# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)p (16 **Del.C.** §122(3)p)
16 **DE Admin. Code** 4405

## PROPOSED

### 4405 Free Standing Surgical Centers

### PUBLIC NOTICE

The Office of Health Facilities Licensing and Certification, Health Systems Protection Section, Division of Public Health, Department of Health and Social Services, is proposing revisions to the State of Delaware Regulations Governing Free Standing Surgical Centers. Due to the extensive number of amendments the Division has concluded that the current regulations should be repealed and replaced in their entirety with the proposed regulations being published. The purpose of the amendments is to update the requirements so that they are in concert with current healthcare standards and to align them more closely with current federal requirements. On January 1, 2012, the Division plans to publish as proposed the amended regulations and hold them out for public comment per Delaware law.

Copies of the proposed regulations are available for review in the January 1, 2012 edition of the Delaware *Register of Regulations*, accessible online at: http://regulations.delaware.gov or by calling the Office of Health Facilities Licensing and Certification at (302) 283-7220.

Any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by Monday, January 30, 2012 at:

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### 4405 Free Standing Surgical Centers

~~**1.0 Definitions**~~

~~**"Division"** means the Delaware Division of Public Health.~~

~~**"Free Standing Surgical Center"** (hereafter referred to as FSSC) means a facility which operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization. The term does not include:~~

- ~~a facility that is licensed as part of a hospital, or;~~
- ~~a facility that provides services and/or accommodations for patients who stay overnight, or;~~
- ~~a facility which is used as an office or clinic for the private practice of a physician, podiatrist or dentist except when:~~
  - ~~it holds itself out to the public or other health care providers as an FSSC or similar facility, or;~~
  - ~~it is operated or used by a person or entity different than the physician(s), or;~~
  - ~~patients are charged a fee for use of the facility in addition to the physician's professional services.~~

~~**"Person"** means sole proprietor, partnership, unincorporated association, corporation or any state, county, or local governmental unit.~~

~~**2.0 General Terms, Conditions and Requirements**~~

~~2.1 Chief Executive Officer~~

~~2.1.1 Responsibility: The chief executive officer shall be the official representative of the governing body and the chief executive officer of the surgical center. The chief executive officer shall be delegated responsibility and authority in writing by the governing body for the management of the surgical center and shall provide liaison among the governing body, provider staff and other departments of the surgical center.~~

~~2.1.2 Duties: The chief executive officer shall be responsible for the development of surgical center policies and procedures for employee and provider staff use. All policies and procedures shall be reviewed and/or updated as necessary but at least annually.~~

~~2.2 Governing Body~~

~~2.2.1 Responsibility: The Governing Body shall provide facilities, personnel, and services necessary for the welfare and safety of the patients.~~

~~2.2.2 Duties: The Governing Body shall:~~

~~2.2.2.1 adopt by-laws in accordance with legal requirements;~~

~~2.2.2.2 meet at least annually and maintain accurate records of such meetings;~~

~~2.2.2.3 appoint committees consistent with the needs of the surgical center;~~

~~2.2.2.4 make appointments and delineations of clinical and surgical privileges of practitioners based upon the standard of granting of privileges within the community, including surrounding providers of surgical services;~~

~~2.2.2.5 establish a formal means of liaison with the provider staff;~~

~~2.2.2.6 approve by-laws, rules and regulations of the provider staff or physicians with surgical privileges;~~

~~2.2.2.7 adopt appropriate policies on admissions, surgical procedures, and the timely completion of medical records;~~

~~2.2.2.8 conduct with the active participation of the provider staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of utilization. This information shall provide a basis for the revision of facility policies and the granting or continuation of clinical privileges;~~

~~2.2.2.9 require that the facility's Quality Assurance Program ensure the adequate investigation, control and prevention of infectious diseases. All reportable communicable diseases are to be reported according to established rules and regulations of the Department of Health and Social Services;~~

~~2.2.2.10 develop admission policies and procedures in writing with appropriate guidelines by the provider staff and adopted by the Governing Body.~~

~~2.3 Attending Staff~~

~~2.3.1 Physician - an individual who has received a Doctor of Medicine or Doctor of Osteopathy degree and is currently fully licensed to practice medicine in the State of Delaware.~~

~~2.3.2 Anesthesiologists~~

~~2.3.2.1 Physician anesthetists - an individual who is a physician certified by the American Board of Anesthesiology or who has training and experience in the field of anesthesiology, substantially equivalent to that required for such certification.~~

~~2.3.2.2 Nurse or dentist anesthetists - licensed nurse or dentist who is able to provide general anesthesia. Their performance shall be under the overall direction of director of anesthesia services or his/her qualified anesthetist designee; otherwise, their performance shall be under the overall direction of the surgeon or obstetrician responsible for the patient's care.~~

~~2.3.3 Dentist - an individual who is a graduate of a recognized school of Dentistry licensed to practice in the State of Delaware.~~

~~2.3.4 Podiatrist - an individual who is a graduate of a recognized school of Podiatry licensed to practice in the State of Delaware.~~

~~2.3.5 Registered Nurse means a graduate of an approved school of nursing and who is licensed to practice in the State of Delaware.~~

~~2.3.6 Emergency Personnel - licensed medical staff and licensed registered nurse staff who are qualified by relevant training, experience and current competence in emergency care. When emergency medical technicians or other allied health personnel are used, their duties and responsibilities are to the physician(s) and nurse(s) providing care in the emergency situations.~~

~~2.3.7 Ancillary Staff - auxiliary person(s) in the facility at all times to provide total care for patients. Workers are assigned clearly defined duties for which they are trained.~~

~~2.4 Ownership - The ownership and control of the facility and the property on which the FSSC is located shall be disclosed to the Department of Health and Social Services. Proof of this ownership shall be available in the facility. Any change in ownership shall be reported to Office of Health Facilities Licensing and Certification in writing immediately prior to or after the change.~~

~~2.5 All required records maintained by FSSC shall be open to inspection by the authorized representative of the Department of Health and Social Services.~~

2.6 Hours of services for the FSSC shall be conspicuously posted.

**3.0 Licensing Requirements**

3.1 The term "free standing surgical center" shall not be used as a part of the name of any facility or description of services in the State unless it has been so classified by the Department of Health and Social Services.

3.2 License:

3.2.1 a license shall be effective for a twelve (12) month period and may be issued for that period only if the FSSC is in full compliance with these regulations.

3.2.2 a provisional license may be granted by the Department of Health and Social Services for a period not exceeding three (3) months when the FSSC is in compliance with most but not all of these regulations and has demonstrated the ability and willingness to comply within the three (3) month period. Additional provisional licenses may be granted provided a good faith effort is being made to meet regulatory compliance.

3.2.3 a license is not transferable from person to person nor from one location to another.

3.2.4 the license shall be conspicuously posted.

3.2.5 all applications for renewal of licenses shall be filed with the Division at least thirty (30) days prior to expiration.

**4.0 Medical Records**

4.1 Facilities: The center shall provide sufficient space and equipment for the processing and the safe storage of records.

4.2 Personnel: A person knowledgeable and trained in the management of Medical Records shall be responsible for the proper administration and functioning of the medical records section.

4.3 Security: Medical records shall be protected from loss, damage and unauthorized use.

4.4 Preservation: With the exception of medical records of minors (individuals under the age of 18 years), medical records shall be preserved as original records or on microfilm for no less than five (5) years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility.

4.4.1 Medical records of minors shall be preserved for the period of minority plus five (.5) years (i.e., 23 years) or as stipulated by State law.

4.4.2 Facilities shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

4.4.3 The sole responsibility for the proper destruction of all medical records shall be in the facility and destroyed in accordance with their administrative policy.

4.5 Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:

4.5.1 complete patient identification and a unique identification number;

4.5.2 admission and discharge dates;

4.5.3 chief complaint and admission diagnosis;

4.5.4 medical history and physical examination competed prior to surgery;

4.5.5 diagnostic tests, laboratory and x-ray reports when appropriate;

4.5.6 physician progress notes if appropriate;

4.5.7 properly executed informed consent;

4.5.8 a pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record and a post-anesthesia follow up and any allergic and abnormal drug reactions;

4.5.9 a pre-op diagnosis and nursing and other ancillary care personnel notes are required;

4.5.10 a completed detailed description of operative procedures, findings and post-operative diagnosis recorded and signed by the attending surgeon;

4.5.11 a pathology report of tissue removed during surgery in accordance with facility policies;

4.5.12 all medication and treatment orders in writing and signed by the prescribing physician. Telephone and verbal orders are designated as such, signed and dated by a legally designated person, and countersigned by the prescribing physician within 72 hours;

4.5.13 patient's condition on discharge, final diagnosis, and instructions given patient for follow-up care.

