DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) <u>Heading of the Part</u>: Ambulatory Surgical Treatment Center Licensing Requirements
- 2) <u>Code Citation</u>: 77 Ill. Adm. Code 205
- 3) <u>Section Numbers</u>: <u>Proposed Actions</u>: 205.110 Amendment 205.118 Amendment 205.530 Amendment 205.710 Amendment
- 4) <u>Statutory Authority</u>: Ambulatory Surgical Treatment Center Act [210 ILCS 5]
- 5) <u>A Complete Description of the Subjects and Issues Involved</u>: The Ambulatory Surgical Treatment Center Licensing Requirements are being amended to implement language from Public Act 98-1123, which amended the definition for ASTCs and added a requirement for compliance with federal rules as a prerequisite for certification. Other amendments include adding change of ownership requirements that are similar to those in the Hospital Licensing Requirements, clarifying the requirements for the examination of removed tissues, and other technical changes.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) <u>Published studies or reports, and sources of underlying data, used to compose this</u> <u>rulemaking</u>: None
- 7) <u>Will this rulemaking replace any emergency rulemaking currently in effect</u>? No
- 8) <u>Does this rulemaking contain an automatic repeal date</u>? No
- 9) <u>Does this rulemaking contain incorporations by reference</u>? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) <u>Statement of Statewide Policy Objectives</u>: This rulemaking does not create a state mandate.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

12) <u>Time, Place and Manner in which interested persons may comment on this proposed</u> <u>rulemaking</u>: Interested persons may present their comments concerning this rulemaking within 45 days after this issue of the *Illinois Register* to:

> Elizabeth Paton Assistant General Counsel Department of Public Health Division of Legal Services 535 W. Jefferson St., 5th Floor Springfield, Illinois 62761

> (217)782-2043 e-mail: <u>dph.rules@illinois.gov</u>

- 13) Initial Regulatory Flexibility Analysis:
 - A) <u>Types of small businesses, small municipalities and not for profit corporations</u> <u>affected</u>: Ambulatory Surgical Treatment Centers
 - B) <u>Reporting, bookkeeping or other procedures required for compliance</u>: Facilities will be required to remain in compliance with federal requirements.
 - C) <u>Types of professional skills necessary for compliance</u>: None
- 14) <u>Regulatory Agenda on which this rulemaking was summarized</u>: This rule was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not known when the most recent Regulatory Agenda was drafted.

The full text of the Proposed Amendments begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH CHAPTER I: DEPARTMENT OF PUBLIC HEALTH SUBCHAPTER b: HOSPITAL AND AMBULATORY CARE FACILITIES

PART 205

AMBULATORY SURGICAL TREATMENT CENTER LICENSING REQUIREMENTS

SUBPART A: GENERAL PROVISIONS

Section

- 205.110 Definitions
- 205.115 Incorporated and Referenced Materials
- 205.118 Conditions of Licensure
- 205.120 Application for Initial Licensure
- 205.125 Application for License Renewal
- 205.130 Approval of Surgical Procedures
- 205.135 Diagnostic Cardiac Catheterization Procedures

SUBPART B: OWNERSHIP AND MANAGEMENT

Section

- 205.210 Ownership, Control and Management
- 205.220 Organizational Plan
- 205.230 Standards of Professional Work
- 205.240 Policies and Procedures Manual

SUBPART C: PERSONNEL

| Section | |
|---------|--|
| | |

- 205.310 Personnel Policies
- 205.320 Presence of Qualified Physician
- 205.330 Nursing Personnel
- 205.340 Basic Life Support
- 205.350 Laboratory Services

SUBPART D: EQUIPMENT, SUPPLIES, AND FACILITY MAINTENANCE

Section 205.410

| 205.410 | Equipment |
|---------|-----------|
| 0 - 100 | a |

205.420 Sanitary Facility

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

SUBPART E: GENERAL PATIENT CARE

Section

- 205.510 Disaster Preparedness
- 205.520 Preoperative Care
- 205.530 Operative Care
- 205.540 Postoperative Care
- 205.550 Infection Control

