

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 122(3)p (16 Del.C. §122(3)p)
16 DE Admin. Code 3355

PROPOSED

PUBLIC NOTICE

3355 Free Standing Surgical Centers

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code) and under the authority of Title 16 of the **Delaware Code**, Chapter 1, Section 122(3)(p), Delaware Health and Social Services (DHSS)/ Division of Health Care Quality (DHCQ) is proposing regulations governing Free Standing Surgical Centers.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed regulatory amendments must submit same by email to Corinna.Getchell@Delaware.gov or by fax to 302-292-3931 by 4:30 p.m. on August 1, 2022. Please identify in the subject line: Regulations Governing Free Standing Surgical Centers.

The action concerning the determination of whether to adopt the proposed regulations will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services/Division of Health Care Quality is proposing regulations governing Free Standing Surgical Centers.

Statutory Authority

16 Del.C. §122(3)(p)

Background

As more services are being provided in the community setting, it is necessary to ensure outpatient surgical services are provided in accordance with recognized standards of practice.

Summary of Proposal

Summary of Proposed Changes

The Division of Health Care Quality plans to publish the "proposed" amendments to the regulations governing free standing surgical centers and hold them out for public comment per Delaware law. The purpose of this proposed amendment is to update the requirements to be consistent with federal requirements and nationally recognized standards of practice to ensure patients receive safe and quality care from a free standing surgical center.

Public Notice

In accordance with the state public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, Delaware Health and Social Services/Division of Health Care Quality gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments must be received by 4:30 p.m. on August 1, 2022.

Fiscal Impact

Not applicable

***Please Note: The Regulatory Flexibility Analysis and Impact Statement for this regulation, as required by 29 Del. C. Ch. 104, is available at:**

<http://regulations.delaware.gov/register/july2022/proposed/26 DE Reg 31RFA 07-01-22.pdf>

3355 Free Standing Surgical Centers

1.0 Purpose

Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 Del.C. §122(3)(p). These regulations establish standards with respect to the operation of free standing surgical centers.

2.0 Definitions

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:

“Certified Registered Nurse Anesthetist” means an individual currently licensed as an advanced practice nurse pursuant to Title 24, Chapter 19 of the Delaware Code.

“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. The "Clinical Director" and "Director" may be the same individual if that individual is dually qualified.

“Department” means the Delaware Department of Health and Social Services.

“Dentist” means a person currently licensed as a dentist by Title 24, Chapter 11 of the Delaware Code.

“Dietitian” means a person currently licensed as a dietitian by Title 24, Chapter 38 of the Delaware Code.

“Director” means the individual appointed by the governing body to act on its behalf in the overall management of the free standing surgical center. The director shall have: 1) a Baccalaureate Degree; 2) five (5) years healthcare experience; and 3) one (1) year supervisory experience in a surgical setting.

“Free Standing Surgical Center”, abbreviated as FSSC, means a facility, 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.

“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 FSSC is vested.

“Healthcare Professional” means a person currently licensed as a physician, dentist, podiatrist, licensed independent practitioner or registered nurse.

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

“Licensed Independent Practitioner” means a person currently licensed as an advanced practice nurse pursuant to Title 24, Chapter 17 of the Delaware Code, or a person currently licensed as a physician's assistant pursuant to Title 24, Chapter 19 of the Delaware Code.

“Modification of Ownership and Control” means a change of ownership or transfer of responsibility for the FSSC's operation.

“Patient” means a person who receives health care services from a FSSC.

“Physician” means a person currently licensed as a physician 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.

“Podiatrist” means a person currently licensed as a podiatrist by Title 24, Chapter 5 of the Delaware Code.

“Registered Nurse” means a person currently licensed as a registered nurse pursuant to Title 24, Chapter 19 of the Delaware Code.

“Serious Injury” means physical injury that creates a substantial risk of death, or that causes serious disfigurement, serious impairment of health or serious loss or impairment of the function of any bodily organ.

“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.