4.6 Other records: The facility shall maintain:

4.6.1 a register of all operations performed (entered daily);

~~4.6.2 statistical information concerning all admissions, discharges, deaths and other information such as blood usage, surgery complications, etc., required for the effective administration of the facility;~~

~~4.6.3 master patient index file.~~

~~4.7 Nursing records: Standard nursing practice and procedure shall be followed in the recording of medications and treatments, including operative and post-operative notes. Nursing notes shall include notation of the instructions given patients pre-operatively and at the time of discharge. All recordings shall be in ink, and properly signed including name and identifying title.~~

~~4.8 Entries: All orders for diagnostic procedures, treatments and medications shall be signed by the physician submitting them and entered in the medical record in ink or in type. Authentication may be by written signature, identifiable initials or computer key. The use of rubber stamp signatures is acceptable under the following strict conditions:~~

~~4.8.1 The physician whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it and may not be used for controlled substances;~~

~~4.8.2 The physician places in the administrative office of the facility a signed statement to the effect that he/she is the only one who has the stamp and is the only one who will use it.~~

**~~5.0 Personnel~~**

~~5.1 Recruitment: The recruitment and employment of personnel shall be made without regard to sex, race, creed, handicap or national origin as long as qualifications are commensurate with anticipated job responsibilities.~~

~~5.2 Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed, i.e., job descriptions, health records, evaluation of employee's work performance.~~

~~5.3 Orientation: The purpose and objectives of the surgical center shall be explained to all personnel as part of an overall orientation program which is documented in the individual employee record.~~

~~5.4 Staffing:~~

~~5.4.1 A staff of persons sufficient in number and adequately trained to meet requirements for care shall be employed.~~

~~5.4.2 In addition to staff engaged in direct care and treatment of patients, there must be sufficient personnel or contractual services to provide basic services such as laundry, housekeeping and plant maintenance.~~

~~5.4.3 Routine inservice training shall be given and documented in the individual employee record.~~

~~5.4.4 Current state licensure and/or registration number and date of expiration for all licensed personnel shall be maintained in the individual employee record.~~

~~5.5 Employment: No employee shall be less than eighteen years of age.~~

**~~6.0 Medical Staff Services~~**

~~6.1 All persons admitted to the FSSC shall be under the care of a licensed physician in the State of Delaware.~~

~~6.2 The FSSC shall arrange for one (1) or more licensed physicians to be on premises during all hours of surgical services.~~

~~6.3 The FSSC shall arrange for one (1) or more licensed physicians to be called in an emergency and shall be immediately available either in person or by electronic devices on a 24 hour basis.~~

~~6.4 A medical director shall be appointed and shall be responsible for the direction, provision and quality of medical care.~~

~~6.5 Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. Each member must be licensed and approved by the Delaware Board of Medical Practice.~~

~~6.6 Medical staff participate in the development and maintenance of a patient care evaluation system (quality assurance) including peer review and audit.~~

~~6.7 Medical staff must develop and implement written medical policies, including medical staff bylaws or their equivalent.~~

~~6.8 Medical practitioner shall be required to have a residence within the defined primary and/or secondary service population of the FSSC.~~

**~~7.0 Nursing Services~~**

7.1 Nursing Administration: The facility shall have an organized nursing department under the supervision of a Director of Nursing (or its equivalent) who is currently licensed by the State of Delaware as a professional registered nurse and who has responsibility and accountability for all nursing services.

7.2 The Director of Nursing (or its equivalent) shall be responsible for:

7.2.1 delivery of appropriate nursing services to patients;

7.2.2 development and maintenance of appropriate nursing service objectives, standards of nursing practice, nursing policy and procedure manuals and written job descriptions for all levels of nursing personnel;

7.2.3 coordination of nursing services with other patient services;

7.2.4 establishment of a means of adequately assessing and planning the nursing needs of patients and staffing to meet those needs;

7.2.5 staff development including education which includes provisions for CPR certification or review.

7.3 Nursing Personnel: There shall be sufficient licensed and auxiliary nursing personnel on duty to meet the total nursing needs of patients:

7.3.1 At least one registered nurse shall be in the facility at all times when a patient is in the facility;

7.3.2. Nursing personnel shall be assigned duties consistent with their education and experience.

7.4 Medications and treatments: Medications and treatments shall be administered in accordance with all applicable laws and acceptable standards of practice.

7.5 Staff Meetings: Meetings of the nursing staff shall be held regularly to discuss, review and evaluate nursing care. Written minutes of these meetings shall be maintained and distributed to staff.

7.6 Inservice Education: All nursing personnel shall receive inservice education at least semi-annually which shall include, but not be limited to, infection control, fire and safety procedures.

7.7 Evaluations: There shall be an adequate plan of continuous evaluation of nursing care. The Director of Nursing shall periodically evaluate the adequacy of the facility to meet the nursing needs of its patients and shall participate in planning for needed improvements or revisions of facilities and services.

7.8 Circulating Nurse: A registered nurse, qualified by education and experience in operating room nursing, shall be present as a circulating nurse in each operating room during operative procedures.

**8.0 Infection Control**

8.1 Prevention and Control Services

8.1.1 The facility shall establish and implement an infection prevention and control program. The chief executive officer shall ensure the development and implementation of the program.

8.1.2 The facility shall establish and implement written policies and procedures regarding infection prevention and control, for patients and employees including, but not limited to the following:

8.1.3 A system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all patients or personnel having these infections, diseases or conditions;

8.1.4 Reportable diseases shall be reported to the Director of the Division of Public Health;

8.1.5 Care of patients with communicable diseases;

8.1.6 Policies and procedures for exclusion from work and authorization to return to work for personnel with communicable diseases;

8.1.7 Surveillance techniques to minimize sources and transmission of infection;

8.1.8 Sterilization, disinfection and cleaning practices and techniques used in the facility including, but not limited to the following:

8.1.8.1 Care of utensils, instruments, solutions, dressings, articles and surfaces;

8.1.8.2 Selection, storage, use and disposition of disposable and non-disposable patient care items;

8.1.8.3 Methods to ensure that sterilized materials are packaged and labeled to maintain sterility and to permit identification of expiration dates;

8.1.8.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic micro-organisms;

8.1.8.5 Techniques to be used during each patient contact, including handwashing before and after caring for a patient;

8.1.8.6 Criteria and procedures for isolation of patients;

8.1.9 Each service in the facility shall develop written infection control policies and procedures for that service.

8.1.10 All personnel shall receive orientation at the time of employment and continuing inservice education regarding the infection prevention and control program.

8.1.11 The chief executive officer shall evaluate written reports of State and local inspections, including results of cultures taken of food, equipment and personnel, and shall take the necessary corrective action.

8.1.12 Facilities providing surgical services in an operating room and recovery area shall establish and implement policies and procedures regarding infection prevention and control, including but not limited to the following:

- Use of aseptic technique and scrub procedures;
- Gowning and operating room attire;
- Traffic control;
- Cleaning of the operating room after each procedure and care of operating room equipment and anesthesia equipment.

8.2 Infectious Disease and Waste Removal

8.2.1 The facility shall establish and implement policies and procedures for the collection, storage, handling and disposition of all pathological and infectious wastes within the facility, and for the collection, storage, handling and disposition of all pathological and infectious wastes to be removed from the facility, including, but not limited to the following:

8.2.2 Needles and syringes shall be destroyed or disposed of in a safe and proper manner.

8.2.3 Needles and syringes and other solid, sharp, or rigid items shall be placed in a puncture resistant container and incinerated or compacted prior to disposal.

8.2.4 Non-rigid items, such as blood tubing and disposable equipment and supplies, shall be incinerated or placed in double, heavy duty, impervious plastic bags and disposed.

8.2.5 Fecal matter and liquid waste, such as blood and blood products, shall be flushed into the sewerage system.

8.2.6 All pathology specimens and waste, including gross and microscopic tissue removed surgically or by any other procedure, shall be incinerated.

8.2.7 Solid waste from the laboratory shall be incinerated or autoclaved prior to disposal.

8.2.8 Liquid waste from the laboratory shall be autoclaved prior to disposal into the sewerage system.

8.2.9 All tissue, including gross and microscopic tissue, removed surgically or by any other procedure shall be incinerated or interred.

8.2.10 Collection, storage, handling and disposition procedures of all pathological and infectious wastes within the facility shall meet the requirements of all state and federal codes.

**9.0 Hospitalization**

The FSSC must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the FSSC. The FSSC must have a written transfer agreement with such a hospital or all physicians performing surgery in the FSSC must have admitting privileges at such a hospital.

**10.0 Administration of Anesthesia**

10.1 The anesthesia services must be under the direction of a Board Certified or Board eligible anesthesiologist if general anesthesia is to be used or anesthesia other than local procedures.

10.2 In cases where other than local anesthesia is employed the anesthetic must be administered by only:

10.2.1 A qualified anesthesiologist or

10.2.2 A physician qualified to administer anesthesia or a certified nurse anesthetist. In those cases where a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician.

**11.0 Pharmaceutical Services**

11.1 Medications must be purchased, stored, administered and dispensed in compliance with applicable State and Federal Statutes and Regulations. Those requirements include, but are not limited to the following:

11.1.1 Standing orders shall be written and administered in compliance with the regulations of the Board of Medical Practice.

11.1.2 Verbal orders must be countersigned by the prescriber within 72 hours of receipt.

11.1.3 A policy and procedure manual must be established and approved by the Governing Board:

11.1.3.1 It shall be reviewed annually.

11.1.3.2 Any additions or deletions should show an effective date.

11.1.3.3 It shall contain automatic stop orders; labeling requirements; discontinued medication policy; drug storage policy; charting policy; medication error policy; drug recall policy; prescriber medication order procedure; outdated medication procedures.

11.1.4 Rubber stamp signatures are not acceptable for controlled substances orders.

11.1.5 Medication must be stored according to the latest USP/NF standards.

11.1.5.1 Room temperatures 59° to 86° F (15° to 30° C); refrigerator 36° to 46°F (2.2° to 7.8° C).

11.1.6 Medications shall be properly secured in locked areas only accessible to authorized persons:

11.1.6.1 Schedule II medications shall be under double lock.

11.1.7 Internal medications shall be stored separately from external medications.

11.1.8 All medications shall be accurately and plainly labeled:

11.1.8.1 Dispensed medications shall be labeled in compliance with 24 **Del.C.** §2563.

11.1.8.2 Prepacks must be labeled in compliance with Board of Pharmacy Regulation B.

11.1.9 All medications on site or dispensed must be in packaging which complies with the latest edition of USP/NF.

11.1.10 Medications not in sealed unit dose packaging shall not be returned to the container for reuse.

11.1.11 Medications discontinued must be properly documented on the patient's chart or other applicable record.

11.1.11.1 Controlled substance documentation should contain two signatures.

11.1.12 Only licensed physicians or nurses may administer medications.

11.1.13 Only a physician or pharmacist may dispense medications.

11.1.13.1 Nurses may assist the physician with dispensing provided the physician directly supervises that person (24 **Del.C.** §2521).

