59A-4.123 RISK MANAGEMENT AND QUALITY ASSURANCE.

(1) The facility shall maintain a risk management and quality assurance committee as required in Section 400.147, F.S.

(2) The facility shall use AHCA Form 3110-0009, Revised, January, 2002, October, 2001, "Confidential Nursing Home Initial Adverse Incident Report – 1 Day," and AHCA Form 3110-0010, 3110-0010A, and 3110-0010B, Revised, January, 2002, "Confidential Nursing Home Complete Adverse Incident Report – 15 Day," which are incorporated by reference when reporting events as stated in Section 400.147, F.S. These forms may be obtained from the Agency for Health Care Administration, Long Term Care Unit, 2727 Mahan Drive, MS 33, Tallahassee, FL 32308.

(3) Each facility shall use AHCA Form 3110-0008, Revised, October 2008, "Nursing Home Monthly Liability Claim Information", which are incorporated by reference when reporting liability claims filed against it as required by Section 400.147(9), F.S. These forms may be obtained from the Agency for Health Care Administration, Long Term Care Unit, 2727 Mahan Drive, MS 33, Tallahassee, FL 32308.

STATUTES:

400.071 Application for license.

(5) As a condition of licensure, each facility must establish and submit with its application a plan for quality assurance and for conducting risk management.

400.118 Quality assurance; early warning system; monitoring; rapid response teams.

(1) The agency shall establish an early warning system to detect conditions in nursing facilities that could be detrimental to the health, safety, and welfare of residents. The early warning system shall include, but not be limited to, analysis of financial and quality-of-care indicators that would predict the need for the agency to take action pursuant to the authority set forth in this part.

(2) The agency shall also create teams of experts that can function as rapid response teams to visit nursing facilities identified through the agency’s early warning system. Rapid response teams may visit facilities that request the agency’s assistance. The rapid response teams shall not be deployed for the purpose of helping a facility prepare for a regular survey.
400.119 Confidentiality of records and meetings of risk management and quality assurance committees.

(1) Incident reports filed with the risk manager and administrator of a long-term care facility licensed under this part or part I of chapter 429, notifications of the occurrence of an adverse incident, and adverse incident reports from the facility are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(2)(a) The meetings of an internal risk management and quality assurance committee of a long-term care facility licensed under this part or part I of chapter 429 are exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution.

(b) Records of those meetings are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(3)(a) If the Agency for Health Care Administration has a reasonable belief that conduct by a staff member or employee of a facility is criminal activity or grounds for disciplinary action by a regulatory board, the agency may disclose records made confidential and exempt pursuant to this section to the appropriate law enforcement agency or regulatory board.

(b) Records disclosed to a law enforcement agency remain confidential and exempt until criminal charges are filed.

(4) Records made confidential and exempt under this section and that are obtained by a regulatory board are not available to the public as part of the record of investigation and prosecution in a disciplinary proceeding made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon request by a health care professional against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

400.147 Internal risk management and quality assurance program.

(1) Every facility shall, as part of its administrative functions, establish an internal risk management and quality assurance program, the purpose of which is to assess resident care practices; review facility quality indicators, facility incident reports, deficiencies cited by the agency, and resident grievances; and develop plans of action to correct and respond quickly to identified quality deficiencies. The program must include:

(a) A designated person to serve as risk manager, who is responsible for implementation and oversight of the facility's risk management and quality assurance program as required by this section.

(b) A risk management and quality assurance committee consisting of the facility risk manager, the administrator, the director of nursing, the medical director, and at least three
other members of the facility staff. The risk management and quality assurance committee shall meet at least monthly.

(c) Policies and procedures to implement the internal risk management and quality assurance program, which must include the investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to residents.

(d) 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 licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

(e) The development of appropriate measures to minimize the risk of adverse incidents to residents, including, but not limited to, education and training in risk management and risk prevention for all nonphysician personnel, as follows:

1. Such education and training of all nonphysician personnel must be part of their initial orientation; and

2. At least 1 hour of such education and training must be provided annually for all nonphysician personnel of the licensed facility working in clinical areas and providing resident care.

(f) The analysis of resident grievances that relate to resident care and the quality of clinical services.

(2) The internal risk management and quality assurance program is the responsibility of the facility administrator.

(3) In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of adverse incidents to residents and violations of residents’ rights shall be encouraged and their implementation and operation facilitated.

