

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

FINAL

ORDER

4405 Free Standing Surgical Centers

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services (“DHSS”) initiated proceedings to adopt amendments to the State of Delaware Regulations governing Free Standing Surgical Centers. The DHSS proceedings to amend the regulations were initiated pursuant to 29 **Delaware Code** Chapter 101 and authority as prescribed by 16 **Delaware Code**, Section 122(3)p.

On July 1, 2014 (Volume 18, Issue 1), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 **Delaware Code** Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by July 31, 2014, after which time the DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying “Summary of Evidence.”

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations governing Free Standing Surgical Centers were published in the *Delaware State News*, the *News Journal* and the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (July 1, 2014 through July 31, 2014). Entities offering written comments included:

- State Senator Karen E. Peterson
- Paula F. Paul, PA-C, Delaware Academy of Physician Assistants (DAPA) Chair, Legislative and Policy Outreach Committee
- Raymond M. Krett, Jr., Administrator/Director of Nursing, First State Surgery Center
- Danielle Glover, MPA, Association of periOperative Registered Nurses (AORN) Legal and Government Affairs Associate
- Nancy Fan, M.D., Medical Society of Delaware, President
- Cheryl Gamble, CRNA MSN, President, Delaware Association of Nurse Anesthetists Co-Chair, DANA Government Affairs Committee
- Jacob A. Good
- AmSurg Corporation, Peter J. Shanley, Esquire, Shanley & Associates, P.A.
- Peter J. Shanley, Esquire, Shanley & Associates, P.A.

Public comments and the DHSS (Agency) responses are as follows:

State Senator Karen E. Peterson

The purpose of this letter is to request an amendment to Section 3.2.1.11 of the proposed regulations for Free Standing Surgical Centers.

Section 3.2.1.11 states: “**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 prior to applying for licensure to the Department.**”

I request that the following language be added:

“The local government shall certify that the proposed use will not conflict with any zoning restrictions, deed restrictions, and will not adversely affect the quality of life in adjacent residential communities. The applicant shall provide proof to the local government that the owners of all properties within 1,000 feet of the FSSC property were notified of the intent to file the application and were provided with the name and address of the local government official responsible for certifying the appropriateness of the use of the property.”

The proposed language will protect residents whose properties abut those of the Free Standing Surgical Center, as in the case of The Landings which is immediately adjacent to the First State Surgery Center. All-night activity in the parking lot (patients leaving, employees coming and going) will be disruptive to the residents whose homes are situated next to the

Center's parking lot. There are numerous other communities in my district that could also be adversely affected by this proposal.

Agency Response: The Agency appreciates and acknowledges these comments. Local governments are best positioned to address quality of life issues within their communities. The Agency will revise the regulation to read "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".

**Paula F. Paul, PA-C, Delaware Academy of Physician Assistants
Chair, Legislative and Policy Outreach Committee**

The Delaware Academy of Physician Assistants (DAPA) is pleased to have the opportunity to comment on the Proposed regulations: 4405 Free Standing Surgery Centers.

DAPA represents the approximately 450 physician assistants in our state. Many of our PA's work in general surgery and surgical subspecialties in both hospitals and free standing surgery centers.

We have 2 specific comments that are detailed below along with the relevant section of the regulations.

We appreciate the opportunity to comment on these regulations. Our comments are as follows:

1. Section 6.7.2 requires that a physician be on call and available to be on-site within 30 minutes. We would suggest that this be revised to require that the physician be available immediately via electronic communications.

Physician assistants have had considerable experience with similar on-site requirements which used to be part of the Medical Practice Act until it was removed in 2012. Time-related onsite requirements are outdated and being removed from most modern legislation and regulations. With the modern developments of telecommunications (and telemedicine) electronic contact is sufficient to deal with emergencies. In the case of a true emergency it is more appropriate to call an ambulance to transfer the patient to the emergency room of the nearest hospital rather than wait 30 minutes.

2. Section 6.7.7 refers to **licensed independent practitioners** but does not define this term. We would suggest that a definition of this term be added to the definitions section of the regulation as follows:

Add to definitions, Section 2.0

"Licensed Independent Practitioners": This term includes physician assistants and advanced practice nurses.

6.6.5 All newly hired employees and contractors must pass a competency evaluation test 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 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 (via electronic communication)]**

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 (needs to be defined)** 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.

Agency Response: The Agency appreciates and acknowledges these comments. Based upon review of current national standards, the Agency will revise 6.7.2 to read "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." In addition, the Agency will define "Licensed Independent Practitioner" as "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**."

**Raymond M. Krett, Jr., Administrator/Director of Nursing
First State Surgery Center**

On behalf of the First State Surgery Center, we appreciate the opportunity to review and provide our comments on the

Proposed Regulations for Free Standing Surgery Centers.

While we agree substantially with the majority of the proposed regulations, there are several that we would like to offer comments, questions and suggestions. This letter serves to provide you with those comments, questions and suggestions as follows:

- 2.0 Definitions – the definition “Director” references the requirement for a degree in a “health related field.” We agree that a degree and experience are necessary, but as the Director often handles business aspects of the center, we suggest that the requirements be expanded to allow individuals with Business Management or Finance Degree. The pertinent section may read “a Baccalaureate degree in health care, business management or finance; ...”

