**By** Senator Rich

34-01598A-10 20102586__

A bill to be entitled

An act relating to health care regulation; amending s. 395.0197, F.S.; revising provisions relating to the requirement for certain medical facilities to maintain an internal risk management program and submit adverse incident reports; amending s. 395.3025, F.S.; substituting the Department of Health for the Agency for Health Care Regulation with respect to the use of patient records in disciplinary proceedings; amending s. 400.462, F.S.; revising definitions relating to home health care services; amending s. 400.476, F.S.; revising provisions relating to home health care staffing requirements; clarifying that an alternate administrator must meet the same standards as an administrator; specifying training requirements for home health aides; providing contractual requirements for home health agency personnel; requiring at least one home health agency service to be provided by agency employees; creating s. 400.4775, F.S.; specifying the duties and responsibilities for the home health agency administrator, director of nursing, nurses, therapists, home health aides, and certified nursing assistants; amending s. 400.487, F.S.; revising provisions relating to home health service agreements, plans of care, and the supervision of services; specifying requirements for the provision of drugs and treatment orders; creating s. 400.493, F.S.; providing patients' rights for persons receiving home health services; requiring the home health agency to



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investigate complaints; requiring the agency to furnish the patient with written notice of such rights; amending s. 400.933, F.S.; revising provisions relating to the Agency for Health Care Administration's acceptance of inspections conducted by accrediting organizations; amending s. 400.969, F.S.; revising the grounds for imposing penalties against intermediate care facilities for developmentally disabled persons; amending s. 408.05, F.S.; directing the Florida Center for Health Information and Policy Analysis to collect data on patient safety in health facilities; amending s. 408.7056, F.S.; conforming a cross-reference; amending s. 408.805, F.S.; revising provisions relating to the calculation of license fees charged by the agency; amending s. 408.811, F.S.; clarifying that agency inspection reports are not subject to administrative challenges; amending s. 429.65, F.S.; revising definitions relating to adult family-care homes to require the provider to reside in the home; amending ss. 458.331 and 459.015, F.S.; conforming cross-references; amending s. 641.55, F.S.; revising provisions relating to the requirement for managed care organizations to maintain an internal risk management program and submit adverse incident reports; requiring the State Fire Marshal to conduct a study of the adequacy of firesafety standards in assisted living facilities; requiring a report to the Governor and Legislature; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Effective January 1, 2011, section 395.0197, Florida Statutes, is amended to read:

395.0197 Internal risk management program.—

(1) ~~Every licensed facility shall,~~ As a part of its administrative functions, each licensed facility shall establish an internal risk management program that includes all of the following components:

(a) The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents causing injury to patients.

(b) The development of appropriate measures to minimize the risk of adverse incidents causing injury to patients, including, but not limited to:

1. Risk management and risk prevention education and training of all nonphysician personnel as follows:

a. ~~Such~~ Education and training of all nonphysician 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 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 their ~~the~~ respective practice act.

2. ~~A prohibition,~~ Except when emergency circumstances require otherwise, a prohibition 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.

3. 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.

4. 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.

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

(d) A system for informing a patient or an individual identified pursuant to s. 765.401(1) that the patient was the subject of an adverse incident~~, as defined in subsection (5)~~. Such notice shall be given by an appropriately trained person



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designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury. Documentation of the notification should be maintained by the facility.

(e) The development and implementation of a ~~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.

(2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager, licensed under s. 395.10974, who is responsible for implementation and oversight of the ~~such~~ facility's internal risk management program as required by this section.

(a) A risk manager may ~~must~~ not be ~~made~~ responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.

~~(3) In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of medical malpractice and patient injury claims shall be encouraged and their implementation and operation facilitated. Such additional approaches may include extending internal risk management programs to health care providers' offices and the assuming of provider liability by a licensed health care facility for acts or omissions occurring within the~~



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~~licensed facility. Each licensed facility shall annually report to the agency and the Department of Health the name and judgments entered against each health care practitioner for which it assumes liability. The agency and Department of Health, in their respective annual reports, shall include statistics that report the number of licensed facilities that assume such liability and the number of health care practitioners, by profession, for whom they assume liability.~~

~~(4) The agency shall adopt rules governing the establishment of internal risk management programs to meet the needs of individual licensed facilities. Each internal risk management program shall include the use of incident reports to be filed with an individual of responsibility who is competent in risk management techniques in the employ of each licensed facility, such as an insurance coordinator, or who is retained by the licensed facility as a consultant.~~

(b) The risk manager ~~individual responsible for the risk management program~~ shall have free access to all medical records of the licensed facility.

(3) ~~The incident~~ Reports of adverse incidents 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 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.

(4) For an incident to be an adverse incident that must be reported to the agency pursuant to this section, it must be: of concern to both the public and health care practitioners and providers; clearly identifiable and measurable and thus feasible to include in a reporting system; and of such a nature that the risk of occurrence is significantly influenced by the policies and procedures of the licensed facility. In addition, the incident must be unambiguous, usually preventable, serious, and any of the following: adverse; indicative of a problem in the facility's safety systems; or important for public credibility or public accountability. The incident must also be on the most current list set forth by the National Quality Forum.

(5) Adverse incidents shall be reported electronically by the facility through an online portal to the agency within 15 calendar days after the occurrence. The agency may grant an extension to this reporting requirement upon receiving justification submitted by the facility administrator to the agency.

(a) An adverse incident listing an individual licensed by the Department of Health as directly involved in the incident must be immediately forwarded to the Department of Health and is subject to s. 456.073.

(b) The reports are exempt from disclosure under chapter 119 or any other law providing access to public records; not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the Department of Health or the appropriate regulatory authority; and are not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings ordinarily made

available to the public.

(c) The facility's chief executive officer, or designee, shall certify quarterly, through the electronic submission portal, that all adverse incidents from the previous quarter have been reported and that the reports are accurate.

(6) Within 60 days after the occurrence of an adverse incident, the agency shall require the facility to electronically submit a final report. The final report should include a copy of the root-cause analysis, any risk management or patient safety lessons learned, the plan of correction, and the results obtained during the plan's implementation in the facility. The agency may investigate adverse incidents and prescribe measures that must or may be taken in response to the incident. These reports are exempt from disclosure under chapter 119 or any other law providing access to public records, and are not discoverable or admissible in any civil or administrative action.

(7) The agency shall publish on the agency's website:

(a) At least quarterly, a summary and trend analysis of adverse incidents received pursuant to this section, which does not include information that identifies the patient, the reporting facility, or the health care practitioners involved.