3.0 Licensure Requirements and Procedures

3.1 General requirements

- 3.1.1 No person shall establish, conduct or maintain in this State any FSSC without first obtaining a license from the Department.
- 3.1.2 A license issued hereunder shall be subject, at any time, to revision or revocation by the State.
- 3.1.3 A license is not transferable from person to person, entity to entity or from one location to another.
- 3.1.4 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.
- 3.1.5 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 admitted patients shall not exceed the total number of licensed beds.
- 3.1.6 Separate licenses are required for FSSCs maintained in separate locations, even though operated under the same management.
- 3.1.7 Any FSSC that undergoes a modification of ownership and control is required to re-apply as a new FSSC and must meet the current design and construction standards recognized by the Department.
- 3.1.8 Licenses will be issued for specific hours of operation and FSSCs may not operate beyond those hours for which it is licensed.
- 3.1.9 The submission 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.
- 3.1.10 Patients shall not be admitted to a FSSC until a license has been issued.

3.2 Application process

- 3.2.1 All persons or entities wanting to apply to open a FSSC shall submit to the Department the following information:
 - 3.2.1.1 A Statement of Intent describing the services to be offered by the FSSC;
 - 3.2.1.2 A completed application for licensure;
 - 3.2.1.3 The names, addresses and types of facilities previously and currently owned or managed by the applicant;
 - 3.2.1.4 Identity of:
 - 3.2.1.4.1 Each officer and director of the corporation, if the entity is organized as a corporation;
 - 3.2.1.4.2 Each general partner or managing member, if the entity is organized as an unincorporated entity;
 - 3.2.1.4.3 The governing body; and
 - 3.2.1.4.4 Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest in a licensee's operation or related businesses.
 - 3.2.1.5 Proof of not-for-profit status, if claiming tax-exempt status;
 - 3.2.1.6 Disclosure of any officer, director, partner, employee, managing member or member of the governing body with a felony criminal record;
 - 3.2.1.7 Name of the director and the person designated to act in the absence of the director;
 - 3.2.1.8 A list of management personnel, including credentials;
 - 3.2.1.9 A plan for providing orientation, continuing education, and training for personnel or independent contractors during the first year of operation;
 - 3.2.1.10 Policy and procedure manuals;
 - 3.2.1.11 Applicants wanting to open a FSSC to accommodate patient stays of 23 hours and 59 minutes must have written approval from the local government having jurisdiction certifying that the proposed use will not conflict with any zoning restrictions, deed restrictions and local noise ordinances prior to applying for licensure to the Department; and
 - 3.2.1.12 Any other information required by the Department.
- 3.2.2 A currently licensed FSSC wishing to change its hours of operation to accommodate patient stays of 23 hours and 59 minutes must request approval in writing from the local government having jurisdiction. Once written approval is received from the local government having jurisdiction, the FSSC may then apply to the Department for approval of the extended hours.

3.3 Issuance of licenses

3.3.1 Initial license:

- 3.3.1.1 An initial license shall be granted for a period of nine (9) calendar months to every FSSC that completes the application process consistent with these regulations and whose policies and procedures demonstrate compliance with the rules and regulations pertaining to FSSC licensure.
- 3.3.1.2 An initial license will permit a FSSC to hire or contract with personnel and begin to offer services.
- 3.3.1.3 All FSSCs shall have an on-site survey, conducted by the Department, during the first nine (9) calendar months of operation.
- 3.3.1.4 A FSSC, at the time of an initial on-site survey, must meet the definition of a FSSC 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 FSSC or that are not in substantial compliance with these regulations will not be granted a license.
- 3.3.1.5 An initial license may not be renewed.

3.3.2 Provisional license:

- 3.3.2.1 A provisional license shall be granted, for a period of less than one year, to all FSSCs that:
 - 3.3.2.1.1 Are not in substantial compliance with these rules and regulations; or
 - 3.3.2.1.2 Fail to renew a license within the timeframe prescribed by these regulations.
- 3.3.2.2 The Department shall designate the conditions and the time period under which a provisional license is issued.
- 3.3.2.3 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 FSSC.
- 3.3.2.4 A license will not be granted after the provisional licensure period to any FSSC that is not in substantial compliance with these rules and regulations.