SUBPART F: RECORDS AND REPORTS

Section

- 205.610 Clinical Records and Reports
- 205.620 Statistical Data

SUBPART G: LIMITED PROCEDURE SPECIALTY CENTERS

Section

- 205.710 Pregnancy Termination Specialty Centers
- 205.720 Personnel (Repealed)
- 205.730 General Patient Care (Repealed)
- 205.740 Preoperative Requirements (Repealed)
- 205.750 Postoperative Requirements (Repealed)
- 205.760 Reports (Repealed)

SUBPART H: LICENSURE PROCEDURES

Section

- 205.810 Complaints
- 205.820 Notice of Violation
- 205.830 Plan of Correction
- 205.840 Adverse Licensure Action
- 205.850 Fines and Penalties
- 205.860 Hearings

SUBPART I: BUILDING DESIGN, CONSTRUCTION STANDARDS, AND PHYSICAL REQUIREMENTS

Section

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 205.1310 Plant and Service Requirements
- 205.1320 General Considerations
- 205.1330 New Construction, Additions and Major Alterations
- 205.1340 Minor Alterations and Remodeling Changes
- 205.1350 Administration Department and Public Areas
- 205.1360 Clinical Facilities
- 205.1370 Support Service Areas
- 205.1380 Diagnostic Facilities
- 205.1390 Other Building Services
- 205.1400 Details and Finishes
- 205.1410 Construction, Including Fire-Resistive Requirements, and Life Safety

SUBPART J: MECHANICAL

Section

- 205.1510 General
- 205.1520 Thermal and Acoustical Insulation
- 205.1530 Steam and Hot Water Systems
- 205.1540 Air Conditioning, Heating and Ventilating Systems

SUBPART K: PLUMBING AND OTHER PIPING SYSTEMS

Section

- 205.1610 General
- 205.1620 Plumbing Fixtures
- 205.1630 Water System
- 205.1640 Drainage Systems
- 205.1650 Identification

SUBPART L: ELECTRICAL

Section

- 205.1710 General
- 205.1720 Switchboards and Power Panels
- 205.1730 Panelboards
- 205.1740 Lighting
- 205.1750 Receptacles (Convenience Outlets)
- 205.1760 Grounding
- 205.1770 Equipment Installation in Special Areas
- 205.1780 Emergency Electric Service

NOTICE OF PROPOSED AMENDMENTS

205.1790 Fire Alarm System

205.TABLE A General Pressure Relationships and Ventilation Rates of Ambulatory Surgery Area

AUTHORITY: Implementing and authorized by the Ambulatory Surgical Treatment Center Act [210 ILCS 5].

SOURCE: Amended July 18, 1974; emergency amendment at 3 Ill. Reg. 10, p. 43, effective February 23, 1979, for a maximum of 150 days; amended at 3 Ill. Reg. 30, p. 371, effective July 23, 1979; amended at 5 Ill. Reg. 12756, effective November 4, 1981; amended at 6 Ill. Reg. 6220, 6225, and 6226, effective May 17, 1982; amended at 6 Ill. Reg. 10974, effective August 30, 1982; amended at 6 Ill. Reg. 13337, effective October 20, 1982; amended at 7 Ill. Reg. 7640, effective June 14, 1983; codified at 8 Ill. Reg. 9367; amended at 9 Ill. Reg. 12014, effective July 23, 1985; amended at 10 Ill. Reg. 8806, effective June 1, 1986; amended at 10 Ill. Reg. 21906, effective January 15, 1987; amended at 11 Ill. Reg. 14786, effective October 1, 1987; amended at 12 Ill. Reg. 3743, effective February 15, 1988; amended at 12 Ill. Reg. 15573, effective October 1, 1988; amended at 13 Ill. Reg. 16025, effective November 1, 1989; emergency amendment at 14 Ill. Reg. 5596, effective March 26, 1990, for a maximum of 150 days; amended at 14 Ill. Reg. 13802, effective August 15, 1990; amended at 15 Ill. Reg. 17770, effective December 1, 1991; amended at 17 Ill. Reg. 3507, effective March 3, 1993; amended at 18 Ill. Reg. 11939, effective July 22, 1994; amended at 18 Ill. Reg. 17250, effective December 1, 1994; amended at 22 Ill. Reg. 9335, effective May 20, 1998; amended at 22 Ill. Reg. 22019, effective December 4, 1998; amended at 24 Ill. Reg. 2691, effective February 18, 2000; amended at 25 Ill. Reg. 7471, effective May 31, 2001; amended at 26 Ill. Reg. 16556, effective October 25, 2002; amended at 27 Ill. Reg. 13457, effective July 25, 2003; amended at 31 Ill. Reg. 7278, effective May 7, 2007; amended at 32 Ill. Reg. 14326, effective August 12, 2008; amended at 33 Ill. Reg. 13395, effective September 10, 2009; amended at 34 Ill. Reg. 7915, effective May 25, 2010; amended at 38 Ill. Reg. 19208, effective September 9, 2014; expedited correction at 39 Ill. Reg. 5519, effective September 9, 2014; amended at 40 Ill. Reg., effective

