64B8-9.001 Physician Office Incident Reporting

(1) Definitions.

(a) "Adverse incident" for purposes of reporting to the department, is defined in Section 458.351, F.S., as an event over which the physician or other licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

1. The death of a patient.
2. Brain or spinal damage to a patient.
3. The performance of a surgical procedure on the wrong patient.
4. The performance of a wrong-site surgical procedure; the performance of a wrong surgical procedure; or the surgical repair of damage to a patient resulting 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 and if one of the listed procedures in this paragraph results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical or sensory function; or any condition that required transfer of the patient.
5. A procedure to remove unplanned foreign objects remaining from a surgical procedure.
6. Any condition that required the transfer of a patient to a hospital licensed under Chapter 395, F.S., from any facility or any office maintained by a physician for the practice of medicine which is not licensed under Chapter 395, F.S.

(b) "Licensee" for purposes of this rule, includes a physician or physician assistant issued a license, registration, or certificate, for any period of time, pursuant to Chapter 458, F.S.

(c) "Office maintained by a physician" as that term is used in Section 458.351(1), F.S., is defined as a business location where the physician delivers medical services regardless of whether other physicians are practicing at the same location or the business is non-physician owned.

(2) Incident Reporting System. An incident reporting system shall be established for each physician office.
(a) Incident Reports. The incident reporting system shall include the prompt, postmarked and sent by certified mail within 15 calendar days after the occurrence of the adverse incident, reporting of incidents to the Department of Health, Consumer Services Unit, 4052 Bald Cypress Way, Bin #C75, Tallahassee, Florida 32399. The report shall be made on the Physician Office Adverse Incident Report. The report must be submitted by every licensee who was involved in the adverse incident. If multiple licensees are involved in the adverse incident, they may meet this requirement by signing off on one report; however, each signee is responsible for the accuracy of the report. This report shall contain the following information:

1. The patient’s name, locating information, gender, age, diagnosis, date of office visit, and purpose of office visit.

2. A clear and concise description of the incident including time, date, and exact location within the office.

3. A listing of all persons then known to be involved directly in the incident, including license numbers and locating information, and a description of the person’s exact involvement and actions.

4. A listing of any witnesses not previously identified in subparagraph 3.

5. The name, license number, locating information, and signature of the physician or licensee submitting the report, along with date and time that the report was completed.

(b) Incident Report Review and Analysis. Evidence of compliance with this paragraph will be considered in mitigation in the event the Board takes disciplinary action.

1. The physician shall be responsible for the regular and systematic reviewing of all incident reports filed by the physician or physician assistant under the physician's supervision, for the purpose of identifying factors that contributed to the adverse incident and identifying trends or patterns as to time, place, or persons. The physician shall implement corrective actions and incident prevention education and training indicated by the review of each adverse incident and upon emergence of any trend or pattern in incident occurrence.

2. Copies of incident reports shall be maintained in the physician office.

(3) Death Reports. Notwithstanding the provisions of this rule and Section 458.351, F.S., an adverse incident which results in death shall be reported immediately to the medical examiner pursuant to Section 406.12, F.S.

**AUTHORITY:** Specific Authority 458.309(1), 458.351(6) FS.
Law Implemented 458.351 FS.

**HISTORY**
New 3-9-00.

**64B8-9.0075 Standards of Practice in Certain Office Settings.**
(1) Standards of care and standards of practice require that Florida licensed physicians and physician assistants provide their patients appropriate medical care under sanitary conditions; that medical care is provided pursuant to informed consent, adequately documented and lawfully billed to the patients and/or other payors; and that persons assisting in the delivery of medical care to their patients are licensed, certified, and/or supervised as required by law. Except as specifically provided for in the following practice settings, physicians and physician assistants may neither delegate to others nor reasonably rely upon others to ensure compliance with these patient responsibilities.

(2) Physicians and physician assistants with a practice setting in a hospital or other facility licensed pursuant to Chapter 395 or 400, F.S., or who practice in a federally qualified health clinic or other state or federally regulated program that provides an equivalent risk management and oversight of physicians and physician assistants, may reasonably rely upon the licensed facility to ensure that medical care is provided under sanitary conditions, lawfully billed to the patients and/or other payors and that persons assisting in the delivery of medical care to their patients are licensed, certified, and/or supervised as required by law.

(3) Licensed physicians and physician assistants in a clinic registered under Chapter 400, Part XIII, F.S., may reasonably rely upon a Florida licensed medical director to ensure compliance with the responsibilities set forth in Section 400.991, F.S., only if the medical director has specifically agreed to accept the responsibilities set forth in Section 400.9935(1), F.S.

AUTHORITY: Specific Authority 458.309, 458.331(1)(v) FS.
Law Implemented 458.331(1) FS.

HISTORY
New 11-13-00, Amended 6-4-02, 12-20-06.

64B8-9.009 Standard of Care for Office Surgery.

NOTHING IN THIS RULE RELIEVES THE SURGEON OF THE RESPONSIBILITY FOR MAKING THE MEDICAL DETERMINATION THAT THE OFFICE IS AN APPROPRIATE FORUM FOR THE PARTICULAR PROCEDURE(S) TO BE PERFORMED ON THE PARTICULAR PATIENT.

(1) Definitions.

