ARTICLE 17. OUTPATIENT SURGICAL CENTERS

R9-10-1701. Definitions

In this Article, unless the context otherwise requires: [These terms are no longer used or will be defined in R9-10-101, which contains definitions used in more than one Article in the Chapter.]

- 1. "Advance directives" means a living will, prehospital medical care directive, or health care power of attorney.
- 2. "Circulating nurse" means a licensed nurse who is responsible for the functioning of the operating room during a surgical procedure and who does not directly assist the surgeon.
- 3.1. "Inpatient care" means postsurgical services provided in a hospital as defined in Article 2.
- 4. "Licensed nurse" means an individual licensed pursuant to A.R.S. Title 32, Chapter 15.
- 5. "Medical staff" means physicians, podiatrists, dentists, and other practitioners licensed pursuant to A.R.S. Title 32 and who are privileged by agreement with the facility, as defined in the facility's medical staff bylaws, to attend patients.
- 6.2. "Outpatient surgical services" means those anesthesia and surgical services provided to a patient in an outpatient surgical center which that do not require planned inpatient care following a surgical procedure.
- 7. "Patient's representative" means either a person acting on behalf of a patient with the written consent of the patient or the patient's legal guardian, or a surrogate pursuant to A.R.S. § 36-3201(13).
- 3. "Personnel" means employees or contractors of an outpatient surgical center who provide direct patient care in the outpatient surgical center.
- 8.4. "Surgical suite" means an area of an outpatient surgical center which that includes one or more operating rooms and one or more recovery rooms.

R9-10-1702. Administration

- **A.** The governing authority shall consist of one or more persons responsible for the organization and administration of the outpatient surgical center. The A governing authority shall:
 - 1. Consist of one or more persons responsible for the organization and administration of the outpatient surgical center;
 - 4.2. Adopt policies and procedures for the operation of the <u>outpatient</u> surgical center to ensure compliance with state laws, rules, and local ordinances;
 - 2.3. Adopt the Approve medical staff bylaws;

3.4. Grant, or deny, suspend, or revoke clinical privileges of physicians and other members of the medical staff and delineate, in writing, the clinical privileges of each medical staff member, according to the medical staff bylaws; and

- 5. Appoint an administrator who has the authority and responsibility for managing the outpatient surgical center;
- <u>6.</u> Establish the scope of services provided by the outpatient surgical center; and
- 4.7. Adopt a quality management plan that complies with R9-10-1708.
- B. The governing authority shall appoint an administrator who shall have authority and responsibility to manage the facility. The An administrator shall:
 - 1. Be responsible to the governing authority <u>for all services provided at the outpatient</u> <u>surgical center;</u>
 - 2. Act as a liaison between the governing authority, medical and facility staff, and employees of the outpatient surgical center;
 - 3. Develop Establish, document, and implement written administrative policies and procedures governing that:
 - a. Personnel employment Include employee job descriptions, duties, and qualifications;
 - b. <u>Cover employee</u>, orientation, <u>and</u> in-service <u>education for employees and volunteers</u>;
 - <u>c.</u> <u>Cover staffing</u>, and recordkeeping;
 - b.d. <u>Cover Patient patient</u> admissions, rights and responsibilities, grievances, medical treatment, discharge instructions, discharge, and recordkeeping;
 - e. Advance directives;
 - e. Cover the provision of medical services, nursing services, and health-related services in the outpatient surgical center's scope of services;
 - <u>f.</u> Cover when informed consent is required and by whom informed consent may be given;
 - g. Cover the receipt of and process for resolving complaints;
 - h. Cover health care directives;
 - <u>i.</u> Cover food services, if applicable;
 - d.j. Medications Cover medication procurement and dispensing;
 - e.k. <u>Cover contract</u> Contract services;
 - f. Infection control, housekeeping, and maintenance;
 - 1. Cover environmental services, including equipment inspection and maintenance;