SUBPART A: GENERAL PROVISIONS

Section 205.110 Definitions

"Act" means the Ambulatory Surgical Treatment Center Act.

"Ambulatory Surgical Center" shall have the meaning ascribed to it in 42 CFR 416.

NOTICE OF PROPOSED AMENDMENTS

"Ambulatory Surgical Treatment Center"

The term "Ambulatory Surgical Treatment Center" or "ASTC" or "facility", for the purposes of this Part, includes:

Any institution or building devoted primarily to the maintenance and operation of facilities for the performance of surgical procedures, and any place that meets and complies with the definition of an ambulatory surgical treatment center under the Act and this Part, as evidenced by use of the facilities by physicians, podiatrists or dentists in the performance of surgical procedures that constitutes more than 50 percent of the activities at that location.

Any place, located within an institution or building, such as a surgical suite or an operating room with related facilities in a physician's office or group practice clinic, devoted primarily to the *performance of surgical procedures.* This provision shall apply regardless of whether or not the institution or building in which the place is located is devoted primarily to the maintenance and operation of facilities for the performance of surgical procedures. This provision shall include any place that meets the definition of an ambulatory surgical center under the rules of the federal Centers for Medicare & Medicaid Services. However, when a place is located within, and operated in conjunction with, the offices of a single physician, podiatrist, or dentist, or a group of physicians, podiatrists, or dentists, it shall not be considered an ambulatory surgical treatment center unless: it meets the definition of and has expressed an intent to apply for certification as an ambulatory surgical center under the rules of the federal Centers for Medicare & Medicaid Services; or it is used by physicians, podiatrists, or dentists who are not part of the practice; or it is utilized by the physicians or podiatrists for surgical procedures that constitute more than 50 percent of the activities at that location.

The term "Ambulatory Surgical Treatment Center", for the purposes of this Part, does not include:

Hospitals: Any institution, place, building or agency required to be licensed pursuant to the Hospital Licensing Act.

NOTICE OF PROPOSED AMENDMENTS

Long-Term Care Facilities: Any person or institution required to be licensed pursuant to the Nursing Home Care Act, the Specialized Mental Health Rehabilitation Act of 2013, or the ID/DD Community Care Act.

State Facilities: Hospitals or ambulatory surgical treatment centers maintained by the State or any Department or agency thereof, where such department or agency has authority under law to establish and enforce standards for the hospitals or ambulatory surgical treatment centers under its management and control.

Federal Facilities: *Hospitals or ambulatory surgical treatment centers maintained by the federal government or agencies thereof.*

Dental Surgery Facilities: Any place, agency, clinic, or practice, public or private, whether organized for profit or not, devoted exclusively to the performance of dental or oral surgical procedures. (Section 3(A) of the Act)

"Certified Registered Nurse Anesthetist" means a registered professional nurse who has been certified as a nurse anesthetist by the American Association of Nurse Anesthetists.