11.1.14 Stock supplies of controlled drugs can only be destroyed via procedures established by ONDD or DEA.

11.1.15 Syringes must be stored and destroyed in compliance with 16 **Del.C.** §4757, State CSA Regulation 5.

11.1.16 An emergency kit with quantities and types of medication determined by the medical staff shall be on the premises:

11.1.16.1 A copy will be filed with the Board of Pharmacy.

11.1.16.2 Written notification of any additions or deletions must be sent to the Division within 10 days after the change becomes effective.

11.1.16.3 A log must be maintained on the premises for a period of 2 years from the last entry. It must show the date of administration or dispensing, the time, the name, strength and quantity of the drug involved, the name of the patient and the initials of the person removing the medication. The same information concerning the receipt of medication must be documented.

11.1.17 The site must be properly registered under the State and Federal Controlled Substances Acts.

**12.0 Surgical Services**

12.1 Location: The operating room (s) and accessory areas shall be located so that in and out traffic is properly controlled.

12.2 Patient Preparation Area: A patient preparation area with adjacent toilet facilities must be provided near the surgical suite. This area must provide for privacy and comfort of the patients and for storage of patient's clothing.

12.3 Surgical Privileges Roster: An up-to-date roster of staff providers specifying the approved surgical privileges of each shall be kept on file and available to nursing staff.

12.4 Doorways and Corridors: The minimum width of doors for patients and equipment shall be 3'0". Doors to accommodate stretchers must be at least 3'8" wide. The minimum width of corridors serving surgery suites and recovery and patient preparation areas from these areas must be at least 8 feet.

12.5 Operating Room(s): Each room shall be large enough to accommodate equipment and personnel for surgical procedures to be performed. If general anesthesia is to be administered during the surgery, the room shall contain a minimum of 350 square feet and; adequate provisions shall be made for an emergency communication system connecting the surgical suite.

12.6 Recovery Room(s): The FSSC must have a separate recovery room.

~~12.7 Waiting Area: Public waiting area with toilet facilities, drinking fountains and telephones shall be provided.~~

~~12.8 Structural Features: All other structural features must be in compliance with construction guidelines as defined in Section 15.0 of these regulations.~~

~~12.9 Ancillary Areas: In addition to operating room(s), the following physically separated areas shall be provided within the suite and shall be separated by doors and/or walls:~~

~~12.9.1 scrub area~~

~~12.9.2 cleanup room~~

~~12.9.3 instrument and supply storage~~

~~12.9.4 janitor's facilities~~

~~12.10 Scrub Area: The scrub area shall be adjacent to the operating room to permit immediate access to the room after scrubbing. Scrub sink(s) with knee or foot controls shall be installed in the scrub area.~~

~~12.11 Clean-Up Facilities: Clean and soiled utility rooms shall be arranged and provided with equipment necessary for proper patient care and for the processing of soiled equipment, including a pressurized steam sterilizer, or equivalent, storage cabinets and work counters with sinks.~~

~~12.12 Staff Dressing Room: Rooms shall be provided for both men and women, each containing a toilet, handsink and provisions for storage of clothing.~~

~~12.13 Oxygen: A supply of oxygen shall be available and stored in accordance with rules and regulations of State Fire Prevention Commission.~~

~~12.14 Equipment: The following minimum equipment must be available in the surgical suite:~~

~~12.14.1 cardiac monitor~~

~~12.14.2 resuscitator~~

~~12.14.3 defibrillator~~

~~12.14.4 aspirator~~

~~12.14.5 thoracotomy set~~

~~12.14.6 tracheotomy set and equipment for airway maintenance~~

~~12.14.7 suction equipment~~

~~12.14.8 emergency call system~~

~~12.14.9 ventilatory assistance equipment including airways, manual breathing bag and ventilator.~~

**~~13.0 Laboratory and Radiologic Services~~**

~~13.1 The FSSC shall have provisions for the required laboratory, x-ray and other diagnostic services.~~

~~13.2 Whether these services are provided on-site or by contract, the provision of the services must meet state codes as set forth by the Department of Health and Social Services and Authority on Radiation Protection.~~

~~13.3 Prior to construction, the floor plans and equipment arrangements of all new installations or modifications of existing installations, utilizing x-rays for diagnostic purposes shall be sent to the Radiation Control Office, P.O. Box 637, Dover, DE 19903, for review and approval [DRCR F.3(b)J]. The required information is denoted in Appendices A and B of the Delaware Radiation Control Regulations (DRCR).~~

~~13.4 Each person having a radiation machine facility shall apply for registration of such facility with the Radiation Control Office (see above) prior to the operation of a radiation machine. Application for registration shall be completed on forms furnished by the Radiation Control Office and shall contain all the information required by the form and accompanying instructions [DRCR B.4 (b)].~~

**~~14.0 Fire Safety~~**

~~14.1 Fire safety in FSSC's shall comply with adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the Fire Regulations is the responsibility of the State Fire Prevention Commission. All applications for license or renewal of license must include with the application, a letter certifying compliance by the Fire Marshal having jurisdiction. Notification of non-compliance with Rules and Regulations of State Fire Prevention Commission shall be grounds for revocation of license.~~

~~14.2 Staff shall be made familiar, by regular fire drills at least quarterly, with emergency and evacuation plans. Written records shall be kept of such drills.~~

~~14.3 Emergency plans shall be posted in a conspicuous place on all floors.~~

~~14.4 Smoking regulations are adopted on control smoking, and include the posting of "No Smoking" signs in any room, ward, or compartment where flammable liquids, combustible gases, or oxygen are used or stored, and in any other hazardous location.~~

14.5 Flammable and Explosive Gases

14.5.1 A separate room shall be provided for the storage of flammable gases in accordance with the requirements of NFPA Life Safety Code 99 Standards (Health Care Facilities Standards) if such gases are used.

14.5.2 Space for reserve storage of nitrous oxide and oxygen cylinders shall be provided and constructed of one hour fire resistive construction and in accordance with NFPA 56 Standards.

14.6 Furnishing and Decorations

14.6.1 No furnishings, decorations or other objects are placed as to obstruct exits or visibility of exits.

14.6.2 No furnishings or decorations of an explosive or highly flammable character are used. Furnishings and decorations are in accordance with NFPA Standards.

14.6.3 All combustible curtains including cubicle curtains are rendered and maintained flame-retardant.

**15.0 Plant, Equipment and Physical Environment**

15.1 Building:

15.1.1 All NEW construction, extensive remodeling or conversions shall comply with the standards set forth under the Outpatient Surgical Facility section of the current or subsequent editions of "Guidelines for Construction and Equipment of Hospital and Medical Facilities", a publication of the U.S. Department of Health and Human Services.

15.1.2 One set of plans is to be submitted to Office of Health Facilities Licensing and Certification for their review and approval prior to construction or remodeling.

15.2 Plumbing:

15.2.1 The plumbing shall meet the requirements of all municipal, state or county codes. Where there are no local codes, provisions of the Department of Health and Social Services regulations governing a detailed plumbing code shall prevail.

15.3 Heating:

15.3.1 The heating equipment for all sections of the FSSC shall be adequate, safe, protected and easily controlled. It shall be capable of maintaining the temperature in each room at a minimum of 72°F (21°C). Portable heating equipment is strictly prohibited in a FSSC.

15.4 Lighting:

15.4.1 Each room must be adequately lighted at all times for maximum safety, comfort, sanitation and efficiency of operation. This includes hallways, stairways, storerooms, bathrooms, dressing rooms, operating rooms and recovery rooms.

15.4.2 All entrance and/or egress doors must be properly lighted at all times during operation hours of the FSSC.

15.5 Exhaust:

15.1.1 At least two (2) exhaust outlets shall be provided in each operating room, not less than four (4) inches above the floor.

15.1.2 All rooms shall be ventilated to help prevent condensation, mold growth and noxious odors.

15.6 Electrical:

15.6.1 All electrical requirements shall be in compliance with all municipal or county codes.

15.7 Mechanical Equipment:

15.7.1 Mechanical equipment shall be kept in working order at all times.

15.8 Housekeeping:

15.8.1 Facility shall establish and implement a written work plan for housekeeping operations, with categorization of cleaning assignments as daily, weekly, monthly or annually within each area of FSSC.

15.9 Pest Control:

15.9.1 The building shall be so constructed and maintained to prevent the entrance or existence of rodents and insects at all times.

15.10 Furnishings:

15.10.1 All furnishings shall be clean and in good repair. All equipment and materials necessary for cleaning, disinfecting and sterilizing shall be provided.

15.11 Thermometers:

15.11.1 Thermometers shall be maintained in refrigerators, freezers and storerooms used for perishables and other items subject to deterioration.