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the definition to read “...1) a Baccalaureate Degree; 2) five (5) years healthcare experience; and 3) one (1) year supervisory experience in a surgical setting.”

- 3.1.5 suggest a clarification as a surgery center routinely schedule more patients during the day than the total number of licensed beds. Suggested language in the second sentence “...The number of admitted patients shall not exceed...” to avoid the unintended consequence of not distinguishing between a scheduled patient and an admitted patient.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the second sentence of 3.1.5 to read “The number of admitted patients shall not exceed the total number of licensed beds.”

- 3.1.7 presents an issue that we also see in the entire 3.4. We believe that the Modification of Ownership and Control re-application requirement is a burdensome process for the centers. The voiding of the current license and the requirement to re-apply as a new center and be required to meet current construction/design standards for routine business decisions controlled by corporate bylaws and contracts, such as the retirement of a physician owner, is overly burdensome. These decisions do not impact the continuity or quality of care.

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another. Therefore, to ensure the provision of quality care in a safe surgical setting, regulation 3.1.7 will remain as written.

- 3.1.8 requires approval for hours of operation. We are unclear on the purpose of this approval requirement. We believe that the center’s leadership should determine the operational hours of the center based on patient needs and an effective business model. We agree with a requirement of notification of changes in operational hours.

Agency Response: The Agency appreciates and acknowledges these comments. The license for a free standing surgical center (FSSC) will be issued for specific hours of operation. If the FSSC chooses to operate beyond the hours specified on the license, the FSSC must notify the Agency and obtain the necessary approvals. The regulation will remain as written.

- 3.2.1.11 & 3.2.2 require local government approval. We are unclear on the purpose of these requirements. Local government regulations, such as zoning and other restrictions, must always be followed. These processes should be concurrent, but one should not be contingent upon the other.

Agency Response: The Agency appreciates and acknowledges these comments. The local government written approval is required by any free standing surgical center (FSSC) wishing to accommodate patient stays of 23 hours and 59 minutes. To clarify, regulation 3.2.1.11 is specific to new FSSC applicants and regulation 3.2.2 is specific to currently licensed (existing) FSSCs; therefore, the regulations will remain as written.

- 3.4 presents an issue that we also saw in 3.1.7 above. We believe that the Modification of Ownership and Control section requires further discussion, review and revision. The proposed MOC’s restrict the natural cycle of any business, such as appointing new partners or the retirement of a partner. These are business decisions, made in accordance with bylaws and contracts, much like any other business and they do not affect quality or continuity of patient care. To require an entire administrative process for natural changes in staffing, ownership, etc, is an unnecessary burden. As proposed, a facility that has been in operation for 10 years that has a Partner retire therefore relinquishing their partnership, would have their license voided, be required to reapply as an initial license and undergo renovations to meet the current construction standards – is this the intent of the proposed regulations?

We question the need/intent of the proposed regulations in regards to the routine business of the facility/corporation. We question why it is significant to the State if a partner moves from a full share to a half share or vice versa, why it is significant if a decision is made to offer a partnership to an individual that would positively impact the facility. We question the intent of this section as it relates to the provision of quality patient care.

Agency Response: The Agency appreciates and acknowledges these comments. The intent of the free standing surgical center (FSSC) regulations is not to restrict the natural cycle of business, but to ensure the provision of quality care in a safe environment. As stated in regulation 3.1.3, FSSC licenses are non-transferable from person to person, entity to entity or from one location to another. The Agency will delete regulations 3.4.5.8 and 3.4.5.9.

- 3.4.1 requires the facility to report any proposed MOC to the department a minimum of 30 calendar days prior to the change. This requirement is inconsistent with the reporting requirement of other licensure and accreditation agencies such as CMS and AAAHC.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency follows a protocol which requires a thirty (30) calendar day notice to ensure the continuity of operations during a modification of ownership and control. Therefore, the regulations will remain as written.

- 3.4.3 & 3.4.4 the proposed list of MOC's voids the current license, requires re-application for licensure, which would be treated as an initial license and requires the facility to meet the current design and construction standards. These requirements are burdensome as well as raise concerns of how a transition period would be handled. Does the facility receive a 'different license' to continue operations or does the facility stop operations since it essentially doesn't have a license?

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another. The Agency follows a protocol to ensure the continuity of operations during the transition. Therefore, the regulations will remain as written.

- 6.8.5 requires two (2) registered nurses, with specialized training or experience in emergency care, including ACLS certification be available at all times when patients are present. We question the requirement for two ACLS nurses when one ACLS nurse has been proven sufficient in Position Statements by a number of Medical and Nursing Associations (AORN, etc). Is the underlying purpose of this requirement to be that there must be two medical professionals at all times, one of which must be a registered nurse with ACLS Certification?

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the regulations to delete 6.8.5 and add "7.7 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." In addition, the definition of healthcare professionals will be added to 2.0 Definitions.

- 7.6.6 proposes significant requirements for nutritional services. We suggest that the dietitian requirement should be removed as this requirement is burdensome to the center. The nursing staff is trained to provide appropriate beverages, snacks and meals to outpatient surgical patients. We believe the state should follow the lead of CMS which has recently removed the need for consultants such as a Radiology Consultant, which was burdensome. Additionally, the annual training requirement for food service can be accomplished efficiently and effectively through internet or a self-study requirement.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise 7.6.6 to read "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."