"Credentials Committee" means the qualified consulting committee, or another committee designated by the qualified consulting committee, that appraises and reviews physician credentials.

"Department" means the Department of Public Health of the State of Illinois. (Section 3(C) of the Act)

"Hospital" shall have the meaning ascribed to it in the Hospital Licensing Act.

"Licensed Practical Nurse" means a person licensed under the Nurse Practice Act to practice practical nursing.

"Overnight Stay" means the expected duration of services exceeds 24 hours following an admission.

"Qualified Anesthesiologist" means a physician who is licensed to practice

NOTICE OF PROPOSED AMENDMENTS

medicine in all its branches in the State of Illinois and who is a Diplomate of the American Board of Anesthesiology; or American College of Anesthesiology; or who is a Diplomate of the American Osteopathic Board of Anesthesiology; or who is Board eligible or possesses training and experience equivalent to that eligibility; or who possesses training and experience acceptable to the Department and whose primary practice is anesthesiology.

"Qualified Consulting Committee" means a committee whose members are qualified surgeons, obstetricians, gynecologists, anesthesiologists or pathologists or other consulting physicians consisting of not fewer than three members who shall establish the required standards commensurate with the size, scope, extent and complexity of service programs and procedures for which the facility is licensed. The qualified consulting committee or other committee designated by the qualified consulting committee shall act as the credentials committee.

"Qualified Consulting Surgeon, Obstetrician, Gynecologist, Anesthesiologist, Pathologist, or other Consulting Physician" means a physician who is licensed in the State of Illinois and who is a Diplomate of an appropriate specialty board or who has completed the training and experience required for specialty board certification.

"Qualified Dentist" means a dentist who is licensed to practice under the Illinois Dental Practice Act.

"Qualified Infection Control Professional" means an individual who either has training, education and experience or has certification in the principles and methods of infection control. The individual shall maintain his or her qualifications through ongoing education and training.

"Qualified Physician" means an individual who is licensed to practice medicine in all its branches in the State of Illinois under the Medical Practice Act of 1987.

"Qualified Podiatrist" means a podiatrist who is licensed to practice under the Podiatric Medical Practice Act of 1987.

"Qualified Practitioner" means a licensed practitioner who is authorized within his or her scope of practice to perform a history and physical examination and who is authorized by the ASTC to conduct a history and physical examination. This may include nurse practitioners and physician assistants.

NOTICE OF PROPOSED AMENDMENTS

"Registered Professional Nurse" means a registered nurse or a registered professional nurse who is licensed under the Nurse Practice Act and practices professional nursing.

"Student Nurse" means a person enrolled in a course of instruction at an approved school of professional or practical nursing and who is supervised by a nursing instructor of the school.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 205.118 Conditions of Licensure

- a) No person shall open, conduct or maintain an ambulatory surgical treatment center without first obtaining a license from the Department. (Section 4 of the Act)
 - 1) A person or facility not licensed under the Act or the Hospital Licensing Act shall not hold itself out to the public as a "surgery center" or as a "center for surgery". (Section 6 of the Act)
 - 2) Any person opening, conducting or maintaining an ambulatory surgical treatment center without a license issued pursuant to the Act shall be guilty of a business offense punishable by a fine of \$10,000 and each day's violation shall constitute a separate offense.
 - 3) Any person opening, conducting or maintaining an ambulatory surgical treatment center who violates any other provision of the Act shall be guilty of a business offense punishable by a fine of not more than \$10,000. (Section 12 of the Act)
 - 4) The operation or maintenance of an ambulatory surgical treatment center in violation of the Act or this Part is declared a public nuisance inimical to the public welfare. The Director of the Department, in the name of the People of the State, through the Attorney General or the State's Attorney of the county in which the violation occurs, may, in addition to other remedies provided in the Act, bring action for an injunction to restrain such violation or to enjoin the future operation or maintenance of any such ambulatory surgical treatment center. (Section 13 of the Act)
- b) The applicant shall file a statement of ownership as provided in Section

