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Aspen State Regulation Set: R 1.06 RISK MANAGEMENT (LICENSURE)

ST - R0000 - Initial Comment

Title Initial Comment

Type Memo Tag

Regulation Definition

Interpretive Guideline

Custom Help

ST - R0001 - Program Requirements

Title Program Requirements

s. 395.0197(1)(a), F.S.

Type Rule

Regulation Definition

Every licensed facility shall, as a part of its administrative functions, establish an internal risk management program. Such program shall include:

The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

s. 395.0197 (1) (a), F.S.

59A-10.002 (6), F.A.C.

59A-10.002 (10), F.A.C.

59A-10.002 (14), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review risk management policies and procedures.

Trace the facility's process through a sample of adverse incidents.

Consider and assess the risk manager's role in the investigation and analysis.

Review the monthly or quarterly summary reports for documentation of incident investigation and analysis.

Review quality assurance/performance improvement, and any other appropriate committee minutes for documentation of incident investigation and analysis.

Custom Help

ST - R0002 - Program Requirements

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Aspen State Regulation Set: R 1.06 RISK MANAGEMENT (LICENSURE)

Title Program Requirements

s. 395.0197(1)(c), F.S.

Type Rule

Regulation Definition

The analysis of patient grievances that relate to patient care and the quality of medical services.

s. 395.0197 (1) (c), F.S.

59A-10.002 (10), F.A.C

Interpretive Guideline

GUIDANCE TO SURVEYORS

Determine if facility has a patient satisfaction and/or complaint form.

Review form(s).

Select a sample of patient grievances related to patient care and the quality of medical services. Trace the process.

Review policies and procedures establishing the process that refers issues related to quality of care to the Risk Manager, Quality Assurance/Performance Improvement and the facility representative.

Review evidence that issues related to quality of care/medical care are analyzed including outcomes.

PROBES

Has the Risk Manager/facility representative performed an analysis of the grievance?

Consider the facility staff response to the patient regarding his/her grievance:

Were the issues identified?

Were corrective actions taken?

Were the corrective actions implemented monitored for effectiveness?

Custom Help

Review monthly or quarterly summary reports for documentation of analysis of patient grievances.

ST - R0003 - Program Requirements

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Title Program Requirements

s. 395.0197(1)(b), F.S.

Type Rule

Regulation Definition

The development of appropriate measures to minimize the risk of adverse incidents to patients.

s. 395.0197 (1) (b), F. S.

59A-10.002(14), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Risk Manager's role in the development and implementation of risk reduction and risk prevention strategies.

Consider evidence that patient and non-patient department staff have involvement in the process.

Review previous incidents identified as risk/process improvement opportunities including the analysis of the incident and trends.

PROBES

Is the analysis wide-ranging?

Has the facility staff taken corrective action?

What measures were implemented?

Were the measures relevant to the incident?

Have outcome measures focused on the identified problems established by trending of the data?

Does the Risk Manager communicate regarding adverse outcomes to the representatives of the department(s) involved?

Custom Help

Review summary reports provided to the Governing Board for documentation of risk identification and risk reduction activities.

ST - R0004 - Incident Reporting System

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Title Incident Reporting System

s. 395.0197(1)(e), F.S.

Type Rule

Regulation Definition

The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the health care facility to report adverse incidents.

An incident reporting system shall be established for each facility. Procedures shall be detailed in writing and disseminated to all employees of the facility.

All new non-physician personnel, within 30 days of employment, shall be instructed about the operation of the system and the responsibilities of it.

s. 395.0197 (1) (e), F.S.

59A-10.002 (8), F.A.C.

59A-10.005, F.A.C.

59A-10.0055 (1), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the policies and procedures for incident reporting.

Interview a sample of staff to determine their awareness of the responsibilities, requirements, and method for incident reporting.

Review a sample of personnel files for education and training on incident reporting.

PROBES

What are the guidelines for reporting incidents?

Does staff understand who reports, what is reported, when and where to report, how to report, and why to report?

Can facility staff provide and account for dissemination of information on the incident reporting system to all health care providers, agents and employees?

Did all new non-physician personnel receive, within 30 days of employment, instruction about the operation of and the responsibilities of the incident reporting system?

