

## **CHAPTER 64B8-9 STANDARDS OF PRACTICE FOR MEDICAL DOCTORS**

### **64B8-9.001 Physician Office Incident Reporting.**

#### **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.

*Specific Authority 458.309(1), 458.351(6) FS. Law Implemented 458.351 FS. History—New 3-9-00.*