3.3.3 Annual License:

- 3.3.3.1 An annual license shall be granted, for a period of one year (12 months) to all FSSCs which are, and remain, in substantial compliance with these rules and regulations.
- 3.3.3.2 An annual 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, revoked or surrendered prior to the expiration date.
- 3.3.3.3 FSSCs must reapply for licensure at least 30 days prior to the expiration date of the license.
- 3.3.3.4 FSSCs 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.
- 3.3.3.5 An annual license may not be issued to a FSSC which is not in substantial compliance with these regulations or whose deficient practices present an immediate threat to the health and safety of its patients.

3.4 Modification of ownership and control (MOC)

- 3.4.1 Any proposed MOC must be reported to the Department a minimum of 30 calendar days prior to the change.
- 3.4.2 An MOC occurs whenever the ultimate legal authority for the responsibility of the FSSC's operation is transferred.
- 3.4.3 An MOC voids the current license in possession of the FSSC.
- 3.4.4 An MOC will be treated as an initial license and the FSSC must meet the current design and construction standards recognized by the Department.
- 3.4.5 An MOC may include but is not limited to:
 - 3.4.5.1 Transfer of the FSSC's legal title;
 - 3.4.5.2 Transfer of full ownership rights;
 - 3.4.5.3 Transfer of the majority interest;
 - 3.4.5.4 Transfer of ownership interests that result in the owner with the majority interest becoming a minority interest owner;
 - 3.4.5.5 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights;
 - 3.4.5.6 Transfer resulting in a measurable impact upon the operational control of the FSSC;
 - 3.4.5.7 Dissolution of any partnership that owns, or owns a controlling interest in the FSSC;

- 3.4.5.8 Merger of a FSSC owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled; or
- 3.4.5.9 The consolidation of a corporate FSSC owner with one or more corporations.
- 3.4.5.10 Any other transfer or action under 8 **Del.C.** is considered an MOC under these regulations.
- 3.4.6 Transactions which do not constitute an MOC include, but are not limited to the following:
 - 3.4.6.1 Changes in the membership of a corporate board of directors or board of trustees;
 - 3.4.6.2 Two or more corporations merge and the originally licensed corporation survives;
 - 3.4.6.3 Changes in the membership of a non-profit corporation; or
 - 3.4.6.4 Corporate stock transfers or sales that do not result in a transfer of interest or ownership.
- 3.4.7 Applications for licensure, as a result of an MOC must include a description of:
 - 3.4.7.1 Any actual or anticipated change in the health care services provided before the MOC;
 - 3.4.7.2 Any actual or anticipated change in staff, including the composition of staff;
 - 3.4.7.3 Any actual or anticipated change in policies and procedures; and
 - 3.4.7.4 Any change in the manner of delivery of health care services.
- 3.5 Fees. Fees shall be in accordance with 16 **Del.C.** §122 (3)p.
- 3.6 Inspection. A representative of the Department shall periodically inspect every FSSC 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.
- 3.7 Notice to patients. The FSSC 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.
- 3.8 Exclusions from licensure. The following persons, associations or organizations are not required to obtain a FSSC license:
 - 3.8.1 A FSSC that is directly adjacent to and licensed as part of a hospital; or
 - 3.8.2 A FSSC which is used as an office for the private practice of a physician, podiatrist or dentist.