Custom Help

Per diem, "float/pool", contact/agency staff are not exempt from this requirement.

ST - R0005 - Incident Reporting System

Title Incident Reporting System

s. 395.0197(1)(e), F.S.

Type Rule

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Regulation Definition

The incident reporting system shall include the prompt reporting of incidents within 3 business days after their occurrence to the risk manager, or the risk manager designee.

s. 395.0197 (1) (e), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review a sample of Incident/Occurrence Reports for determining that incidents are reported within three (3) business days to the risk manager or to the risk manager designee.

Interview a sample of staff to determine the facility's method for reporting within 3 business days.

If there is a risk manager designee, verify evidence of appointment.

Custom Help

ST - R0006 - Incident Reporting System

Title Incident Reporting System

59A-10.0055(2), F.A.C.

Type Rule

Regulation Definition

Reports shall be on a form developed by the facility for that purpose and shall contain at least the following information.

1. The patient's name, locating information, admission diagnosis, admission date, age and sex;
2. A clear and concise description of the incident including time, date, exact location, and exact elements as needed for the annual report based on ICD-9-CM;
3. Whether or not a physician was called; and if so, a brief statement of said physician's recommendations as to medical treatments, if any;
4. A listing of all persons then known to be involved

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review a sample of incident/occurrence reports filed since the date of the previous survey.

Select a sample of incident/occurrence reports to determine compliance with the incident form requirements.

The sample size is based on the issues identified.

PROBES

What are the types of incident reports used in the facility?

Does the incident/occurrence report form contain the

Custom Help

Facilities may have incident reports, occurrence reports, variance reports, and/or medication error reports. All of these reports/forms are considered to be part of an incident reporting system.

Note the nature and type of incidents that have been reported to the risk manager, as this will assist you in other areas of the survey process.

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directly in the incident, including witnesses, along with locating information for each;

required information?

5. The name, signature, and position of the person completing the reports, along with date and time that the report was completed

59A-10.0055 (2), F.A.C.

ST - R0007 - Licensed Risk Manager Responsibility

Title Licensed Risk Manager Responsibility

s. 395.0197(2), F.S.

Type Rule

Regulation Definition

The governing body of every facility shall employ a licensed risk manager who shall be responsible for implementation and oversight of the facility's internal risk management program.

A risk manager shall not be made responsible for more than four internal risk management programs in separately licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.

s. 395.0197(2), F.S.

s. 395.10971, F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the facility's organizational chart.

Review reporting lines of authority.

Verify that the risk manager has a current license.

Interview the licensed risk manager and verify the number of current facilities for which the risk manager currently has responsibility.

Review licensed risk manager's position description for responsibilities.

Review the licensed risk manager's personnel file to establish the risk manager's employment status with the facility, including date of employment. If the licensed risk manager is employed per contract with the facility, review the contract.

Custom Help

Verify with AHCA FRAES system that risk manager is currently licensed.

Verify with AHCA FRAES system for the number of licensed facilities for which the licensed risk manager is responsible.

How many hours a week is the licensed risk manager on-site?

How is the licensed risk manager responsible and accountable for the risk management program?

How is the licensed risk manager involved in day to day risk management activities?

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PROBES

Inquire about the amount of time that the licensed health care risk manager spends on-site at each facility for which the risk manager is responsible.

Verify participation in administrative and clinical meetings.

ST - R0008 - Risk Manager Access to Records

Title Risk Manager Access to Records

s. 395.0197(4), F.S.

Type Rule

Regulation Definition

The risk manager shall have free access to all medical records of the facility.

s. 395.0197 (4), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Verify that the risk manager has access to all medical records of the facility.

Custom Help

ST - R0009 - Fifteen (15) Day Reports

Title Fifteen (15) Day Reports

s. 395.0197 (7), F.S.

Type Rule

Regulation Definition

Any of the following adverse incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence:

1. The death of a patient;

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review a sample of incident/occurrence reports filed since the date of the previous survey to determine compliance with Code 15 reporting. (If Adverse Incident Reports/Code 15's are not submitted within the 15 calendar days the risk manager shall submit immediately and include the reasons for not filing timely.)