15.12 Emergency Power:

~~15.12.1 An emergency generator shall be provided as an emergency power source for lighting and equipment of operating rooms, recovery rooms and corridors in accordance with NFPA Standards.~~

~~15.13 Laundry and Linens:~~

~~15.13.1 Written provisions shall be made for the proper handling of linens and washable goods.~~

~~15.13.2 Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for FSSC's shall meet all local and state regulations.~~

~~15.13.3 Soiled Processing:~~

~~15.13.3.1 If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.~~

~~15.13.3.2 Soiled Linen Transportation: Soiled linen shall be enclosed in an impervious bag and removed from surgery units after each procedure.~~

~~15.13.3.3 Soiled Linen Carts: Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.~~

~~15.13.3.4 Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.~~

~~15.13.4 Processing: The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.~~

~~15.13.5 Washing Temperatures: The temperatures of water during water process shall be controlled to provide a minimum temperature of 165° (74°C) for at least 25 minutes.~~

~~15.13.6 Clean Processing:~~

~~15.13.6.1 The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.~~

~~15.13.6.1 Clean Linen Storage Room: Adequate provisions shall be made for storage of clean linen.~~

~~15.13.6.2 Procedures: Adequate procedures for the handling of all laundry and for the positive identification and proper packaging and storage of sterile linens must be developed and followed.~~

~~15.14 Incineration:~~

~~15.14.1 Agreement: If there is no pathological incinerator on the premises, the facility must have an agreement with another facility that has an approved pathological incinerator for the proper disposal of pathological waste.~~

~~15.14.2 Incinerator for Pathological Waste: Any pathological waste incinerator must meet the appropriate Clean Air Act of the state.~~

~~15.14.3 Refuse Incinerators: Refuse incinerators are prohibited.~~

**~~16.0 Patient Rights~~**

~~16.1 Facility shall support and protect the fundamental human, civil, constitutional and statutory rights of each patient by establishing written policies regarding the rights of patients. These policies and procedures shall be available to the patients and the general public.~~

~~16.2 Each patient shall have impartial access to treatment, regardless of race, religion, sex, ethnic background, age or handicap.~~

~~16.3 Each patient's personal dignity shall be recognized and respected in the provision of all case and treatment.~~

~~16.4 Each patient shall receive individualized treatment with the provision of adequate and humane services regardless of the source(s) of financial support.~~

~~16.5 Each patient is assured confidential treatment of his or her medical/health record and shall approve or refuse its release to any individual outside the facility, except as required by law or third party payment contract.~~

**~~17.0 Discharge~~**

~~All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.~~

**~~18.0 Severability~~**

~~Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.~~

**1.0 Definitions**

1.1 The following words and terms, when used in these regulations shall have the meanings ascribed to them in this section, except where the context indicates a different meaning:

"**Ambulatory Surgical Center**" means a "**Free Standing Surgical Center**".

"**Clinical Director**" means a registered nurse, currently licensed to practice nursing pursuant to Title 24, Chapter 19 of the **Delaware Code**, who is sufficiently qualified to provide general supervision and direction of the services offered by the free standing surgical center.

"**Department**" means the Delaware Department of Health and Social Services.

"Director" means the individual appointed by the governing body to act on its behalf in the overall management of the facility. The director shall have a Baccalaureate Degree in health or a related field.

"**Free Standing Surgical Center**" means a place, other than a hospital or the office of a physician, dentist or podiatrist, or professional association thereof, which is maintained and operated for the purpose of providing surgical services and in which the expected duration of services would not exceed 23 hours 59 minutes following an admission. Free standing surgical center includes those facilities that hold themselves out to be ambulatory surgical centers for reimbursement purposes.

"**Governing Body**" means the individual, group or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of the free standing surgical center is vested.

"**Incident**" means a circumstance or occurrence that may be injurious to a patient or that may result in an adverse outcome to the patient.

"**Modification of Ownership and Control**" means a change of ownership or transfer of responsibility for the facility's operation.

"**Nurse**" means an individual who is currently licensed to practice nursing pursuant to Title 24, Chapter 19 of the **Delaware Code**.

"**Patient**" means a person who receives a health care service from a provider.

"**Physician**" means a person currently licensed as such by Title 24, Chapter 17 of the **Delaware Code**.

"**Plan of Correction**" means a written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.

"**Surgery**" means a procedure performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be surgery. The term surgery as used in these Regulations does not include the administration by nursing personnel of some injections – subcutaneous, intramuscular, or intravenous – when ordered by a physician. All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

## 2.0 Licensure Requirements and Procedures

2.1 General requirements

2.1.1 No person shall establish, conduct or maintain in this State any free standing surgical center without first obtaining a license from the Department.

2.1.2 A license issued hereunder shall be subject, at any time, to revision or revocation by the State.

2.1.3 A license is not transferable from person to person, entity to entity or from one location to another.

2.1.4 The license shall be posted in a conspicuous place on the licensed premises, at or near the entrance in a manner which is plainly visible and easily read by the public.

2.1.5 Each license shall be issued for a specific number and class of operating rooms along with the specific number of pre-operative and post-anesthesia recovery beds to support them. The number of patients shall not exceed the total number of licensed beds.

2.1.6 Separate licenses are required for facilities maintained in separate locations, even though operated under the same management.

2.1.7 Any facility that undergoes a modification of ownership and control is required to re-apply as a new facility.

2.2 Application process

2.2.1 All persons or entities applying for a license shall submit a written letter of intent to the Department describing the services to be offered by the facility and requesting a licensure application from the Department.

2.2.1.1 The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department.

2.2.1.2 Patients shall not be admitted to a free standing surgical center until a license has been issued.

2.2.1.3 Applicants shall not hold themselves out to the public as being a free standing surgical center until a license has been issued.

2.2.2 In addition to a completed application for licensure, applicants shall submit to the Department the following information:

2.2.2.1 The names, addresses and types of facility previously and currently owned or managed by the applicant;

2.2.2.2 Identity of:

2.2.2.2.1 Each officer and director of the corporation, if the entity is organized as a corporation;

2.2.2.2.2 Each general partner or managing member, if the entity is organized as an unincorporated entity;

2.2.2.2.3 The governing body; and

2.2.2.2.4 Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest of 5% or more in a licensee's operation or related businesses.

2.2.2.3 Proof of not-for-profit status, if claiming tax-exempt status;

2.2.2.4 Disclosure of any officer, director, partner, employee, managing member or member of the governing body with a felony criminal record;

2.2.2.5 Name of the individual (director/administrator/etc.) who is responsible for the management of the free standing surgical center;

2.2.2.6 A list of management personnel, including credentials;

2.2.2.7 A plan for providing orientation, continuing education, and training for personnel or independent contractors during the first year of operation;

2.2.2.8 Policy and procedure manuals; and

2.2.2.9 Any other information required by the Department.

2.3 Issuance of licenses

2.3.1 Probationary license:

2.3.1.1 A probationary license shall be granted for a period of nine (9) calendar months to every facility that completes the application process consistent with these regulations and whose policies and procedures demonstrate compliance with the rules and regulations pertaining to free standing surgical center licensure.

2.3.1.2 A probationary license will permit a facility to hire or contract with personnel and establish a patient caseload.

2.3.1.3 All free standing surgical centers shall have an on-site survey, conducted by the Department, during the first nine (9) calendar months of operation.

2.3.1.4 A free standing surgical center, at the time of an initial on-site survey, must meet the definition of a free standing surgical center as contained within these regulations and must be in operation and caring for patients. Facilities that, at the time of an on-site survey, do not meet the definition of a free standing surgical center or that are not in substantial compliance with these regulations will not be granted a license.

2.3.1.5 A probationary license may not be renewed.

2.3.2 Provisional license:

2.3.2.1 A provisional license shall be granted, for a period of less than one year, to all free standing surgical centers that:

2.3.2.1.1 Are not in substantial compliance with these rules and regulations; or

2.3.2.1.2 Fail to renew a license within the timeframe prescribed by these regulations.

2.3.2.2 The Department shall designate the conditions and the time period under which a provisional license is issued.

2.3.2.3 A provisional license may not be renewed unless a Plan of Correction for coming into substantial compliance with these rules and regulations has been approved by the Department and implemented by the free standing surgical center.

2.3.2.4 A license will not be granted after the provisional licensure period to any free standing surgical center that is not in substantial compliance with these rules and regulations.

2.3.3 License:

2.3.3.1 A license shall be granted, for a period of one year (12 months) to all free standing surgical centers which are and remain in substantial compliance with these rules and regulations.

2.3.3.2 A license shall be effective for a twelve-month period following date of issue and shall expire one year following such date, unless it is modified to a provisional, suspended or revoked, or surrendered prior to the expiration date.

2.3.3.3 Free standing surgical centers must apply for licensure at least 30 days prior to the expiration date of the license.

2.3.3.4 Free standing surgical centers which have not been inspected/surveyed during a licensure year may apply for and be issued a new license until an inspection/survey is completed.

2.3.3.5 A license may not be issued to a free standing surgical center which is not in substantial compliance with these regulations and/or whose deficient practices present an immediate threat to the health and safety of its patients.

2.4 Disciplinary proceedings

2.4.1 The Department may impose sanctions (subsection 2.4.2 of this section) singly or in combination when it finds a licensee or former licensee has:

2.4.1.1 Violated any of these regulations;

2.4.1.2 Failed to submit a reasonable timetable for correction of deficiencies;

2.4.1.3 Failed to correct deficiencies in accordance with a timetable submitted by the applicant and agreed upon by the Department;

2.4.1.4 Exhibited a pattern of cyclical deficiencies which extends over a period of two (2) or more years;

2.4.1.5 Engaged in any conduct or practices detrimental to the welfare of the patients;

2.4.1.6 Exhibited incompetence, negligence or misconduct in operating the free standing surgical center or in providing services to patients;

2.4.1.7 Mistreated or abused patients cared for by the free standing surgical center;

2.4.1.8 Violated any statutes relating to Medical Assistance or Medicare reimbursement for those facilities who participate in those programs; or

2.4.1.9 Refused to allow the Department access to the facility or records for the purpose of conducting inspections/surveys/investigations as deemed necessary by the Department.