Danielle Glover, MPA, Association of periOperative Registered Nurses (AORN)

Legal and Government Affairs Associate

AORN represents the interests of 160,000 perioperative registered nurses in the United States and abroad who facilitate the management, teaching, and practice of perioperative nursing, are engaged in perioperative research, are enrolled in nursing education, and perioperative nurses who work in related business and industry sectors. AORN estimates that 40% of its 42,000 perioperative nurse members work in hospital outpatient and free standing ambulatory surgical center environments.

In 2012 AORN submitted comments for proposed revisions to the regulations governing Free Standing Surgical Centers 16 DE Admin. Code 4405 requesting the Delaware Division of Public Health retain its requirement that a qualified registered nurse serve in the role of circulator in Delaware free standing surgical centers or, at the very least, retain its registered nurse circulator requirement for patients undergoing procedures under general anesthesia and moderate and deep sedation.

In the operating room, patients are powerless to make decisions on their own behalf. The registered nurse circulator provides high-quality nursing care through patient assessment, diagnosis, outcome identification, planning, implementation and evaluation. In this role, the registered nurse circulator is often the single advocate for the patient's safety during surgery. No other person is more knowledgeable or qualified to handle the multiple critical issues surrounding patient safety in the operating room than the registered nurse who is specifically trained in perioperative nursing.

AORN is supportive of the proposed rule changes published on July 1, 2014. We appreciate the Delaware Division of Public Health's choice to keep patient safety first and follow best practices by retaining its requirement that a registered nurse be present as a circulating nurse in each operating room where moderate/deep/general anesthesia/sedation is administered during operative procedures.

Agency Response: The Agency appreciates and acknowledges these comments. The regulation will remain as written.

Nancy Fan, M.D., Medical Society of Delaware, President

On behalf of the Medical Society of Delaware, thank you for your work in the crafting of these proposed regulations and for the opportunity to provide comments. We agree substantially with the regulations and look forward to their implementation. In this letter we offer a number of technical amendments and suggestions:

- 2.0 Definitions – the definition of “Clinical Director” requires a “registered nurse” specifically. We agree that the position requires medical expertise, but suggest widening the qualifications to “means a person with a degree in medical or nursing care, currently licensed in their field” to allow for a broader scope of those who may meet the criteria.

Similarly, the definition “Director” references the requirement for a degree in a “health related field.” We agree that a degree and experience are necessary, but as the Director often handles business aspects of a practice and expansion to allow individuals with Business Management or Finance. Suggested pertinent section may read “an advanced degree in health care, business management or finance; ...” This would also allow for physicians to be Directors as they may not have a Baccalaureate in health specifically.

Agency Response: The Agency appreciates and acknowledges these comments. The “Clinical Director” is responsible for the supervision and direction of services, which includes nursing services, offered by the free standing surgical center. Similar to the Centers for Medicare and Medicaid Services regulations for ambulatory surgical centers, nursing services must be under the leadership of a registered nurse; therefore, the definition of “Clinical Director” will remain as written. The Agency will revise the definition of “Director” to read “...1) a Baccalaureate Degree; 2) five (5) years healthcare experience; and 3) one (1) year supervisory experience in a surgical setting.”

- 3.1.5 should be tweaked for clarification purposes. Suggested language in the second sentence “...The number of admitted patients shall not exceed...” to avoid the unintended consequence of not distinguishing between a scheduled patient and those currently in care.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the second sentence of 3.1.5 to read “The number of admitted patients shall not exceed the total number of licensed beds.”

- 3.1.7 presents an issue that we also see in 3.4 which is not allowing for ease of retirement or new hire which is the natural cycle of any business. The process for a Modification of Ownership and Control creates patient care issues where none existed previously. The natural cycle of hires and retirements are business decisions which do not affect the quality or continuity of care and are made in accordance with bylaws much like any other business. Again, patients are not affected by these decisions and to require an entire administrative process for natural changes in staffing, in addition to 3.1.7, particularly 3.4.5.8 and 3.4.5.9, is an unnecessary burden that creates a potential to harm care where none existed previously.

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another; therefore, regulation 3.1.7 will remain as written. The Agency will delete regulations 3.4.5.8 and 3.4.5.9.

- Related, 3.4.1 and 3.4.3 raise concerns of how a transition period is handled if there is a modification. These present potentially huge burdens. The notice requirement may not be possible to comply with in some circumstances. Perhaps a “when practicable” wording modification for notice would be in order. Regarding new licenses upon MOC, this requires the facility to undergo a process that may subject it to all new design and construction standards which are not only costly and burdensome, but affect provision of care.

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another. The Agency follows a protocol which requires a thirty (30) calendar day notice to ensure the continuity of operations during a modification of ownership and control. Therefore, to ensure the provision of quality care in a safe surgical setting, the regulations will remain as written.

- 3.2.1.11 & 3.2.2 require local government approval. We are unclear on the purpose of these requirements. Local government regulations, such as zoning and other restrictions, must always be followed. These processes should be concurrent, but one should not be contingent upon the other.

