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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED AMENDMENTS

- 1) Heading of the Part: Ambulatory Surgical Treatment Center Licensing Requirements
- 2) Code Citation: 77 Ill. Adm. Code 205
- 3) 

<u>Section Numbers:</u>	<u>Adopted Action:</u>
205.110	Amended
205.115	Amended
205.118	Amended
205.210	Amended
205.220	Amended
205.230	Amended
205.240	Amended
205.350	Amended
205.410	Amended
205.420	Amended
205.510	Amended
205.520	Amended
205.540	Amended
205.550	New Section
205.610	Amended
205.620	Amended
205.860	Amended
205.1370	Amended
- 4) Statutory Authority: Ambulatory Surgical Treatment Center Act [210 ILCS 5]
- 5) Effective Date of Rulemaking:
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 8) A copy of the adopted amendments, including any material incorporated by reference, is on file in the agency's principal office and is available for public inspection.
- 9) Notice of Proposal Published in Illinois Register: 37 Ill. Reg. 14565 – September 13, 2013
- 10) Has JCAR issued a Statement of Objections to these rules? No

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11) Difference(s) between proposal and final version:

The following changes were made in response to comments received during the first notice or public comment period:

1. In Section 205.110, “does not exceed” was changed to “exceeds”.
2. In Section 205.110, "either" was added after "who" and ", education and experience or has certification" was added after "training", and "Certification is recommended but not required." was deleted.
3. Section 205.115(a)(3), the following was added:
  - D) Department of Health and Human Services, United States Public Health Service, Centers for Disease Control and Prevention, "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", July 2011, which may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333.
4. In Section 205.210(a)(4), "who has education, training and experience, or certification in infection control, and" was deleted.
5. In Section 205.410(b), "the facility shall" was deleted and the following was added: "written policies and procedures shall include documentation that the facility has considered, selected and implemented nationally recognized guidelines, including".
6. In Section 205.520, subsection (a) was reinstated. "If a patient is medically evaluated, examined and referred" and "specific health information," were added, and "pertinent records thereof shall be" remained stricken. The rest of the subsections in Section 205.520 were re-lettered.
7. In Section 205.550(e), the following was added after "Settings": ", 'Guidelines for Disinfection and Sterilization in Healthcare Facilities' or 'Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care'; or the Association of periOperative Registered Nurses (AORN) publication, 'Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Centers' "".
8. In Section 205.1370, (a) was reinstated to read, "A control station shall be located to permit visual surveillance of all traffic that enters the surgical area. Personnel who have

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~~a communicable disease shall be excluded from the surgical area. A control station shall be located to permit visual surveillance of all traffic that enters the operating suite.~~

9. Section 205.1370(j) was deleted.

10. In Section 205.1380, (k) was changed to “Traffic patterns in the surgical area shall be designed to facilitate movement of the patients and personnel into, through and out of defined areas, including restricted and semi-restricted areas. Traffic flow shall be tailored to the types of procedures offered in the ASTC. Signage shall clearly delineate the traffic flow.”

The following changes were made in response to comments and suggestions of JCAR:

1. In Section 205.1370(o), “that minimally has restricted and semi-restricted areas of traffic patterns.” was deleted.

2. In the third line of Section 205.1370(y), “restricted areas” was changed to “operating room”.

In addition, various typographical, grammatical, and form changes were made in response to the comments from JCAR.

- 12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreements issued by JCAR? Yes
- 13) Will this rulemaking replace an emergency rule currently in effect? No
- 14) Are there any amendments pending on this Part? No
- 15) Summary and Purpose of Rulemaking: The proposed amendments to Part 205 reflect changes in the U.S. Department of Health and Human Services’ Centers for Medicare & Medicaid Services Ambulatory Surgery Centers Conditions for Coverage (42 CFR 416). The amendments create a governing body; expand the requirements for the ASTC’s organizational plan and the standards of professional work; require the ASTC’s policies and procedures manual to include a data-driven quality assessment program; and update the requirements for emergency post-operative and pre-operative care.

A new Section, Infection Control (Section 205.550), is being added, and Section 205.115 (Incorporated and Referenced Materials) is being updated to reflect the requirements in the new Infection Control Section. Sections 205.350 and 205.860 are being amended to

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clean up obsolete statutory references, and Section 205.610 is being amended to require ASTCs to comply with the Pregnancy Termination Report Code (77 Ill. Adm. Code 505).

- 16) Information and questions regarding these adopted amendments shall be directed to:

Susan Meister  
Division of Legal Services  
Department of Public Health  
535 West Jefferson, 5<sup>th</sup> Floor  
Springfield, Illinois 62761  
e-mail: [dph.rules@illinois.gov](mailto:dph.rules@illinois.gov)

The full text of the adopted amendments begins on the next page:

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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	Equipment
205.420	Sanitary Facility

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SUBPART E: GENERAL PATIENT CARE

Section

- | 205.510 ~~Disaster Preparedness~~Emergency Care
- 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

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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

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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. \_\_\_\_\_, effective \_\_\_\_\_.