(a) Surgery. For the purpose of this rule, surgery is defined as any operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.
(b) Surgeon. For the purpose of this rule, surgeon is defined as a licensed physician performing any procedure included within the definition of surgery.

(c) Equipment. For the purpose of this rule, implicit within the use of the term of equipment is the requirement that the specific item named must meet current performance standards.

(d) Office surgery. For the purpose of this rule office surgery is defined as surgery which is performed outside of any facility licensed under Chapter 390 or 395, F.S. Office surgical procedures shall not be of a type that generally result in blood loss of more than ten percent (10%) of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; directly involve major blood vessels; or are generally emergent or life threatening in nature.

(e) Pediatric patients are defined as those patients who are thirteen (13) years of age or under.

(2) General Requirements for Office Surgery.

(a) The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C.

(b) The requirement set forth in paragraph (2)(a) above for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(c) The surgeon must maintain a log of all Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, the name of the physician who provided medical clearances, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, the type of post-operative care, duration of recovery, disposition of the patient upon discharge, list of medications used during surgery and recovery, and any adverse incidents, as identified in Section 458.351, F.S. The log and all surgical records shall be provided to investigators of the Department of Health upon request.

(d) In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of fifty (50) mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.

(e) Liposuction may be performed in combination with another separate surgical
procedure during a single Level II or Level III operation, only in the following circumstances:

1. When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;

2. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000cc of supernatant fat;

3. Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

(f) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed eight (8) hours. Except for elective cosmetic and plastic surgery, the surgeon shall not keep patients past midnight in a physician's office. For elective cosmetic and plastic surgical procedures, the patient must be discharged within twenty-four (24) hours of presenting to the office for surgery; an overnight stay is permitted in the office provided the total time the patient is at the office does not exceed twenty-three (23) hours and fifty-nine (59) minutes including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

(g) The Board of Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," approved by House Delegates on October 21, 1986, and last amended on October 21, 1998, as the standards for anesthetic monitoring by any qualified anesthesia provider.

1. These standards apply to general anesthetics, regional anesthetics, and monitored anesthesia care (Level II and III as defined by this rule) although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards address only the issue of basic anesthesia monitoring, which is one (1) component of anesthesia care.

2. In certain rare or unusual circumstances some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. For purpose of this rule, "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

3. Under extenuating circumstances, the responsible supervising physician or anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record. These standards are not intended for the application to the care of the obstetrical patient in labor or in the conduct of pain management.
a. Standard I.

I. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

II. OBJECTIVE. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the supervising physician or anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

b. Standard II.

I. During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

II. OXYGENATION.

(A) OBJECTIVE. To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

(B) METHODS.

(I) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

(II) Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as a pulse oximetry shall be employed.* Adequate illumination and exposure of the patient are necessary to assess color.*

III. VENTILATION.

(A) OBJECTIVE. To ensure adequate ventilation of the patient during all anesthetics.

(B) METHODS.

(I) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*

(II) When an endotracheal tube or laryngeal mask is inserted, its correct positioning
must be verified by clinical assessment and by identification of carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.*

(III) When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

(IV) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

IV. CIRCULATION. 64B8-9.009

(A) OBJECTIVE. To ensure the adequacy of the patient's circulatory function during all anesthetics.

(B) METHODS.

(I) Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*

(II) Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*

(III) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one (1) of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

V. BODY TEMPERATURE.

(A) OBJECTIVE. To aid in the maintenance of appropriate body temperature during all anesthetics.

(B) METHODS. Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

(h) The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Rule 64B8-9.007, F.A.C. Management of post surgical care is the responsibility of the operating surgeon and may be delegated only as set forth in subsection 64B8-9.007(3), F.A.C. If there is an overnight stay at the office in relation to any surgical procedure:

1. The office must provide at least two (2) monitors, one (1) of these monitors must be certified in Advanced Cardiac Life Support (ACLS), and maintain a monitor to patient ratio of at least one (1) monitor to two (2) patients. Once the surgeon has
signed a timed and dated discharge order, the office may provide only one (1) monitor to monitor the patient. The monitor must be certified in Advanced Cardiac Life Support. The full and current crash cart required below must be present in the office and immediately accessible for the monitors.

2. The surgeon must be reachable by telephone and readily available to return to the office if needed. For purposes of this subsection, "readily available" means capable of returning to the office within fifteen (15) minutes of receiving a call.

(i) A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed.

(j) The surgeon shall establish a risk management program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

2. The identification of trends or patterns of incidents,

3. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and

4. The documentation of these functions and periodic review no less than quarterly of such information by the surgeon.

(k) The surgeon shall report to the Department of Health any adverse incidents that occur within the office surgical setting. This report shall be made within fifteen (15) days after the occurrence of an incident as required by Section 197, Chapter 99-397, Laws of Florida.

(l) A sign must be prominently posted in the office which states that the office is a doctor's office regulated pursuant to the rules of the Board of Medicine as set forth in Rule Chapter 64B8, F.A.C. This notice must also appear prominently within the required patient informed consent.

(m) All physicians performing office surgery must be qualified by education, training, and experience to perform any procedure the physician performs in the office surgery setting.

(3) Level I Office Surgery.

(a) Scope. Level I office surgery includes the following:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquillization of the patient.
2. Liposuction involving the removal of less than 4000cc supernatant fat is permitted.

3. Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

4. Pre-operative medications not required or used other than minimal pre-operative tranquilization of the patient; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted in level I Office Surgery.