Custom Help

The informed consent issue Only Applies to the surgical repair of damage to a patient from a planned surgical procedure (s. 395.1097 (7)(g), F.S.). It does not give the facility an exemption from reporting any of the other adverse incidents as defined under s. 395.1097 (7), F.S.

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2. Brain or spinal damage to a patient;	Review a sample of medical records for reports which appear to meet reporting requirements for compliance.	List of committees the Risk Manager attends and a sample of each committee's minutes.
3. The performance of a surgical procedure on the wrong patient;	Review the facility policy and procedure for informed consent.	Tracking and trending.
4. The performance of a wrong-site surgical procedure;	Review the facility's consent form to determine if the specific risks of the surgical procedure were disclosed to the patient.	OR Log past 24 months or printout of all returns to surgery.
5. The performance of a wrong surgical procedure;	Review the facility's consent form to ensure that the facility's policy and procedure was followed.	Review OR Quality Assurance and Performance Improvement activities.
6. The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;	PROBES	Review Quality Assurance and Performance Improvement activities, initiatives, outcomes.
7. The surgical repair of damage resulting to a patient from a planned surgical procedure where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process; or	Is there a process in place for determining reportable incidents? How does it function?	Infection control committee meeting minutes and initiatives.
8. The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.	Is there a system developed to report the required adverse events to the state?	Returns to ED.
s. 395.0197 (7), F.S.	Were adverse incidents submitted within 15 calendar days?	Hospital re-admissions.
	If an adverse incident report was not submitted within the 15 calendar days, was an extension request completed? Does the facility have a record of the extension request?	Transfers from an ASC to a hospital.
	Determine who has the final authority for determination that an incident meets the definition of an "adverse incident" to be reported to the agency.	Transfers to a higher level of care.
	Have any discharged patients required readmission for previous treatment or surgical episodes?	Discharge summaries and/or coding that indicates an adverse occurrence/outcome.
		NON-REPORTING COMPLAINTS. (This also applies to s. 395.0056(1)(2), F.S.)
		If a Code 15 was not filed for an adverse incident, review the incident report, medical record, policies and procedures,

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Have any current patients required additional surgery, and/or treatment interventions as a result of an adverse incident?

and any other necessary documentation to determine if the incident met the criteria to be reported as a Code 15.

Was an incident report filed?

Review the incident that is the subject of the complaint and determine whether it involved conduct by a licensee that is potentially subject to disciplinary action.

Did the facility notify DOH, Medical Quality Assurance, Consumer Services of any disciplinary action taken? (If not, advise the facility that it needs to file with the Department of Health.)

Verify the letter was sent to DOH, MQA.

Risk managers may be a licensee named in the complaint.

Disciplinary action is defined by the practice act of the involved practitioner and Chapter 456 Florida Statutes.

Surveyor may contact DOH, MQA for assistance.

Reference 11/21/2003 memo from Polly Weaver, Chief of Field Operations re: "Protocol: Referring Health Care Practitioners to the Department of Health (DOH) New FRAES Data Fields.

Disciplinary action referral form @ http://www.doh.state.fl.us/mqa/enforcement/enforce_home.htm

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Title Fifteen (15) Day Reports

s. 395.0197(7), F.S.

Type Rule

Regulation Definition

The report shall be made on AHCA form 3140-5001 (Code 15), which is incorporated by reference.

Any reportable incidents, pursuant to this section that are submitted more than 15 calendar days from occurrence by the facility must be justified in writing by the facility administrator.

The agency may require an additional final report.

s. 395.0197 (7), F.S.

59A-10.0065, F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Determine if late reports have an approved extension form and justification for the late filing from the facility administrator.

PROBES

Was the proper AHCA form used?

Custom Help

Is the risk manager using the most current reporting form available on the AHCA web site?

ST - R0011 - Risk Management Education and Training

Title Risk Management Education and Training

s. 395.0197(1)(b)1.a.b., F.S.

Type Rule

Regulation Definition

Risk management and risk prevention education and training of all non-physician personnel as follows:

- a. Such education and training of all non-physician personnel as part of their initial orientation; and
- b. At least 1 hour of such education and training annually for all personnel of the licensed facility working

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review orientation program(s) for documentation that the incident reporting system and adverse incident reporting (Code 15 and Annual Incident Reporting) is included.