SUBPART A: GENERAL PROVISIONS

**Section 205.110 Definitions**

"Act" ~~for the purposes of this Part~~ means the Ambulatory Surgical Treatment Center Act ~~[210 ILCS 5]~~.

"Ambulatory Surgical Treatment Center"

The term "Ambulatory Surgical Treatment Center" or "ASTC" or



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"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, as evidenced by use of the facilities by physicians, ~~or~~ podiatrists or dentists in the performance of surgical procedures ~~that~~which 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~~which meets the definition of an ambulatory surgical center under the rules of the federal Centers for Medicare & Medicaid Services ~~(42 CFR 416)~~. However, when ~~such~~ a place is located within, and operated in conjunction with, the offices of a single physician, ~~or~~ podiatrist, or dentist, or a group of physicians, ~~or~~ 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 ~~(42 CFR 416)~~; or it is used by physicians, ~~or~~ podiatrists, or dentists who are not part of the practice; or it is utilized by the physicians or podiatrists for surgical procedures ~~that~~which 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 ~~[210 ILCS 85]~~.*

*Long-Term Care Facilities: Any person or institution required to be licensed pursuant to the Nursing Home Care Act ~~[210 ILCS 45]~~, the Specialized Mental Health Rehabilitation Act of 2013, or*

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*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~~Nursing and Advanced Practice Nursing Act ~~[225 ILCS 65]~~ 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 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 such~~

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eligibility; or who possesses training and experience acceptable to the Department and whose ~~possesses~~ primary practice is anesthesiology.

"Qualified Consulting Committee" means a committee whose members are qualified ~~surgeons, obstetricians, gynecologists, anesthesiologists~~ ~~Surgeons, Obstetricians, Gynecologists, Anesthesiologists~~ or ~~pathologists~~ ~~Pathologists~~ or other ~~consulting physicians~~ ~~Consulting Physicians~~ consisting of not ~~fewer~~ ~~less~~ than ~~three~~ ~~3~~ 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 ~~[225 ILCS 60]~~.

~~"Qualified Dentist" means a dentist who is licensed to practice under the Illinois Dental Practice Act [225 ILCS 25].~~

"Qualified Podiatrist" means a podiatrist who is licensed to practice under the Podiatric Medical Practice Act of 1987 ~~[225 ILCS 100]~~.

"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

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include nurse practitioners and physician assistants.

"Registered Professional Nurse" means a registered nurse or a registered professional nurse who is licensed under the ~~Nurse Nursing and Advanced Practice Nursing~~ Act ~~[225 ILCS 65]~~ 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 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.115 Incorporated and Referenced Materials**

- a) The following regulations and standards are incorporated in this Part:
- 1) Private and ~~Professional Association Standards~~professional association standards:
    - A) The following standards of the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE), which may be obtained from the American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc., 1791 Tullie Circle, N.E., Atlanta, Georgia 30329:
      - i) Standard No. 52.1: Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter (1992) (see Section 205.1540(i)).
      - ii) Standard No. 52.2: Method of Testing General Ventilation Air Cleaning Devices for Removal Efficiency by Particle Size (1999) (see Section 205.1540(i)).
      - iii) Standard No. 55: Thermal Environmental Conditions for Human Occupancy and Addendum (1992) (see Section 205.1540(i)).
      - iv) Standard No. 58: Method of Testing for Rating Room Air Conditioner and Packaged Terminal Air Conditioner

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- Heating Capacity (1986) (see Section 205.1540(i)).
  - v) Standard No. 62: Ventilation for Acceptable Indoor Air Quality (1999) (see Section 205.1540(i)).
  - vi) Standard No. 63.1: Method of Testing Liquid Line Refrigerant Driers (1995) (see Section 205.1540(i)).
  - vii) Standard No. 63.2: Methods of Testing the Filtration Capability of Refrigerant Liquid Line Filters and Filter-Driers (1996) (see Section 205.1540(i)).
  - viii) Standard No. 64: Methods of Testing Remote Mechanical-Draft Evaporative Refrigerant Condensers (1995) (see Section 205.1540(i)).
  - ix) Standard No. 68: Laboratory Method of Testing to Determine the Sound Power in a Duct (1997) (see Section 205.1540(i)).
  - x) Handbook of Fundamentals (2001) (see Section 205.1540(p)).
- B) The following National Fire Protection Association (NFPA) standards, which may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02169:
- i) No. 101: Life Safety Code (2000), Chapters 20 and 21 (New and Existing Ambulatory Health Care Occupancies).
  - ii) No. 99 (1999): Standard for Health Care Facilities. (See Section 205.1410.)
  - iii) No. 70 (1999): National Electrical Code. (See Sections 205.1760, 205.1770 and 205.1780.)
  - iv) No. 80 (1999): Standard for Fire Doors and Fire Windows. (See Section 205.1400(f).)