5. Chances of complication requiring hospitalization are remote.

(b) Standards for Level I Office Surgery.

1. Training Required. Surgeon's continuing medical education should include: proper dosages; management of toxicity or hypersensitivity to regional anesthetic drugs. Basic Life Support Certification is recommended but not required.

2. Equipment and Supplies Required. Oxygen, positive pressure ventilation device, Epinephrine (or other vasopressor), Corticoids, Antihistamine and Atropine if any anesthesia is used.

3. Assistance of Other Personnel Required. No other assistance is required, unless the specific surgical procedure being performed requires an assistant.

(4) Level II Office Surgery.

(a) Scope.

1. Level II Office Surgery is that in which peri-operative medication and sedation are used intravenously, intramuscularly, or rectally, thus making intra and post-operative monitoring necessary. Such procedures shall include, but not be limited to: hemorrhoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat.

2. Level II Office surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity. "Reasonable proximity" is defined as not to exceed thirty (30) minutes transport time to the hospital.
2. Training Required. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board eligibility by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to establish comparable background, training, and experience. One (1) assistant must be currently certified in Basic Life Support and the surgeon must be currently certified in Advanced Cardiac Life Support.

3. Equipment and Supplies Required.

a. Full and current crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, the following resuscitative medications:

I. Adenosine 6 mg/2 ml x 3
II. Albuterol Inhaler
III. Amiodarone 150 mg x 2
IV. Atropine 0.4 mg/ml; 3 ml
V. Calcium chloride 10%; 10 ml
VI. Dextrose 50%; 50 ml
VII. Diphenhydramine 50 mg
VIII. Dopamine 200 mg minimum
IX. Epinephrine 1:10,000 dilution; 10 ml
X. Epinephrine 1:1000 dilution; 1 ml x 3
XI. Flumazenil 0.1 mg/ml; 5 ml x 2
XII. Furosemide 40 mg
XIII. Hydrocortisone or Methylprednisolone or Dexamethasone
XIV. Lidocaine 100 mg
XV. Magnesium sulfate 1 gm x 2
XVI. Naloxone 0.4 mg/ml; 3 ml
XVII. Propranolol 1 mg x 1
XVIII. Sodium bicarbonate 50 mEq/50 ml
XIX. Succinylcholine 1 vial
XX. Vasopressin 20 units x 2

XXI. Verapamil 5 mg x 2

b. A Benzodiazepine must be stocked, but not on the crash cart.

c. Suction devices, endotracheal tubes, laryngoscopes, etc.

d. Positive pressure ventilation device (e.g. Ambu) plus oxygen supply.

e. Double tourniquet for the Bier block procedure.

f. Monitors for blood pressure/EKG/Oxygen saturation.

g. Emergency intubation equipment.

h. Adequate operating room lighting.

i. Emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.

j. Appropriate sterilization equipment.

k. IV solution and IV equipment.

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthesist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, a licensed registered nurse with post-anesthesia care unit experience or the equivalent, credentialed in Advanced Cardiac Life Support or, in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.

(5) Level IIA Office Surgery.

(a) Scope. Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of five (5) minutes or less and in which chances of complications requiring hospitalization are remote.

(b) Standards for Level IIA Office Surgery.

1. The standards set forth in subsection 64B8-9.009(4), F.A.C., must be met except for the requirements set forth in subparagraph 64B8-9.009(4)(b)4., F.A.C., regarding assistance of other personnel.

2. Assistance of Other Personnel Required. During the procedure, the surgeon must
be assisted by a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or by a licensed registered nurse or a licensed practical nurse. Additional assistance may be required by specific procedure or patient circumstances. Following the procedure, a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or a licensed registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified in Advanced Cardiac Life Support, or, in the case of pediatric patients, Pediatric Advanced Life Support.

(6) Level III Office Surgery.

(a) Scope.

1. Level III Office Surgery is that surgery which involves, or reasonably should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:

a. Intravenous sedation beyond that defined for Level II office surgery;

b. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; or

c. Major conduction anesthesia.

2. Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery.

   a. All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center.

   b. For all ASA II patients above the age of forty (40), the surgeon must obtain, at a minimum, an EKG and a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient is deemed to be a complicated medical patient, the patient must be referred to an appropriate consultant for an independent medical clearance. This requirement may be waived after evaluation by the patient's anesthesiologist.

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

1. Training Required. 64B8-9.009

   a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. In addition, the surgeon must have knowledge of the principles of general anesthesia.

   b. One (1) assistant must be currently certified in Basic Life Support and the surgeon
must be currently certified in Advanced Cardiac Life Support.

2. Emergency procedures related to serious anesthesia complications should be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location.

3. Equipment and Supplies Required.

a. Equipment, medication, including at least thirty-six (36) ampules of dantrolene on site, and monitored post-anesthesia recovery must be available in the office.

b. The office, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping.

c. Blood pressure monitoring equipment; EKG; end tidal CO2 monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device.

d. Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure.

e. IV solutions and IV equipment.

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed in Advanced Cardiac Life Support, or in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient has recovered from anesthesia.