Select a sample of new employees, existing employees, and agency (contract) personnel for evidence of training at

Custom Help

Per diem, "float/pool", contract/Agency staff are not exempt from this requirement.

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in clinical areas and providing patient care, except those persons licensed as health care practitioners who are required to complete continuing education coursework pursuant to chapter 456 or the respective practice act.

c. This training shall include risk prevention education and training including the importance of accurate and timely incident reporting.

s. 395.0197 (1) (b) 1.a. b., F.S.

59A-10.005, F.A.C.

59A-10.0055 (1), F.A.C.

ST - R0012 - Systems Review and Analysis

Title Systems Review and Analysis

59A-10.0055(3), F.A.C.

Type Rule

Regulation Definition

The risk manager shall be responsible for the regular and systematic reviewing of all incident reports including 15-day incident reports for the purposes of identifying trends or patterns as to time, place or persons.

The incident reports shall be used to develop categories of incidents that identify problem areas.

59A-10.0055 (3), F.A.C.

59A-10.002 (14), F.A.C.

orientation and annual review.

Interview employees in regard to their education and training. (Example: RN's, CNA's, PT's, RT's, etc.)

PROBES

Describe the process to report an adverse incident in the facility.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review all tracking and trending reports for the period since the previous survey.

Review results to ascertain that the risk manager has trended the information to identify patterns and any problem areas.

Discuss the guidelines used.

PROBES

What type of system does the risk manager utilize to track and trend incidents?

Custom Help

Consider data collected and studied for trends. Did analysis determine whether trends represent real or potential problems in the delivery of care or services?

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ST - R0013 - Systems Review and Analysis

Title Systems Review and Analysis

s. 395.0197(4), F.S.

Type Rule

Regulation Definition

Upon emergence of any trend or pattern in incident occurrence the risk manager shall develop recommendations for appropriate corrective actions and risk management prevention education and training.

The incident reports shall be used to develop categories of incidents that identify problem areas. Once identified, procedures shall be adjusted to correct the problem areas.

s. 395.0197 (4), F.S.

59A-10.0055 (3), F.A.C.

59A-10.002 (14), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review all pertinent documents for verification that the Risk Manager's recommendations were developed and the corrective action(s) implemented.

Discuss and review documentation as to whether the corrective action(s) was effective and if not was the plan revised.

Verify that action has been taken to reduce and prevent risks to patients.

Review in-service education documents for programs pertinent to risk management education and training relating to the corrective action(s).

PROBES

Describe the manner by which the Risk Manager ensures that staff from individual departments/units identify safety hazards and risk exposures in clinical and facility-wide systems.

Does staff receive feedback regarding incident reports that they completed?

Has an incident report that you filed resulted in a change?

Custom Help

Are the results of trend analysis distributed and discussed with the individuals and departments involved?

Are corrective actions being monitored for effectiveness? How? Frequency? Results?

Are risks to patients being prevented and reduced? Review documentation.

Review any policies, procedures, or protocols related to the corrective action(s) implemented.

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ST - R0014 - Systems Review and Analysis

Title Systems Review and Analysis

s. 395.0197(13)(14)(15), F.S.

Type Rule

Regulation Definition

Evidence of the incident reporting and analysis system and copies of summary reports, incident reports filed within the facility, and evidence of recommended and accomplished corrective actions shall be made available for review to any authorized representative of the Agency upon request during normal working hours.

s. 395.0197 (13) (14) (15), F.S.

59A-10.0055 (3) (b), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

All facility records are to be made available to surveyors upon request.

Custom Help

If the facility representative refuses to provide documentation cite appropriate Risk Management tags and notify the Field Office Manager.

ST - R0015 - Systems Review and Analysis

Title Systems Review and Analysis

s. 395.0197(1)(b)4., F.S.

Type Rule

Regulation Definition

Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition.

s. 395.0197 (1) (b) 4., F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Does the facility have an established procedure/protocol to prevent wrong site, wrong procedure, wrong patient surgery?

How does the facility identify the correct patient and the correct site for procedures?