2.4.2 Disciplinary sanctions include any of the following:

2.4.2.1 Permanent revocation of a license which extends to:

2.4.2.1.1 The Facility;

2.4.2.1.2 An Owner;

2.4.2.1.3 Officers/directors, partners, managing members or members of a governing body who have a financial interest of five percent (5%) or more in the free standing surgical center; and

2.4.2.1.4 Corporation officers.

2.4.2.2 Suspension of a license.

2.4.2.3 A letter of reprimand.

2.4.2.4 Placement on provisional status with the following requirements:

2.4.2.4.1 Report regularly to the Department upon the matters which are the basis of the provisional status;

2.4.2.4.2 Limit practice to those areas prescribed by the Department; and/or

2.4.2.4.3 Suspend surgery.

2.4.2.5 Refuse a license.

2.4.2.6 Refuse to renew a license.

2.4.2.7 The Department may request the Superior Court to impose a civil penalty of not more than $10,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

2.4.2.7.1 In lieu of seeking a civil penalty, the Department, in its discretion, may impose an administrative penalty of not more than $10,000 for a violation of these regulations. Each day a violation continues constitutes a separate violation.

2.4.2.7.2 In determining the amount of any civil or administrative penalty imposed, the Court or the Department shall consider the following factors:

2.4.2.7.2.1 The seriousness of the violation, including the nature, circumstances, extent and gravity of the violation and the threat or potential threat to the health or safety of a patient;

2.4.2.7.2.2 The history of violations committed by the person or the person's affiliate, agent, employee or controlling person;

2.4.2.7.2.3 The efforts made by the facility to correct the violation(s);

2.4.2.7.2.4 Any misrepresentation made to the Department; and

2.4.2.7.2.5 Any other matter that affects the health, safety or welfare of a patient.

2.4.2.8 Other disciplinary action as appropriate.

2.4.3 Imposition of disciplinary action

2.4.3.1 Before any disciplinary action is taken, except as authorized by 2.4.4, the following shall occur:

2.4.3.1.1 The Department shall give 20 calendar days written notice to the holder of the license, setting forth the reasons for the determination.

2.4.3.1.2 The disciplinary action shall become final 20 calendar days after the mailing of the notice unless the licensee, within such 20 calendar day period, shall give written notice of the facility's desire for a hearing.

2.4.3.1.3 If the licensee gives such notice, the facility shall be given a hearing before the Secretary of the Department or her/his designee and may present such evidence as may be proper.

2.4.3.1.4 The Secretary of the Department or her/his designee shall make a determination based upon the evidence presented.

2.4.3.1.5 A written copy of the determination and the reasons upon which it is based shall be sent to the facility.

2.4.3.1.6 The decision shall become final 20 calendar days after the mailing of the determination letter unless the licensee, within the 20 calendar day period, appeals the decision to the appropriate court of the State.

2.4.4 Order to immediately suspend a license

2.4.4.1 In the event the Department identifies activities which the Department determines present an immediate jeopardy or imminent danger to the public health, welfare and safety requiring emergency action, the Department may issue an order temporarily suspending the licensee's license, pending a final hearing on the complaint. No order temporarily suspending a license shall be issued by the Department, with less than 24 hours prior written or oral notice to the licensee or the licensee's attorney so that the licensee may be heard in opposition to the proposed suspension. An order of temporary suspension under this section shall remain in effect for a period not longer than 60 calendar days from the date of the issuance of said order, unless the suspended licensee requests a continuance of the date for the final hearing before the Department. If a continuance is requested, the order of temporary suspension shall remain in effect until the Department has rendered a decision after the final hearing.

2.4.4.2 The licensee, whose license has been temporarily suspended, shall be notified forthwith in writing. Notification shall consist of a copy of the deficiency report and the order of temporary suspension pending a hearing and shall be personally served upon the licensee or sent by mail, return receipt requested, to the licensee's last known address.

2.4.4.3 A licensee whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Department shall schedule the hearing on an expedited basis provided that the Department receives the licensee's written request for an expedited hearing within five (5) calendar days from the date on which the licensee received notification of the Department's decision to temporarily suspend the licensee's license.

2.4.4.4 As soon as possible, but in no event later than 60 calendar days after the issuance of the order of temporary suspension, the Department shall convene for a hearing on the reasons for suspension. In the event that a licensee, in a timely manner, requests an expedited hearing, the Department shall convene within 15 calendar days of the receipt by the Department of such a request and shall render a decision within 30 calendar days.

2.4.4.5 In no event shall an order of temporary suspension remain in effect for longer than 60 calendar days unless the suspended licensee requests an extension of the order of temporary suspension pending a final decision of the Department. Upon a final decision of the Department, the order of

temporary suspension may be vacated in favor of the disciplinary action ordered by the Department.

2.4.5 Application for licensure after revocation or voluntary surrender of a license in avoidance of revocation action.

2.4.5.1 The application for license after termination of rights to provide services shall follow the procedure for initial licensure application.

2.4.5.2 In addition to the licensure application, the free standing surgical center must also submit and obtain approval of a detailed plan regarding how the free standing surgical center intends to correct the deficient practices that lead to the original termination action. Submission of evidence supporting compliance with the plan and cooperation with Department monitoring during probationary and provisional licensure status is required for reinstatement to full licensure status.

2.4.5.3 Upon successful completion of the probationary period, the free standing surgical center will be granted a provisional license for a period no less than one (1) year but no greater than two (2) years. The provisional period will be identified by the Department after having considered the circumstances that created the original action for license revocation.

2.4.5.4 A license will be granted to the free standing surgical center after the provisional licensure period if:

2.4.5.4.1 The free standing surgical center has remained in substantial compliance with these rules and regulations; and

2.4.5.4.2 The free standing surgical center fulfilled the expectations of the detailed plan of correction that was created to address the deficient practices that gave rise to the license termination action.

2.4.5.5 A license will not be granted after the probationary or provisional licensure period to any facility that is not in substantial compliance with these rules and regulations.

2.5 Modification of ownership and control (MOC)

2.5.1 Any proposed MOC must be reported to the Department a minimum of 30 calendar days prior to the change.

2.5.2 An MOC occurs whenever the ultimate legal authority for the responsibility of the facility's operation is transferred.

2.5.3 An MOC voids the current license in possession of the facility.

2.5.4 An MOC will be treated as an initial license and the building must meet the current design and construction standards recognized by the Department.

2.5.5 An MOC may include but is not limited to:

2.5.5.1 Transfer of the facility's legal title;

2.5.5.2 Transfer of full ownership rights to a new owner;

2.5.5.3 Transfer of the majority interest to a new owner;

2.5.5.4 Transfer of ownership interests that result in the owner with the majority interest becoming a minority interest owner;

2.5.5.5 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights;

2.5.5.6 Transfer resulting in a measurable impact upon the operational control of the facility;

2.5.5.7 Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

2.5.5.8 One partnership is replaced by another through the removal, addition, or substitution of a partner;

2.5.5.9 Removal of the general partner, or general partners, if the facility is owned by a limited partnership;

2.5.5.10 Merger of a free standing surgical center owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled; or

2.5.5.11 The consolidation of a corporate free standing surgical center owner with one or more corporations.

2.5.6 Transactions which do not constitute an MOC include, but are not limited to, the following:

2.5.6.1 Changes in the membership of a corporate board of directors or board of trustees;

2.5.6.2 Two or more corporations merge and the originally licensed corporation survives;

2.5.6.3 Changes in the membership of a non-profit corporation; or

2.5.6.4 Corporate stock transfers or sales that do not result in a transfer of interest or ownership.

2.5.7 Applications for licensure, as a result of an MOC must include a description of:

2.5.7.1 Any actual or anticipated change from the health care services provided before the MOC;

2.5.7.2 Any actual or anticipated change in staff, including the composition of staff;

2.5.7.3 Any actual or anticipated change in policies and procedures; and

2.5.7.4 Any change in the manner of delivery of health care services.

2.6 Fees

2.6.1 Fees shall be in accordance with 16 **Del.C.** §122 (3)p.

2.7 Inspection

2.7.1 A representative of the Department shall periodically inspect every free standing surgical center for which a license has been issued under this chapter. Inspections by authorized representatives of the Department may occur at any time and may be scheduled or unannounced.

2.8 Notice to patients

2.8.1 The free standing surgical center shall notify each patient (or the patient's authorized representative) scheduled for an upcoming surgical procedure of the voluntary surrender of its license, or as directed under an order of denial, revocation or suspension of license issued by the Department.

2.9 Exclusions from licensure

The following persons, associations or organizations are not required to obtain a free standing surgical center license:

2.9.1 A facility that is directly adjacent to and licensed as part of a hospital; or

2.9.2 A facility which is used as an office for the private practice of a physician, podiatrist or dentist.

## 3.0 General Requirements

3.1 All records maintained by the free standing surgical center shall at all times be open to inspection by the authorized representatives of the Department.

3.2 No policies shall be adopted by the free standing surgical center which are in conflict with these regulations.

3.3 Reports of incidents, accidents and medical emergencies shall be kept on file at the facility for a minimum of five (5) years.

3.4 The free standing surgical center shall advise the Department in writing within 15 calendar days following any change in the designation of the director or clinical director within the facility.

3.5 The free standing surgical center may not establish separate facilities without first contacting and receiving approval from the Department.

3.6 The free standing surgical center may contract for services to be provided to its patients. Individuals providing services under contract must meet the same requirements as those persons employed directly by the facility.

3.7 The free standing surgical center shall advise the Department in writing at least 30 calendar days prior to closure of the facility and voluntary surrender of a license.

3.8 The free standing surgical center must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.

3.9 Patients admitted to the free standing surgical center will be permitted to stay 23 hours and 59 minutes, starting from the time of admission. The time calculation begins when the patient is moved from the waiting room to begin the preparation for surgical services. This time must be documented in the patient's medical record. The discharge occurs when the physician has signed the discharge order and the patient has left the recovery room.

3.10 The free standing surgical center must have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the free standing surgical center.

3.10.1 There must be a written transfer agreement with a local hospital; or

3.10.2 All physicians performing surgery in the free standing surgical center must have admitting privileges at a local hospital.

3.11 Report of major adverse incidents

3.11.1 The facility must report all major adverse incidents involving a patient to the Department within 48 hours in addition to other reporting requirements required by law.