**AUTHORITY:** Specific Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.331(1)(g), (t), (v), (w), 458.351 FS.

**HISTORY**
New 2-1-94, Amended 5-17-94, Formerly 61F6-27.009, Amended 9-8-94, 11-15-94, Formerly 59R-9.009, Amended 2-17-00, 12-7-00, 2-27-01, 8-1-01, 8-12-01, 3-25-02, 3-22-05, 4-19-05, 10-23-05, 10-10-06.

**ANNOTATIONS**

Compliance

A plastic surgeon failed to comply with Rule 64B8-9.009, F.A.C., by utilizing a registered nurse, instead of an anesthesiologist, certified registered nurse anesthetist, or physician assistant as required by the rule, and also had the nurse perform other duties during a surgical procedure that were prohibited by the rule. In
Negligence

Former Rule 59R-9.009 [now Rule 64B8-9.009, F.A.C.,] prescribed the standards of practice for medical doctors, specifically, the standard of care for office surgery. Title 59 of the Florida Administrative Code was consistent with Chapter 458.331, F.S., in that it regulated the medical practice and provided for disciplinary actions, but did not purport to give any protections to any particular class of people beyond the public at large. As such, a violation of former Rule 59R-9.009 [now Rule 64B8-9.009, F.A.C.,] could not be construed to constitute negligence per se. Lingle v. Dion, 776 So.2d 1073, 2001 Fla. App. LEXIS 1088, 26 Fla. L. Weekly D 404.

Validity

The court reversed the order of the administrative law judge that held that paragraph 64B8-9.009(4)(b) and sub-subparagraph 64B8-9.009(6)(b)1.a., F.A.C., constituted invalid exercises of delegated legislative authority by appellants. The ALJ’s holding was not supported by competent substantial evidence and therefore, was in error. Florida Board of Medicine, Florida Society of Anesthesiologists and Florida Hospital Association, Inc. v. Florida Academy of Cosmetic Surgery, Inc.; Charles Graper, M.D., D.D.S., F.A.C.S.; R. Gregory Smith, M.D.; Florida Society of Plastic Surgery, Inc., and Florida Society of Dermatology, Inc., 24 FALR 1003 (2002).

DOAH ruled that Rule 64B8-9.009(4)(b) and (6)(b), F.A.C., were invalid exercises of delegated legislative authority. DOAH also ruled that the remaining sections of Rule 64B8-9.009 were not invalid. DOAH held that the requirements for hospital privileges and transfer agreements with hospitals as contained within subsections (4)(b) and (6)(b) of the rule violated 120.52(8) and 455.517, F.S. Florida Academy of Cosmetic Surgery, Inc. vs. Department of Health, Board of Medicine, 22 FALR 4608 (2000).

Subparagraph 64B8-9.009(6)(b)1.a., F.A.C., is invalid to the extent that it requires a licensed anesthesiologist other than the surgeon to provide direct supervision of the administration and maintenance of anesthesia in level III surgery. By its administrative rule, the Board has exceeded its rulemaking authority because it has adopted a practice standard that precludes the provision of anesthesia in all level III outpatient surgeries by a certified registered nurse anesthetist (CRNA). While the Board has studies to support its rule, the same rule was challenged on other grounds in Florida Academy of Cosmetic Surgery v. Department of Health, Board of Medicine (DOAH 2000) where the ALJ found that there was no evidence to indicate any significant difference in patient outcomes whether anesthesia was administered by a CRNA or an anesthesiologist. The judge’s ruling was reversed in Florida Board of Medicine v. Florida Academy of Cosmetic Surgery Inc., 808 So.2d 243 (Fla. 1st DCA 2002), only because the judge used the wrong standard of review of the evidence. Ortiz v. Department of Health, Board of Medicine Court of Appeal of Florida, Fourth District, 26 FALR 3205 (2004).

The Department failed to establish that a doctor exceeded the eight-hour limit on office surgery. Rule 64B8-9.009(2), F.A.C., did not establish how the time for performing surgery was calculated. Department of Health, Board of Medicine v. Kurt Steven Dangl, M.D., 2005 Fla. Div. Adm. Hear. LEXIS 1115.
64B8-9.0091 Requirement for Physician Office Registration; Inspection or Accreditation.

(1) Registration.

(a) Every licensed physician who holds an active Florida license and performs Level II surgical procedures in Florida with a maximum planned duration of more than five (5) minutes or any Level III office surgery, as fully defined in Rule 64B8-9.009, F.A.C., shall register the office with the Department of Health. It is the physician's responsibility to ensure that every office in which he or she performs Levels II or III surgical procedures as described above is registered, regardless of whether other physicians are practicing in the same office or whether the office is non-physician owned.

(b) In order to register an office for surgical procedures, the physician must comply with the Department's Rule 64B-4.003, F.A.C., and provide documentation to support compliance with Rule 64B8-9.009, F.A.C.

(c) The physician must immediately notify the Department, in writing, of any changes to the registration information.

(d) The registration shall be posted in the office.

(2) Inspection.

(a) Unless the physician has previously provided written notification of current accreditation by a nationally recognized accrediting agency or an accrediting organization approved by the Board the physician shall submit to an annual inspection by the Department. Nationally recognized accrediting agencies are the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). All nationally recognized and Board-approved accrediting organizations shall be held to the same Board-determined surgery and anesthesia standards for accrediting Florida office surgery sites.

(b) The office surgery inspection fee set forth in the Department's Rule 64B-4.002, F.A.C., shall be remitted for each practice location.