(b) An annual report that describes and summarizes adverse incidents that have been submitted, and highlights patient safety lessons learned, common root-cause analysis findings, and notable corrective action plans implemented.

~~(5) For purposes of reporting to the agency pursuant to this section, the term "adverse incident" means an event over which health care personnel could exercise control and which is~~

~~associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:~~

~~(a) Results in one of the following injuries:~~

~~1. Death;~~

~~2. Brain or spinal damage;~~

~~3. Permanent disfigurement;~~

~~4. Fracture or dislocation of bones or joints;~~

~~5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;~~

~~6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or~~

~~7. 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;~~

~~(b) Was 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;~~

~~(c) 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~~

~~(d) Was a procedure to remove unplanned foreign objects~~



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~~remaining from a surgical procedure.~~

~~(6)(a) 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 include:~~

~~1. The total number of adverse incidents.~~

~~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.~~

~~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 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 chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed~~



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~~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 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. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings 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 written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.~~

~~(7) 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:~~

~~(a) The death of a patient;~~



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~~(b) Brain or spinal damage to a patient;~~

~~(c) The performance of a surgical procedure on the wrong patient;~~

~~(d) The performance of a wrong-site surgical procedure;~~

~~(e) The performance of a wrong surgical procedure;~~

~~(f) The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;~~

~~(g) 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~~

~~(h) The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.~~

~~The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency. The agency may require an additional, final report. These reports shall not be available to the public pursuant to s. 119.07(1) or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board, nor shall they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings 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 written request by a health care professional against whom~~



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~~probable cause has been found, any such records which form the basis of the determination of probable cause. 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) The agency shall publish on the agency's website, no less than quarterly, a summary and trend analysis of adverse incident reports received pursuant to this section, which shall not include information that would identify the patient, the reporting facility, or the health care practitioners involved. The agency shall publish on the agency's website an annual summary and trend analysis of all adverse incident reports and malpractice claims information provided by facilities in their annual reports, which shall not include information that would identify the patient, the reporting facility, or the practitioners involved. The purpose of the publication of the summary and trend analysis is to promote the rapid dissemination of information relating to adverse incidents and malpractice claims to assist in avoidance of similar incidents and reduce morbidity and mortality.~~

(8)~~(9)~~ 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 if~~, when~~ the allegation is that the sexual misconduct occurred ~~at the facility or~~ on the grounds of



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the facility.

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

(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.

(d) Report to the Department of Health every allegation of sexual misconduct, as defined in chapter 456 and the respective practice act, by a licensed health care practitioner which ~~that~~ involves a patient.

(9) ~~(10)~~ Any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse shall:

(a) Notify the local police; and

(b) Notify the licensed facility's ~~hospital~~ risk manager and the administrator.

For purposes of this subsection, "sexual abuse" means acts of a sexual nature committed for the sexual gratification of anyone upon, or in the presence of, a vulnerable adult, without the vulnerable adult's informed consent, or a minor. The term ~~"Sexual abuse"~~ includes, but is not limited to, the acts defined in s. 794.011(1)(h), fondling, exposure of a vulnerable adult's or minor's sexual organs, or the use of the vulnerable adult or minor to solicit for or engage in prostitution or sexual performance. The term ~~"Sexual abuse"~~ does not include any act intended for a valid medical purpose or any act that ~~which~~ may reasonably be construed to be a normal caregiving action.

(10) ~~(11)~~ A person who, with malice or with intent to

discredit or harm a licensed facility or any person, makes a false allegation of sexual misconduct against a member of a licensed facility's personnel commits ~~is guilty of~~ a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

~~(12) In addition to any penalty imposed pursuant to this section or part II of chapter 408, the agency shall require a written plan of correction from the facility. For a single incident or series of isolated incidents that are nonwillful violations of the reporting requirements of this section or part II of chapter 408, the agency shall first seek to obtain corrective action by the facility. If the correction is not demonstrated within the timeframe established by the agency or if there is a pattern of nonwillful violations of this section or part II of chapter 408, the agency may impose an administrative fine, not to exceed $5,000 for any violation of the reporting requirements of this section or part II of chapter 408. The administrative fine for repeated nonwillful violations may not exceed $10,000 for any violation. The administrative fine for each intentional and willful violation may not exceed $25,000 per violation, per day. The fine for an intentional and willful violation of this section or part II of chapter 408 may not exceed $250,000. In determining the amount of fine to be levied, the agency shall be guided by s. 395.1065(2)(b).~~

(11)~~(13)~~ The agency shall have access to all licensed facility records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (5) or subsection (6)~~, subsection (7), or subsection (9)~~ are exempt from disclosure ~~not available to the public~~ under s. 119.07(1),



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and are not ~~nor shall they be~~ discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency, the Department of Health, or the appropriate regulatory board.~~, nor shall~~ Records obtained pursuant to s. 456.071 may not be made available to the public as part of the record of investigation for and prosecution in disciplinary proceedings ~~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 written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause, except that, with respect to medical review committee records, s. 766.101 controls.~~

(12)~~(14)~~ The meetings of the committees and governing board of a licensed facility held solely for ~~the purpose of achieving the objectives of~~ risk management purposes as provided by this section are ~~shall~~ not ~~be~~ open to the public pursuant to ~~under the provisions of~~ chapter 286. The records of such meetings are confidential and exempt from s. 119.07(1), except as provided in subsection (11) ~~(13)~~.

(13)~~(15)~~ ~~The agency shall review,~~ As part of its licensure inspection process, the agency shall review the internal risk management program of ~~at~~ each licensed facility ~~regulated by this section~~ to determine whether the program meets the 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 such incidents under this section.

(14)~~(16) There shall be~~ No monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager, licensed under s. 395.10974, for the implementation and oversight of the internal risk management program in a facility licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such ~~internal risk management~~ program if the risk manager acts without intentional fraud.

(15)~~(17)~~ A privilege against civil liability is ~~hereby~~ granted to any licensed risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the licensed risk manager or facility acted in bad faith or with malice in providing such information.

~~(18) If the agency, through its receipt of any reports required under this section or through any investigation, has a reasonable belief that conduct by a staff member or employee of a licensed facility is grounds for disciplinary action by the appropriate regulatory board, the agency shall report this fact to such regulatory board.~~

(16)~~(19)~~ No ~~It shall be unlawful for any~~ person may ~~to~~ coerce, intimidate, or preclude a risk manager from lawfully executing his or her reporting obligations pursuant to this chapter. Such action is ~~unlawful action shall be~~ subject to civil monetary penalties not to exceed $10,000 per violation.