(4) Each internal risk management and quality assurance program shall include the use of incident reports to be filed with the risk manager and the facility administrator. The risk manager shall have free access to all resident records of the licensed facility. The incident reports are part of the workpapers of the attorney defending the licensed facility in litigation relating to the licensed facility and are subject to discovery, but are not admissible as evidence in court. A person filing an incident report is not subject to civil suit by virtue of such incident report. As a part of each internal risk management and quality assurance program, the incident reports shall be used to develop categories of incidents which identify problem areas. Once identified, procedures shall be adjusted to correct the problem areas.

(5) For purposes of reporting to the agency under this section, the term “adverse incident” means:
(a) An event over which facility personnel could exercise control and which is associated in whole or in part with the facility's intervention, rather than the condition for which such intervention occurred, and which results in one of the following:

1. Death;
2. Brain or spinal damage;
3. Permanent disfigurement;
4. Fracture or dislocation of bones or joints;
5. A limitation of neurological, physical, or sensory function;
6. Any condition that required medical attention to which the resident has not given his or her informed consent, including failure to honor advanced directives;
7. Any condition that required the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident’s condition prior to the adverse incident; or
8. An event that is reported to law enforcement or its personnel for investigation; or

(b) Resident elopement, if the elopement places the resident at risk of harm or injury.

(6) The internal risk manager of each licensed facility shall:

(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 at the grounds of the facility;
(b) Report every allegation of sexual misconduct to the administrator of the licensed facility; and
(c) Notify the resident representative or guardian of the victim that an allegation of sexual misconduct has been made and that an investigation is being conducted.

(7) The facility shall initiate an investigation and shall notify the agency within 1 business day after the risk manager or his or her designee has received a report pursuant to paragraph (1)(d). The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery. The notification must include information regarding the identity of the affected resident, the type of adverse incident, the initiation of an investigation by the facility, and whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The notification is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.
(8)(a) Each facility shall complete the investigation and submit an adverse incident report to the agency for each adverse incident within 15 calendar days after its occurrence. If, after a complete investigation, the risk manager determines that the incident was not an adverse incident as defined in subsection (5), the facility shall include this information in the report. The agency shall develop a form for reporting this information.

(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under 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 who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

(c) The report submitted to the agency must also contain the name of the risk manager of the facility.

(d) The adverse incident report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board.

(9) Abuse, neglect, or exploitation must be reported to the agency as required by 42 C.F.R. s. 483.13(c) and to the department as required by chapters 39 and 415.

(10) By the 10th of each month, each facility subject to this section shall report any notice received pursuant to s. 400.0233(2) and each initial complaint that was filed with the clerk of the court and served on the facility during the previous month by a resident or a resident's family member, guardian, conservator, or personal legal representative. The report must include the name of the resident, the resident's date of birth and social security number, the Medicaid identification number for Medicaid-eligible persons, the date or dates of the incident leading to the claim or dates of residency, if applicable, and the type of injury or violation of rights alleged to have occurred. Each facility shall also submit a copy of the notices received pursuant to s. 400.0233(2) and complaints filed with the clerk of the court. This report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in such actions brought by the agency to enforce the provisions of this part.

(11) The agency shall review, as part of its licensure inspection process, the internal risk management and quality assurance program at each facility regulated by this section to determine whether the program meets standards established in statutory laws and rules, is being conducted in a manner designed to reduce adverse incidents, and is appropriately reporting incidents as required by this section.

(12) There is no monetary liability on the part of, and a cause of action for damages may not arise against, any risk manager for the implementation and oversight of the internal risk management and quality assurance program in a facility licensed under this part as required by this section, or for any act or proceeding undertaken or performed within the scope of the functions of such internal risk management and quality assurance program if the risk manager acts without intentional fraud.
(13) If the agency, through its receipt of the adverse incident reports prescribed in subsection (7), or through any investigation, has a reasonable belief that conduct by a staff member or employee of a facility is grounds for disciplinary action by the appropriate regulatory board, the agency shall report this fact to the regulatory board.

(14) The agency may adopt rules to administer this section.

(15) Information gathered by a credentialing organization under a quality assurance program is not discoverable from the credentialing organization. This subsection does not limit discovery of, access to, or use of facility records, including those records from which the credentialing organization gathered its information.