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

205.120(b)(1). The applicant shall agree to update the information required in the statement of ownership every six months from the initial date of filing. (Section 7a of the Act)

- c) Financial Statements
 - 1) *Financial statements shall be filed* annually on or before April 1 of each year for the previous calendar year, or within three months after the close of the fiscal period of the licensee.
 - 2) *Financial statements shall be filed with the Department* on forms provided by the Department or on annual financial statements prepared on forms used by the applicant or licensee. They shall include at least the following items: detailed balance sheets, statements of income, and statements of expense. (Section 7b of the Act)
- cd) Every facility licensed under the Act, and any premises proposed to be conducted as a facility by an applicant for a license, shall be open during its regular business hours to an inspection authorized in writing by the Director. No notice need be given to any person prior to any inspection. (Section 9 of the Act)
- <u>d</u>e) Any corporation operating an ambulatory surgical treatment center devoted primarily to providing facilities for abortion must have a physician who is licensed to practice medicine in all of its branches and is actively engaged in the practice of medicine at the ambulatory surgical treatment center, on the Board of Directors as a condition to licensure of the ambulatory surgical treatment center. (Section 6.1 of the Act)
- ef) Each license shall be issued only for the premises and persons named in the application and shall not be transferable or assignable (Section 6 of the Act). Only those facilities, services, programs and procedures included in the application shall be licensed. A new application is required for any one or more of the following:
 - 1) Change in ownership of the facility. <u>A change of ownership occurs when:</u>
 - A) Ownership and responsibility for the operation of the assets constituting the licensed entity are transferred from the licensee to another person or another legal entity, including, but not limited to, a corporation, limited liability company, partnership or sole

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

proprietor, as part of an asset purchase or similar transaction;

- B) In a partnership, when the removal, addition or substitution of a partner alters control of the partnership by more than 51%; or
- C) In a corporation, when the licensee corporation merges into another corporation or is party to a consolidation transaction with one or more corporations, resulting in the creation of a new corporation.
- 2) Change in location of the facility.
- 3) Any remodeling or other change in the facility's physical plant that increases or decreases the number of rooms in which surgical procedures are performed.
- <u>f</u>) The transactions described in subsection (f)(1) do not constitute a change in ownership when all of the entities that are parties to the transaction are under common control or ownership before and after the transaction is completed. In these transactions, the name of the corporation, its officers, its independent subsidiaries and any other relevant information that the Department may require shall be made available to the Department upon request.
- g) The transfer of corporate stock, the change of a membership interest, or the merger of another corporation into the licensee corporation does not constitute a change of ownership if the licensee corporation remains in existence.
- hg) The license shall be valid for one year, unless sooner suspended or revoked, and shall be renewable annually upon approval by the Department and payment of a license fee of \$300 as provided in Section 205.125. (Section 6 of the Act)
- The license shall be posted in a conspicuous place on the licensed premises. A placard or registry of all physicians on staff in the facility shall be centrally located and available for inspection to any interested persons. (Section 6 of the Act)
- ji) The facility shall give written notice to the Department no later than seven days after any one or more of the following:
 - 1) Any personnel changes involving the facility's administrative staff,

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

medical director or supervising nurse.

- 2) For a corporation, any change in any shareholders equity involving 5% or more interest.
- 3) Any change in the Registered Agent or person or persons legally authorized to receive service of process for the facility.
- <u>k)</u> An ambulatory surgical treatment center that elects to have an agreement with the federal Centers for Medicare and Medicaid Services, as provided in 42 CFR 416, must also meet the Medicare conditions as an ambulatory surgical center, as set forth in 42 CFR 416, and have an active agreement with the federal Centers for Medicare and Medicaid Services to participate in Medicare as an ambulatory surgical center provider in Illinois. (Section 6.8 of the Act)