(17) The agency may impose administrative fines on licensed facilities for violations of the reporting requirements of this section. In determining the amount of fine to be levied, the agency shall consider the factors listed in s. 395.1065(2)(b).

(a) Before imposing a fine for a nonwillful violation, the agency shall first seek to obtain corrective action by the facility for a single incident or series of isolated incidents.

(b) If the correction of a nonwillful violation is not accomplished within the timeframe established by the agency or if there is a pattern of nonwillful violations, the agency may impose an administrative fine of up to $5,000. However, the administrative fine for repeated nonwillful violations may not exceed $10,000.

(c) The agency may impose an administrative fine of up to $25,000 per violation per day for each intentional and willful violation. However, the fine for an intentional and willful violation may not exceed $250,000.

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

Section 2. Effective January 1, 2011, paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.—

(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:

(e) The Department of Health ~~agency~~ upon issuance of a subpoena ~~issued~~ pursuant to s. 456.071. However, ~~but~~ the records obtained ~~thereby~~ must be used solely by ~~for the purpose of~~ the department ~~agency~~ and the appropriate regulatory ~~professional~~ board in its investigation, prosecution, and appeal of disciplinary proceedings. If the department ~~agency~~ requests

copies of the records, the facility may not ~~shall~~ charge ~~no~~ more than its actual copying costs, including reasonable staff time. The records must be sealed and may ~~must~~ not be made available to the public pursuant to s. 119.07(1) or any other statute providing access to records, and may not be made ~~nor may they be~~ available to the public as part of the record of investigation for and prosecution in disciplinary proceedings ~~made available to the public~~ by the department ~~agency~~ or the appropriate regulatory board. However, the department ~~agency~~ must make available, upon written request by a practitioner against whom probable cause has been found, any ~~such~~ records that form the basis of the determination of probable cause.

Section 3. Subsections (2) and (14) of section 400.462, Florida Statutes, are amended, present subsections (27) through (29) of that section are renumbered as subsections (28) through (30), respectively, and new subsections (27) and (31) are added to that section, to read:

400.462 Definitions.—As used in this part, the term:

(2) "Admission" means a decision by the home health agency, during or after an evaluation visit with the patient ~~to the patient's home~~, that there is reasonable expectation that the patient's medical, nursing, and social needs for skilled care can be adequately met by the agency in the patient's place of residence. Admission includes completion of an agreement with the patient or the patient's legal representative to provide home health services as required in s. 400.487(1).

(14) "Home health services" means health and medical services and medical supplies furnished by an organization to an individual in the individual's home or place of residence. The



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term includes organizations that provide one or more of the following:

(a) Nursing care.

(b) Physical, occupational, respiratory, or speech therapy.

(c) Home health aide services.

(d) Dietetics and nutrition practice and nutrition counseling.

(e) Medical supplies and durable medical equipment~~, restricted to drugs and biologicals~~ prescribed by a physician.

(27) "Primary home health agency" means the agency responsible for the services furnished to patients and for implementation of the plan of care.

(28)~~(27)~~ "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.

(29)~~(28)~~ "Skilled care" means nursing services or therapeutic services required by law to be delivered by a health care professional who is licensed under part I of chapter 464; part I, part III, or part V of chapter 468; or chapter 486 and who is employed by or under contract with a licensed home health agency or is referred by a licensed nurse registry.

(30)~~(29)~~ "Staffing services" means services provided to a health care facility, school, or other business entity on a temporary or school-year basis pursuant to a written contract by licensed health care personnel and by certified nursing assistants and home health aides who are employed by, or work under the auspices of, a licensed home health agency or who are registered with a licensed nurse registry.

(31) "Temporary" means employment provided on an interim



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basis, such as for employee absences, during short-term skill shortages, or due to seasonal workloads.

Section 4. Section 400.476, Florida Statutes, is amended to read:

400.476 Staffing requirements; notifications; limitations on staffing services.—

(1) ADMINISTRATOR.—

(a) An administrator may manage only one home health agency, except that an administrator may manage up to five home health agencies if all five home health agencies have identical controlling interests as defined in s. 408.803 and are located within one agency geographic service area or within an immediately contiguous county. If the home health agency is licensed under this chapter and is part of a retirement community that provides multiple levels of care, an employee of the retirement community may administer the home health agency and up to a maximum of four entities licensed under this chapter or chapter 429 which all have identical controlling interests as defined in s. 408.803. An administrator shall designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence. An alternate administrator must meet the same standards as an administrator as defined in s. 400.462 and is subject to the same limitations under this paragraph.

(b) An administrator of a home health agency who is a licensed physician, physician assistant, or registered nurse licensed to practice in this state may also be the director of nursing for a home health agency. An administrator may serve as a director of nursing for up to the number of entities

authorized in subsection (2) only if there are 10 or fewer full-time equivalent employees and contracted personnel in each home health agency.

(2) DIRECTOR OF NURSING.—

(a) A director of nursing may be the director of nursing for:

1. Up to two licensed home health agencies if the agencies have identical controlling interests as defined in s. 408.803 and are located within one agency geographic service area or within an immediately contiguous county; or

2. Up to five licensed home health agencies if:

a. All of the home health agencies have identical controlling interests as defined in s. 408.803;

b. All of the home health agencies are located within one agency geographic service area or within an immediately contiguous county; and

c. Each home health agency has a registered nurse who meets the qualifications of a director of nursing and who has a written delegation from the director of nursing to serve as the director of nursing for that home health agency when the director of nursing is not present.

If a home health agency licensed under this chapter is part of a retirement community that provides multiple levels of care, an employee of the retirement community may serve as the director of nursing of the home health agency and up to a maximum of four entities, other than home health agencies, licensed under this chapter or chapter 429 which all have identical controlling interests as defined in s. 408.803.

(b) A home health agency that provides skilled nursing care may not operate for more than 30 calendar days without a director of nursing. The ~~A~~ home health agency ~~that provides skilled nursing care~~ and the director of nursing ~~of a home health agency~~ must notify the agency within 10 business days after termination of the services of the director of nursing ~~for the home health agency~~. The ~~A~~ home health agency ~~that provides skilled nursing care~~ must notify the agency of the identity and qualifications of the new director of nursing within 10 days after the new director is hired.