Agency Response: The Agency appreciates and acknowledges these comments. The local government written approval is required by any free standing surgical center (FSSC) wishing to accommodate patient stays of 23 hours and 59 minutes. To clarify, regulation 3.2.1.11 is specific to new FSSC applicants and regulation 3.2.2 is specific to currently licensed (existing) FSSCs; therefore, the regulations will remain as written.

- 6.8.5 requires two registered nurses where one ACLS Nurse has been proven sufficient by a number of Associations. We suggest that the underlying purpose is met to state that there must be two medical professionals at all times, one of which must be a registered nurse with ACLS training.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the regulations to delete 6.8.5 and add “7.7 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.” In addition, the definition of healthcare professionals will be added to 2.0 Definitions.

7.6.6 requires a dietitian to be available for consultation and requires annual training. We suggest that the dietitian requirement should be lowered to suggested, “shall” replaced with “may.” We believe the state should follow the lead of

CMS which has recently removed the need for consultants such as a Radiology Consultant, which drive up costs. Additionally, the annual training requirement for food service can be accomplished efficiently and effectively through internet or a self-study requirement.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise 7.6.6 to read "All employees/contractors 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."

**Cheryl Gamble, CRNA MSN, President, Delaware Association of Nurse Anesthetists
Co-Chair, DANA Government Affairs Committee**

The Delaware Association of Nurse Anesthetists (DANA) applauds the work of the Department for its efforts in proposing revisions to Regulation 4405- Free Standing Surgical Centers.

DANA is comprised of certified registered nurse anesthetists (CRNAs) who work in hospitals, surgery centers, and office-based practices throughout Delaware and the surrounding area. The organization strives to assure the highest standards of anesthesia care for patients and promotes professionalism among its members. With these goals in mind, DANA expresses its support of the proposed amendments but offers three (3) suggested changes for purposes of clarity:

1. Add clarifying language at the end of Section 2.0.

In section 2.0 following the definition of "Surgery", DANA proposes adding the phrase: "Nothing in this definition is intended to restrict the practice of qualified licensed healthcare professionals practicing in accordance with Delaware law."

DANA suggests adding this language to avoid unintended confusion about the appropriate role of qualified licensed healthcare professionals in Free Standing Surgical Centers. The statute that authorizes this regulation, 16 **Del.C.** §122(3)p, makes it clear that Regulation 4405 shall not expand or limit the scope of practice afforded to professionals under other provisions of Delaware law.

Since the Delaware Code clearly outlines the parameters of practice for all licensed healthcare professionals in their respective practice acts, DANA respectfully submits that adding the proposed language clarifies that the roles of these licensees are not changed simply by virtue of working in Free Standing Surgical Centers. For example, a Certified Registered Nurse Anesthetist (CRNA) is authorized and licensed in Delaware to provide sedation, regional and general anesthesia in the ordinary course of CRNA nursing practice using "needles" and injecting "therapeutic substances" as those terms appear in section 2.0 of the proposed regulations but the broad definition of "Surgery" in that section could be misconstrued to define CRNA practice as surgery which is limited to the practice of medicine.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise 6.6.4 by adding the following sentence, "Nothing in these regulations is intended to restrict the practice of qualified licensed healthcare professionals practicing in accordance with Delaware law."

2. Unify terminology in sections 6.0 and 7.0.

For the sake of clarity DANA suggests choosing one phrase to use throughout the regulation to refer to licensed healthcare professionals who are not physicians. In sections 6.7.7, 7.2, and 7.3 the proposed regulation refers to "licensed independent practitioner", "qualified licensed independent healthcare practitioner", and "qualified licensed healthcare practitioner."

DANA suggests using the phrase "qualified licensed healthcare professional" which is used in other sections of the Delaware Code.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise 6.7.7, 7.2 and 7.3 to consistently use "licensed independent practitioner". In addition, "licensed independent practitioner" has been added to regulation 2.0 Definitions.

3. Add language in section 7.4 to reflect the current standard of care in evaluating a patient for proper recovery from anesthesia.

In accordance with the Centers for Medicare and Medicaid Services¹ and the Delaware law, DANA suggests adding the phrase "or certified registered nurse anesthetist" after the word "physician" to reflect the appropriate standard of care and current practice of evaluating patients for proper recovery from anesthesia.

¹ The Federal Regulations direct that a physician or anesthetist must evaluate a patient for proper anesthesia recovery prior to discharge from an ambulatory surgery center. See 42 CFR 416.42(a) - Standard: Anesthetic Risk and Evaluation (2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will add "or certified registered nurse anesthetist" to 7.4. In addition, "Certified Registered Nurse Anesthetist" was added to regulation 2.0 Definitions.

I am writing to voice my concerns for the proposed rules and regulation changes for the Free Standing Surgical Centers.

I live in, and also am a board member of, a neighborhood that is surrounded by medical office facilities on 3 sides. Some of these facilities have an interest in the proposed Free Standing Surgical Centers. These facilities are within 20 - 30 feet from the office building to the dwelling units of the neighborhood. The parking lots are also in very close proximity to several other homes.

Having patients and visitors at these facilities continuously around the clock would be very disturbing to the residents of the homes and to our community 24 hours a day. The majority of us have purchased our homes well before the medical buildings were built. Our quality of life during the day has diminished since the facilities have been built with excessive noise, car alarms, trespassers, and even medical waste blowing into our yards from the dumpsters. Having a 23 hour and 59 minute surgical facility would mean 24 hours of nuisance noise and further diminishing our quality of life at home.