(c) The inspection conducted pursuant to this rule shall be announced at least one week in advance of the arrival of the inspector(s).

(d) The Department shall determine compliance with the requirements of Rule 64B8-9.009, F.A.C.

(e) If the office is determined to be in noncompliance, the physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action. Upon written notification from the physician that all deficiencies
have been corrected, the Department is authorized to re-inspect for compliance. If the physician fails to submit a corrective action plan within 30 days of the inspection, the Department is authorized to re-inspect the office to ensure that the deficiencies have been corrected.

(f) The deficiency notice and any subsequent documentation shall be reviewed for consideration of disciplinary action under any of the following circumstances:

1. When the initial notice of deficiencies contain deficiencies that constitute immediate and imminent danger to the public;

2. The physician fails to provide the Department with documentation of correction of all deficiencies within thirty days from the date of inspection;

3. Upon a finding of noncompliance after a reinspection has been conducted pursuant to paragraph (2)(e) of this rule.

(g) Documentation of corrective action shall be considered in mitigation of any offense.

(h) Nothing herein shall limit the authority of the Department to investigate a complaint without prior notice.

(3) Accreditation.

(a) The physician shall submit written notification of the current accreditation survey of his or her office(s) from a nationally recognized accrediting agency or an accrediting organization approved by the Board in lieu of undergoing an inspection by the Department.

(b) A physician shall submit, within thirty (30) days of accreditation, a copy of the current accreditation survey of his or her office(s) and shall immediately notify the Board of Medicine of any accreditation changes that occur. For purposes of initial registration, a physician shall submit a copy of the most recent accreditation survey of his or her office(s) in lieu of undergoing an inspection by the Department.

(c) If a provisional or conditional accreditation is received, the physician shall notify the Board of Medicine in writing and shall include a plan of correction.

**AUTHORITY:** Specific Authority 458.309(1), (3) FS.
Law Implemented [456.069](#), [456.072(1)(cc)](#), [458.309(3)](#) FS.

**HISTORY**
New 5-15-00, Amended 9-18-01, 8-5-03, 9-1-03, 2-9-05, 8-22-06.
64B8-9.0092 Approval of Physician Office Accrediting Organizations.

(1) Definitions.

(a) "Accredited" means full accreditation granted by a Board approved accrediting agency or organization. "Accredited" shall also mean provisional accreditation provided that the office is in substantial compliance with the accrediting agency or organization's standards; any deficiencies cited by the accrediting agency or organization do not affect the quality of patient care, and the deficiencies will be corrected within thirty days of the date on which the office was granted provisional accreditation.

(b) "Approved accrediting agency or organization" means nationally recognized accrediting agencies: American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Approved organizations also include those approved by the Board after submission of an application for approval pursuant to this rule.

(c) "Department" means the Department of Health.

(2) Application. An application for approval as an accrediting organization shall be filed with the Board office at 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-3253, and shall include the following information and documents:

(a) Name and address of applicant;

(b) Date applicant began to operate as an accrediting organization;

(c) Copy of applicant's current accreditation standards;

(d) Description of accreditation process, including composition and qualifications of accreditation surveyors; accreditation activities; criteria for determination of compliance; and deficiency follow-up activities. Accreditation surveyors shall meet the following qualifications:

1. The surveyor must be an ABMS board certified physician with two (2) years experience performing office surgery; or

2. A Florida Health Care Risk Manager licensed through AHCA with two (2) years experience serving as a risk manager in a surgical facility; or

3. An ABMS board certified anesthesiologist with two (2) years experience administering anesthesia in a surgical facility.

4. In addition to the above-outlined qualification, accreditation surveyors may not have any discipline imposed on his or her license within the preceding seven (7) years, may not be in direct competition with the subject of the review or have any direct or indirect contractual relationship with the inspected facility or any of its physicians.

(e) A list of all physician offices located in Florida that are accredited by the
applicant, if any. If there are no accredited Florida physician offices, but there are
accredited offices outside Florida, a list of the accredited offices outside of Florida is
required.

(f) Copies of all adverse incident reports filed with the state by any of the applicants
accredited offices pursuant to Section 458.331, F.S.

(g) Statement of compliance with all requirements as specified in this rule.

(3) Standards. The standards adopted by an accrediting organization for surgical and
anesthetic procedures performed in a physician office shall meet or exceed
provisions of Chapters 456 and 458, F.S., and rules promulgated thereunder.
Standards shall require that all health care practitioners be licensed or certified to
the extent required by law.

(4) Requirements. In order to be approved by the Board, an accrediting organization
must demonstrate compliance with the following requirements:

(a) The accrediting agency must implement, administer and monitor a mandatory
quality assurance program approved by the Board of Medicine that meets the
following minimum standards:

1. General Provisions. Each office surgery facility surgical center shall have an
ongoing quality assurance program that objectively and systematically monitors and
evaluates the quality and appropriateness of patient care, evaluates methods to
improve patient care, identifies and corrects deficiencies within the facility, alerts the
Medical Director to identify and resolve recurring problems, and provides for
opportunities to improve the facility's performance and to enhance and improve the
quality of care provided to the public.

a. Such a system shall be based on the mission and plans of the organization, the
needs and expectations of the patients and staff, up-to-date sources of information,
and the performance of the processes and their outcomes.