How is the surgical site identified?

Custom Help

Does the verification process for correct site/procedure surgery begin with scheduling?

Does the facility implement the use of a check list pre-procedure or pre-operatively and immediately prior to the procedure?

Does the facility conduct a "time-out" prior to the procedure?

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How does the facility identify and confirm the correct procedure(s)?

Does the facility use more than one patient identifier?

Does the facility involve the patient and his/or her family members in identifying the patient, correct site, and correct procedure? If so, what systems does the facility have in place for appropriate communication techniques for any identified language or communication barriers?

What designated method does the facility use for identifying patients?

Does facility staff have a method to verify that the identification process contains correct information?

Are protocols and procedures to prevent wrong site, wrong procedure, wrong patient incidents used facility-wide?

How is education and training of staff (including physicians) regarding the facility's procedures and protocols accomplished? Review documentation.

How does the facility monitor compliance with the protocols for quality control purposes?

ST - R0016 - Summary Data

Title Summary Data

59A-10.0055(3), F.A.C.

Type Rule

Regulation Definition

Summary data accumulated shall be systematically maintained for 3 years.

59A-10.0055 (3), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Verify that the past 3 years of accumulated summary data has been maintained and reviewed.

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ST - R0017 - Summary Reports

Title Summary Reports

59A-10.0055 (3) (a), F.A.C.

Type Rule

Regulation Definition

At least quarterly or more often as may be required by the governing body, the risk manager shall provide a summary report to the governing body which includes information about activities of risk management as defined herein.

59A-10.0055 (3) (a), F.A.C.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the governing body minutes for risk management documentation. Interview the licensed risk manager and staff re: methodology.

PROBES

Does the governing body act on the quarterly reports?

Custom Help

Consider whether the quarterly report contains summary information regarding the following:
Occurrence/incident report trends by category, addressing both frequency and severity;
Problems identified and specific actions taken to reduce the occurrences, frequency and severity or to eliminate their causes;
Results of corrective actions;
Completed risk management programs and
Current risk management issues and strategies.

ST - R0018 - Annual Report

Title Annual Report

s. 395.0197 (6) (a) (b) (c), F.S.

Type Rule

Regulation Definition

Each licensed facility subject to this section shall submit an annual report to the agency summarizing the incident reports that have been filed in the facility for that year. The report shall be on a form prescribed by rule of the agency and submitted to the agency.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the Annual Report(s) submitted to AHCA for:

--Timeliness

Custom Help

If incidents are identified that are not included in the Annual Report the risk manager shall submit an amended Annual Report to the agency.

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The report shall include:

1. The total number of adverse incidents causing injury to patients. (Reference s. 395.0197(5)(a)(b)(c)(d), F.S.)
2. A listing, by category, of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.
3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.
4. A code number using the health care professional's licensure number and a separate code number identifying all other individuals directly involved in adverse incidents causing injury to patients, the relationship of the individual to the licensed facility, and the number of incidents in which each individual has been directly involved. Each licensed facility shall maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.
5. A description of all malpractice claims filed against the licensed facility, including the total number of pending and closed claims and the nature of the incident which led to, the persons involved in, and the status and disposition of each claim. Each report shall update status and disposition for all prior reports.

(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under

- Verification the AHCA form is being used.
- Number of incidents reported.
- Types of incidents.
- Number and types of claims.

The Annual Report includes:

- Death;
- Brain or spinal damage;
- Permanent disfigurement;
- Fracture or dislocation of bones or joints;
- A limitation of neurological, physical, or sensory function which continues after discharge from the facility;
- Any condition that required specialized medial attention or surgical intervention resulting from non-emergency medical intervention other than an emergency medical condition, to which the patient has not given his or her informed consent;
- Injuries that require the transfer of the patient within or outside the facility to a unit providing a more acute care level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- Was the performance of a surgical procedure on the wrong patient;
- A wrong surgical procedure;
- A wrong-site surgical procedure;
- A surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Review a sample of malpractice claims filed since the date

NON-REPORTING COMPLAINTS. (This also applies to s. 395.0056(1)(2), F.S.)