1. ~~If~~ A home health agency that provides skilled nursing care and that operates for more than 30 calendar days without a director of nursing~~, the home health agency~~ commits a class II deficiency. In addition to the fine for a class II deficiency, the agency may issue a moratorium in accordance with s. 408.814 or revoke the home health agency's license. The agency shall fine a home health agency that fails to notify the agency as required in this paragraph $1,000 for the first violation and $2,000 for a repeat violation. The agency may not take administrative action against a home health agency if the director of nursing fails to notify the department upon termination of services as the director of nursing for the home health agency.

2.~~(c)~~ A home health agency that is not Medicare or Medicaid certified and does not provide skilled care or provides only physical, occupational, or speech therapy is not required to have a director of nursing and is exempt from this paragraph ~~(b)~~.

(3) TRAINING.—A home health agency shall ensure that each



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certified nursing assistant employed by or under contract with the home health agency and each home health aide employed by or under contract with the home health agency is adequately trained to perform the tasks of a home health aide in the home setting.

(a) Only home health aides who have successfully completed a home health aide training and competency test as provided under s. 400.497 may be used by the home health agency to provide home health aide services whether on a full-time, temporary, per diem, or other basis. A home health aide is not considered to have successfully passed a competency test if the aide does not have a passing score as specified in rule.

(b) If a home health aide has been evaluated as "unsatisfactory" in conducting a particular task during a competency test, the aide may not perform that task without being directly supervised by a licensed nurse until the aide receives training in that task and is subsequently evaluated as "satisfactory."

(4) HOME HEALTH AGENCY PERSONNEL.—

(a) At least one home health agency service must be provided directly by home health agency employees. However, additional services may be provided under contract with another home health agency or organization. The contract must be in writing and, at a minimum, must specify the following:

1. That patients are accepted for care only by the primary home health agency.

2. The home health services to be furnished by the contracted personnel.

3. The necessity for the contracted personnel to conform to all applicable agency policies, including practitioner

qualifications and standards of practice.

4. The responsibility of the contracted personnel to participate in developing plans of care.

5. The manner in which the provision of home health services will be controlled, coordinated, and evaluated by the primary home health agency.

6. The procedures for contracted personnel to submit clinical and progress notes, schedules of visits, and periodic patient evaluations.

7. The procedures for payment for services furnished by the contracted personnel.

(b) If the home health agency contracts with home health agency personnel on an hourly or per-visit basis, the home health agency must have a written contract with such personnel which conforms to the contractual requirements specified in paragraph (a).

(c) If home health aide services are provided by an individual who is not directly employed by the home health agency, the services of the aide must be provided under written contract as provided in paragraphs (a) and (b). If the home health agency contracts with another organization for the provision of home health aide services, at a minimum, the home health agency is responsible for:

1. Ensuring the overall quality of the care provided by the aide;

2. Overseeing the services provided by the home health aide as described in s. 400.487; and

3. Ensuring that the home health aides have met the training requirements or competency test requirements of s.

400.497.

(5) ~~(4)~~ STAFFING.—Staffing services may be provided anywhere within the state.

Section 5. Section 400.4775, Florida Statutes, is created to read:

400.4775 Personnel duties.—The home health agency and its staff must comply with all professional standards and principles that apply to health care practitioners providing services in a home health agency setting, including, but not limited to, state practice acts and the home health agency's policies and procedures. All home health agency personnel must ensure that services furnished are effectively coordinated and support the objectives outlined in the patient's plan of care. The clinical record or minutes of case conferences must document that effective interchange, reporting, and coordination of patient care occurs.

(1) ADMINISTRATOR.—

(a) The duties of an administrator include organizing and directing the agency's ongoing functions; maintaining an ongoing liaison with the board members and the staff; employing qualified personnel and ensuring adequate staff education and evaluations; ensuring the accuracy of public information materials and activities; implementing an effective budgeting and accounting system; and ensuring that the home health agency operates in compliance with this part and chapter 408, part II of this chapter, and rules adopted pursuant to those laws.

(b) Administrator duties relating to organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level

must be clearly set forth in writing and be readily identifiable. Administrative and supervisory functions may not be delegated to another agency or organization, and all services not furnished directly, including services provided through contracts, must be monitored and controlled by the primary home health agency.

(2) DIRECTOR OF NURSING.—The director of nursing, or a similarly qualified alternate, must be available at all times during operating hours and participate in all activities relevant to the professional services furnished, including, but not limited to, the oversight of nursing services, home health aides, and certified nursing assistants and the assignment of personnel.

(3) NURSING SERVICES.—

(a) The registered nurse shall make the initial evaluation visit, regularly reevaluate the patient's nursing needs, initiate the plan of care and necessary revisions, furnish those services requiring substantial and specialized nursing skill, initiate appropriate preventive and rehabilitative nursing procedures, prepare clinical and progress notes, coordinate services, inform the physician and other personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in in-service programs, and supervise and teach other nursing personnel.

(b) The licensed practical nurse shall furnish services in accordance with agency policies, prepare clinical and progress notes, assist the physician and registered nurse in performing specialized procedures, prepare equipment and materials for



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treatments observing aseptic technique as required, and assist the patient in learning appropriate self-care techniques.

(4) THERAPY SERVICES.—

(a) Any physical or occupational therapy services offered by the home health agency, directly or under contract, must be provided by an appropriately licensed therapist or therapy assistant and in accordance with the plan of care. The therapist and therapy assistant must meet all professional qualifications specified in their respective state practice acts and related rules.

1. A physical or occupational therapist assists the physician in evaluating level of function, helps develop and revise the plan of care, prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

2. A physical or occupational therapy assistant performs services that are planned, delegated, and supervised by a physical or occupational therapist; assists in preparing clinical notes and progress reports; participates in educating the patient and family; and participates in in-service programs.

(b) Speech therapy services shall be furnished only by or under the supervision of a qualified speech pathologist or audiologist as required in the state practice act and related rules.

(5) HOME HEALTH AIDES AND CERTIFIED NURSING ASSISTANTS.- Home health aides and certified nursing assistants provide services that are ordered by the physician in the plan of care and that the home health aide is permitted to perform under state law.

(a) The duties of a home health aide and certified nursing assistant include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered and as specified in state rules. Any home health aide services offered by a home health agency must be provided by a qualified home health aide or certified nursing assistant.

(b) The home health aide and certified nursing assistant shall be assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide and certified nursing assistant must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide and certified nursing assistant.