- <u>m.</u> Cover infection control;
- g.n. Cover quality Quality management, and recordkeeping including incident documentation;
- h.o. Cover emergency Emergency treatment provided at the outpatient surgical center; and
- <u>p.</u> <u>Include a disaster plan; and</u>
- i. Equipment inspection.
- 4. Ensure that all the policies and procedures are available to:
 - <u>a.</u> <u>all All</u> employees <u>and contractors</u> in the facility <u>of the outpatient surgical center</u>, and
 - <u>b.</u> <u>The Department within two hours after the Department's request;</u>
- 5. Develop and implement a quality management plan;
- 6. Employ personnel to provide outpatient surgical services;
- 7.5. Ensure that a pharmacy maintained by the facility the outpatient surgical center is licensed according registered pursuant to A.R.S. Title 32, Chapter 18 or as otherwise provided by law;
- 8.6. Ensure that pathology services are provided by a laboratory licensed, or exempt from licensure, pursuant to A.R.S. Title 36, Chapter 4.1 that holds a certificate of accreditation or certificate of compliance issued by the U.S. Department of Health and Human Services under the 1988 amendments to the Clinical Laboratories Act of 1967;
- 9.7. Designate, in writing, an individual to be on duty, in charge, and have with access to all areas related to patient care and operation of the physical plant when the administrator is not present; and
- 10.8. If the outpatient surgical center meets the definition of "abortion clinic" in A.R.S. § 36-449.01, ensure that abortions and related services are provided in compliance with the requirements in Article 15.

R9-10-1703. Patient Rights

- A. The administrator shall give each patient or patient's representative a written list of patient rights prior to services being provided. The patient or patient's representative shall acknowledge, in writing, receipt of the list of patient rights.
- **B.** The administrator shall post a list of patient rights in a conspicuous area.

C. Personnel shall apprise each patient or patient's representative of the following rights and shall make a reasonable effort to ensure that language barriers or physical handicaps do not prevent each patient or patient's representative from becoming aware of these rights:

- 1. To be treated with consideration, respect, and full recognition of the patient's dignity and individuality, including privacy in treatment and personal care needs;
- 2. To be free from chemical, physical, and psychological abuse or neglect;
- 3. To refuse or withdraw consent for treatment or give conditional consent for treatment;
- 4. To have medical and financial records kept in confidence and the release of such records shall be by written consent of the patient or the patient's representative except as otherwise required or permitted by law;
- 5. To be informed of the following:
 - a. Proposed surgical procedures and the risks involved;
 - b. Policy on advance directives;
 - e. Costs of services prior to obtaining services or prior to a change in rates, charges, or services;
 - d. Notice of third party coverage, including Medicare and Arizona Health Care
 Cost Containment System coverage; and
 - e. The patient grievance process.

An administrator shall ensure that:

- 1. Each patient or patient's representative is given a written list of patient rights before services are provided;
- 2. A list of patient's rights is posted in a conspicuous area of the outpatient surgical center; and
- <u>3.</u> <u>Each patient:</u>
 - <u>a.</u> <u>Has privacy in treatment and personal care needs;</u>
 - b. <u>Is free from chemical, physical, and psychological abuse or neglect;</u>
 - <u>c.</u> <u>Either consents to or refuses treatment;</u>
 - <u>d.</u> May refuse or withdraw consent for treatment before treatment is initiated;
 - d. Has access to the patient's medical record; and
 - e. Is informed of the following:
 - <u>i.</u> <u>Proposed surgical procedures and the risks involved;</u>
 - <u>ii.</u> The outpatient surgical center's policy on health care directives;
 - <u>iii.</u> The costs of services before services are provided and before a change in rates, charges, or services;

<u>iv.</u> Notice of third-party coverage, including Medicare and Arizona Health
 <u>Care Cost Containment System coverage; and</u>

<u>v.</u> The patient complaint process.

R9-10-1704. Personnel

- **A.** The An administrator shall ensure that personnel are employed:
 - 1. <u>Personnel are available</u> to meet the needs of patients and that job descriptions which define qualifications, duties, and responsibilities are established for all personnel.;
 - B-2. Personnel, prior to before being employed and annually thereafter, shall submit one of the following as every 12 months after the date of employment, provide evidence of freedom from pulmonary infectious tuberculosis as required in R9-10-1???; and: [Updated requirements that will be applicable to all health care institutions in which TB testing is required will be in Article 1.]
 - 3. Within the first week of employment, an employee receives orientation that:
 - <u>a.</u> <u>Is specific to the duties to be performed by the employee, and</u>
 - <u>b.</u> <u>Includes training on personnel policies and patient rights.</u>
 - 1. A report of a negative Mantoux skin test taken within six months of submitting the report,
 - 2. A written statement from a physician stating that, upon an evaluation of a positive

 Mantoux skin test taken within six months of submitting the physician's statement or a

 history of a positive Mantoux skin test, the individual was found to be free from

 tuberculosis.
- C. The administrator shall provide orientation to each employee within the first week of employment. Orientation shall be specific to the position held by the employee.
- **D.B.** Employees who provide direct patient care An administrator shall ensure that personnel:
 - 1. Be Are 18 years of age or older;
 - 2. Be Are certified in cardiopulmonary resuscitation within the first month of employment, and maintain current certification thereafter; and
 - 3. Attend six hours of in-service education per year which that is exclusive of orientation, and cardiopulmonary resuscitation and relates to the purposes and function of an outpatient surgical center.
- **E.C.** The An administrator shall ensure that personnel records are maintained which include:
 - 1. Include:
 - <u>a.</u> Application An employee's application for employment;