If an Annual Report incident was not reported as an adverse incident, review the incident report, medical record, policies and procedures, and any other necessary documentation to determine if the incident met the criteria to be reported as an "adverse incident" on the annual report.

Did the incident meet the definition for reporting on the Annual Report? If so, was it reported by the facility?

If not reported, who determined incident was not reportable? What was the rationale for not reporting the incident?

Did facility personnel file an incident report with the risk manager on the adverse incident within the required 3 business days?

Review the incident that is the subject of the complaint and determine whether it involved conduct by a licensee that is potentially subject to disciplinary action.

Did the facility notify DOH, Medical Quality Assurance, Consumer Services of any disciplinary action taken? (If not, advise the facility that it needs to file with the Department of Health.)

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chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the incidents potentially involved conduct by a health care professional that is subject to disciplinary action, in which case the provisions of s. 455.621 shall apply.

(c) The report submitted to the agency shall also contain the name and license number of the risk manager of the licensed facility, a copy of its policy and procedures, which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures.

s. 395.0197 (6) (a) (b) (c), F.S

of the last survey.

Review a sample of disciplinary actions and outcomes against practitioners and the reporting of all actions to Department of Health/Medical Quality Assurance.

Review the facility's results of outcome measures, QA/PI initiatives; risk prevention and risk reduction strategies for the year. (Reference s. 395.1097(6)(c), F.S.)

PROBES

Is there a process in place for determining reportable incidents? How does it function?

Is there a system developed to report the required adverse events to the state?

Determine who has the final authority for determination that an incident meets the definition of an "adverse incident" to be reported to the agency.

Have any discharged patients required readmission for previous treatment or surgical episodes?

Have any current patients required additional surgery, and/or treatment interventions as a result of an adverse incident?

Any transfers to a higher level of care?

Review facility's annual reports for compliance of reporting the following:

Total number of pending and closed claims;

Verify the letter was sent to DOH, MQA.

Risk managers may be a licensee named in the complaint.

Disciplinary action is defined by the practice act of the involved practitioner and Chapter 456 Florida Statutes.

Surveyor may contact DOH, MQA for assistance.

Reference 11/21/2003 memo from Polly Weaver, Chief of Field Operations re: "Protocol: Referring Health Care Practitioners to the Department of Health (DOH) New FRAES Data Fields.

Disciplinary action referral form @ http://www.doh.state.fl.us/mqa/enforcement/enforce_home.htm

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Claim number for each claim;

Nature of incident;

License numbers of persons involved in the claim and

Status or disposition of the claim.

ST - R0019 - Annual Report

Title Annual Report

s. 395.0197 (3), F.S.

Type Rule

Regulation Definition

Each licensed facility shall annually report to the Agency and the Department of Health the name and judgments entered against each healthcare practitioner for which it assumes liability.

s. 395.0197 (3), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review documentation of reporting.

PROBES

Does the facility have a report that identifies and summarizes actions against practitioners?

Have these identified practitioners been reported to the Department of Health and Agency for Healthcare Administration?

Custom Help

ST - R0020 - Sexual Misconduct

Title Sexual Misconduct

s. 395.0197 (9) (10), F.S.

Type Rule

Regulation Definition

The internal risk manager shall:

Interpretive Guideline

GUIDANCE TO SURVEYORS

Custom Help

Does facility staff know what actions to

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(a) Investigate every allegation of sexual misconduct which is made against a member of the facility's personnel who has direct patient contact, when the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility;

(b) Report every allegation of sexual misconduct to the administrator of the licensed facility; and

(c) Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted.

s. 395.0197 (9), F.S.

Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation shall:

(a) Notify the local police; and

(b) Notify the hospital risk manager and the administrator.

s. 395.0197 (10), F.S.

Was the sexual misconduct incident reported and investigated?

What were the results of the investigation and the outcomes?

Did the facility implement a corrective action plan?

If an allegation of sexual misconduct involved a licensed health care practitioner, was the allegation reported to the Department of Health?

Was the administrator notified?

Was the police department notified?

Was Department of Children & Families or Adult Protective Services notified?

Interview the risk manager and a sample of staff.

PROBES

Review and discuss actions described in the policies and procedures if an incident involving sexual misconduct occurs. Were policies and procedures followed?