Section 6. Section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; ~~physician's, physician assistant's, and advanced registered nurse practitioner's~~ treatment orders; ~~patient assessment; establishment and review of~~ plan of care; provision of services; orders not to resuscitate.—

(1) Services provided by a home health agency must be covered by an agreement between the home health agency and the patient or the patient's legal representative specifying the home health services to be provided, the rates or charges for services paid with private funds, and the sources of payment, which may include Medicare, Medicaid, private insurance,

personal funds, or a combination thereof. A copy of the agreement must be provided to the patient or the patient's legal representative. A home health agency providing skilled care must make an assessment of the patient's needs within 48 hours after the start of services.

(2) If ~~When~~ required by ~~the provisions of~~ chapter 464; part I, part III, or part V of chapter 468; or chapter 486, the attending physician, physician assistant, or advanced registered nurse practitioner, acting within his or her respective scope of practice, shall establish treatment orders for a patient who is to receive skilled care. The treatment orders must be signed by the physician, physician assistant, or advanced registered nurse practitioner before a claim for payment for the skilled services is submitted by the home health agency. If the claim is submitted to a managed care organization, the treatment orders must be signed within the time allowed under the provider agreement. The treatment orders shall be reviewed, as frequently as the patient's illness requires, by the physician, physician assistant, or advanced registered nurse practitioner in consultation with the home health agency.

(3) Home health care and treatment must follow a written plan of care. The plan of care must be reviewed by the attending physician, physician assistant, or advanced registered nurse practitioner who provided treatment orders under subsection (2) and home health agency personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently if there is a patient-elected transfer, a significant change in condition resulting in a change in the personnel assignment, or a discharge and return to the same home

health agency during the 60-day time period. Home health agency professional staff must promptly alert the physician or other professional who provided treatment orders to any changes that suggest a need to alter the plan of care. ~~A home health agency shall arrange for supervisory visits by a registered nurse to the home of a patient receiving home health aide services in accordance with the patient's direction, approval, and agreement to pay the charge for the visits.~~

(4) ~~Each patient has the right to be informed of and to participate in the planning of his or her care.~~ Each patient must be provided, upon request, a copy of the plan of care established and maintained for that patient by the primary home health agency.

(5) If ~~When~~ nursing services are ordered, the home health agency to which a patient has been admitted for care must provide the initial admission visit, all service evaluation visits, and the discharge visit by a direct employee. Services provided by others under contractual arrangements to a home health agency must be monitored and managed by the admitting home health agency. The admitting home health agency is fully responsible for ensuring that all care provided through its employees or contract staff is delivered in accordance with this part and applicable rules.

(6) The ~~skilled care~~ services provided by a home health agency, directly or under contract, must be supervised and coordinated in accordance with the plan of care and must be provided by or under the supervision of a registered nurse.

(a) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit. The

registered nurse or other professional must make an on-site visit to the patient's home at least every 2 weeks. The visit need not occur when the home health aide is providing care.

(b) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home at least every 60 days. To ensure that the home health aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(7) Drugs and treatments may be administered by agency staff only pursuant to treatment orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered pursuant to the home health agency's policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders must be put in writing and signed and dated with the date of receipt by the registered nurse or therapist responsible for furnishing or supervising the ordered services. Verbal orders may be accepted only by personnel authorized to do so by applicable state practice acts and applicable rules as well as pursuant to the home health agency's policies.

(8) ~~(7)~~ Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional



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conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and rules adopted by the agency.

Section 7. Section 400.493, Florida Statutes, is created to read:

400.493 Patient rights.—

(1) The home health agency must protect and promote the rights of each patient under its care, including each of the following:

(a) The patient has the right to participate in the provision of his or her care. The home health agency must advise the patient in advance of the right to participate in planning his or her care or treatment and in any changes to that plan. The home health agency must advise the patient in advance of any change in the plan of care before the change is made.

(b) The patient has the right to be informed about the care to be provided and any changes in the furnishing of that care. The home health agency must inform the patient in advance about the care and treatment to be furnished and any changes in the care and treatment. The home health agency must advise the patient of which practitioners will be furnishing care and the proposed frequency of their visits.

(c) The patient has the right to have his or her property treated with respect.

(d) The patient has the right to exercise his or her rights as a patient of the home health agency, including the right to voice grievances regarding the violations of those rights. The patient may not be subjected to discrimination or reprisal for voicing such grievances.

(2) The patient and his or her immediate family or representative must be informed of the right to report complaints to the statewide toll-free telephone number as required under s. 408.810(5).

(3) The home health agency must investigate complaints made by a patient, or the patient's family or guardian on behalf of the patient, pursuant to this section, and must document both the existence of the complaint and the resolution of the complaint.

(4) The home health agency must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment. The home health agency must maintain documentation showing that it has complied with this subsection.

Section 8. Subsection (2) of section 400.933, Florida Statutes, is amended to read:

400.933 Licensure inspections and investigations.—

(2) ~~The agency shall accept,~~ In lieu of its own periodic inspections for licensure, the agency shall accept ~~submission of the following~~:

(a) The survey or inspection of an accrediting organization if~~, provided~~ the accreditation of the licensed home medical equipment provider is not conditional or provisional and ~~provided~~ the licensed home medical equipment provider authorizes the release ~~of,~~ and the agency receives the report of~~,~~ the accrediting organization.~~; or~~

(b) A copy of a valid medical oxygen retail establishment permit issued by the Department of Health, pursuant to chapter



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Section 9. Subsection (1) of section 400.969, Florida Statutes, is amended to read:

400.969 Violation of part; penalties.—

(1) In addition to the requirements of part II of chapter 408, and except as provided in s. 400.967(3), a violation of any provision of federal certification required pursuant to s. 400.960(8), this part, part II of chapter 408, or applicable rules is punishable by payment of an administrative or civil penalty not to exceed $5,000.

Section 10. Effective January 1, 2011, subsections (1) and (2) of section 408.05, Florida Statutes, are amended to read:

408.05 Florida Center for Health Information and Policy Analysis.—

(1) ESTABLISHMENT.—The agency shall establish a Florida Center for Health Information and Policy Analysis. The center shall establish a comprehensive health information system to provide for the collection, compilation, coordination, analysis, indexing, dissemination, and use of ~~utilization of both~~ purposefully collected and extant health-related data and statistics. The center shall be staffed with public health experts, biostatisticians, information system analysts, health policy experts, risk management experts, economists, and other staff necessary to carry out its functions.