b. Each system for quality assurance, which shall include utilization review, must be
defined in writing, approved by the accrediting agencies governing body, enforced,
and shall include:

I. A written delineation of responsibilities for key staff;

II. A policy for all members of the organized medical staff, whereby staff members
do not initially review their own cases for quality assessment and improvement
program purposes;

III. A confidentiality policy that complies with all applicable federal and state
confidentiality laws;

IV. Written, measurable criteria and norms;

V. A description of the methods used for identifying problems;

VI. A description of the methods used for assessing problems, determining priorities
for investigation, and resolving problems;
VII. A description of the methods for monitoring activities to assure that the desired results are achieved and sustained; and

VIII. Documentation of the activities and results of the program.

c. Each quality assurance program shall include a peer review systems that entails the following:

I. Peer review is performed at least every six months and includes reviews of both random cases and unanticipated adverse office incidents as defined in Section 458.351, F.S., and as set forth in sub-subparagraph (4)(a)1.d. of this rule;

II. If the peer review sources external to the facility are employed to evaluate delivery of medical care, the patient consent form is so written as to waive confidentiality of the medical records or in the alternative medical records reviewed by such external peer review sources must use confidential patient identifiers rather than patient names; and

III. Peer review must be conducted by a recognized peer review organization or a licensed medical doctor or osteopathic physician other than the operating surgeon.

d. Each quality assurance program shall include a system where all adverse incidents as defined in Section 458.351, F.S., are reviewed. In addition to those incidents set forth in Section 458.351, F.S., the following incidents shall also be reviewed:

I. Unplanned hospital admissions that occurred within seven (7) days from the date the patient left the facility;

II. Unscheduled return to the operating room for complication of a previous procedure;

III. Untoward result of procedure such as infection, bleeding, wound dehiscence or inadvertent injury to other body structure;

IV. Cardiac or respiratory problems during stay at facility or within 48 hours of discharge;

V. Allergic reaction of medication;

VI. Incorrect needle or sponge count;

VII. Patient or family complaint;

VIII. Equipment malfunction leading to injury or potential injury to patient.

e. Each quality assurance program shall include an adverse incident chart review program which shall following information, in addition to the operative procedure performed:

I. Identification of the problem;

II. Immediate treatment or disposition of the case;
III. Outcome;

IV. Analysis of reason for problem; and

V. Assessment of efficacy of treatment.

2. Each office surgery facility shall have in place a systematic process to collect data on process outcomes, priority issues chosen for improvement, and the satisfaction of the patient. Processes measured shall include:

   a. Appropriate surgical procedures;

   b. Preparation of patient for the procedure;

   c. Performance of the procedure and monitoring of the patient;

   d. Provision of post-operative care;

   e. Use of medications including administration and monitoring of effects;

   f. Risk management activities;

   g. Quality assurance activities including at least clinical laboratory services and radiology services;

   h. Results of autopsies if needed.

3. Each center shall have a process to assess data collected to determine:

   a. The level and performance of existing activities and procedures;

   b. Priorities for improvement, and

   c. Actions to improve performance.

4. Each center shall have a process to incorporate quality assurance and improvement activities in existing office surgery facility processes and procedures.

   (b) The accrediting agency must implement, administer and monitor anesthesia-related accreditation standards and quality assurance processes that meet the following minimum standards and are reviewed and approved by the Board of Medicine:

   1. Each accredited facility must have an anesthesia provider who participates in an ongoing continuous quality improvement and risk management activities related to the administration of anesthesia in that facility.

   2. Each facility must have a written quality improvement plan that specifies the individuals who are responsible for performing each element of the plan.

   3. The written plan should be in place to continually assess, document and improve the outcome of the anesthesia care provided.
4. The plan must include a review of quality indicators, to include measures of patient satisfaction.

5. The plan must include an annual review and check of anesthesia equipment to ensure compliance with current safety standards and the standards for the release of waste anesthetic gases.

6. The quality assurance plan should include routine review of anesthesia and surgical morbidity and adverse, sentinel or outcome events which include but are not limited to the following:

   a. Follow-up on post-op day 1 and day 14;
   
   b. Cancellation rates and reasons:
   
   c. Central nervous system or peripheral nervous system new deficit;
   
   d. Need for reversal agents: narcotic, benzodiazepine;
   
   e. Reintubation;
   
   d. Unplanned transfusion;
   
   e. Aspiration pneumonitis;
   
   f. Pulmonary embolus;
   
   g. Local anesthetic toxicity;
   
   h. Anaphylaxis;
   
   i. Possible Malignant Hyperthermia;
   
   j. Infection;
   
   k. Return to operating room;
   
   l. Unplanned Post-procedural Treatment in physician's office or emergency department within 30 days after discharge;
   
   m. Unplanned Admission to hospital or acute care facility within 30 days;
   
   n. Cardiopulmonary Arrest or Death within 30 days;
   
   o. Continuous Quality Indicators;
   
   p. Cardiovascular complications in recovery requiring treatment (including: arrhythmias; hypotension, hypertension);
   
   q. Respiratory complications in recovery requiring treatment (including asthma);
   
   r. Nausea not controlled within 2 hrs. in recovery;
s. Pain not controlled within 2 hrs. in recovery;

t. Postoperative vomiting rate;

u. Prolonged PACU stay in excess of 2 hrs.;

v. Medication error;

w. Injuries, e.g. eye, teeth;

x. Time to return to light activities of daily living (ADL);

y. Common postoperative sequelae, eg sore throat, muscle pain, headache;

z. Post-dural puncture headache or transient radicular irritation;

aa. Discharge without escort or against medical advice (AMA);

bb. Patient satisfaction;

c. Equipment maintenance.