Review background screening of involved staff member.

Review police report if accessible.

take if an incident involving sexual misconduct occurs? Interview sample of staff.

Any occurrences?

Were policies and procedures followed?

What were outcomes?

ST - R0021 - Recovery Room Two (2) Person Requirement

Title Recovery Room Two (2) Person Requirement

s. 395.0197 (1) 2., F.S.

Type Rule

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Regulation Definition

A prohibition, except when emergency circumstances require otherwise, against a staff member of the licensed facility attending a patient in the recovery room, unless the staff member is authorized to attend the patient in the recovery room and is in the company of at least one other person. However, a licensed facility is exempt from the two-person requirement if it has:

- a. Live visual observation;
 - b. Electronic observation; or
 - c. Any other reasonable measure taken to ensure patient protection and privacy.
- s. 395.0197 (1) 2., F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review facility policy and procedures for prohibitions against staff members attending patients in the recovery room alone.

Review the facility policy, i.e. either each authorized staff person in the recovery room is accompanied by at least one other person or the recovery room has live visual observation; or electronic observation; or any other reasonable measure taken to ensure patient protection and privacy.

Request the schedule of recovery room personnel for all shifts.

Review policies and procedures regarding the two-person requirement.

Tour the recovery room, preferably in the afternoon.

Interview staff regarding recovery room procedures and staffing patterns.

PROBES

How does the facility handle live visual observation, electronic observation, or any other reasonable measure to ensure patient protection and privacy?

What type of electronic observation is used?

Who monitors the camera when patients are present in the recovery room?

What type of documentation is maintained by the facility?

Custom Help

If the facility uses two types of observation then the facility should have policies and procedures for both.

This might be a component of the Department of Nursing Services policies and procedures.

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ST - R0022 - Unlicensed Person

Title Unlicensed Person

s. 395.0197 (1) (b) 3., F.S.

Type Rule

Regulation Definition

A prohibition against an unlicensed person from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment, and such assistance or participation is done under the direct and immediate supervision of a licensed physician and is not otherwise an activity that may only be performed by a licensed health care practitioner.

s. 395.0197 (1) (b) 3., F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review a sample of personnel files for current position descriptions.

Custom Help

Example: Company Representatives;
surgeon's personal scrub.

ST - R0025 - Duty To Notify Patients

Title Duty To Notify Patients

s. 395.1051, F.S.; s. 395.1097(1)(d), F.

Type Rule

Regulation Definition

A system for informing a patient or an individual identified pursuant to s. 765.401(1) (Advanced Directives/Healthcare Surrogate), in person, that the patient was the subject of an adverse incident that resulted in serious harm to the patient, as defined in subsection (5).

s. 395.1051, F.S.

s. 395.1097 (1) (d), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the policies and procedures developed to enable patient notification (or the patient's healthcare surrogate) of all adverse incidents.

Refer to definition of adverse incident, s. 395.0197 (5), F.S.

Review all Code 15's and Annual Report incidents to determine whether the patient and/or healthcare surrogate

Custom Help

Are staff and physicians aware of the duty to notify patients of an adverse incident?

"Adverse incident " means an event over which health care personnel could exercise control & which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which results in one of the following injuries:

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s. 395.1097 (5), F.S.

was informed of the incident.

Verify documentation that the patient was notified following the adverse incident.

Interview patient(s) involved in adverse incident if the patient is accessible.

PROBES

Did facility develop and implement a system for patient notification?

Does facility staff evaluate the system for informing patients that they have been the subject of an adverse incident?

Death

Brain or spinal damage

Permanent disfigurement

Fracture or dislocation of bones or joints

A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility

Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent

Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident

The performance of a surgical procedure on the wrong patient

The performance of a wrong surgical procedure

The performance of a wrong-site surgical procedure

The performance of a surgical procedure

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that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition

The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed consent process

The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

ST - R0026 - Notify By Appropriately Trained Person

Title Notify By Appropriately Trained Person

s. 395.1051, F.S.; s. 395.0197(1)(d), F.