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- v) No. 90A (1999): Standard for the Installation of Air-Conditioning and Ventilating Systems. (See Section 205.1540.)
  - vi) No. 90B (1999): Standard for the Installation of Warm Air Heating and Air-Conditioning Systems. (See Section 205.1540.)
  - vii) No. 255 (2000): Standard Method of Test of Surface Burning Characteristics of Building Materials. (See Sections 205.1410 and 205.1520.)
  - viii) No. 701 (1999): Standard Methods of Fire Tests for Flame Propagation of Textiles and Films. (See Section 205.1400(j).)
  - ix) No. 72 (1999): National Fire Alarm Code.
  - x) No. 241 (1996): Standard for Safeguarding Construction, Alteration, and Demolition Operations.
- C) Underwriters Laboratories, Inc. (UL), Publication No. 181 (1996): Factory-Made Air Ducts and Air Connectors, which may be obtained from Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, Illinois 60062. (See Section 205.1710.)
- D) American College of Cardiology/Society for Cardiac Angiography and Interventions, Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards, published in the Journal of the American College of Cardiology, 2001; 37:2170-2214, which may be obtained from the American College of Cardiology, Educational Services, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.
- E) [Association of periOperative Registered Nurses, "Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Settings" \(2012\), which may be obtained from the Association of periOperative Registered Nurses, 2170 South Parker Road, Suite 400, Denver, Colorado 80231.](#)

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- 2) Federal [Regulationsregulations](#):
- [A\)](#) Rules of the Centers for Medicare & Medicaid Services governing Medicare program coverage of Ambulatory Surgical Services (42 CFR 416, October 1, ~~2011~~2008) under the Social Security Act (42 USC 1395). (See definition of "Ambulatory Surgical Treatment Center" in Section 205.110 and Section 205.130(d).)
- [B\)](#) [Rules of the Centers for Medicare & Medicaid Services governing federal certification of laboratory requirements \(42 CFR 493, October 1, 2011\). \(See Section 205.350, Laboratory Services.\)](#)
- 3) [Federal Government Publications](#):
- [A\)](#) [Department of Health and Human Services, United States Public Health Service, Centers for Disease Control and Prevention, "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", which may be obtained from National Technical Information Service \(NTIS\), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161.](#)
- [B\)](#) [Department of Health and Human Services, United States Public Health Service, Centers for Disease Control and Prevention, "Guidelines for Hand Hygiene in Health-Care Settings", October 25, 2002, which may be obtained from the National Technical Information Service \(NTIS\), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161.](#)
- [C\)](#) [Department of Health and Human Services, United States Public Health Service, Centers for Disease Control and Prevention, "Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008", which may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333.](#)
- [D\)](#) [Department of Health and Human Services, United State Public Health Service, Centers for Disease Control and Prevention, "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", July 2011, which may be obtained](#)

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from the Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333.

- b) All incorporations by reference of federal regulations and guidelines and the standards of nationally recognized organizations refer to the regulations, guidelines and standards on the dates specified and do not include any amendments or editions subsequent to the date specified.
- c) The following statutes and State administrative rules~~regulations~~ are referenced in this Part:
  - 1) State of Illinois Statutes~~statutes~~:
    - A) Ambulatory Surgical Treatment Center Act [210 ILCS 5]
    - B) Illinois Dental Practice Act [225 ILCS 25]
    - C) Nurse Practice Act [225 ILCS 65]
    - D) Podiatric Medical Practice Act of 1987 [225 ILCS 100]
    - E) Safety Glazing Materials Act [430 ILCS 60]
    - F) Hospital Licensing Act [210 ILCS 85]
    - G) Nursing Home Care Act [210 ILCS 45]
    - H) Illinois Health Facilities Planning Act [20 ILCS 3960]
    - I) Illinois Administrative Procedure Act [5 ILCS 100]
    - J) Laser System Act of 1997 [420 ILCS 56]
    - K) Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25]
    - L) Physician Assistant Practice Act of 1987 [225 ILCS 95]
    - M) Administrative Review Law [735 ILCS 5/Art. III]
    - N) Specialized Mental Health Rehabilitation Act of 2013 [210 ILCS



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O) ID/DD Community Care Act [210 ILCS 47]

2) State of Illinois Administrative Rulesrules:

A) Department of Public Health, Illinois Plumbing Code (77 Ill. Adm. Code 890)

B) Illinois Emergency Management Agency, General Provisions for Radiation Protection (32 Ill. Adm. Code 310)

C) Department of Public Health, Control of Sexually Transmissible Infections~~Diseases~~ Code (77 Ill. Adm. Code 693)