25 DE Reg. 627 (12/01/21)

4.0 General Requirements

- 4.1 The FSSC shall be in compliance with federal, state and local laws and codes.
- 4.2 The provisions of 42 CFR Ch. IV, Part 416, Subparts A, B and C, are hereby adopted as the regulatory requirements for FSSCs in Delaware. 42 CFR Ch. IV, Part 416 is hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.3 The provisions of the National Fire Protection Association's Life Safety Code, as adopted and modified by the State Fire Prevention Regulations, are hereby adopted as the regulatory requirements for FSSCs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.4 The provisions of the Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, are hereby adopted as the regulatory requirements for FSSCs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.5 The provisions of the ~~2018~~ 2022 Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities, are hereby adopted as the regulatory requirements for FSSCs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
 - 4.5.1 When a FSSC is classified under this law or regulation and plans to construct, extensively remodel or convert any buildings, one (1) copy of properly prepared plans and specifications for the entire FSSC shall be submitted to the Department.
 - 4.5.2 An approval, in writing, shall be obtained from the Department before construction/renovation/remodeling work is begun.
 - 4.5.3 Upon completion of construction/renovation/remodeling, in accordance with the plans and specifications, the Department will inspect and approve the site prior to occupancy/use by the FSSC.
 - 4.5.4 All facilities shall either be at grade level or shall be equipped with ramps or elevators to allow easy access for persons with disabilities.
 - 4.5.5 The FSSC shall comply with all local and state building codes and ordinances as pertain to this occupancy.
 - 4.5.6 Waiver of a standard requires Department approval. Waiver requests must be made in writing, include the full justification behind the request and address issues of safety and infection control. Waivers are an exception to established standards and will only be approved for compelling reason.

- 4.6 The provisions of the State of Delaware Food Code, 16 **DE Admin. Code** 4458, are hereby adopted as the regulatory requirements for FSSCs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.7 The provisions of the State of Delaware, Department of Natural Resources and Environmental Control, Regulations Governing Solid Waste, 7 **DE Admin. Code** 1301, are hereby adopted as the regulatory requirements for FSSCs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.8 No policies shall be adopted by the FSSC which are in conflict with these regulations.
- 4.9 The FSSC shall advise the Department in writing within 15 calendar days following any change in the designation of the director or clinical director within the FSSC.
- 4.10 The FSSC 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 FSSC.
- 4.11 The FSSC shall advise the Department in writing at least 30 calendar days prior to closure of the FSSC and voluntary surrender of a license.
- 4.12 All records maintained by the FSSC shall at all times be open to inspection by authorized representatives of the Department.
- 4.13 The FSSC 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.
- 4.14 Reports of incidents, accidents and medical emergencies shall be kept on file at the FSSC for a minimum of five (5) years.
- 4.15 Report of major adverse incidents
 - 4.15.1 The FSSC must report all major adverse incidents involving a patient to the Department within 48 hours in addition to other reporting requirements required by law.
 - 4.15.2 A major adverse incident includes but is not limited to:
 - 4.15.2.1 Suspected abuse, neglect, mistreatment, financial exploitation, solicitation or harassment of patients;
 - 4.15.2.2 An accident that causes serious injury to a patient;
 - 4.15.2.3 A medication error with the potential to result in adverse health outcomes for the patient;
 - 4.15.2.4 Surgery on the wrong patient or wrong body part; or
 - 4.15.2.5 The unexpected death of a patient.
 - 4.15.3 Major adverse incidents must be investigated by the FSSC.
 - 4.15.4 The FSSC must submit a complete report to the Department within 30 calendar days of the incident.
- 4.16 For those FSSCs that apply for and receive approval to remain open overnight:
 - 4.16.1 Patients admitted to the FSSC will be permitted to stay 23 hours and 59 minutes, starting from the time of admission.
 - 4.16.2 The time calculation begins when the patient is moved from the waiting room to begin the preparation for surgical services.
 - 4.16.3 This time must be documented in the patient's medical record.
 - 4.16.4 The discharge occurs when the physician has signed the discharge order and the patient has left the recovery room.

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5.0 Governing Body

- 5.1 Each FSSC shall have an organized governing body (governing authority, owner or person(s) designated by the owner).
- 5.2 The governing body responsibilities include, but are not limited to:
 - 5.2.1 Appointing a qualified director in writing;
 - 5.2.2 Appointing members of the clinical staff, ensuring their competence and delineating their job responsibilities;
 - 5.2.3 Annual review and evaluation of the FSSC policies and services;
 - 5.2.4 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meetings; and
 - 5.2.5 Adopting governing body and medical staff bylaws for the orderly development and management of the FSSC.

- 5.2.5.1 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.
- 5.3 There shall be a description of each type of service offered.
- 5.4 The governing body shall provide for full disclosure of ownership to the Department.