3.11.2 A major adverse incident includes but is not limited to:

3.11.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment of patients;

3.11.2.2 An accident that causes serious injury to a patient;

3.11.2.3 A medication error with the potential to result in adverse health outcomes for the patient;
3.11.2.4 Surgery on the wrong patient or wrong body part; or
3.11.2.5 The unexpected death of a patient.
3.11.3 Major adverse incidents must be investigated by the facility.
3.11.4 The facility must submit a complete report to the Department within 30 calendar days of the incident.
3.12 There must be a staff member trained in the use of the facility emergency equipment available at all times in the facility when patients are present.
3.13 The facility shall be in compliance with federal, state and local laws and codes.

**4.0 Governing Body**

4.1 Each free standing surgical center shall have an organized governing body (governing authority, owner or person(s) designated by the owner).
4.2 The governing body shall be ultimately responsible for:
4.2.1 The management and control of the facility;
4.2.2 The assurance of quality care and services:
4.2.2.1 The governing body must ensure the existence and use of a Quality/Performance Improvement program that:
4.2.2.1.1 Is defined, implemented and maintained by the facility;
4.2.2.1.2 Addresses the facility's priorities and that all improvements are evaluated for effectiveness;
4.2.2.1.3 Specifies data collection methods, frequency and details;
4.2.2.1.4 Clearly establishes expectations for safety; and
4.2.2.1.5 Adequately allocates sufficient staff, time, information systems and training to implement the Quality/Performance Improvement program.
4.2.3 Compliance with all federal, state and local laws and regulations;
4.2.4 Adoption of written policies and procedures which describe the functions and services of the facility;
4.2.5 Providing a sufficient number of appropriately qualified personnel;
4.2.6 Providing physical resources and equipment, supplies and services for the provision of safe, effective and efficient delivery of care services;
4.2.7 Developing an organizational structure establishing lines of authority and responsibility;
4.2.8 Appointing a qualified director;
4.2.9 Appointing members of the clinical staff, ensuring their competence and delineating their clinical privileges;
4.2.10 Appointing committees consistent with the needs of the surgical center;
4.2.11 Quarterly review of infection control and quality/performance improvement data and analysis;
4.2.12 Annual review and evaluation of the facility policies and services;
4.2.13 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meetings; and
4.2.14 Compliance with other relevant health and safety requirements.
4.3 There shall be a description of each type of service offered.
4.4 There shall be written policies and procedures pertaining to each service offered.
4.5 There shall be a description of the system for the maintenance of patient records.
4.6 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.

**5.0 Administration/Personnel**

5.1 Director
5.1.1 There shall be a full-time facility director.
5.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the facility.
5.1.3 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:
5.1.3.1 Interpretation and execution of the policies adopted by the governing body;
5.1.3.2 Program planning, budgeting, management and program evaluation;
5.1.3.3 Maintenance of the facility's compliance with licensure regulations and standards;

5.1.3.4 Preparation and submission of required reports;

5.1.3.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;

5.1.3.6 Documentation of complaints relating to the conduct or actions by employees/contractors and action taken secondary to the complaints;

5.1.3.7 Conducting or supervising the resolution of complaints received from patients in the delivery of care or services by the facility; and

5.1.3.8 Reviewing policies and procedures at least annually, and reporting, in writing, to the governing body on the review.

5.1.4 The director shall designate, in writing, a similarly qualified person to act in the absence of the director.

5.2 Supervision of clinical services

5.2.1 The director shall appoint a full-time employee as the clinical director.

5.2.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.

5.2.3 The clinical director shall:

5.2.3.1 Be a registered nurse with at least one year of surgical and administrative/supervisory experience;

5.2.3.2 Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and

5.2.3.3 Provide general supervision and direction of the services offered by the free standing surgical center.

5.2.4 In the absence of the clinical director, an equally qualified designee must be appointed.

5.3 Contract services

5.3.1 The facility maintains responsibility for all services provided to the patient.

5.3.2 Services provided by the facility through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:

5.3.2.1 The services to be provided by the contractor;

5.3.2.2 The necessity to conform to all facility policies;

5.3.2.3 The procedure for annual assurance of clinical competence of all individuals utilized under contract;

5.3.2.4 The procedure for supervision of services of the contracted individuals; and

5.3.2.5 A renewal clause or language that states the contract will be renewed annually.

5.3.3 The facility must ensure that personnel and services contracted meet the requirements specified in these regulations for free standing surgical center personnel and services.

5.4 Written policies

5.4.1 Policy manuals shall be prepared and followed which outline the procedures and practices of the facility.

5.4.2 The facility shall establish written policies regarding:

5.4.2.1 The rights and responsibilities of patients;

5.4.2.2 The handling and documentation of incidents, accidents and medical emergencies. Reports of these events shall be kept on file at the facility;

5.4.2.3 Control of the exposure of patients and staff to persons with communicable diseases;

5.4.2.4 Reporting of all reportable communicable diseases to the Department;

5.4.2.5 The patient's or the patient's family or representative's right to have concerns addressed without fear of reprisal. This policy must include the mechanism for informing the patient of the right to report concerns/complaints to the Department at a telephone number established for that purpose;

5.4.2.6 A grievance procedure for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance:

5.4.2.6.1 The grievance process must specify timeframes for review of the grievance and the provisions of a response.

5.4.2.6.2 The free standing surgical center, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is or fails to be furnished.

5.4.2.6.3 The free standing surgical center must document how the grievance was addressed, as well as provide the patient with written notice of its investigation. The notice must contain the name

of a free standing surgical center contact person, the steps taken to investigate the grievance, the results of the grievance process and the date the grievance process was completed.

5.4.2.7 The procedure to be followed in the event that the facility is not able to provide services scheduled for any particular day or time;

5.4.2.8 Infection control;

5.4.2.9 Employment/Personnel. Such policy shall include:

5.4.2.9.1 Qualifications, responsibilities and requirements for each job classification;

5.4.2.9.2 Pre-employment requirements;

5.4.2.9.3 Position descriptions;

5.4.2.9.4 Orientation policy and procedure for all employees and contractors;

5.4.2.9.5 Inservice education policy;

5.4.2.9.6 Annual performance review and competency testing; and

5.4.2.9.7 The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.

5.4.2.10 Admission of patients to facility services, delivery of those services and discharge of patients;

5.4.2.11 The use and removal of records and the conditions for release of information in accordance with statutory provisions pertaining to confidentiality;

5.4.2.12 The immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the facility; and

5.4.2.13 Waste Disposal.

5.4.3 The facility shall review its written policies at least annually, and revise them as necessary. Documentation of the annual review must be maintained by the facility.

5.4.4 Policies shall be made available to representatives of the Department upon request.

5.5 Personnel records

5.5.1 Records of each employee/contractor shall be available upon request by authorized representatives of the Department.

5.5.2 For all individuals, employees or contractors, the facility shall maintain current individual personnel records on-site which shall contain at least:

5.5.2.1 Written verification of compliance with pre-employment requirements;

5.5.2.2 Documentation of clinical competence;

5.5.2.3 Evidence of current professional licensure, registration or certification as appropriate;

5.5.2.4 Educational preparation and work history;

5.5.2.5 Written performance evaluations conducted, at least, annually; and

5.5.2.6 A written and signed job description.

5.6 Health history

5.6.1 Minimum requirements for tuberculosis (TB) testing are those currently recommended by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services:

5.6.1.1 A baseline testing must be completed upon hire and, thereafter, as determined by a TB risk assessment.

5.6.1.2 No person found to have active TB in an infectious stage shall be permitted to give care or service to patients.

5.6.1.3 Any person having a positive skin test but a negative chest X-ray must complete a statement annually attesting that they have experienced no symptoms which may indicate active TB infection.

5.6.1.4 A report of all TB test results and all attestation statements shall be on file at the facility.

5.6.2 Any individual who cannot adequately perform the duties required or who may jeopardize the health or safety of the patients shall be relieved of their duties and removed from the facility until such time as the condition is resolved. This includes infections of a temporary nature.

5.7 Staff development

5.7.1 All employees/contractors, including medical staff, are required to complete an orientation program.

5.7.2 An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards, and shall include but not be limited to:

5.7.2.1 Organizational structure of the facility;

5.7.2.2 Facility patient care policies and procedures;
5.7.2.3 Infection Control;
5.7.2.4 Philosophy of patient care;
5.7.2.5 Patient rights;
5.7.2.6 Facility personnel and administrative policies;
5.7.2.7 Job description;
5.7.2.8 Disaster Preparedness; and
5.7.2.9 Applicable state regulations governing the delivery of services.

5.7.3 Documentation of orientation must include the date and hours, content, and name and title of the person providing the orientation.

5.7.4 It is the responsibility of the facility to ensure that employees/contractors are proficient to carry out the care assigned in a safe, effective and efficient manner.

5.7.5 All newly hired employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter.

5.7.6 Attendance records must be kept for all orientation and continuing education programs.

5.8 Medical staff

5.8.1 All persons admitted to the free standing surgical center shall be under the care of a physician.

5.8.2 One (1) or more physicians must be on premises during all hours of surgical services and until all patients have been discharged or must be on call and immediately available on-site within 30 minutes.

5.8.3 A medical director shall be appointed and shall be responsible for the direction, provision and quality of medical care.

5.8.4 All members of the free standing surgical center's medical staff must be appointed to their position within the facility by the governing body.

5.8.5 Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted.

5.8.6 Medical staff privileges must be granted by the governing body, in writing, and must specify, in detail, the types of procedures that each physician may perform within the facility.