D) Department of Public Health, Control of Communicable Diseases Code (77 Ill. Adm. Code 690)

E) Department of Public Health, Control of Tuberculosis Code (77 Ill. Adm. Code 696)

F)~~D~~) Pollution Control Board, Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities (35 Ill. Adm. Code 724)

G)~~E~~) Pollution Control Board, Nonhazardous Special Waste Handling and the Uniform Program (35 Ill. Adm. Code 809)

H)~~F~~) Department of Public Health, Rules ofPractice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)

I)~~G~~) Capital Development Board, Illinois Accessibility Code (71 Ill. Adm. Code 400)

J)~~H~~) Illinois Emergency Management Agency, Standards for Protection Against Radiation (32 Ill. Adm. Code 340)

K)~~I~~) Illinois Emergency Management Agency, Use of X-rays in the Healing Arts Including Medical, Dental, Podiatry, and Veterinary Medicine (32 Ill. Adm. Code 360)

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- L) Department of Public Health, Health Care Professional Credentials Data Collection Code (77 Ill. Adm. Code 965)
- M) Department of Public Health, Pregnancy Termination Report Code (77 Ill. Adm. Code 505)

(Source: Amended at 38 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 205.120(b)(1). The applicant shall agree to update the information required in

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*the statement of ownership every six months from the initial date of filing.*  
(Section 7a of the Act)

~~c) b)~~ Financial Statements

- 1) *Financial statements shall be filed annually on or before April 1~~5~~ 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)*

~~d) e)~~ *Every facility licensed under ~~the~~~~this~~ 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)*

~~e) d)~~ *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)*

~~f) e)~~ *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.
- 2) Change in location of the facility.
- 3) Any remodeling or other change in the facility's physical plant ~~that~~~~which~~ increases or decreases the number of rooms in which surgical procedures are performed.

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~~g)~~ *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)*

~~h)~~ *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)*

~~i)~~ 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, medical director ~~staff physicians~~, 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~~ ~~person(s)~~ legally authorized to receive service of process for the facility.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART B: OWNERSHIP AND MANAGEMENT

**Section 205.210 Ownership, Control and Management**

a) The ASTC shall have a governing body that assumes full responsibility for determining, implementing and monitoring policies governing the facility's operation:

- 1) The governing body shall review and approve the facility's organizational plan.
- 2) The governing body shall ensure that ASTC policies and programs provide quality health care in a safe environment.
- 3) The governing body shall have oversight and accountability for the facility's Quality Assessment and Performance Improvement Program;

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shall allocate sufficient resources for the Program; and shall, at least annually, evaluate the Program's effectiveness.

- 4) The governing body shall approve an infection control program designed to prevent, identify and manage infections and communicable diseases. The governing body shall appoint a qualified infection control professional who will direct the infection control program. The governing body shall, at least annually, evaluate the effectiveness of the infection control program.
- 5) The governing body shall establish, protect and promote patient rights, including respect for patients' property and privacy, patient safety, the confidentiality of clinical records, and the exercise of patient rights. The governing body shall designate a grievance officer and shall establish, subject to approval by the governing body, a documented system by which allegations will be reported, investigated and responded to. Allegations will include allegations of violations/grievances relating to, but not limited to, mistreatment, neglect, or verbal, mental, sexual or physical abuse.
- 6) The governing body shall have oversight and accountability for developing and maintaining a written Disaster Preparedness Plan pursuant to Section 205.510 and shall review reports and recommendations at least annually.
- 7) The governing body shall review and approve the facility's organizational plan (see Section 205.220).

- b) Ownership, control and management shall be disclosed at the time of application and upon renewal. The names and addresses of each person with financial interest in the facility shall be submitted to the Department.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.220 Organizational Plan**

- a) An organizational plan shall be known to the staff and available for public information in the facility. The document shall clearly set forth the organization, duties, responsibility, accountability and relationships of professional staff, including a designated qualified infection control professional, a designated grievance officer, and other personnel.

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- b) The plan shall include details of a quality assessment and performance improvement program, an infection control program, a patient rights plan, and a disaster preparedness plan.
- c) The organizational plan shall be submitted to the governing body for review and approval and shall be submitted to the Department with the initial licensure application.
- d) All owners, administrators, professional staff and ancillary personnel shall act in accordance with the organizational plan, ~~this document. This document shall be submitted to the Department with the initial application and thereafter will be reviewed at regular inspections by the Department.~~
- e) The Department will review the organizational plan at regular inspections.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.230 Standards of Professional Work**

~~The Management and/or the~~ owner or manager of the ambulatory surgical treatment center shall maintain proper standards of professional work in the ~~licensed~~ facility.