The Departments proposal for **Section 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 local government having jurisdiction prior to applying for licensure to the Department**, is very vague, and has no guidelines or standards to follow for approval.

Senator Karen Peterson sent the Department another proposal to add to **Section 3.2.1.11** which reads something like:

The local government shall certify that the proposed use will not conflict with any zoning restrictions, deed restrictions, and will not adversely affect the quality of life in adjacent communities.

In addition to Karen's proposal I would also like amend Section 3.2.1.11 to read: **Section 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 local government having jurisdiction prior to applying for licensure to the Department. The local government shall certify that the proposed use will not conflict with any zoning restrictions, deed restrictions, and will not adversely affect the quality of life in adjacent communities. All members residing in communities within 1000 feet of the FSSC shall be notified by the facility of their intent and the facility shall conduct a meeting with the community or communities at a convenient and neutral location. 50% of community's approval shall be required prior to applying for government approval.**

Acceptance of this proposal will certainly assure not only our quality of life is protected, but also of the quality of life for other communities throughout Delaware.

Please notify Senator Karen Peterson and myself of your decision, and if denied, state a reason for denial.

Agency Response: The Agency appreciates and acknowledges these comments. Local governments are best positioned to address quality of life issues within their communities. The Agency will revise the regulation to read "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".

AmSurg Corporation, Peter J. Shanley, Esquire, Shanley & Associates, P.A.

Please accept this correspondence in response to the above referenced proposed Restated Regulation 4405 Free Standing Surgical Centers of Title 16 of the Administrative Code of the State of Delaware. I submit this correspondence on behalf of my client, AmSurg Corp. ("AmSurg").

Background

AmSurg is the largest ambulatory surgery company in United States, with 244 surgery centers in 35 states and the District of Columbia. AmSurg performs over 392,313 procedures per year. A few statistics on the breakdown of services provided by AmSurg facilities nationally:

- 152 of the AmSurg centers are exclusive to gastroenterology ("GI")
- 37 of the AmSurg centers are exclusive to ophthalmology.
- 55 of the centers are multispecialty.

By the end of 2013, over 98 percent (in the United States) of the AmSurg centers were fully accredited by the Joint Commission or the Accreditation Association for Ambulatory Health Care.

In Delaware, AmSurg operates four Free Standing Surgery Centers ("FSSC"), three are GI dedicated and one is multispecialty. The three GI centers offer services in Lewes and Newark and the multispecialty center is located in Dover.

AmSurg is committed to the highest quality, efficiency, access and cost, which is consistently achieved by its medical staffs and administration. Notably, all of the AmSurg facilities in Delaware share significant ownership with physicians, and more importantly, such physician owners are directly involved in overseeing clinical matters and setting care standards.

Comments

The July 1, 2014 Public Notice states that "any person who wishes to make written suggestions, testimony, briefs or other written materials concerning the proposed regulations must submit same to [you] by Thursday, July 31, 2014". On behalf of AmSurg, I would like to state that such Public Notice may be considered technically compliant with the Delaware Administrative Procedures Act, we nevertheless offer a general procedural objection for purpose of reservation

of all available rights. As such, AmSurg reserves the right to challenge the proposed rules on procedural grounds.

Before I give you specific comments on proposed Regulation 4405, I question whether the information in the Public Notice complies with Section 10115(a)(1) of Subchapter II of Chapter 101 of Title 29 of the Delaware Code. I also suggest that the complete restatement of Rule 4405 and the adverse effect this restatement will have on existing licensed FSSCs require that the comment period be extended to Friday, August 29, 2014, and that a public hearing be held on proposed Regulation 4405, at an appropriate time after the end of the comment period.

I will now give you AmSurg's specific concerns in numbered paragraph format for ease of reference.

1. Because proposed Regulation 4405 completely replaces existing Regulation 4405, all existing FSSCs should be grandfathered for ten full calendar years after the effective date of the adoption of Regulation 4405.

Agency Response: The Agency appreciates and acknowledges these comments. The intent of the free standing surgical center (FSSC) regulations is to ensure the FSSC is utilizing current accepted standards of practice. Grandfathering all existing FSSCs for ten (10) full years could potentially delay the FSSC implementation of current accepted standards of practice and would be inconsistent with the Agency's mission.

2. Existing Delaware law provides that free-standing diagnostic endoscopy facilities and pain management centers are exempt from Delaware licensure otherwise applicable to FSSCs. The definition of "Surgery" in Section 2.0 of proposed Regulation 4405 arguably includes GI procedures and pain management services. Both specialties should be expressly excluded from the definition of Surgery. These exclusions should also be included in the definition of FSSC.

Agency Response: The Agency appreciates and acknowledges these comments. The existing law does not exempt free standing diagnostic endoscopy facilities and pain management centers from state licensure. A Delaware Attorney General's interpretation, issued on January 12, 1995, exempted single specialty diagnostic endoscopy and pain management centers from licensure as a free standing surgical center. Therefore, the regulations will remain as written.