(Source: Amended at 40 Ill. Reg. _____, effective _____)

SUBPART E: GENERAL PATIENT CARE

Section 205.530 Operative Care

- a) Surgical procedures shall be performed only by a qualified physician, dentist or podiatrist within the limits of the defined specific surgical practice privileges that have been granted to that individual by the consulting committee or a committee designated by the consulting committee.
- b) Administration of Anesthesia
 - 1) For the purposes of this Section, anesthesia shall include general anesthesia, intravenous sedation, spinal or epidural anesthesia, and any other specific anesthesia technique that is designated by the consulting committee.
 - 2) Anesthesia may be administered only by the following persons, each having been granted specific anesthesia privileges by the consulting committee or a committee designated by the consulting committee:
 - A) A qualified anesthesiologist (as defined in Section 205.110 of this Part.)

NOTICE OF PROPOSED AMENDMENTS

- B) A physician licensed to practice medicine in all its branches.
- C) A dentist who has been approved by the Department of Financial and Professional Regulation to administer anesthesia for dental surgery only pursuant to Section 8.1 of the Illinois Dental Practice Act [225 ILCS 25].
- D) A certified registered nurse anesthetist (as defined in Section 205.110 of this Part) who is implementing the orders of a qualified anesthesiologist, or the physician, dentist, or podiatrist who is performing the procedure. The qualified anesthesiologist, physician, dentist, or podiatrist who has ordered the anesthesia must be on the premises of the facility during the administration of the anesthesia.
- E) A registered nurse. If the ASTC policy allows the registered nurse to deliver moderate sedation ordered by a physician licensed to practice medicine in all its branches, podiatrist, or dentist, the following are required:
 - i) The registered nurse must be under the supervision of a physician licensed to practice medicine in all its branches, podiatrist, or dentist during the delivery or monitoring of moderate sedation and have no other responsibilities during the procedure.
 - ii) The registered nurse must maintain current Advanced Cardiac Life Support certification or Pediatric Advanced Life Support certification as appropriate to the age of the patient.
 - iii) The supervising physician licensed to practice medicine in all its branches, podiatrist, or dentist must have training and experience in delivering and monitoring moderate sedation and possess clinical privileges at the ASTC to administer moderate sedation or analgesia.
 - iv) The supervising physician licensed to practice medicine in all its branches, podiatrist, or dentist must remain physically present and available on the premises during the

NOTICE OF PROPOSED AMENDMENTS

delivery of moderate sedation for diagnosis, consultation, and treatment of emergency medical conditions.

- v) The supervising physician licensed to practice medicine in all its branches, podiatrist, or dentist must maintain current Advanced Cardiac Life Support certification or Pediatric Advanced Life Support certification as appropriate to the age of the patient.
- vi) Local, minimal, and moderate sedation shall be defined by the Division of Professional Regulation of the Department of Financial and Professional Regulation. Registered nurses shall be limited to administering medications for moderate sedation at doses rapidly reversible pharmacologically as determined by rule by the Division of Professional Regulation of the Department of Financial and Professional Regulation. (Section 6.7(b) of the Act)
- vii) Nothing in the Act or this Section precludes a registered nurse from administering medication for the delivery of local or minimal sedation ordered by a physician licensed to practice medicine in all its branches, podiatrist, or dentist. (Section 6.7(a) of the Act)
- F) *A podiatrist licensed under the Podiatric Medical Practice Act of* 1987. (Section 6.5 of the Act)
- 3) An anesthesia assistant who is licensed as a physician's assistant pursuant to the Physician Assistant Practice Act of 1987 [225 ILCS 95] may assist in the administration of anesthesia only under the direct supervision of a qualified anesthesiologist (as defined in Section 205.110 of this Part).
- 4) The person administering anesthesia, or a person who has equivalent practice privileges, shall be present in the facility during the recovery of the patient to whom anesthesia was administered.
- c) Examination of Removed Tissues
 - 1) All tissues removed during surgery, except tissues and materials exempted under subsection (c)(3), shall be examined by a consulting pathologist,

NOTICE OF PROPOSED AMENDMENTS

who shall provide a written report of the examination to the attending physician.