6.0 Administration/Personnel

- 6.1 Director
 - 6.1.1 There shall be a full-time FSSC director.
 - 6.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the FSSC.
 - 6.1.3 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:
 - 6.1.3.1 Interpretation and execution of the policies adopted by the governing body;
 - 6.1.3.2 Program planning, budgeting, management and program evaluation;
 - 6.1.3.3 Maintenance of the FSSC's compliance with licensure regulations and standards;
 - 6.1.3.4 Preparation and submission of required reports;
 - 6.1.3.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;
 - 6.1.3.6 Documentation of complaints relating to the conduct or actions by employees/contractors/medical staff and action taken secondary to the complaints;
 - 6.1.3.7 Conducting or supervising the resolution of complaints received from patients regarding the delivery of care or services; and
 - 6.1.3.8 Reviewing policies and procedures at least annually, and reporting, in writing, to the governing body on the review.
 - 6.1.4 The director shall designate, in writing, a person who meets the director qualifications to act in the absence of the director.
- 6.2 Supervision of clinical services
 - 6.2.1 The director shall appoint, in writing, a full-time employee as the clinical director.
 - 6.2.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.
 - 6.2.3 The clinical director shall:
 - 6.2.3.1 Be a registered nurse with at least one year of surgical and administrative/supervisory experience;
 - 6.2.3.2 Participate in all activities related to the services provided, including the qualifications of personnel and contractors as related to their assigned duties; and
 - 6.2.3.3 Provide general supervision and direction of the services offered by the FSSC.
 - 6.2.4 The director shall designate, in writing, a person who meets the clinical director qualifications to act in the absence of the clinical director.
- 6.3 Contract services
 - 6.3.1 The FSSC maintains responsibility for all services provided to the patient.
 - 6.3.2 Services provided by the FSSC through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:
 - 6.3.2.1 The services to be provided by the contractor;
 - 6.3.2.2 The necessity to conform to all FSSC policies;
 - 6.3.2.3 The procedure for annual assurance of clinical competence of all individuals utilized under contract;
 - 6.3.2.4 The procedure for supervision of services of the contracted individuals; and
 - 6.3.2.5 A renewal clause or language that states the contract will be renewed annually.
 - 6.3.3 The FSSC must ensure that personnel and services contracted meet the requirements specified in these regulations for FSSC personnel and services.
- 6.4 Written policies
 - 6.4.1 Policy manuals shall be prepared and followed which outline the procedures and practices of the FSSC.
 - 6.4.2 The FSSC shall establish written policies which include, but are not limited to:
 - 6.4.2.1 Compliance with state licensure law;
 - 6.4.2.2 Governing body and management;

- 6.4.2.3 Surgical services;
- 6.4.2.4 Quality assessment and performance improvement;
- 6.4.2.5 Environment;
- 6.4.2.6 Medical staff;
- 6.4.2.7 Nursing services;
- 6.4.2.8 Medical records;
- 6.4.2.9 Pharmaceutical services;
- 6.4.2.10 Laboratory and radiologic services;
- 6.4.2.11 Patient rights;
- 6.4.2.12 Infection control;
- 6.4.2.13 Patient admission, assessment and discharge;
- 6.4.2.14 The handling and documentation of incidents, accidents and medical emergencies;
- 6.4.2.15 The procedure to be followed in the event that the FSSC is not able to provide services scheduled for any particular day or time;
- 6.4.2.16 Reporting of all reportable communicable diseases to the Department; and
- 6.4.2.17 Employment/Personnel. Such policies shall include:
 - 6.4.2.17.1 Qualifications, responsibilities and requirements for each job classification;
 - 6.4.2.17.2 Pre-employment requirements;
 - 6.4.2.17.3 Position descriptions;
 - 6.4.2.17.4 Orientation;
 - 6.4.2.17.5 Inservice education;
 - 6.4.2.17.6 Annual performance review and competency testing; and
 - 6.4.2.17.7 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.