3. In Section 2.0 of proposed Regulation 4405, the term "Director" is defined as an individual appointed by the governing body to act on its behalf in the overall management of the facility and the Director shall have: 1) a Baccalaureate Degree in a health related field; 2) five (5) years healthcare experience; and 3) one (1) year supervisory experience in a surgical setting. In existing Regulation 4405, the concept of "Director" is found in Section 2.1 where the reference is to "Chief Executive Officer". There is no reference in Section 2.1 that the CEO must have a Baccalaureate Degree in a health related field. Many FSSCs have CEOs that do not have a Baccalaureate Degree in a health related field. If the proposed Regulation 4405 is adopted as written, will the fact that many of the CEOs do not meet the definition of "Director" mean that the FSSCs would lose their licenses? We recommend that the second sentence of this definition be modified to read: "The director shall have education and experience sufficient to oversee the administrative and clinical responsibilities of the FSSC as determined by the Governing Body."

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has revised the definition of "Director" to read "...1) a Baccalaureate Degree; 2) five (5) years healthcare experience; and 3) one (1) year supervisory experience in a surgical setting." The Agency will not apply this regulation to directors appointed prior to the effective date of this regulation. Directors appointed on or after the effective date of this regulation must comply with the new standards.

4. Section 3.1.7 requires that any FSSC that undergoes a modification or ownership re-apply for licensure meeting new design and construction standards. We recommend that this Section be revised to state: "Any FSSC that undergoes a modification of ownership and control is required to notify the State of that new ownership."

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another. Therefore, to ensure the provision of quality care in a safe surgical setting, regulation 3.1.7 will remain as written.

5. Section 3.4 of proposed Regulation 4405 covers the modification of ownership and control ("MOC"). Ownership is covered in Section 2.4 of existing Regulation 4405. If there is a change in ownership under the existing Regulation, the change must be reported to the Office of Health Facilities Licensing and Certification in writing immediately prior to or after the change. In Section 3.4.3 of proposed Regulation 4405, a MOC voids the current license and possession of the facility. This provision in effect makes it difficult for an Owner of a FSSC to transfer ownership because to do so will cancel the facility's license and subject the new owner and the facility to the then applicable licensing requirements pursuant to Section 3.4.4. We recommend that Sections 3.4.3 and 3.4.4 be deleted.

Agency Response: The Agency appreciates and acknowledges these comments. As stated in regulation 3.1.3, free standing surgical center (FSSC) licenses are non-transferable from person to person, entity to entity or from one location to another. Therefore, the regulations will remain as written.

6. Existing Regulation 4405 provides for the appointment of a CEO, a Medical Director and a Director of Nursing. Proposed Regulation 4405 requires the appointment of a Director (Section 6.1.1), a Clinical Director (Section 6.2.1) and a Medical Director (Section 6.7.3). Presumably, the term Clinical Director in Section 6.2.1 of proposed Regulation 4405 is designed to replace the position of the Director of Nursing in existing Regulation

4405. In Section 6.2.3.1, the Clinical Director must be a registered nurse with at least one year of surgical and administrative/supervisory experience. Section 7.1 in existing Regulation 4405 provides that the Director of Nursing must currently be licensed by the State of Delaware as a professional registered nurse. The requirement that the Clinical Director have at least one year of surgical and administrative/supervisory experience may mean that a number of Directors of Nursing may not qualify for the position of Clinical Director under proposed Regulation 4405. In many FSSCs, the position of Director and Clinical Director under proposed Regulation 4405 and the position of CEO and Director of Nursing under existing Regulation 4405 would be held by the same individual, i.e. a registered nurse. In those circumstances under proposed Regulation 4405, it is doubtful that the same person could be both the Director and the Clinical Director unless proposed Section 6.2.3 is modified to make it clear that a nurse licensed in Delaware as a professional registered nurse meets the requirement that the Director have a baccalaureate degree in health (Definition of Director). In addition, the requirement that the Clinical Director have at least one year of surgical experience may exclude endoscopy and other nurses from acting as a Clinical Director. The requirement that the Clinical Director have one year of surgical and administrative/supervisory experience may also prevent in many cases FSSCs from promoting within. We recommend that Section 6.2.3.1 be modified to delete the words "with at least one year of surgical and administrative/supervisory experience."

Agency Response: The Agency appreciates and acknowledges these comments. The Clinical Director of a FSSC must have surgical and administrative/supervisory experience to ensure the provision of quality care in a safe setting. Therefore, the regulation will remain as written.

7. Section 6.6.5 in proposed Regulation 4405 requires that all newly hired employees and contractors must pass a competency evaluation test prior to providing care to patients and annually thereafter. Proposed Regulation 4405 does not provide any material guidance relating to the criteria for a "competency evaluation test". We suggest that the language be modified to state that "all newly hired employees and contractors must have a written validation of competency upon orientation, prior to providing care to patients, and annually thereafter."

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise 6.6.5 to read "All newly hired employees and contractors must have a written validation of competency upon orientation, prior to providing care to patients, and annually thereafter."

8. Section 6.8.5 provides that there must be two registered nurses with specialized training or experience in emergency care, including Advanced Cardiac Life Support Certification, available in the FSSC to provide emergency treatment whenever there is a patient in the facility. If in fact every FSSC must have two qualified registered nurses in the facility when patients are present, most Delaware licensed FSSCs will not qualify. We suggest that Section 6.8.5 be modified to provide that there be two (2) clinical staff, one of which must have specialized training or experience in emergency care, including ACLS certificate, available in the FSSC to provide emergency treatment at all times when patients are present.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will revise the regulations to delete 6.8.5 and add "7.7 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." In addition, the definition of healthcare professionals will be added to 2.0 Definitions.