(2) HEALTH-RELATED DATA.—The comprehensive health information system operated by the ~~Florida~~ center must ~~for Health Information and Policy Analysis shall~~ identify the best available data sources, ~~and~~ coordinate the compilation of extant health-related data and statistics, and purposefully collect



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data on:

(a) The extent and nature of illness and disability of the state population, including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality.

(b) The impact of illness and disability of the state population on the state economy and on other aspects of the well-being of the people in this state.

(c) Environmental, social, and other health hazards.

(d) Health knowledge and practices of state residents ~~the people in this state~~ and determinants of health and nutritional practices and status.

(e) Health resources, including physicians, dentists, nurses, and other health professionals, by specialty and type of practice and acute, long-term care and other institutional care facility supplies and specific services provided by hospitals, nursing homes, home health agencies, and other health care facilities.

(f) Utilization of health care by type of provider.

(g) Health care costs and financing, including trends in health care prices and costs, the sources of payment for health care services, and federal, state, and local expenditures for health care.

(h) Family formation, growth, and dissolution.

(i) The extent of public and private health insurance coverage in this state.

(j) The quality of care provided by various health care providers.

(k) Patient safety in health facilities. The center is



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responsible for collecting and analyzing adverse incidents submitted by licensed facilities and certified organizations under ss. 395.0197 and 641.55. Such incidents may be reviewed for accuracy, completeness, and compliance. The center is also responsible for the agency's reporting requirements under s. 395.0197.

Section 11. Paragraph (b) of subsection (14) of section 408.7056, Florida Statutes, is amended to read:

408.7056 Subscriber Assistance Program.—

(14)

(b) Meetings of the panel are ~~shall be~~ open to the public unless the provider or subscriber whose grievance will be heard requests a closed meeting or the agency or the department determines that information that ~~which~~ discloses the subscriber's medical treatment or history or information relating to internal risk management programs as provided in s. 641.55 ~~defined in s. 641.55(5)(c), (6), and (8)~~ may be revealed at the panel meeting, in which case that portion of the meeting during which a subscriber's medical treatment or history or internal risk management program information is discussed is ~~shall be~~ exempt from ~~the provisions of~~ s. 286.011 and s. 24(b), Art. I of the State Constitution. All closed meetings shall be recorded by a certified court reporter.

Section 12. Section 408.805, Florida Statutes, is amended to read:

408.805 Fees required; adjustments. ~~Unless otherwise limited by authorizing statutes,~~ License fees must be reasonably calculated by the agency to cover its costs in carrying out its responsibilities under this part, authorizing statutes, and



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applicable rules, including the cost of licensure, inspection, and regulation of providers.

(1) Licensure fees shall be adjusted to provide for biennial licensure under agency rules.

(2) The agency shall annually adjust licensure fees, including fees paid per bed, by not more than the change in the Consumer Price Index based on the 12 months immediately preceding the increase.

(3) An inspection fee must be paid as required in authorizing statutes.

(4) Fees are nonrefundable.

(5) If ~~When~~ a change is reported which ~~that~~ requires issuance of a license, a fee may be assessed. The fee must be based on the actual cost of processing and issuing the license.

(6) A fee may be charged to a licensee requesting a duplicate license. The fee may not exceed the actual cost of duplication and postage.

(7) Total fees collected may not exceed the cost of administering this part, authorizing statutes, and applicable rules.

Section 13. Paragraph (a) of subsection (6) of section 408.811, Florida Statutes, is amended to read:

408.811 Right of inspection; copies; inspection reports; plan for correction of deficiencies.—

(6)(a) Each licensee shall maintain as public information, available upon request, records of all inspection reports pertaining to that provider which ~~that~~ have been filed by the agency unless those reports are exempt from or contain information that is exempt from s. 119.07(1) and s. 24(a), Art.



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I of the State Constitution or is otherwise made confidential by law. ~~Effective October 1, 2006,~~ Copies of such reports shall be retained in the records of the provider for at least 3 years following the date the reports are filed and issued, regardless of a change of ownership. Inspection reports are not subject to challenge under s. 120.569 or s. 120.57.

Section 14. Subsections (2) and (11) of section 429.65, Florida Statutes, are amended to read:

429.65 Definitions.—As used in this part, the term:

(2) "Adult family-care home" means a full-time, family-type living arrangement, in a private home, under which one to two individuals who reside in the home and own or rent the home provide ~~a person who owns or rents the home provides~~ room, board, and personal care, on a 24-hour basis, for no more than five disabled adults or frail elders who are not relatives. The following family-type living arrangements are not required to be licensed as an adult family-care home:

(a) An arrangement whereby the person who resides in the home and owns or rents the home provides room, board, and personal care ~~services~~ for not more than two adults who do not receive optional state supplementation under s. 409.212. The person who provides the housing, meals, and personal care must own or rent the home and reside therein.

(b) An arrangement whereby the person who owns or rents the home provides room, board, and personal services only to his or her relatives.

(c) An establishment that is licensed as an assisted living facility under this chapter.

(11) "Provider" means the one or two individuals who are ~~a~~



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~~person who is~~ licensed to operate an adult family-care home.

Section 15. Effective January 1, 2011, subsection (9) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(9) If ~~When~~ an investigation of a physician is undertaken, the department shall promptly furnish to the physician or the physician's attorney a copy of the complaint or document that ~~which~~ resulted in the initiation of the investigation. For purposes of this subsection, such documents include, but are not limited to: ~~the pertinent portions of an annual report submitted to the department pursuant to s. 395.0197(6);~~ a report of an adverse incident which is provided to the department pursuant to s. 395.0197; a report of peer review disciplinary action submitted to the department pursuant to s. 395.0193(4) or s. 458.337, if ~~providing that~~ the investigations, proceedings, and records relating to such peer review disciplinary action shall continue to retain their privileged status even as to the licensee who is the subject of the investigation, as provided by ss. 395.0193(8) and 458.337(3); a report of a closed claim submitted pursuant to s. 627.912; a presuit notice submitted pursuant to s. 766.106(2); and a petition brought under the Florida Birth-Related Neurological Injury Compensation Plan, pursuant to s. 766.305(2). The physician may submit a written response to the information contained in the complaint or document which resulted in the initiation of the investigation within 45 days after service to the physician of the complaint or document. The physician's written response shall be considered by the probable cause panel.