5.8.7 Medical staff privileges must be reappraised by the facility at least every 24 months.

5.8.8 If the free standing surgical center assigns patient care responsibilities to licensed independent practitioners other than physicians, it must have:

5.8.8.1 Established credentialing and privileging procedures approved by the governing body, and

5.8.8.2 Policies and procedures, approved by the governing body, for overseeing and evaluating clinical activities.

5.9 Nursing services

5.9.1 Nursing services must be under the direction of a clinical director.

5.9.2 There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all facility patients are met.

5.9.3 Patient care responsibilities must be delineated for all nursing service personnel.

5.9.4 Nursing services must be provided in accordance with recognized standards of practice.

5.9.5 There must be a registered nurse available at all times in the facility when patients are present.

5.9.5.1 There must be two (2) registered nurses, with specialized training or experience in emergency care, including Advanced Cardiac Life Support certification, available to provide emergency treatment whenever there is a patient in the facility.

5.9.6 Individual patient assignments on a given day must be documented clearly on an assignment sheet which must be kept on file for one (1) year from date of procedure.

## 6.0 General Patient Care Management

6.1 The admission policies shall be discussed with each patient entering the facility or their representative, if applicable.

6.2 Not more than 30 calendar days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment, completed by a physician or other qualified licensed independent healthcare practitioner, to determine whether there is anything in the patient's overall condition that would affect the planned surgery that requires additional interventions to reduce risk to the patient or may indicate that the facility is not the appropriate setting for the surgery. The medical history and physical

assessment must be comprehensive in order to determine the patient's readiness for surgery and specifically indicate that the patient is cleared for surgery in the ambulatory setting. The comprehensive medical history and physical assessment must include at a minimum:

6.2.1 Medical history:

6.2.1.1 Chief complaint;

6.2.1.2 History of present illness;

6.2.1.3 Past medical and surgical history;

6.2.1.4 Allergies;

6.2.1.5 Medications; and

6.2.1.6 Psychosocial assessment.

6.2.2 Physical assessment:

6.2.2.1 Vital signs;

6.2.2.2 Head and neck;

6.2.2.3 Heart and lungs;

6.2.2.4 Abdomen;

6.2.2.5 Rectal/pelvic;

6.2.2.6 Extremities;

6.2.2.7 Neurological; and

6.2.2.8 Other pertinent physical findings.

6.2.3 Diagnosis and impression; and

6.2.4 A record of any changes within the 30 day timeframe.

6.3 A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

6.4 Anesthesia must be administered by:

6.4.1 A qualified anesthesiologist;

6.4.2 A physician qualified to administer anesthesia; or

6.4.3 A certified registered nurse anesthetist (CRNA), in which case, the anesthetist must be under the supervision of the anesthesiologist or operating physician.

6.5 The patient's post-surgical condition must be assessed and documented by a qualified licensed healthcare practitioner with post-operative care experience.

6.6 Before discharge from the facility, each patient must be evaluated by a physician for proper anesthesia recovery. It is expected that a patient will actually leave the facility within 15 – 30 minutes of the time when the physician signs the discharge order.

6.7 The free standing surgical center must provide each patient with written discharge instructions and overnight supplies. Patients shall be informed, prior to leaving the facility, of their prescriptions, post-operative instructions, and physician contact information for follow-up care. When appropriate, the facility shall make a follow-up appointment for the patient with their physician.

6.8 The free standing surgical center must ensure that each patient has a discharge order, signed by the physician who performed the surgery or procedure.

6.9 The free standing surgical center must ensure that all patients are discharged in the company of a responsible adult, unless individually exempted in writing by the attending physician.

6.10 The free standing surgical center shall provide nutritional services for the patients as follows:

6.10.1 Assure the availability of meals, beverages and supplemental snacks in accordance with each patient's individual needs.

6.10.2 Provide or make arrangements for a minimum of one (1) meal daily which is of suitable quality and quantity for patients who are in the center for six (6) or more hours. The meal shall meet at least 1/3 of an adult's current recommended dietary allowance (RDA) of the Food and Nutrition Board, National Academy of Sciences-National Research Council.

6.10.3 Provide or make arrangements for a minimum of two(2) meals daily which are of suitable quality and quantity for patients who are in the center for 12 or more hours. The meals shall meet at least 2/3 of an adult's current recommended dietary allowance (RDA) of the Food and Nutrition Board, National Academy of Sciences-National Research Council.

6.10.4 Provide therapeutic diets as necessary in accordance with each patient's individual needs.

6.10.5 If meals are prepared by the free standing surgical center, food must be stored, prepared and served in accordance with the State of Delaware Food Code.

6.10.5.1 Meals prepared on-site must be approved by a dietitian;

6.10.5.2 A dietitian shall be available for consultation with staff on basic and special nutritional needs and proper food handling techniques and shall provide in-service training to staff on these topics at least annually; and

6.10.5.3 A full-time qualified food service manager shall direct and supervise the storage, preparation and serving of food.

6.10.6 Food that is prepared for the free standing surgical center at an alternate site shall be prepared in a facility which is in compliance with the State of Delaware Food Code and has been issued a permit.

6.10.6.1 A diet kitchen shall be readily available to the nursing staff and additional diet kitchens shall be part of each patient floor in all multi-story facilities. The equipment provided shall furnish ice and between-meal nourishment to patients. The diet kitchen shall contain, at a minimum, the following equipment:

6.10.6.1.1 Double sink, unless disposables are used at all times;

6.10.6.1.2 Microwave oven;

6.10.6.1.3 Refrigerator;

6.10.6.1.4 Hand-washing sink;

6.10.6.1.5 Counter space;

6.10.6.1.6 Separate storage areas for edibles and non-edibles; and

6.10.6.1.7 Ice machine.

6.10.7 Appropriate food containers and utensils shall be available as needed for use by disabled patients.

6.10.8 Equipment for adequate refrigeration and for the heating of foods shall be provided if needed to assist in the provision of meals and snacks.

6.10.9 Meals and snacks shall be documented in the patient's medical record.

## 7.0 Infection Control

7.1 The facility shall establish and implement an infection prevention and control program which shall be based upon nationally recognized infection control guidelines/standards (i.e. CDC, AORN, etc.).

7.2 The facility must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases. All areas of the facility must be clean and sanitary.

7.3 The facility must maintain an ongoing program to prevent, control and investigate infections and communicable diseases. As part of this ongoing program, the facility must have an active surveillance component that covers both patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

7.4 The facility must designate in writing, a qualified licensed healthcare professional who will lead the facility's infection control program. The facility must determine that the individual has had training in the principles and methods of infection control.

7.5 The facility's infection control program must be integrated into its quality improvement program. Infection control data and program activities are an ongoing component of the quality improvement program and actions are taken in response to data analyses to improve the facility's infection control performance.

7.6 The facility's infection control professional must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the facility. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the facility's infection control outcomes. The plan should be specific to each particular area of the facility, including, but not limited to, the waiting room(s), the recovery room(s) and the surgical areas.

## 8.0 Quality/Performance Improvement Program

8.1 The facility must take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers.

8.2 The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

8.3 The facility must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the facility.

8.4 The facility must set priorities for its performance improvement activities that:

8.4.1 Focus on high risk, high volume and problem-prone areas;

8.4.2 Consider incidence, prevalence and severity of problems in those areas; and

8.4.3 Affect health outcomes, patient safety and quality of care.

8.5 The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the facility. The facility must use the data collected to:

8.5.1 Monitor the effectiveness and safety of its services and quality of its care; and

8.5.2 Identify opportunities that could lead to improvements and changes in its patient care.

8.6 Performance improvement activities must track adverse patient events by:

8.6.1 Examining their causes;

8.6.2 Implementing improvements;

8.6.3 Ensuring that improvements are sustained over time; and

8.6.4 Ensuring that all staff members are familiar with the preventive strategies targeting adverse events.

8.7 The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the facility's services and operations. The facility must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, a description of the project and a description of the project's results.

**9.0 Environment**

9.1 The facility must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

9.2 Physical plant

9.2.1 All construction – new, renovations, or remodeling – must conform to the design and construction standards recognized by the Department.

9.2.2 In the event that there is a conflict between the design and construction standard utilized by the Department and the minimum standard set forth herein, the higher standard or requirement shall prevail.

9.2.3 When a facility is classified under this law or regulation and plans to construct, extensively remodel or convert any building, one (1) copy of properly prepared plans and specifications for the entire facility shall be presented to the Department.

9.2.4 An approval, in writing, shall be obtained from the Department before construction/renovation/remodeling work is begun.

9.2.5 Upon completion of construction/renovation/remodeling, in accordance with the plans and specifications, the Department will inspect and determine whether to approve the site prior to occupancy/use by the facility.

9.2.6 All facilities shall either be at grade level or shall be equipped with ramps or elevators to allow easy access for persons with disabilities.

9.2.7 The facility shall comply with all local and state building codes and ordinances as pertain to this occupancy.

9.3 Laundry and linens

9.3.1 An adequate supply of clean linen or disposable materials shall be maintained.

9.3.2 Clean linen shall be stored, handled and transported to prevent contamination.

9.3.3 Linens shall be maintained in good repair.

9.3.4 There shall be distinct areas for the storage and handling of clean and soiled linens.

9.3.5 Soiled linen shall be handled, transported, stored and processed in a manner to prevent leakage and the spread of infection.

9.3.6 Soiled linen not processed on a daily basis must be stored in a separate properly ventilated storage area.

9.3.7 Soiled linen must be removed from the procedure room after each procedure.

9.3.8 Carts used to transport soiled linen must be constructed of impervious materials and must be cleaned and disinfected after each use.

9.3.9 Laundry processed on-site:

9.3.9.1 The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.

9.3.9.2 The temperature of water during the washing process shall be controlled to provide a minimum temperature of 165° Fahrenheit for 25 minutes or 130° Fahrenheit if the soap/detergent supplier will verify that their products will work effectively at that lower temperature. A label indicating same shall be affixed to the laundry machine.