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

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

6.5 Personnel records

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

6.5.2 For all employees/contractors, the FSSC shall maintain current individual personnel records on-site which shall contain at least:

- 6.5.2.1 Written verification of compliance with pre-employment requirements;
- 6.5.2.2 Documentation of clinical competence;
- 6.5.2.3 Evidence of current professional licensure, registration or certification as appropriate;
- 6.5.2.4 Educational preparation and work history;
- 6.5.2.5 Written performance evaluations conducted, at least, annually; and
- 6.5.2.6 A written and signed job description.

6.6 Staff development

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

6.6.2 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:

- 6.6.2.1 Organizational structure of the FSSC;
- 6.6.2.2 Patient care policies and procedures;
- 6.6.2.3 Infection control;
- 6.6.2.4 Philosophy of patient care;
- 6.6.2.5 Patient rights;
- 6.6.2.6 Personnel and administrative policies;
- 6.6.2.7 Job description;
- 6.6.2.8 Disaster preparedness; and
- 6.6.2.9 Applicable state regulations governing the delivery of services.

- 6.6.3 Documentation of orientation must include the date and hours, content, and name and title of the person providing the orientation.
- 6.6.4 It is the responsibility of the FSSC to ensure that employees/contractors are proficient to carry out the assigned care in a safe, effective and efficient manner. Nothing in these regulations is intended to restrict the practice of licensed independent practitioners practicing in accordance with Delaware law.
- 6.6.5 All newly hired employees and contractors must have a written validation of competency upon orientation, prior to providing care to patients, and annually thereafter.
- 6.6.6 Attendance records must be kept for all orientation and continuing education programs.
- 6.7 Medical staff
 - 6.7.1 All persons admitted to the FSSC shall be under the care of a physician.
 - 6.7.2 One (1) or more physicians should be in attendance in the FSSC, or in the case of overnight care, immediately available via electronic communication, at all times during patient treatment and recovery and until patients are medically discharged.
 - 6.7.3 A medical director shall be appointed and shall be responsible for the direction, provision and quality of medical care.
 - 6.7.4 All members of the FSSC's medical staff must be appointed to their position within the FSSC by the governing body.
 - 6.7.5 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 FSSC.
 - 6.7.6 Medical staff privileges must be reappraised by the FSSC at least every 24 months.
 - 6.7.7 If the FSSC assigns patient care responsibilities to licensed independent practitioners other than physicians, it must have:
 - 6.7.7.1 Established credentialing and privileging procedures approved by the governing body; and
 - 6.7.7.2 Policies and procedures, approved by the governing body, for overseeing and evaluating clinical activities.
- 6.8 Nursing services
 - 6.8.1 Nursing services must be under the direction of a clinical director.
 - 6.8.2 There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all FSSC patients are met.
 - 6.8.3 Patient care responsibilities must be delineated for all nursing service personnel.
 - 6.8.4 Nursing services must be provided in accordance with recognized standards of practice.
 - 6.8.5 A registered nurse, qualified by education and experience in operating room nursing, shall be present as a circulating nurse in each operating room where moderate/deep/general anesthesia/sedation is administered during operative procedures.
 - 6.8.6 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.

7.0 General Patient Care Management

- 7.1 The admission policies shall be discussed with each patient entering the FSSC or their representative, if applicable.
- 7.2 The FSSC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must:
 - 7.2.1 Include the timeframe for medical history and physical examination to be completed prior to surgery.
 - 7.2.2 At a minimum, address the following factors:
 - 7.2.2.1 Patient age;
 - 7.2.2.2 Diagnosis;
 - 7.2.2.3 The type and number of procedures scheduled to be performed on the same surgery date;
 - 7.2.2.4 Known comorbidities;
 - 7.2.2.5 Planned anesthesia level; and
 - 7.2.2.6 Be based on nationally recognized standards of practice and guidelines.
- 7.3 Upon admission to the FSSC, each patient must have a pre-surgical assessment completed by the physician or licensed independent practitioner. The patient's medical record must include documentation that the patient was examined prior to the commencement of surgery for changes since the comprehensive medical history and physical assessment.