Section 16. Effective January 1, 2011, subsection (9) of section 459.015, Florida Statutes, is amended to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(9) If ~~When~~ an investigation of an osteopathic physician is undertaken, the department shall promptly furnish to the osteopathic physician or his or her attorney a copy of the complaint or document that ~~which~~ resulted in the initiation of the investigation. For purposes of this subsection, such documents include, but are not limited to: ~~the pertinent portions of an annual report submitted to the department pursuant to s. 395.0197(6);~~ a report of an adverse incident which is provided to the department pursuant to s. 395.0197; a report of peer review disciplinary action submitted to the department pursuant to s. 395.0193(4) or s. 459.016, if ~~provided that~~ the investigations, proceedings, and records relating to such peer review disciplinary action ~~shall~~ continue to retain their privileged status even as to the licensee who is the subject of the investigation, as provided by ss. 395.0193(8) and 459.016(3); a report of a closed claim submitted pursuant to s. 627.912; a presuit notice submitted pursuant to s. 766.106(2); and a petition brought under the Florida Birth-Related Neurological Injury Compensation Plan, pursuant to s. 766.305(2). The osteopathic physician may submit a written response to the information contained in the complaint or document which resulted in the initiation of the investigation within 45 days after service to the osteopathic physician of the complaint or document. The osteopathic physician's written response shall be considered by the probable cause panel.

Section 17. Effective January 1, 2011, section 641.55, Florida Statutes, is amended to read:

641.55 Internal risk management program.—

(1) ~~Every organization certified under this part shall,~~ As a part of its administrative functions, each certified organization shall establish an internal risk management program that includes all of ~~which shall include~~ the following components:

(a) The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents causing injury to patients;

(b) The development of appropriate measures to minimize the risk of ~~injuries and~~ adverse incidents causing injury to patients, including risk management and risk prevention education and training of all nonphysician personnel as follows:

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

2. At least 1 hour of ~~such~~ education and training annually for all nonphysician personnel of the organization who work in clinical areas and provide patient care;

(c) The analysis of patient grievances which relate to patient care and the quality of medical services; and

(d) The development and implementation of a ~~an incident~~ reporting system for adverse incidents based upon the affirmative duty of all providers and all agents and employees of the organization to report such ~~injuries and adverse~~ incidents to the risk manager.

(2) The risk management program is ~~shall be~~ the responsibility of the governing authority or board of the



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organization. Every organization that ~~which~~ has an annual premium volume of $10 million or more and that ~~which~~ directly provides health care in a building owned or leased by the organization shall hire a risk manager, certified under ss. 395.10971-395.10975, who is ~~shall be~~ responsible for implementation of the organization's risk management program ~~required by this section~~. A part-time risk manager may ~~shall~~ not be responsible for risk management programs in more than four organizations or facilities. Every organization that ~~which~~ does not directly provide health care in a building owned or leased by the organization and every organization with an annual premium volume of less than $10 million shall designate an officer or employee of the organization to serve as the risk manager.

~~(3) In addition to the programs mandated by this section, other innovative approaches intended to reduce the frequency and severity of medical malpractice and patient injury claims shall be encouraged and their implementation and operation facilitated. Additional approaches may include extending risk management programs to provider offices or facilities.~~

(3)~~(4)~~ The agency ~~for Health Care Administration~~ shall adopt rules ~~necessary to carry out the provisions of this section, including rules~~ governing the establishment of required internal risk management programs to meet the needs of individual organizations and each specific organization type governed by this part. ~~The office shall assist the agency in preparing these rules.~~ Each internal risk management program must ~~shall~~ include the use of adverse incident reports ~~to be~~ filed with the risk manager. The risk manager shall have free



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access to all organization or provider medical records. The ~~incident~~ reports are ~~shall be~~ considered ~~to be a~~ part of the workpapers of the attorney defending the organization in litigation relating to the organization ~~thereto~~ and are ~~shall be~~ subject to discovery, but not be admissible as evidence in court. A~~, nor shall any~~ person filing such an incident report is not ~~be~~ subject to civil suit by virtue of the ~~incident~~ report and the matters it contains. As a part of each internal risk management program, the ~~incident~~ reports shall be used ~~utilized~~ to develop categories of adverse incidents which identify problem areas. Once identified, procedures must be adjusted to correct these problem areas.

(4) For an incident to be an adverse incident that must be reported to the agency pursuant to this section, it must be: of concern to both the public and health care practitioners and providers; clearly identifiable and measurable and thus feasible to include in a reporting system; and of such a nature that the risk of occurrence is significantly influenced by the policies and procedures of the organization. In addition, the incident must be unambiguous, usually preventable, serious, and any of the following: adverse; indicative of a problem in the facility's safety systems; or important for public credibility or public accountability. The incident must also be on the most current list set forth by the National Quality Forum.

(5) Adverse incident must be reported electronically by the organization through an online portal to the agency within 15 calendar days after the occurrence. The agency may grant an extension to this reporting requirement upon receiving justification submitted by the organization's administrator to

the agency.

(a) All adverse incidents listing an individual licensed by the Department of Health as directly involved in the incident must be immediately forwarded to the Department of Health and are subject to s. 456.073.

(b) The reports are exempt from disclosure under chapter 119 or any other law providing access to public records; not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the Department of Health or the appropriate regulatory authority; and are not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings ordinarily made available to the public.

(c) The organization's chief executive officer, or designee, shall certify quarterly, through the electronic submission portal, that all adverse incidents from the previous quarter have been reported and that the reports are accurate.

(6) Within 60 days after the occurrence of an adverse incident, the agency shall require the organization to electronically submit a final report. The final report should include a copy of the root-cause analysis, any risk management or patient safety lessons learned, the plan of correction, and the results obtained during the plan's implementation in the organization. The agency may investigate adverse incidents and prescribe measures that must or may be taken in response to the incident. These reports are exempt from disclosure under chapter 119 or any other law providing access to public records, and are not discoverable or admissible in any civil or administrative action.

(7) The agency shall have access to all of the organization's records necessary to carry out the provisions of this section. The records obtained by the agency under subsection (6) or subsection (7) are exempt from disclosure under s. 119.07(1) and are not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency, the Department of Health, or the appropriate regulatory board. Records obtained pursuant to s. 456.071 may not be made available to the public as part of the record of investigation for and prosecution in disciplinary proceedings.