- 2) A copy of the pathology report shall be filed in the patient's clinical record within seven days <u>after removal of the tissue</u>.
- 3) The following tissues and materials are exempt from this requirement and do not need to be examined by a pathologist:
 - A) Foreskin, fingernails, toenails, and teeth that are removed during surgery.
 - B) Bone, cartilage, and soft tissue removed during the course of surgery and determined by the attending physician not to require pathological examination.
 - C) Cataract lenses that are removed during the course of eye surgery.
 - D) Foreign substances (e.g., wood, glass, pieces of metal, including previously inserted surgical hardware) that are removed during surgery.
- d) All x-rays, except those exempted by the consulting committee and as specified in the facility's policies and procedures manual, shall be read by a physician, podiatric physician, or dentist, each of whom shall have practice privileges at the facility, or by a consulting radiologist approved by the consulting committee. A copy of the x-ray report shall be filed in the patient's clinical record within seven days.
- e) A registered nurse, qualified by training and experience in operating room nursing, shall be present in the operating room and function as the circulating nurse during all invasive or operative procedures requiring aseptic technique. As used in this subsection, "circulating nurse" means a registered nurse who is responsible for coordinating all nursing care, patient safety needs, and the needs of the surgical team in the operating room during an invasive or operative procedure requiring aseptic technique. (Section 6.5(2.5) of the Act)

(Source: Amended at 40 Ill. Reg. _____, effective _____)

SUBPART G: LIMITED PROCEDURE SPECIALTY CENTERS

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Section 205.710 Pregnancy Termination Specialty Centers

- a) A facility will be considered a pregnancy termination specialty center if it meets each of the following conditions:
 - 1) Procedures performed at the facility are limited to procedures to terminate pregnancy performed within 18 weeks assessed gestational age (beginning on the first day of the last menstrual period), and other gynecologic procedures related to the termination of pregnancy. Assessed gestational age may be determined by patient history or by clinical assessment.
 - 2) The <u>facilitycenter</u> does not use general, epidural, or spinal anesthesia for any of the procedures performed. If intravenous sedation is used, mechanical ventilation devices and intubation equipment shall be available on site.
 - 3) The program narrative and policies of the facility are limited to the performance of procedures to terminate pregnancy and other procedures related to the termination of pregnancy.
- b) The following exceptions and modifications of the requirements of this Part apply to pregnancy termination specialty centers. Pregnancy termination specialty centers shall comply with each of the requirements of this Part, unless specifically excepted or modified by the provisions of this subsection.
 - 1) The initial and renewal application need only include the name, address, and telephone number of all owners, administrators, and medical directors of the <u>facilitycenter</u> (in lieu of compliance with Section 205.120(b)(5) through (7) and Section 205.125(b)(5) through (7)). However, the other information required in these provisions shall be maintained at the <u>facilitycenter</u> and be available for inspection by the Department. The information shall include the original or notarized copies of credentials of all licensed or certified personnel.
 - 2) Compliance with Section 205.540(d) is not required, if the medical director or a physician practicing at the facility has a professional working relationship or agreement, maintained in writing at the facility and verifiable by the Department, with a physician who does have admitting or practice privileges at a licensed hospital within <u>approximately</u> 15<u>-30</u>

NOTICE OF PROPOSED AMENDMENTS

minutes from the facility and who will assume responsibility for all facility patients requiring <u>hospitalization or inpatient hospitalization</u>such follow-up care.