- a) A qualified consulting committee shall be appointed in writing by the management ~~and/or~~ owner of the ambulatory surgical treatment center and shall establish and enforce standards for professional work in the facility and standards of competency for physicians. The qualified consulting committee shall meet not less than quarterly and shall document all meetings with written minutes. ~~The These written~~ minutes shall be maintained at the facility and shall be available for Department inspection ~~by the Department~~.
  - 1) The membership of the qualified consulting committee shall reflect the types of procedures performed. If the facility performs more than 50 procedures per month, or more than 10% of the total procedures performed are in a specific specialty area, then ~~there shall be~~ a consulting physician of that specialty shall be on the qualified consulting committee.
  - 2) The qualified consulting committee shall review the development and content of the facility's written policies and procedures ~~of the center~~, including the details of the quality assessment and performance

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improvement program, the infection control program, the patient rights plan, the disaster preparedness plan, the procedures for granting privileges, and the quality of the surgical procedures performed. The ~~reviews~~Evidence of such review shall be ~~documented~~reecorded in the minutes.

3) The qualified consulting committee shall establish the scope of procedures to be performed at the facility and shall periodically review and amend the scope of procedures as appropriate.

4)3) ~~Physicians~~Credentials shall be provided by those physicians seeking practice privileges at the facility shall provide their credentials. ~~The~~These ~~credentials shall be reviewed by the~~ credentials committee shall periodically reappraise and review physician credentials and shall identify and record specific practice privileges pursuant to the Health Care Professional Credentials Data Collection Code~~identified and recorded.~~ A record~~Reecord~~ of ~~such~~ accepted practice privileges shall be available for facility staff use and for public information within the facility.

5)4) Each member of the medical staff granted specific surgical practice privileges shall provide at every re-credentialing period, a notarized statement or documentation indicating the name of the ~~Illinois~~Illinois' licensed ~~hospital or hospitals~~hospital(s) where he or she has~~they have~~ skilled-equivalent practice privileges. ~~The~~Such statements or documentation shall be available for Department inspection ~~by the Department.~~ A list of privileges granted to each medical staff member of the ambulatory surgical treatment center shall be available at all times for facility staff use ~~by the staff of the center~~ and for Department inspection ~~by Department staff.~~ As used in this subsection (a)(5), "skilled-equivalent" means the ability to perform similar procedures requiring the same level of training and expertise.

6)5) The qualified consulting committee shall act as a tissue committee and shall review at least quarterly, pathological reports from procedures performed by each physician on the staff when applicable. ~~The~~Evidence of such review shall be ~~documented~~reecorded in the minutes.

b) A qualified physician shall be designated as the medical director~~"Medical Director."~~

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- 1) The ~~medical director~~Medical Director shall secure compliance with the policies and procedures pertaining to medical and surgical procedures, approved by the qualified consulting committee.
- 2) The ~~medical director~~Medical Director shall ~~implement~~be responsible for the implementation of medical policies and procedures contained in the facility's policies and procedures manual (Section 205.240) governing the professional personnel involved directly in the care of patients undergoing surgical procedures, including their preoperative and postoperative care and follow-up.
- 3) The ~~medical director~~Medical Director shall establish and secure compliance ~~with~~of standards for ~~patient~~the observation of patients by nursing personnel during the postoperative period.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.240 Policies and Procedures Manual**

- a) ~~In cooperation with the medical and professional staff, the~~The management/owner of the ambulatory surgical treatment center shall formulate a written policies and procedures manual, ~~which. This shall be done in cooperation with the medical and professional staff and~~ shall be submitted to~~approved by~~ the qualified consulting committee and the governing body for review and approval.
- b) ~~The~~These procedures shall provide for the acceptance, care, treatment, anesthesia services, discharge, referral, and follow-up of all patients and all incidental operations of the facility. ~~This manual shall be available to all staff in the center and shall be followed by them at all times in the performance of their duties.~~
- c) The policies and procedures manual shall include an ongoing data-driven quality assessment and improvement program that addresses measurable improvements in patient health outcomes and improves patient safety by addressing quality of care indicators or performance measures, adverse events, the reduction of medical errors, and infection control. Components of the quality assessment and improvement program shall include:
  - 1) The use of quality indicators or performance measures and data to document improvements in outcomes and to effect improvements in patient care, patient health outcomes, and patient safety;



