hospitals with more than 100 beds, complete 15 incident reviews. Include both open and closed, incident/adverse events, AHCA 15-day reports, grievances, deaths, discharges, include patient interviews, observations and or patient record reviews associated with concerns or those identified by the complaint issues if complaints are assigned to the survey. Remember to include incidents from premises. The surveyor may supplement additional incident reviews if concerns are identified. *(Surveyors will document this information on the Risk Management Survey Report and Worksheet.)*

Note: If conducted in conjunction with a recertification, relicensure survey or complaint survey, for hospitals less than 100 beds, complete 3 incident reviews. For hospitals with more than 100 beds, complete 5 incident reviews. (May expand if any concerns.)

5. INFORMATION GATHERING: STAFF/PATIENT/FAMILY INTERVIEWS/OBSERVATIONS AND FACILITY RECORD REVIEWS

The objective of this task is to determine the facility's compliance with the State Licensure and/or Risk Management regulations through observations, interviews, and document review; and to investigate the concern indicators as outlined during the off-site preparation.

Conduct follow up and more in-depth observations and interviews for risk prevention, risk assessment, incident reporting and process, risk intervention, staff risk management training, staff knowledge of the risk management program, and price transparency. Observations and interviews are focused on the areas of concern. The surveyor may conduct up to three (3) patient interviews and three (3) staff interviews related to risk management and the identified concerns. If there are no concerns identified, staff interviews should focus on asking questions related to culture of safety (as noted below). Note: If conducted in conjunction with a recertification, relicensure or complaint survey, conduct two patient and two staff interviews related to risk management and identified concerns. (May expand if any concerns.)

Additional patient and staff interviews may be conducted if concerns are identified.

Observations (focus on areas of concern):

- Patient and staff interactions
- Language and communication interactions between staff and patient and/or family/patient representative
- General condition of facility
- Environment
- Safety, privacy, and health information confidentiality
- Equipment condition and function

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- Provision of care and treatment

Patient Record Reviews:

- This review is to determine risk management incident compliance and to ensure the facility has an effective risk management process.
- The number of patient records varies with each facility type, size, department (Pharmacy, Surgical services, etc.), previous compliance history and the concerns identified from the concern log.
- Include both open and closed patient medical record reviews.
- Review three (3) discharged patient records, including one patient on observation status, for price transparency requirements.

NOTE: Patient interviews and observations included in samples may not require a review of the patient record. Concern issues may not require a specific patient record review to determine compliance with the identified concern. Observations and interviews may suffice to identify compliance or non-compliance.

Facility Records/Systems Review:

- **Grievances and Incidents/Events**

Grievances and facility incident/event reviews determine if the facility was aware of the concern or other issues identified throughout the survey process. If the facility is aware of issues, the facility staff should be able to present the process and interventions used or in place to mitigate that concern/issue. Review the patient grievances for any complaints related to billing issues.

- **Personnel Records:** This task is to ensure the facility has provided the appropriate content required for risk management training within the timeframes as outlined in the regulations. For Agency compliance determinations, this includes a review of two (2) existing (employed over two years), two (2) new personnel records and two (2) contracted staff employed over thirty (30) days. (See *Risk Management Survey Report and Worksheet*.)

Team Meetings: Team Coordinator conducts team meetings as needed to determine survey progress, findings potential deficiencies, potential imminent risk, and possible survey expansion.

NOTE: For Federally Deemed ASCs & Hospitals - If potential Federal Conditions of Participation/Condition for Certification are identified, the Team Coordinator is required to contact Field Office Management immediately for survey direction and possible expansion of the survey using Centers for Medicare and Medicaid Services (CMS) Form 2802 (Request for Validation Survey) for appropriate Federal Condition approvals.

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6. DECISION MAKING AND ANALYSIS OF FINDINGS

The objective of this task is to integrate findings, review and analyze information collected from observations, interviews, and record reviews, and to determine whether the provider meets compliance as outlined in the rules and regulations.

- **Preparation:** Each team member reviews and reports their pertinent investigational findings, completes the entire *Risk Management Survey Report and Worksheet*, including notes.
- **Team Meeting:** The team as a group discusses surveyor findings, team determines compliance/non-compliance, team consensus for non-compliance, and the decisions documented are for use at the exit conference.
- **Team Discussion:** Determine severity and extent of the non-compliance. Team may need to consider expansion of the survey type and incorporating the Federal Medicare Hospital Condition of Participation (CoP) or the Federal Ambulatory Surgical Center Condition for Certification (CfC) and the associated Appendix/ Interpretive Guidelines and/or Immediate Jeopardy (Appendix Q). The team should discuss the need to gather additional information to determine compliance. Include investigative information to address any concerns as provided by the Field Office Management during offsite preparation.

NOTE: Use the *Exit Conference & Summary Report* section of the *Risk Management Survey Report and Worksheet* to document findings.

7. EXIT CONFERENCE

The objective of this task is to inform the facility staff of the team's findings. The Team Coordinator organizes the Exit Conference. The team decides who will present the team findings (usually the Team Coordinator). If the team anticipates any difficulty with the exit conference, the team should contact the Field Office Supervisor/Manager.

The exit conference provides an opportunity for the surveyor to discuss areas of concern with the administrator and/or staff in charge. The Team Coordinator must follow the guidance in the Non LTC Exit Conference Checklist/Licensure Only Exit Conference Checklists when conducting the Exit Conference. Tag numbers are not provided. Surveyors should document the exit conference on the Risk Management Survey Report and Worksheet.

8. POST SURVEY ACTIVITIES

The general objective of this task is to complete the survey requirements, in accordance with the regulations and Agency protocols. The team members and coordinator are responsible for meeting the timeliness for completing and submitting the survey.

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Hospitals: When citing deficient practice for a premise, the Initial Comments will list the main hospital as well as the premise where deficient practice was identified.

The Team Coordinator is responsible for submitting the final completed Risk Management Survey Report and Worksheet to the Field Office. Additional team members may document on their own Survey Report and Worksheet forms and submit as documentation/notes.

III. REVISIT SURVEYS

If a revisit survey is required, review the previous survey deficiencies and Plans of Action/Correction, and follow the survey process and protocols. The revisit survey is to determine if the identified areas of non-compliance have been corrected. Review of records may be conducted to investigate the corrective actions and current compliance. Often, a desk review revisit will be appropriate.