- 7.4 Surgical procedures must be performed in a safe manner and in accordance with acceptable standards of practice.
- 7.5 Before discharge from the FSSC, each patient must be evaluated by a physician or certified registered nurse anesthetist for proper anesthesia recovery. It is expected that a patient will actually leave the FSSC within 15 – 30 minutes of the time when the physician signs the discharge order.
- 7.6 The FSSC must provide each patient with written discharge instructions and overnight supplies. Patients shall be informed, prior to leaving the FSSC, of their prescriptions, post-operative instructions, and physician contact information for follow-up care. When appropriate, the FSSC shall make a follow-up appointment for the patient with their physician.
- 7.7 The FSSC shall provide nutritional services for patients as follows:
 - 7.7.1 Assure the availability of meals, beverages and supplemental snacks in accordance with each patient's individual needs.
 - 7.7.2 Provide or make arrangements for a minimum of one (1) meal which is of suitable quality and quantity for patients who are in the FSSC 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.
 - 7.7.3 Provide or make arrangements for a minimum of two (2) meals which are of suitable quality and quantity for patients who are in the FSSC 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.
 - 7.7.4 Provide therapeutic diets as necessary in accordance with each patient's individual needs.
 - 7.7.5 Meals prepared on-site must be approved by a dietitian.
 - 7.7.6 All employees/contractors involved in direct patient care shall be trained on basic and special nutritional needs and proper food handling techniques. Training shall be part of the initial orientation and shall be conducted annually thereafter.
 - 7.7.7 Appropriate food containers and utensils shall be available as needed for use by disabled patients.
 - 7.7.8 The provision and consumption of meals and snacks shall be documented in the patient's medical record.
- 7.8 There must be healthcare professionals with specialized training or experience in emergency care including current Advance Cardiac Life Support certification, available in the FSSC to provide emergency treatment at all times when patients are present.

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8.0 Infection Control

- 8.1 The FSSC 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.).
- 8.2 The FSSC must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases.
- 8.3 The FSSC must maintain an ongoing program to prevent, control and investigate infections and communicable diseases. As part of this ongoing program, the FSSC must have an active surveillance component that covers both patients and personnel working in the FSSC. Surveillance includes infection detection through ongoing data collection and analysis.
- 8.4 The FSSC must designate in writing, a qualified licensed healthcare professional who will lead the FSSC's infection control program. The FSSC must determine that the individual has had training in the principles and methods of infection control.
- 8.5 The individual designated to lead the FSSC's infection control program must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the FSSC. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the FSSC's infection control outcomes. The plan should be specific to each particular area of the FSSC, including, but not limited to, the waiting room(s), the recovery room(s) and the surgical areas.
- 8.6 The FSSC'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 FSSC's infection control performance.
- 8.7 Specific Requirements for COVID-19
 - 8.7.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Delaware Division of Public Health Guidance.

- 8.7.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health Guidance.
- 8.7.3 Facilities must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.
- 8.8 The FSSC shall amend their policies and procedures to include:
 - 8.8.1 Work exclusion and return to work protocols for staff tested positive for COVID-19;
 - 8.8.2 Staff refusals to participate in COVID-19 testing;
 - 8.8.3 Staff refusals to authorize release of testing results or vaccination status to the FSSC;
 - 8.8.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and
 - 8.8.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

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9.0 Quality/Performance Improvement Program

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

10.0 Environment

- 10.1 The FSSC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.
- 10.2 Laundry and linens
 - 10.2.1 An adequate supply of clean linen or disposable materials shall be maintained.
 - 10.2.2 Clean linen shall be stored, handled and transported to prevent contamination.
 - 10.2.3 Linens shall be maintained in good repair.
 - 10.2.4 There shall be separate and distinct areas for the storage and handling of clean and soiled linens.
 - 10.2.5 Soiled linen shall be handled, transported, stored and processed in a manner to prevent leakage and the spread of infection.
 - 10.2.6 Soiled linen not processed on a daily basis must be stored in a separate properly ventilated storage area.
 - 10.2.7 Soiled linen must be removed from the operating/procedure room after each procedure.
 - 10.2.8 Carts used to transport soiled linen must be constructed of impervious materials and must be cleaned and disinfected after each use.
 - 10.2.9 Laundry processed on-site:
 - 10.2.9.1 The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.
 - 10.2.9.2 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.
 - 10.2.10 Laundry processed off-site:
 - 10.2.10.1 The FSSC must have a contract with a commercial or hospital laundry.
 - 10.2.10.2 Clean linens returned to the FSSC must be completely wrapped or covered to protect against contamination.
- 10.3 Sanitation and housekeeping
 - 10.3.1 The FSSC shall provide housekeeping services to maintain a clean, sanitary, safe environment which is free from odors.
 - 10.3.2 Operating/procedure rooms shall be thoroughly cleaned after each use.
 - 10.3.3 All cleaning materials, solutions, cleaning compounds and hazardous substances shall be:
 - 10.3.3.1 Properly identified;
 - 10.3.3.2 Stored in a safe place; and
 - 10.3.3.3 Stored separate from patient care items and food.
 - 10.3.4 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the environment.