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- 2) Measurement, identification and analysis of incidence, prevalence, severity and causes of the problems and tracking and implementing improvements that are sustained over time to reduce medical errors and to improve health outcomes;
  - 3) The facility-wide infection control program (Section 205.550); and
  - 4) A focus on performance improvement activities and preventive strategies that address high risk, high volume, and problem-prone areas that affect health outcomes, patient safety, and quality of care, and that address adverse patient events and ensure that improvements are sustained over time.
- 
- d) Data, activities and outcomes of quality assessment and improvement efforts and projects are to be reviewed at least annually and submitted annually in writing to the governing body.
  - e) The policies and procedures manual shall include a methodology for conducting an ongoing comprehensive assessment of the quality of care provided in the facility, including the medical necessity of procedures performed, the appropriateness of care, and methods to revise and implement changes in existing policies and procedures.
  - f) The policies and procedures manual shall include an ongoing infection control program designed to prevent, investigate, manage, control and minimize infections and communicable diseases.
  - g) The policies and procedures manual shall include a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of a fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of patients and staff in the facility. The plan's effectiveness shall be tested and evaluated each year by conducting and evaluating drills, and by promptly implementing any needed corrections. The plan shall be coordinated with State and local authorities, as appropriate.
  - h) The policies and procedures manual shall include a written patient rights plan that includes the designation of a grievance officer, a system to protect and promote patient rights, and a system to investigate violations or incidents and grievances.

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- i) The policies and procedures manual shall be available to all staff in the facility and shall be followed by the staff at all times in the performance of their duties.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART C: PERSONNEL

**Section 205.350 Laboratory Services**

Each ambulatory surgical treatment center shall ~~meet each of the following requirements:~~

- a) Possess a valid Clinical Laboratory Improvement Amendments (CLIA) certificate or waiver for those tests performed by the facility (~~42 CFR 49357 Fed. Reg. 40, pp. 7135-7139, February 28, 1992 Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), no further editions or amendments included~~).
- b) Have a written agreement with a laboratory thatwhich possesses a valid CLIA certificate or waiver to perform any required laboratory procedures thatwhich are not performed in the ASTCcenter.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART D: EQUIPMENT, SUPPLIES, AND FACILITY MAINTENANCE

**Section 205.410 Equipment**

Equipment shall be in good working order and shall be available in numbers sufficient to provide ~~qualitygood~~ patient care based on the types of procedures to be performed in the facility.

- a) Monitoring equipment, suction apparatus, oxygen and related items shall be available within the surgical and postoperative recovery areas. Cardiac and pulmonary resuscitation equipment shall be available in all facilities.
- b) The facility shall have written policies and procedures and shall maintain documentation governing the care, use, decontamination, sterilization, storage and disposal of all materials to ensure that an adequate supply of sterile equipment, instruments and supplies is available for each procedure. Written policies and procedures shall include documentation that the facility has considered, selected

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and implemented nationally recognized guidelines, including the Centers for Disease Control and Prevention publication, "Guidelines for Disinfection and Sterilization in Healthcare Facilities" or "Guide to Infection Prevention in Outpatient Settings"; or the Association of periOperative Registered Nurses (AORN) publication "Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Centers". The policies, procedures and documentation shall include and address:

- 1) Staff orientation and in-service training to understand and implement facility policies and procedures for infection control, and to adhere to manufacturer's instructions for receiving, decontaminating, cleaning, preparing, sterilizing and high-level disinfection, handling, storage and quality control of equipment, supplies and instruments;
  - 2) Preventive maintenance of all central supply service equipment pursuant to manufacturer's instructions or infection control guidelines; and
  - 3) The Infection Control Program (Section 205.550), which shall be under the direction of a designated qualified health care professional with training in infection control.
- c) The facility shall have written procedures to assure safety in storage and use of inhalation anesthetics and medical gases in accordance with NFPA 99.
- d) The facility shall have written procedures to assure the safety in storage and use of all narcotics and medications in accordance with State and federal law.
- e) Facilities using laser equipment shall maintain documentation that the equipment is registered with the Illinois Emergency Management Agency as is required by the Laser System Act of 1997-~~[420 ILCS 56]~~. The facility shall also have a written safety and maintenance program related to the use of the laser equipment.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.420 Sanitary Facility**

- a) The ambulatory surgical treatment center shall ~~ensure~~<sup>insure</sup> maintenance of a safe and sanitary facility by developing and adhering to an infection control program that is based on nationally recognized infection control guidelines, including the Centers for Disease Control and Prevention publication "Guidelines for Isolation

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Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings or "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care", and by ~~maintaining~~with all equipment in good working order. Written procedures shall include provision for maintaining a clean and sanitary facility, including appropriate environmental cleaning, garbage and refuse removal, insect and rodent control, maintenance of water, heat, ventilation and air conditioning, and electrical service.