- 2.b. Verification of training, <u>registration</u>, certification, or licensure, <u>if applicable</u>;
- 3.c. Initial proof Evidence of freedom from infectious tuberculosis and annual verification statement thereafter as required in subsection (A)(2); and
- 4.d. Orientation and in-service training education records.;
- 2. Are maintained by the outpatient surgical center for at least two years after the last date the employee worked in the outpatient surgical center; and
- 3. Are provided to the Department within two hours after the Department's request.

R9-10-1705. Medical Staff

- **A.** The medical staff shall approve bylaws for the conduct of medical staff activities.
- **B.** The medical staff physicians shall conduct medical peer review <u>pursuant according</u> to A.R.S. Title 36, Chapter 4, Article 5 and shall submit recommendations to the governing authority for approval.
- C. The medical staff shall establish written policies and procedures which that define the extent of emergency treatment to be performed in the facility, including cardiopulmonary resuscitation procedures and provisions for the emergency transfer of a patient.

R9-10-1706. Nursing Services

- A. The An administrator shall employ appoint a registered nurse as the director of nursing who shall to be responsible for the management and supervision of nursing services in the outpatient surgical center., including:
- **B.** A director of nursing shall:
 - 1. Developing and implementing written nursing and patient care policies and procedures

 Ensure that policies and procedures are established, documented, and implemented for all nursing services provided in the outpatient surgical center, including medications medication administration, storage, and disposal;
 - 2. Ensuring Ensure that the facility outpatient surgical center is staffed with licensed nurses and nursing assistants based on the number of patients and their health care needs;
 - 3. Participating Participate in quality management activities; and
 - 4. Appointing <u>Designate</u> a registered nurse, in writing, to act in the absence of the director of nursing-;
 - **B.**5. A Ensure that a licensed nurse who does not directly assist the surgeon shall function as a circulating nurse during each surgical procedure is responsible for the functioning of an operating room in which a surgical procedure is performed.

C.6. A Ensure that a registered nurse shall be present in the recovery room whenever patients are in the recovery room. A registered nurse shall be in the facility until all patients are discharged. is present in the:

- a. Recovery room whenever patients are in the recovery room, and
- b. Outpatient surgical center until all patients are discharged; and
- **D.**7. A Ensure that a licensed nurse shall ensure documents that the a patient or the patient's representative acknowledges, in writing, the has received a physician's written discharge instructions.

R9-10-1707. Admission

- **A.** A medical staff physician shall <u>only</u> admit patients to the <u>facility</u> <u>outpatient surgical center</u> who: do not require planned inpatient care and who shall be kept in the facility less than 24 hours.
 - 1. Do not require planned inpatient care, and
 - 2. Will be kept in the facility less than 24 hours.
- **B.** Within 30 days prior to admission before a patient is admitted, a medical staff member shall complete a medical history and physical examination of the patient. The individual responsible for performing the operative procedure shall document the preoperative diagnosis and the procedure to be performed.
- <u>C.</u> The individual responsible for performing the surgical procedure shall document the preoperative diagnosis and the surgical procedure to be performed.
- C.D. The administrator shall ensure that the following documents are in the <u>a</u> patient's medical record prior to before surgery:
 - A medical history and results of a current the physical examination required in subsection
 (B),
 - 2. A preoperative diagnosis and the results of any laboratory tests or <u>diagnostic</u> procedures relative to the surgery and the condition of the patient,
 - 3. Evidence of informed consent by the patient or patient's representative for the surgical procedure and care of the patient,
 - 4. Documentation concerning advance health care directives, and
 - 5. Physician orders.

R9-10-1708. Quality Management

A. The administrator shall establish and implement a quality management plan that monitors and evaluates the provision of all aspects of patient care including physician and contracted services.

B. The quality management plan shall be in writing and describe the objectives, organization, scope, and process for improving quality of care which shall include the monitoring activities.

C. The administrator shall maintain a record of quality management activities and ensure that any conclusions and recommendations on findings of quality management activities are reported to the governing authority.