9. Section 6.8.6 in the proposed Regulation 4405 requires that there be a registered nurse, qualified by education and experience in operating room nursing, be present as a circulating nurse in each operating room where moderate/deep/general anesthesia/sedation is administered during operative procedures. We suggest that Section 6.8.6 be reworded to state: "A registered nurse or CRNA qualified by education and experience, be present in each operating or procedure room where moderate/general anesthesia/sedation is administered."

Agency Response: The Agency appreciates and acknowledges these comments. In accordance with nationally recognized standards of practice, one registered nurse circulator should be dedicated to each patient undergoing an operative procedure and be present for the duration of the intraoperative experience. Therefore, the regulation will remain as written.

10. Section 4.5.4 in existing Regulation 4405 provides that each patient's medical record must contain a medical history and physical examination completed prior to surgery. Proposed Regulation 4405 in Section 7.2 substantially expands what must be in the patient's medical record prior to the date of the scheduled surgery. This Section refers to the term "comprehensive medical history and physical assessment" and provides that it must include at a minimum physical assessments relating to vital signs, head and neck, heart and lungs, abdomen, rectal/pelvic (as appropriate), extremities, neurological, and other pertinent physical findings. We suggest that the Regulation be modified to reflect the fact that in many cases, all these physical assessments are not appropriate.

Agency Response: The Agency appreciates and acknowledges these comments. The comprehensive medical history and physical assessment is used to determine if there is anything in the patient's overall condition that requires additional intervention to reduce risks or to indicate that the free standing surgical center may not be the appropriate setting for the

patient's surgery. Therefore, the regulation will remain as written.

11. Section 11.11.4 provides that each FSSC must establish procedures for the notification to patients regarding the pending destruction of medical records. This is not currently a CMS requirement. To attempt to notify every patient of the destruction of medical records would be overly burdensome on FSSCs. We request that Section 11.11.4 be deleted.

Agency Response: The Agency appreciates and acknowledges these comments. The intent of the regulation is for the free standing surgical center (FSSC) to establish a procedure to notify patients of the pending destruction of medical records. The regulation does not specify the method each FSSC must utilize to comply with this regulation. Therefore, the regulation will remain as written.

12. Section 12.4 of proposed Regulation 4405 provides that orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician within 48 hours. We do not feel that the 48 hours requirement is realistic because it does not take into account weekends/holidays/etc. We suggest that the reference to "within 48 hours" be deleted.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency will remove "within 48 hours" from regulation 12.4.

13. Sections 4.2 through 4.5 incorporate in Regulation 4405 five separate Federal regulations. Specifically, Section 4.2 adopts Part 416, Subparts A, B and C found in 42 CFR Ch. IV. This Regulation is 11 pages in length and applies to ambulatory surgical services.

Section 4.3 incorporates the 2012 National Fire Protection Association's Life Safety Code. This Code is outlined in 43 separate Chapters.

Section 4.4 incorporates the provisions issues by the Centers for Disease Control relating to the transmission of Mycobacterium tuberculosis. These Guidelines are found in a 107 page publication dated December 30, 2005.

Section 4.5 adopts the 2014 Facility Guidelines for Design and Construction of Health Care Facilities. These Guidelines are stated in 397 pages of documentation.

It is not possible for any person to understand the effect of incorporating these provisions in Regulation 4405 within 30 days. Therefore, I request that Sections 4.2 through 4.5 be deleted. If appropriate after public review, they can be added at a later date.

Agency Response: The Agency appreciates and acknowledges these comments. The purpose of the free standing surgical center regulations is to ensure the provision of quality care in a safe surgical setting. Compliance with the specified regulations and standards is required to ensure the provision of quality care in safe surgical setting; therefore, the regulation will remain as written.

Conclusion

Existing Regulation 4405 and any modification thereof should have a positive impact on the delivery of care in Delaware FSSCs. We suggest that overall proposed Regulation 4405 does not meet this criteria and will create unintended consequences. The proposed Regulation does not adequately recognize that certain FSSCs are specialized, particularly GI, ophthalmology and pain management, and that certain provisions in the proposed Regulation are not based on a discernible and rational purpose regarding currently licensed and specialized FSSCs with a consistent track record of good outcomes.

We are also concerned that the Division will incur additional costs of implementation at a time when budget cuts are a regular occurrence among Delaware agencies, particularly in light of the apparent lack of a correlation between the proposed rules and increased quality and efficiency.

We are requesting that the Division of Public Health:

1. Tailor the proposed Regulation to remove or modify the objectionable provisions as noted above;
2. Grandfather existing operational and specialized facilities from the Regulation as discussed above;
3. Rescind or delay the implementation of the proposed Regulation in order to weigh the potential implementation time and costs that will be incurred by both the Division and FSSCs, and whether such implementation will improve quality and increase efficiency among providers; and
4. Delete Sections 4.2 through 4.5.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has evaluated and responded to each comment received during the public comment period. The proposed free standing surgical center regulations incorporate updated standards and guidelines. As of the effective date of these regulations, the Delaware Attorney General's interpretation, issued on January 12, 1995, which exempted single specialty diagnostic endoscopy and pain management centers from licensure as a free standing surgical center is still in effect. Therefore, the Agency will proceed with finalizing the regulations with the non-substantive revisions.