7. Each facility quality improvement plan must require annual reviews conducted by, at a minimum, the medical director, a representative of the anesthesia provider currently providing patient care and a representative of the operating room or recovery nursing staff.

8. The accrediting organization must have at least one anesthesiologist in that organization that implements, administers, and monitors the quality assurance processes set forth above.

(c) Accreditation periods shall not exceed three years.

(d) The accrediting organization shall obtain authorization from the accredited entity to release accreditation reports and corrective action plans to the Board. The accrediting organization shall provide a copy of any accreditation report to the Board office within 30 days of completion of accrediting activities. The accrediting organization shall provide a copy of any corrective action plans to the Board office within 30 days of receipt from the physician office.

(e) If the accrediting agency or organization finds indications at any time during accreditation activities that conditions in the physician office pose a potential threat to patients, the accrediting agency or organization will immediately report the situation to the Department.

(f) An accrediting agency or organization shall send to the Board any change in its accreditation standards within 30 calendar days after making the change.

(g) An accrediting agency or organization shall comply with confidentiality requirements regarding protection of patient records.

(5) Accrediting Organizations shall be approved for a period time not to exceed three
(3) years.

(6) If the Board discovers that an approved accrediting agency has violated or failed to comply with any provision of this rule, the Board shall issue an order to show cause outlining the alleged violation and requiring a representative from the accrediting agency to appear before the Board at its next regularly scheduled meeting to address the Board's concerns. After such an appearance, if the Board determines that a violation occurred, the accrediting agency's status as an office surgery accrediting agency shall be revoked. Failure to appear before the Board upon receipt of an order to show cause shall not preclude the Board from taking action against an accrediting agency.

(7) Renewal of Approval of Accrediting Organizations. Every accrediting organization approved by the Board pursuant to this rule is required to submit to the Board a new complete written application at least three months prior to the end of its term of approval. Upon review of the submission by the Board, written notice shall be provided to the accrediting organization indicating the Board's acceptance of the certification and the next date by which a renewal submission must be filed or of the Board's decision that any identified changes are not acceptable and on that basis denial of renewal of approval as an accrediting organization.

(8) Upon denial of its application, the accrediting organization must wait a minimum of six (6) months prior to reapplying.

(9) Any person interested in obtaining a complete list of approved accrediting organizations may contact the Board of Medicine or Department of Health.

AUTHORITY: Specific Authority 458.309(3) FS.
Law Implemented 458.309(3) FS.

HISTORY
New 3-9-00, Amended 3-25-02, 12-28-04, 1-30-07.

ANNOTATIONS

Compliance

The Board of Medicine properly denied a petitioner's application for approval as an office surgery accrediting organization under Section 459.309(3), F.S. and Rule 64B8-9.0092, F.A.C., when the petitioner failed to comply with various filing requirements. Florida Academy of Cosmetic Surgery, Inc., v. Department of Health, Board of Medicine, 27 FALR 4687 (2005).

Validity

Paragraph 64B8-9.0092(4)(a), F.A.C., was found to be an invalid exercise of delegated legislative authority due to the fact that the rule was open-ended and did not provide sufficient information for applicants to know whether their "internal" quality assurance programs and processes were adequate. Florida Academy of Cosmetic Surgery, Inc. v. Department of Health, Board of Medicine, 28 FALR 82 (2006).
A petitioner failed to demonstrate that paragraph 64B8-9.0092(2)(f), F.A.C., was arbitrary and capricious because it required applicants to file incident reports in violation of Section 120.52(8)(e), F.S. Such a requirement was important to ensure that incident reports were properly recorded, to make the parties aware of the need to take action or to prevent reoccurrences, and to assist in the evaluation of applicants. Florida Academy of Cosmetic Surgery, Inc. v. Department of Health, Board of Medicine, 28 FALR 82 (2006).

Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c), F.A.C., were invalid exercises of delegated legislative authority. The challenged rules were open-ended and did not provide sufficient information for applicants to know whether their "internal" quality assurance programs and processes were adequate. Accordingly, the rules were vague and enabled the Board to exercise unbridled discretion in violation of Section 120.52(8)(d), F.S. Florida Academy of Cosmetic Surgery, Inc. v. Department of Health, Board of Medicine, 2005 Fla. Div. Adm. Hear. LEXIS 1162.
28-104.001 Purpose; Construction.

This chapter implements Section 120.542, F.S., by establishing the procedures for granting or denying petitions for variances and waivers of agency rules, and, should be read in conjunction with the provisions of Sections 120.52(18), 120.52(19), and 120.542, F.S.

AUTHORITY: Specific Authority 120.54(5)(b)8., 120.542(3) FS.
Law Implemented 120.542(3) FS.

HISTORY
New 4-1-97, Amended 1-15-07.

28-104.002 Petition for Variance or Waiver.

(1) A petition for a variance from or waiver of an agency rule shall be filed with the clerk of the agency that adopted the rule, with a copy to the Joint Administrative Procedures Committee, Room 120, The Holland Building, Tallahassee, Florida 32399-1300.