An administrator shall ensure that:

- 1. A plan is established, documented, and implemented for an ongoing quality management program that, at a minimum, includes:
 - <u>a.</u> <u>A method to identify, document, and evaluate incidents;</u>
 - <u>A</u> method to collect data to evaluate the delivery of services related to patient
 care, including physician and contracted services;
 - <u>A</u> method to evaluate the data collected to identify a concern about the delivery
 of services related to patient care;
 - d. A method to make changes or take action as a result of the identification of a concern about the delivery of services related to patient care; and
 - e. The frequency of submitting a documented report required in subsection (2) to the governing authority;
- 2. A documented report is submitted to the governing authority that includes:
 - a. An identification of each concern about the delivery of services related to patient care; and
 - <u>b.</u> Any changes made or actions taken as a result of the identification of a concern about the delivery of services related to patient care;
- 3. The report required in subsection (2) and the supporting documentation for the report are maintained for 12 months after the date the report is submitted to the governing authority; and
- 4. Are provided to the Department within two hours after the Department's request.

R9-10-1709. Surgical Services Requirements

- **A.** The An administrator shall ensure that:
 - <u>1.</u> there is a A current listing of all surgical procedures offered by the facility outpatient surgical center is available at the outpatient surgical center, and
 - <u>2.</u> <u>shall maintain a A</u> chronological register of all surgical procedures performed <u>in the</u> <u>outpatient surgical center is:</u>
 - a. Maintained for at least two years after the date of the last entry, and

- <u>b.</u> <u>Provided to the Department within two hours after the Department's request.</u>
- **B.** The <u>An</u> administrator shall ensure that a roster of medical staff who have surgical or anesthesia privileges at the <u>facility outpatient surgical center</u> is available to the <u>facility medical</u> staff, specifying the privileges and limitations of each <u>person individual</u> on the roster.
- C. The individual responsible for performing the operative procedure shall complete an operative report and any necessary discharge instructions according to medical staff bylaws and facility policies and procedures. The individual responsible for the administration of anesthesia shall complete an anesthesia report and any necessary discharge instructions according to medical staff bylaws and facility policies and procedures. An administrator shall ensure that the individual responsible for:
 - Performing a surgical procedure completes an operative report of the surgical procedure and any necessary discharge instructions according to medical staff bylaws and facility policies and procedures, and
 - 2. Administering anesthesia during a surgical procedure completes an anesthesia report and any necessary discharge instructions according to medical staff bylaws and facility policies and procedures.
- **D.** <u>An administrator shall ensure that a A physician shall remain remains</u> on the premises until all patients are discharged from the recovery room.

R9-10-1710. Medical Records

- A. The An administrator shall ensure that a medical record is established and maintained for each patient which according to A.R.S. § 12-2297 and the outpatient treatment center's policies and procedures.
- **B.** An administrator shall ensure that the medical record for a patient contains includes the following information:
 - 1. Name and address of the patient and patient's representative;
 - 2. Written acknowledgment of the receipt of patient rights,
 - 2. Patient's date of birth;
 - 3. Documentation of advance directives health care directives;
 - 4. Admitting diagnosis;
 - 5. Medical history and physical examination;
 - 6. Laboratory and radiology reports, <u>if applicable</u>;
 - 7. Consent forms;
 - 8. Physician orders and notations progress notes;

9. Surgeon's operative Operative report of the surgical procedure, required in R9-10-1709(C)(1);

- 10. Anesthesia report, required in R9-10-1709(C)(2) $\frac{1}{5}$;
- 11. Nursing care notations progress notes;
- 12. Medications and treatments administered; and
- 13. Written acknowledgment of receipt of discharge instructions by the patient or patient's representative.
- **B.** Medical and facility staff shall sign with surname and date their entries in a patient's medical record.
- C. Staff shall release An administrator shall ensure that information in a medical record information is released only after receiving the patient's or patient representative's written consent, or as otherwise required or permitted by law.
- **D.** The administrator shall ensure that the medical record of a discharged patient is completed within 90 30 days of after the patient's discharge.
- E. Medical An administrator shall ensure that medical records shall be are retained onsite at the facility outpatient surgical center, or are retrievable by facility staff employees of the outpatient surgical center within two hours of after a the Department's request, for a period of one year from after a patient's discharge.
- **F.** The administrator shall ensure that the medical records are maintained for a period of five years, except as provided in A.R.S. § 36 343.
- G. If a facility ceases operation, the governing authority shall ensure the preservation of records and notify the Department, in writing, of the location of the records.