Peter J. Shanley, Esquire, Shanley & Associates, P.A.

Today I sent you a detailed letter discussing proposed restated Regulation 4405- Free Standing Surgical Centers. This letter was submitted to you on behalf of my client, AmSurg Corporation.

In comment 2, I state that existing Delaware law provides that free standing diagnostic endoscopy facilities and pain

management centers are exempt from Delaware Licensure requirement otherwise applicable to FSSCs and comment 2 requests that the definition of "surgery" should be modified in Section 2.0 of proposed Regulation 4405 to expressly exclude both specialties from the definition of "surgery".

The purpose of this letter is to expand on my comment that existing Delaware law exempts endoscopy facilities and pain management centers from Delaware Licensure regulations.

Enclosed is a copy of a July 16, 2009 letter to a redacted ASC that provides pain management procedures. Mary Peterson, Director of the Office of Health Facilities, Licensing and Certification specifically states that pain management centers are excluded from State Licensure in Delaware, Ms. Peterson refers to the enclosed Delaware Attorney General interpretation dated January 12, 1995 that specifically states that pain management and endoscopy centers are excluded from Delaware Licensure requirements because these services do not constitute surgery under Delaware law.

Clearly, proposed Regulation 4405 should exclude these FSSCs as required by Delaware law.

Agency Response: The Agency appreciates and acknowledges these comments. The existing law does not exempt free standing diagnostic endoscopy facilities and pain management centers from state licensure. A Delaware Attorney General's interpretation, issued on January 12, 1995, exempted single specialty diagnostic endoscopy and pain management centers from licensure as a free standing surgical center. Therefore, the regulations will remain as written.

The public comment period was open from July 1, 2014 through July 31, 2014. Minor amendments were made to the proposed regulations based on public comment; these amendments are not substantive in nature. Additionally, some grammatical amendments were made to the proposed regulations. The regulations have been reviewed by the Delaware Attorney General's office and approved by the Cabinet Secretary of DHSS.

FINDINGS OF FACT:

Minor amendments were made to the proposed regulations based on public comment; these amendments are not substantive in nature. Additionally, some grammatical amendments were made to the proposed regulations. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations governing Free Standing Surgical Centers are adopted and shall become effective November 11, 2014, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

4405 Free Standing Surgical Centers

4.0 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 completed 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 GSA 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:
 - 15.5.1 At least two (2) exhaust outlets shall be provided in each operating room, not less than four (4) inches above the floor.
 - 15.5.2 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 care 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 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.

"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 ~~in a health related field~~; 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 Probationary license:
 - 3.3.1.1 A probationary 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 A probationary 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 A probationary 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 License:

- 3.3.3.1 A 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 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, 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 A 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 to a new owner;
 - 3.4.5.3 Transfer of the majority interest to a new owner;
 - 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 One partnership is replaced by another through the removal, addition, or substitution of a partner;~~
 - ~~3.4.5.9 Removal of the general partner, or general partners, if the FSSC is owned by a limited partnership;~~

3.4.5.[408] 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.[449] The consolidation of a corporate FSSC owner with one or more corporations.

3.4.5.[4210] 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.

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 (October 2013 Edition), 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 2012 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, 2005, 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 2014 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 (May 2014 version), 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 (November 2013 version), 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.

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 ~~[pass a competency evaluation test]~~ 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 ~~[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]~~ 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 There must be two (2) registered nurses, with specialized training or experience in emergency care, including current Advanced Cardiac Life Support certification, available in the FSSC to provide emergency treatment at all times when patients are present.]~~
- 6.8.~~65~~ 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.~~76~~ 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 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 FSSC 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 FSSC. The comprehensive medical history and physical assessment must include at a minimum:

7.2.1 Medical history:

7.2.1.1 Chief complaint;

7.2.1.2 History of present illness;

7.2.1.3 Past medical and surgical history;

7.2.1.4 Allergies;

7.2.1.5 Medications; and

7.2.1.6 Psychosocial assessment.

7.2.2 Physical assessment: and

7.2.2.1 Vital signs;

7.2.2.2 Head and neck;

7.2.2.3 Heart and lungs;

7.2.2.4 Abdomen;

7.2.2.5 Rectal/pelvic (as appropriate for the type of surgery being performed);

7.2.2.6 Extremities;

7.2.2.7 Neurological; and

7.2.2.8 Other pertinent physical findings.

7.2.3 Diagnosis and impression.

7.3 Upon admission to the FSSC, each patient must have a pre-surgical assessment completed by the physician or ~~other qualified~~ licensed ~~healthcare 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 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.

7.5 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.

7.6 The FSSC shall provide nutritional services for patients as follows:

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

7.6.2 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.

7.6.3 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.

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

7.6.5 Meals prepared on-site must be approved by a dietitian.

7.6.6 ~~[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. 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.]~~

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

7.6.8 The provision and consumption of meals and snacks shall be documented in the patient's medical record.

[7.7 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.]

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.

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 [within 48 hours].

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) (Final)