- b) Any blood, blood components, organs, semen, or other human tissue showing exposure to human immunodeficiency virus (HIV) as evidenced by two ~~of three~~ reactive ELISA test results (according to the package insert – product circular), or exposure to any other identified causative agent of Acquired Immunodeficiency Syndrome (AIDS), and any blood, blood components, organs, semen, or other human tissue originating from a patient diagnosed with HIV infection or AIDS ~~or ARC~~ as defined in 77 Ill. Adm. Code 693.20, shall be disposed of by the ~~facility~~center in accordance with subsection (c) ~~of this Section~~, or delivered in accordance with subsection (d) ~~of this Section~~ to a research facility ~~to use such blood, blood components, organs, semen, or other human tissue~~ for HIV or AIDS research.
- c) Any ~~such~~ blood, blood components, organs, semen, or other human tissue, and any other materials or ~~paraphernalia~~paraphernalia exposed to, or contaminated by, ~~the~~such blood, blood components, organs, semen, or other human tissue shall be completely incinerated, sterilized, or sealed ~~in order~~ to render the materials innocuous before disposal or removal from the premises.
- 1) Materials shall be incinerated~~The incineration of materials shall be done~~ in accordance with the requirements of the Pollution Control Board concerning the operation of an incinerator ~~(35 Ill. Adm. Code 724)~~.
  - 2) Materials shall be sterilized~~The sterilization of materials shall be done~~ by autoclaving ~~the materials~~ in accordance with the recommendations of the manufacturer of the autoclave. The effectiveness of the autoclave shall be verified and documented at least weekly with a biological spore assay containing B. stearothermophilus.
  - 3) Incinerated or sterilized materials shall be disposed of through routine waste disposal methods.
  - 4) Materials ~~that~~which have not been incinerated or sterilized shall be

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disposed of by a waste hauler with a ~~proper~~ permit from the Illinois Environmental Protection Agency under rules of the Pollution Control Board (~~35 Ill. Adm. Code 809~~). These materials ~~shall~~~~must~~ be sealed, transported, and stored in biohazard containers. ~~The~~~~These~~ containers shall be marked "Biohazard," bear the universal biohazard symbol, and be orange, orange and black, or red. The containers shall be rigid and ~~puncture resistant,~~~~puncture resistant~~ such as a secondary metal or plastic can with a lid that can be opened by a step-on pedal. ~~The~~~~These~~ containers shall be lined with one or two high density polyethylene or polypropylene plastic bags with a total ~~thickness,~~~~thickness~~ of at least 2.5 mil. or equivalent material. The containers shall be sealed before being removed from the facility.

- d) When a ~~facility~~~~center~~ delivers ~~such~~ blood, blood components, organs, semen, or other human tissue to a research facility, the ~~ASTC~~~~center~~ shall file a report with the Department (Division of Laboratories) ~~that~~~~which~~ shall include at least the following information:
- 1) A copy of the request from the research facility for the blood, blood components, organs, semen, or other human tissue;
  - 2) The quantity of blood, blood components, organs, semen, or other human tissue delivered;
  - 3) The name and location of the research facility to which the blood or other human tissue was delivered; and
  - 4) The date and time of delivery.
- e) A research facility, for the purposes of this Section, shall mean any clinical laboratory ~~or licensed under the Clinical Laboratory Act (Ill. Rev. Stat. 1987, ch. 111½, par. 621 et seq.), any~~ blood bank licensed under the Illinois Clinical Laboratory and Blood Bank Act, (Ill. Rev. Stat. 1987, ch. 111½, par. 601-101 et seq.) or any hospital licensed under the Hospital Licensing Act, (Ill. Rev. Stat. 1987, ch. 111½, par. 142 et seq.)

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART E: GENERAL PATIENT CARE

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**Section 205.510 Disaster Preparedness~~Emergency Care~~**

- a) Each facility shall develop and maintain a disaster preparedness plan that includes patients, staff and others in the facility. The plan shall cover~~have a written plan of procedure to be followed in case of~~ fire, natural disasters, functional failure of equipment, explosion, ~~and~~or non-patient medical emergencies or other unexpected events or circumstances. The plan shall be tested annually for effectiveness with drills and written evaluations. Any corrections to the plan shall be promptly implemented~~emergency~~. This plan shall specify persons to be notified and actions to be taken and shall be known by all staff of the facility.
- b) Each facility shall be prepared to manage those medical emergencies ~~that~~which may be associated with procedures performed there.
- c) For the purposes of this Section, "emergency" means a situation, physical condition or one or more practices, methods or operations that present imminent danger of death or serious physical or mental harm to patients of an ASTC.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.520 Preoperative Care**

- a) If a patient is medically evaluated, examined and referred from a private physician's office, hospital, or clinic, specific health information,~~pertinent records thereof shall be~~ if available, ~~shall be and~~ made part of the patient's clinical record at the time the patient is registered and admitted to the ambulatory surgical treatment center.
- b) An up-to-date~~A complete~~ medical history and complete physical examination shall be obtained before beginning any medical procedure. The history and examination shall be documented in the patient's medical record~~and the physical examination shall be complete.~~ Upon admission, each patient shall have a pre-surgical assessment completed by a physician or other qualified practitioner. If patient records are available, changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including any allergies to drugs and biologicals, shall be documented. A preanesthetic evaluation shall be completed specifically identifying any patient sensitivity or contraindications to anesthesia.
- c) The laboratory examinations required on all admissions shall be determined by

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the ~~qualified consulting committee~~Consulting Committee and shall be consistent with the scope and nature of the ambulatory surgical treatment center. The required list or lists of tests shall be in written form and shall be available to all members of the medical staff.