~~(5)(a) Each organization subject to this section must submit an annual report to the agency summarizing the incident reports that were filed in the organization during the preceding calendar year pertaining to services rendered on the premises of the organization. The report must be on a form prescribed by rule of the agency and must include, with respect to medical services rendered on the premises of the organization:~~

~~1. The total number of adverse incidents causing injury to patients.~~

~~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.~~

~~3. A listing, by category, of the types of injuries caused and the number of incidents occurring within each category.~~

~~4. The name of each provider or a code number using each health care professional's license number and a separate code number identifying all other individuals directly involved in~~



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~~adverse incidents causing injury to a patient, the relationship of the individual or provider to the organization, and the number of incidents with the organization in which each individual or provider has been directly involved. Each organization must maintain names of the health care professionals and individuals identified by code numbers for purposes of this section.~~

~~5. A description of all medical malpractice claims filed against the organization or its providers, including the total number of pending and closed claims and the nature of the incident that led to, the persons involved in, and the status and disposition of each claim. Each report must update status and disposition for all prior reports.~~

~~6. A report of all disciplinary actions taken against any provider or any medical staff member of the organization, including the nature and cause of the action.~~

~~(b) The information reported to the agency under paragraph (a) which relates to providers licensed under chapter 458, chapter 459, chapter 461, or chapter 466 must also be reported to the agency quarterly. The agency shall review the information and determine whether any of the incidents potentially involved conduct by a licensee that is subject to disciplinary action, in which case s. 456.073 applies.~~

~~(c) Except as otherwise provided in this subsection, any identifying information contained in the annual report and the quarterly reports under paragraphs (a) and (b) is confidential and exempt from s. 119.07(1). This information must not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available~~



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~~to the public by the agency or the appropriate regulatory board. However, the agency shall make available, upon written request by a practitioner against whom probable cause has been found, any such information contained in the records that form the basis of the determination of probable cause under s. 456.073.~~

~~(d) The annual report shall also contain the name of the risk manager of the organization, a copy of its policy and procedures governing the measures taken by the organization and its risk manager to reduce the risk of injuries and adverse or untoward incidents, and the result of these measures.~~

~~(6) If an adverse or untoward incident, whether occurring in the facilities of the organization or arising from health care prior to enrollment by the organization or admission to the facilities of the organization or in a facility of one of its providers, results in:~~

~~(a) The death of a patient;~~

~~(b) Severe brain or spinal damage to a patient;~~

~~(c) A surgical procedure being performed on the wrong patient; or~~

~~(d) A surgical procedure unrelated to the patient's diagnosis or medical needs being performed on any patient,~~

~~the organization must report this incident to the agency within 3 working days after its occurrence. A more detailed followup report must be submitted to the agency within 10 days after the first report. The agency may require an additional, final report. Reports under this subsection must be sent immediately by the agency to the appropriate regulatory board whenever they contain references to a provider licensed under chapter 458,~~



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~~chapter 459, chapter 461, or chapter 466. These reports are confidential and are exempt from s. 119.07(1). This information is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency shall make available, upon written request by a practitioner against whom probable cause has been found, any such information contained in the records that form the basis of the determination of probable cause under s. 456.073. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken by the organization in response to the incident. The agency shall review each incident and determine whether it potentially involved conduct by the licensee which is subject to disciplinary action, in which case s. 456.073 applies.~~

(8)~~(7)~~ In addition to any penalty imposed under s. 641.52, the agency may impose an administrative fine, not to exceed $5,000, for any violation of the reporting requirements of subsection (5) or subsection (6).

(9)~~(8)~~ The Department of Health ~~agency and~~, upon issuance of a subpoena ~~issued~~ under s. 456.071, and the appropriate regulatory board must be given access to all organization records necessary to carry out the provisions of this section. Any identifying information contained in the records obtained under this section is confidential and exempt from s. 119.07(1). The identifying information contained in records obtained under s. 456.071 is exempt from s. 119.07(1) if ~~to the extent that~~ it is part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the



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agency, the department, or the appropriate regulatory board. ~~However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any such information contained in the records that form the basis of the determination of probable cause under s. 456.073, except that, with respect to medical review committee records, s. 766.101 controls.~~

(10) ~~(9)~~ At least annually, the agency shall review~~, no less frequently than annually,~~ the risk management program of each organization ~~regulated by this section~~ to determine whether the program meets the 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 such incidents under subsections (5) and (6).

(11) ~~(10) There shall be~~ No monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager certified under part IX of chapter 626 for the implementation and oversight of the risk management program in an organization authorized under this chapter for any act or proceeding undertaken or performed within the scope of the function of such ~~risk management~~ program if the risk manager acts without intentional fraud.

~~(11) If the agency, through its receipt of the annual reports prescribed in subsection (5) or through any investigation, has a reasonable belief that conduct by a provider, staff member, or employee of an organization may constitute grounds for disciplinary action by the appropriate regulatory board, the agency shall report this fact to the~~



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~~regulatory board.~~

~~(12) The agency shall send information bulletins to all organizations as necessary to disseminate trends and preventive data derived from its actions under this section or under s. 395.0197.~~

(12) The gross data compiled under this section or s. 395.0197 shall be furnished by the agency upon request to organizations to be used ~~utilized~~ for risk management purposes.

(13) The agency shall adopt rules necessary to administer ~~carry out the provisions of~~ this section.

Section 18. Adult living facilities have become the preferred environment for individuals needing assistance with personal care services as they age and strive to function while having varying degrees of physical or mental impairments. It is the intent of the Legislature that rules adopted and enforced in assisted living facilities include firesafety standards that ensure a safe and secure quality of life for residents.

(1) Under chapter 633, Florida Statutes, the State Fire Marshal is directed to adopt the Florida Fire Prevention Code for statewide application using the most current edition of the Life Safety Code. Assisted living facilities are governed by chapter 429, Florida Statutes, which permits compliance with 1988 firesafety standards and other standards governing firesafety, including the 1994 edition of the Life Safety Code.

(2) The State Fire Marshal is directed to conduct a study of the effectiveness of currently adopted firesafety standards for assisted living facilities and evaluate whether the continued use of such standards sufficiently ensures the safety of staff and residents in the case of a fire emergency. The

study shall include input from the Department of Elderly Affairs, the Agency for Health Care Administration, the Department of Health, and trade organizations representing assisted living facilities. The study shall address, but need not be limited to, the establishment of uniform firesafety standards for fire alarms and other fire protections based on the size of the structure.

(3) The State Fire Marshal shall complete the study and provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 15, 2010. The report shall include, but need not be limited to, recommendations for legislative changes that will enhance the current firesafety standards of assisted living facilities without causing significant adverse impact on the residents or the individual caregivers.

Section 19. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.



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