(2) The petition must include the following information:

(a) The caption shall read:

Petition for (Variance from) or (Waiver of) Rule (Citation)

(b) The name, address, telephone number, and any facsimile number of the petitioner;

(c) The name, address, telephone number, and any facsimile number of the attorney or qualified representative of the petitioner (if any);

(d) The applicable rule or portion of the rule;

(e) The citation to the statute the rule is implementing;

(f) The type of action requested;

(g) The specific facts that demonstrate a substantial hardship or a violation of principles of fairness that would justify a waiver or variance for the petitioner;

(h) The reason why the variance or the waiver requested would serve the purposes of the underlying statute; and

(i) A statement whether the variance or waiver is permanent or temporary. If the variance or waiver is temporary, the petition shall include the dates indicating the duration of the requested variance or waiver.
(3) The petition for a variance or waiver may be withdrawn by the applicant at any time before final agency action.

(4) Upon receipt of a petition for variance or waiver, the agency shall furnish a copy of the petition to any other agency responsible for implementing the rule.

**AUTHORITY:** Specific Authority 120.54(5)(b)8., 120.542(3) FS.
Law Implemented 120.542(5) FS.

**HISTORY**
New 4-1-97, Amended 3-18-98.

28-104.003 Comments on Petition.

(1) Any interested person or other agency may submit written comments on the petition for a variance or waiver within 14 days after the notice required by Section 120.542(6), F.S. The agency shall state in any order whether comments were received by the agency.

(2) The agency shall maintain the comments as part of the record.

(3) The right to comment pursuant to this section does not alone confer party status in any proceeding arising from a petition for variance or waiver.

**AUTHORITY:** Specific Authority 120.54(5)(b)8., 120.542(3) FS.
Law Implemented 120.542(6) FS.

**HISTORY**
New 4-1-97.
§ 120.542. Variances and waivers

(1) Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2) Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule.

(3) The Governor and Cabinet, sitting as the Administration Commission, shall adopt uniform rules of procedure pursuant to the requirements of s. 120.54(5) establishing procedures for granting or denying petitions for variances and waivers. The uniform rules shall include procedures for the granting, denying, or revoking of emergency and temporary variances and waivers. Such provisions may provide for expedited timeframes, waiver of or limited public notice, and limitations on comments on the petition in the case of such temporary or emergency variances and waivers.

(4) Agencies shall advise persons of the remedies available through this section and shall provide copies of this section, the uniform rules on variances and waivers, and, if requested, the underlying statute, to persons who inquire about the possibility of relief from rule requirements.

(5) A person who is subject to regulation by an agency rule may file a petition with
that agency, with a copy to the committee, requesting a variance or waiver from the agency’s rule. In addition to any requirements mandated by the uniform rules, each petition shall specify:

(a) The rule from which a variance or waiver is requested.

(b) The type of action requested.

(c) The specific facts that would justify a waiver or variance for the petitioner.

(d) The reason why the variance or the waiver requested would serve the purposes of the underlying statute.

(6) Within 15 days after receipt of a petition for variance or waiver, an agency shall provide notice of the petition to the Department of State, which shall publish notice of the petition in the first available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which variance or waiver is sought, and an explanation of how a copy of the petition can be obtained. The uniform rules shall provide a means for interested persons to provide comments on the petition.

(7) Except for requests for emergency variances or waivers, within 30 days after receipt of a petition for a variance or waiver, an agency shall review the petition and request submittal of all additional information that the agency is permitted by this section to require. Within 30 days after receipt of such additional information, the agency shall review it and may request only that information needed to clarify the additional information or to answer new questions raised by or directly related to the additional information. If the petitioner asserts that any request for additional information is not authorized by law or by rule of the affected agency, the agency shall proceed, at the petitioner's written request, to process the petition.

(8) An agency shall grant or deny a petition for variance or waiver within 90 days after receipt of the original petition, the last item of timely requested additional material, or the petitioner's written request to finish processing the petition. A petition not granted or denied within 90 days after receipt of a completed petition is deemed approved. A copy of the order granting or denying the petition shall be filed with the committee and shall contain a statement of the relevant facts and reasons supporting the agency’s action. The agency shall provide notice of the disposition of the petition to the Department of State, which shall publish the notice in the next available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which the waiver or variance is sought, a reference to the place and date of publication of the notice of the petition, the date of the order denying or approving the variance or waiver, the general basis for the agency decision, and an explanation of how a copy of the order can be obtained. The agency's decision to grant or deny the petition shall be supported by competent substantial evidence and is subject to ss. 120.569 and 120.57. Any proceeding pursuant to ss. 120.569 and 120.57 in regard to a variance or waiver shall be limited to the agency action on the request for the variance or waiver, except that a proceeding in regard to a variance or waiver may be consolidated with any other proceeding authorized by this chapter.

(9) Each agency shall maintain a record of the type and disposition of each petition, including temporary or emergency variances and waivers, filed pursuant to this
section. On October 1 of each year, each agency shall file a report with the Governor, the President of the Senate, and the Speaker of the House of Representatives listing the number of petitions filed requesting variances to each agency rule, the number of petitions filed requesting waivers to each agency rule, and the disposition of all petitions. Temporary or emergency variances and waivers, and the reasons for granting or denying temporary or emergency variances and waivers, shall be identified separately from other waivers and variances.