Type Rule

Regulation Definition

Such notification shall be given by an appropriately trained person designated by the licensed facility.

s. 395.1051, F.S.

s. 395.1097 (1) (d), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the position description to ensure compliance.

PROBES

Does the policy and procedure provide for the designation and training for the individual?

Custom Help

ST - R0027 - Timely Patient Notification

Title Timely Patient Notification

s. 395.1051, F.S.; s. 395.1097(1)(d), F.

Type Rule

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Regulation Definition

Such notice shall be given by the appropriate person as soon as practicable to allow the patient an opportunity to minimize damage or injury.

s. 395.1051, F.S.

s. 395.1097 (1) (d), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review the timeliness of the patient or surrogate notification.

PROBES

Is there a policy and procedure to notify the patient?

Determine the location of the documentation of the notification?

Did the facility identify potential harm/injury to the patient and was this disclosed to the patient?

Custom Help

ST - R0028 - Patient Safety Plan

Title Patient Safety Plan

s. 395.1012 (1), F.S.

Type Rule

Regulation Definition

Each licensed facility must adopt a patient safety plan.

A plan adopted to implement the requirements of 42 CFR 482.21 (Quality Assurance and Performance Improvement Plan) shall be deemed to comply with this requirement.

s. 395.1012 (1), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review facility's patient safety plan.

If applicable, review QA/PI (HOSPITALS ONLY) plan to assure patient safety issues are addressed within the QA/PI plan.

PROBES

Does the facility have a patient safety plan?

As relevant, consider information facility representatives

Custom Help

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utilized to demonstrate compliance with 42 CFR 482.21
(Quality Assurance and Performance Improvement Plan)
(FOR HOSPITALS ONLY).

ST - R0029 - Patient Safety Officer

Title Patient Safety Officer

s. 395.1012 (2), F.S.

Type Rule

Regulation Definition

Each licensed facility shall appoint a Patient Safety Officer

s. 395.1012 (2), F.S.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Determine if facility management has appointed a Patient Safety Officer.

Review position description.

Interview the Patient Safety Officer regarding roles and responsibilities.

PROBES

Describe the relationship of the Patient Safety Officer to the Patient Safety Plan.

Custom Help

ST - R0030 - Patient Safety Committee

Title Patient Safety Committee

s. 395.1012 (2), F.S.

Type Rule

Regulation Definition

Each licensed facility shall appoint a Patient Safety Committee.

Interpretive Guideline

GUIDANCE TO SURVEYORS

Custom Help

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One member of the committee cannot be employed by nor practicing in the facility.

s. 395.1012 (2), F.S.

Review the composition of the Patient Safety Committee.

Determine the eligibility of the committee member not employed by the facility, not a contracted employee of the facility, nor in practice at the facility.

For ASC's: If the ASC is owned by a corporation, a corporate representative who is not employed by nor practicing at that particular licensed facility may serve as that person.

ST - R0031 - Purpose Of Patient Safety

Title Purpose Of Patient Safety

s. 395.1012 (2), F.S.

Type Rule

Regulation Definition

The purpose of the committee is to:

- a. Promote the health and safety of patients,
- b. Review and evaluate the quality of patient safety measures used by the facility, and
- c. Assist in the implementation of the facility patient safety plan.

s. 395.1012 (2), F.S

Interpretive Guideline

GUIDANCE TO SURVEYORS

Review facility documentation of the Patient Safety Committee activities such as minutes, reports, QA/PI projects and outcomes, patient safety initiatives, etc.

Review the process by which the committee reviews and evaluates the quality of patient safety measures implemented by the facility.

Review the process by which the committee assists in the implementation of the facility's patient safety plan.

PROBES

Do the committee members maintain records (surveys, evaluations, monitoring and corrective actions)?

Custom Help

Consider the following committee activities:
Review of newly introduced materials and procedures;
Evaluation of newly identified hazards/patient safety issues;
Evaluation of facility staff's ability to collect, process, and evaluate information on safety;
Tracking and trending of safety statistics;
QA of patient safety measures; and
Implementation of the facility patient safety plan.

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Does the Patient Safety Committee document the proceedings?

ST - R9999 - Final Observations

Title Final Observations

Type Memo Tag

Regulation Definition

Interpretive Guideline

Custom Help