R9-10-1711. Environmental Standards

- A. The An administrator shall ensure that written compliance with the outpatient surgical center's infection control policies and procedures are established and implemented for the surveillance, control, and prevention of infection, which shall include the following:
 - 1. <u>Surveillance</u>, prevention, and control of infection;
 - 2. Sterilization methods;
 - 2.3. Storage, maintenance, and distribution of sterile supplies and equipment; and
 - 3.4. Disposal of waste, including blood, body tissue, and fluid.
- **B.** The <u>An</u> administrator shall ensure that housekeeping and maintenance services are provided to maintain a safe and sanitary environment.

C. The An administrator shall ensure that equipment is operational, inspected, and maintained in accordance with according to manufacturer's recommendations and the facility's outpatient surgical center's policies and procedures, which shall include the following:

- 1. Testing, calibrating, servicing, or repairing of equipment to ensure that the equipment is operating properly and free from fire and electrical hazards;
- 2. Maintaining records documenting service and calibration information;
- 3. Use, maintenance, and storage of oxygen and other flammable gases in accordance with A.A.C. R9-1-412(B) according to A.A.C. R9-1-412; and
- 4. Use and maintenance of electrical equipment in accordance with A.A.C. R9-1-412(E) according to A.A.C. R9-1-412.
- **D.** The <u>An</u> administrator shall ensure that there is the outpatient surgical center has a functional emergency power source.

R9-10-1712. Emergency Standards

- A. Staff shall provide An administrator shall ensure that emergency treatment is provided to a patient admitted to the outpatient surgical center according to the facility's outpatient surgical center's policies and procedures.
- B. The An administrator shall ensure that: the development of a written disaster plan of operation with procedures to be followed in the event of a fire or threat to patient safety and shall ensure that an emergency evacuation route is posted in every room where patients may be present, except restrooms.
 - 1. A disaster plan is developed, documented, and implemented that includes:
 - a. Procedures to be followed in the event of a fire or threat to patient safety:
 - <u>b.</u> <u>Assigned personnel responsibilities; and</u>
 - <u>Instructions for the evacuation, transport, or transfer of patients; maintenance of medical records; and arrangements to provide any other services related to patient care to meet the patients' needs; and</u>
 - 2. An emergency evacuation route is posted in every room where patients may be present, except restrooms.
- **C.** The An administrator shall ensure that:
 - 1. Fire drills are A fire drill is conducted at least once every three months and that all staff employees on duty participate;
 - 2. Records of the drills include the date, time, and critique of the drills A record of the fire drill includes:

- <u>a.</u> The date and time of the drill;
- b. A critique of the drill; and
- <u>c.</u> Recommendations for improvement, if applicable; and
- 3. Records of the drills are maintained for one year <u>Documentation of a fire drill is</u>

 maintained for 12 months after the date of the fire drill and provided upon request to the

 <u>Department within two hours after the Department's request.</u>
- **D.** The facility shall pass annual inspection for fire safety by the fire authority having jurisdiction.

R9-10-1713. Physical Plant Standards

- A. A.C. R9 1 412(B), Life Safety Code, Chapter 13, Existing Health Care Occupancies.
- **B.** Facilities licensed after the adoption of these rules shall conform to the physical plant health and safety codes and standards referenced in A.A.C. R9-1-411 and R9-1-412.
- C. The administrator shall ensure that there shall be two recovery beds for each operating room, for up to four operating rooms, whenever general anesthesia is administered. One additional recovery bed shall be required for each additional operating room.
- **D.** Recovery beds or gurneys shall be located in a space which provides for a minimum of 70 square feet per bed, allowing three feet or more between beds and between the sides of a bed and the wall.
- An administrator shall ensure that the outpatient surgical center conforms to the applicable physical plant health and safety codes and standards, incorporated by reference in A.A.C. R9-1-412, that were in effect on the date listed on the building permit or zoning clearance submitted with the architectural plans and specifications before initial licensing.
- **B.** An administrator shall ensure that:
 - 1. There are two recovery beds for each operating room, for up to four operating rooms, whenever general anesthesia is administered;
 - 2. One additional recovery bed is available for each additional operating room; and
 - 3. Recovery beds or gurneys are located in a space that provides for a minimum of 70 square feet per bed, allowing three feet or more between beds and between the sides of a bed and the wall.
- **E.C.** The <u>An</u> administrator may provide recliner chairs in the recovery room area that allow a patient to recline for patients who have not received general anesthesia.
- **F.D.** The An administrator shall ensure that the following shall be are available in the surgical suite:
 - 1. Oxygen and the means of administration;

2. Mechanical ventilatory assistance equipment including airways, manual breathing bag, and suction apparatus;

- 3. Cardiac monitor;
- 4. Defibrillator; and
- 5. Cardiopulmonary resuscitation drugs as determined by the facility's outpatient surgical center's policies and procedures.