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

10.4 Waste storage and disposal

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

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

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

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

10.5 Fire safety

10.5.1 The FSSC 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.

10.5.2 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.

10.5.3 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.

11.0 Medical Records

11.1 Medical records must include 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.

11.2 The FSSC 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.

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

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

11.5 There shall be an identified locked area for medical record storage at the FSSC.

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

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

11.8 The FSSC must develop acceptable policies for authentication of any computerized records.

11.9 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.

11.10 Computerized patient records must be printed by the FSSC as requested by authorized representatives of the Department.

11.11 Medical records shall be retained in a retrievable form until destroyed.

11.11.1 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.

11.11.2 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.

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

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

11.11.5 Documentation of record destruction must be maintained by the FSSC.

11.12 The FSSC must maintain compliance with all federal and state laws, regulations and guidelines governing patient privacy and medical records.

12.0 Pharmaceutical Services

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

- 12.2 Drugs must be prepared and administered according to acceptable standards of practice.
- 12.3 The FSSC must designate a specific licensed healthcare professional to provide direction to the FSSC's pharmaceutical service.
- 12.4 Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.
- 12.5 The FSSC must maintain compliance with all federal and state laws, regulations and guidelines governing pharmaceutical services.

13.0 Laboratory and Radiologic Services

- 13.1 FSSCs that perform laboratory services must meet federal and state requirements.
- 13.2 The scope and complexity of radiological services provided within the FSSC, either directly or under arrangement, as an integral part of the FSSC's surgical services shall be specified in writing and approved by the governing body.
- 13.3 FSSCs that provide radiological services must meet professionally approved standards for safety and personnel qualifications.
 - 13.3.1 The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body.
 - 13.3.2 Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations and guidelines governing radiological services.
 - 13.3.3 The FSSC must adopt and implement policies and procedures that provide safety for patients and personnel including but not limited to:
 - 13.3.3.1 Adequate shielding for patients, personnel and surrounding areas;
 - 13.3.3.2 Labeling of radioactive materials, waste and hazardous areas;
 - 13.3.3.3 Transportation of radioactive materials between locations within the FSSC;
 - 13.3.3.4 Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
 - 13.3.3.5 Testing of equipment for radiation hazards;
 - 13.3.3.6 Maintenance of personal radiation monitoring devices;
 - 13.3.3.7 Proper storage of radiation monitoring badges when not in use;
 - 13.3.3.8 Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste; and
 - 13.3.3.9 Methods of identifying pregnant patients.
 - 13.3.4 The FSSC 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 FSSC must ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, guidelines and FSSC policy.
 - 13.3.5 Employees/contractors must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

14.0 Patient Rights

- 14.1 The FSSC 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.
- 14.2 The patient has the right to:
 - 14.2.1 Receive care in a safe setting;
 - 14.2.2 Be fully informed about a treatment or procedure and the expected outcome before it is performed; and
 - 14.2.3 Voice grievances regarding treatment or care that is (or fails to be) furnished;

15.0 Disaster Preparedness

The FSSC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the FSSC 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 FSSC.

16.0 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.

18 DE Reg. 378 (11/01/14)

25 DE Reg. 627 (12/01/21)

26 DE Reg. 31 (07/01/22) (Prop.)