9.3.10 Laundry processed off-site:

9.3.10.1 The facility must have a contract with a commercial or hospital laundry.

9.3.10.2 Clean linens returned to the facility must be completely wrapped or covered to protect against contamination.

9.4 Sanitation and housekeeping

9.4.1 The facility shall provide housekeeping services to maintain a clean, sanitary, safe environment which is free from odors.

9.4.2 Operating/Procedure rooms shall be thoroughly cleaned after each use.

9.4.3 All cleaning materials, solutions, cleaning compounds and hazardous substances shall be:

9.4.3.1 Properly identified;

9.4.3.2 Stored in a safe place; and

9.4.3.3 Stored separate from care items and food.

9.4.4 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the environment.

9.4.5 The facility shall be kept free of insects and rodents. A contract with a pest control agency shall be executed and available for review.

9.5 Waste storage and disposal

9.5.1 All rubbish and refuse containers shall be impervious, lined and clean.

9.5.2 All rubbish and refuse shall be collected, stored and disposed of in a manner designed to prevent transmission of disease.

9.5.3 All contaminated dressings, pathological or similar waste shall be properly disposed of.

9.5.4 All personnel must wash their hands immediately after handling rubbish or refuse.

9.6 Fire safety

9.6.1 The facility shall comply with the ambulatory healthcare requirements of the National Fire Protection Association "Life Safety Code" as adopted and/or modified by the State Fire Prevention Regulations.

9.6.2 The facility must be inspected annually by the fire marshal having jurisdiction and all applications for license (new and renewal) must include documentation, dated within the past 12 months, indicating compliance to all applicable fire code regulations.

9.6.3 Failure to provide documentation from the fire marshal having jurisdiction, dated within the past 12 months, indicating compliance to all applicable fire code regulations shall be grounds for licensure action.

9.6.4 All employees shall be trained in procedures to be followed in the event of a fire and emergency. Training shall be part of initial employee orientation and shall be conducted quarterly thereafter.

9.6.5 A fire drill shall be performed every quarter on each work shift.

9.6.5.1 A written record of each fire drill shall be kept on file at the facility.

9.6.5.2 The written record must include the following:

9.6.5.2.1 Date and time of the drill;

9.6.5.2.2 Description of the emergency fire condition;

9.6.5.2.3 Signatures and titles of those participating in the drill;

9.6.5.2.4 Duration of the drill; and

9.6.5.2.5 Evaluation of the drill.

9.7 Emergency equipment available to the operating rooms must include at least the following:

9.7.1 Emergency call system;

9.7.2 Oxygen;

9.7.3 Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator or other device for the provision of positive pressure rescue breathing;

9.7.4 Cardiac defibrillator;

9.7.5 Cardiac monitoring equipment;

9.7.6 Laryngoscope and endotracheal tubes;

9.7.7 Suction equipment; and

9.7.8 Emergency medical equipment and supplies specified by the medical staff.

**10.0 Medical Records**

10.1 There shall be a separate record maintained at the facility for each patient.

10.2 Every record must be accurate, legible and promptly completed.

10.3 Medical records must include at least the following:

10.3.1 Patient identification;

10.3.2 Significant medical history and results of physical examination;

10.3.3 Pre-operative diagnostic studies (entered before surgery), if performed;

10.3.4 Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;

10.3.5 Any allergies and abnormal drug reactions;

10.3.6 Entries related to medication and anesthesia administration;

10.3.7 Documentation of properly executed informed patient consent;

10.3.8 Written notice of patients' rights;

10.3.9 Discharge diagnosis; and

10.3.10 An advance health-care directive form that complies with 16 **Del.C.** Ch. 25, a statement that a copy of the advance health-care directive form has been requested, or a statement that none has been signed.

10.4 The facility must have a documented system that enables it to systematically develop a unique medical record for each patient, permit timely access to the medical record to support the delivery of care, and store records. Records may exist in hard copy, electronic format, or a combination of the two media.

10.5 All entries in the medical record must be signed and dated by the responsible person in accordance with the facility's policies and procedures.

10.6 A person knowledgeable in the management of medical records shall be responsible for the proper administration and functioning of the medical records section.

10.7 There shall be an identified locked area for medical record storage at the facility.

10.8 Medical records shall be protected from loss, damage and unauthorized use.

10.9 The facility shall ensure that each medical record is treated with confidentiality and is maintained according to professional standards of practice.

10.10 The facility must develop acceptable policies for authentication of any computerized records.

10.11 All patient records shall be available for review by authorized representatives of the Department and to legally authorized persons; otherwise patient records shall be held confidential. The consent of the patient or her/his representative, if the patient is incapable of making decisions, shall be obtained before any personal information is released from her/his records as authorized by these regulations and Delaware law.

10.12 Computerized patient records must be printed by the facility as requested by authorized representatives of the Department.

10.13 The medical records shall be retained in a retrievable form until destroyed.

10.13.1 Records of adults (18 years of age and older) shall be retained for a minimum of five (5) years after the last date of service before being destroyed.

10.13.2 Records of minors (less than 18 years of age) shall be retained for a minimum of five (5) years after the patient reaches 18 years of age.

10.13.3 All records must be disposed of by shredding, burning or other similar protective measure in order to preserve the patient's rights of confidentiality.

10.13.4 The facility must establish procedures for the notification to patients regarding the pending destruction of medical records.

10.13.5 Documentation of record destruction must be maintained by the facility.

**11.0 Pharmaceutical Services**

11.1 Drugs and biologicals used within the facility must be provided safely and in an effective manner, consistent with generally accepted professional standards of pharmaceutical practice.

11.2 Drugs shall be properly secured and accessible only to authorized personnel.

11.3 The facility must designate a specific licensed healthcare professional to provide direction to the facility's pharmaceutical service.

11.4 Drugs must be prepared and administered according to established policies and acceptable standards of practice.

11.5 Adverse reactions to drugs and biologicals must be reported to the physician responsible for the patient and must be documented in the medical record.

11.6 Blood and blood products must be administered only by physicians or registered nurses.

11.7 Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician within 48 hours.

## 12.0 Laboratory and Radiologic Services

12.1 Free standing surgical centers that perform laboratory services must meet federal and state requirements.

12.2 Free standing surgical centers that do not provide laboratory services must have procedures for obtaining routine and emergency laboratory services from a certified laboratory.

12.3 The scope and complexity of radiological services provided within the facility, either directly or under arrangement, as an integral part of the facility's surgical services shall be specified in writing and approved by the governing body.

12.4 Free standing surgical centers that do not provide radiological services must have procedures for obtaining radiological services from an approved facility to meet the needs of patients.

12.5 Free standing surgical centers that provide radiological services must meet professionally approved standards for safety and personnel qualifications.

12.5.1 The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body.

12.5.2 Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations and guidelines governing radiological services.

12.5.3 The facility must adopt and implement policies and procedures that provide safety for patients and personnel including but not limited to:

12.5.3.1 Adequate shielding for patients, personnel and surrounding areas;

12.5.3.2 Labeling of radioactive materials, waste and hazardous areas;

12.5.3.3 Transportation of radioactive materials between locations within the facility;

12.5.3.4 Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;

12.5.3.5 Testing of equipment for radiation hazards;

12.5.3.6 Maintenance of personal radiation monitoring devices;

12.5.3.7 Proper storage of radiation monitoring badges when not in use;

12.5.3.8 Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste; and

12.5.3.9 Methods of identifying pregnant patients.

12.5.4 The facility must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted and current, and that problems identified are corrected in a timely manner. The facility must ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, guidelines and facility policy.

12.5.5 Employees/Contractors must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

12.5.6 Radiologic services must be provided only on the order of licensed independent healthcare practitioners with clinical privileges.

12.5.7 A qualified full-time, part-time or consulting radiologist must supervise ionizing radiology services and must interpret those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge.

12.5.8 Only personnel designated as qualified by the medical staff may use the radiologic equipment and perform procedures.

12.5.9 The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

## 13.0 Patient Rights

13.1 The free standing surgical center must, prior to the start of a surgical procedure, provide the patient or the patient's representative with verbal and written notice of the patient's rights, in a language and manner that the patient or the patient's representative understands.

13.2 The free standing surgical center must post written notice of patient rights in a place or places within the free standing surgical center likely to be noticed by patients or their representatives. The free standing surgical center's notice of rights must include the name, address, and telephone number of the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

13.3 The free standing surgical center must disclose, where applicable, physician financial interests or ownership in the free standing surgical center in accordance with federal requirements. Disclosure of information must be in writing.

13.4 The free standing surgical center must:

13.4.1 Provide the patient or the patient's representative in advance of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms;

13.4.2 Inform the patient or the patient's representative of the patient's right to make informed decisions regarding the patient's care; and

13.4.3 Document in a prominent part of the patient's current medical record, whether the patient has executed an advance directive.

13.5 The patient has the right to:

13.5.1 Exercise his or her rights without being subjected to discrimination or reprisal;

13.5.2 Voice grievances regarding treatment or care that is or fails to be furnished;

13.5.3 Be fully informed about a treatment or procedure and the expected outcome before it is performed;

13.5.4 Personal privacy;

13.5.5 Receive care in a safe setting;

13.5.6 Be free from all forms of abuse, mistreatment or harassment;

13.5.7 Confidentiality of information and medical records;

13.5.8 Be treated with courtesy, consideration, respect and dignity; and

13.5.9 Be served by individuals who are properly trained and competent to perform their duties.

## 14.0 Disaster Preparedness

14.1 The free standing surgical center must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the facility.

14.2 The free standing surgical center must contact state and local authorities and coordinate with them on disaster planning, as warranted and appropriate.

14.3 The free standing surgical center must conduct drills, at least annually, to test the plan's effectiveness. The free standing surgical center must complete a written evaluation of each drill and promptly implement any corrections to the plan.

## 15.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.

**15 DE Reg. 471 (01/01/12) (Prop.)**