- 3) The administrative and public areas of the facility are not required to comply with Section 205.1350.
- 4) A separate examination room is not required; however, adequate space shall be provided to accommodate any equipment necessary for examination, to perform examinations safely, and to allow unobstructed ingress and egress to and from the examination area (in lieu of compliance with Section 205.1360(a)(1)).
- 5) Each room in which procedures to terminate pregnancy are performed shall be at least 120 square feet in size with a minimum dimension of at least 10 feet. Exceptions will be made when the <u>facilitycenter</u> demonstrates that the room size is adequate to accommodate the equipment required for the procedures, to facilitate the <u>safe</u> performance of the procedures <u>safely</u>, and to protect the patients and staff in <u>athe event</u> of fire or other emergency (in lieu of compliance with Section 205.1360(b)(1)).
- 6) A communication system between the control station and each procedure room is not required (in lieu of compliance with Section 205.1360(b)(3)).
- 7) No fewer than three recovery beds or lounge chairs shall be required for each procedure room. However, if the facility's narrative program provides that no more than two procedures per hour will be performed per procedure room, then only two recovery beds or lounge chairs will be required for each procedure room. A minimum of 3 feet shall be provided between each recovery bed or lounge chair, and an unobstructed passageway of a minimum of 4 feet shall be provided at one end of each bed or chair (in lieu of compliance with Section 205.1360(b)(1)).
- 8) The recovery area is not required to include a drug distribution station, charting facilities, nurses station, or storage space for supplies and equipment (in lieu of compliance with Section 205.1360(d)(2)). However, the facility shall provide for direct visual supervision of the recovery area for all patients.

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 9) A toilet for patient use shall be in the recovery area, or in a location that does not require patients to enter public areas or other patient care areas in order to gain access from the recovery area. This toilet shall not be available for public use. A gray diverter valve is not required on the toilet in the recovery area if a means of fluid waste disposal is provided at another location within the <u>facilitycenter</u> (in lieu of compliance with Sections 205.1360(d)(3) and 205.1370(f)).
- 10) A control station for the operating suite is not required (in lieu of compliance with Section 205.1370(a)).
- 11) A scrub station is not required outside the procedure room, if the procedure room contains a sink with <u>hand-washinghandwashing</u> capabilities (in lieu of compliance with Section 205.1370(d)).
- 12) <u>Separate</u> Soiled and clean workrooms are workroom is not required; however, facilities shall be provided for closed clean storage that prevents contamination by soiled materials, and for storage and handling of soiled linens and other soiled materials. These procedures shall be described in the facility'scenter's narrative program (in lieu of compliance with Section 205.1370(e) and (g)).
- 13) Anesthesia and medical gas storage facilities are not required (in lieu of compliance with Section 205.1370(h) and (i)).
- 14) A one-way traffic pattern through staff change areas is not required, but space shall be provided for any changing or gowning that is required by the specific procedures that are being performed, in accordance with the <u>facility'seenter's</u> narrative program (in lieu of compliance with Section 205.1370(k)).
- 15) A change area for patients is not required (in lieu of compliance with Section 205.1370(l)).
- 16) A separate janitor's closet for the surgical suite is not required if the janitor's closet for the <u>facilitycenter</u> is centrally located and contains space for <u>storingthe storage of</u> supplies needed for cleaning both the surgical and non-surgical areas of the <u>facilitycenter</u> (in lieu of compliance with Section 205.1370(n)).

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 17) A minimum corridor width of 5 feet and a minimum door width of 3 feet shall be provided for all corridors and for all doors that are accessible to the public or through which patients may need to be transported in an emergency (in lieu of compliance with Section 205.1400(a)(1), (b)(2), and (b)(3)).
- 18) The requirements of Section 205.1400(d) for flush thresholds and expansion joint covers do not apply.
- Ceilings in procedure and recovery rooms shall be cleanable, but are not required to be washable (in lieu of compliance with Section 205.1400(n)(l)).
- 20) The requirements for elevators in Section 205.1410 do not apply.
- 21) Ventilation, air change, and air filter requirements do not apply; however, temperature shall be maintained in the facility between 68 and 80 degrees Fahrenheit (in lieu of compliance with Section 205.1540 and Table A).
- 22) The requirement for one duplex receptacle for each wall does not apply (in lieu of compliance with Section 205.1750(d)).

(Source: Amended at 40 Ill. Reg. _____, effective _____)