- d) Prior to procedures performed to terminate pregnancy, the physician shall establish the diagnosis of pregnancy by appropriate clinical evaluation and testing. In addition, the patient's blood Rh factor shall be determined.
- e) A written statement indicating informed consent and a signed authorization by the patient for the performance of the specific surgical procedure shall be procured and made part of the patient's clinical record.
- f) Surgical procedures shall not be performed on patients having medical, surgical, or psychiatric conditions or complications as specified by the ~~qualified consulting committee~~Consulting Committee in the ASTC's facility's written policies.
- g) Prior to admission to the facility for a surgical procedure, the patient shall be informed of the following:
  - 1) Patients who receive general anesthesia, intravenous sedation, spinal or epidural anesthesia, or any other specific anesthesia technique designated by the ~~qualified consulting committee shall~~Consulting Committee must not attempt to drive a motor vehicle immediately upon discharge from the facility.
  - 2) Patients ~~shall arrange~~must make arrangements prior to admission for safe transportation upon discharge from the facility ~~upon discharge to return to home or to a similar environment.~~

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.540 Postoperative Care**

- a) All patients' postoperative conditions~~Patients~~ shall be observed and assessed in the facility for a period of time sufficient to ensure that the patient is awake, physiologically stable, manifests no immediate postoperative complications, and is ready to return to home or to a similar environment. Overnight stays are not permissible. Before discharge from the facility, each patient shall be evaluated by a qualified practitioner for proper anesthesia recovery. No patient shall be

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required to leave the ~~facility~~~~center~~ in less than one hour following the ~~procedure~~ or procedures~~procedure(s)~~. Each post-surgical patient's overall condition shall be assessed and documented in the medical record by a qualified practitioner, showing that the patient is ready for discharge or in need of further treatment or monitoring.

- b) Rh factor sensitization prophylaxis shall be provided to all Rh negative patients following procedures performed to terminate pregnancy, in accordance with standard medical procedures.
- c) Patients in whom a complication is known or suspected to have occurred during or after the performance of a surgical procedure shall be informed of the complication~~such condition~~, and arrangements shall be made for treatment of the complication. If the patient is admitted~~In the event of admission~~ to a hospital, a summary of care given in the ambulatory surgical treatment center concerning the suspected complication or complications~~complication(s)~~ shall accompany the patient.
- d) To ensure availability of follow-up care at a ~~licensed~~ hospital, the ambulatory surgical treatment center shall provide written documentation of one of the following:
  - 1) A transfer agreement with a ~~licensed~~ hospital within approximately 15-30 minutes travel time of the facility~~;~~
  - 2) A statement that the medical director of the facility has full admitting privileges at a ~~licensed~~ hospital within approximately 15-30 minutes travel time and that he/she will assume responsibility for all facility patients requiring ~~such~~ follow-up care; or
  - 3) A statement that each staff physician, dentist, or podiatrist has admitting privileges in a ~~licensed~~ hospital within 15-30 minutes travel time of the facility.
- e) Written instructions shall be issued to all patients in accordance with the standards approved by the consulting committee ~~of the ambulatory surgical treatment center~~ and shall include the following:
  - 1) Symptoms of complications associated with procedures performed~~;~~



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- 2) Limitations and ~~or~~ restrictions of activities of the patient~~:-~~
  - 3) Specific telephone number to be used by the patient, at any time, ~~if should~~ any complication or question ~~arises; and arise-~~
  - 4) A date for a follow-up or return visit after the performance of the surgical procedure, which shall be scheduled within six weeks.
- f) Patients shall be discharged only on the written signed order of a physician. The name, or relationship to the patient, of the person accompanying the patient upon discharge from the facility shall be noted in the patient's medical record.
- g) Information on availability of family planning services shall be provided, when desired by the patient, to all patients undergoing a pregnancy termination procedure. When, in the physician's opinion, it is in the best interests of the patient and with the patient's consent, family planning services may be initiated prior to the discharge of the patient.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.550 Infection Control**

- a) Each ASTC shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers and visitors.
- b) Each ASTC shall maintain a written, active and effective facility-wide infection control program. A system designed for the identification, surveillance, investigation, control, and prevention of infectious and communicable diseases in patients and health care workers shall be included in this program.
- c) The ASTC shall designate a person as a Qualified Infection Control Professional to develop and implement policies governing the control of infectious and communicable diseases. The means of qualification (i.e., education, training and experience; or certification) shall be documented.
- d) Policies and procedures for the reporting and care of cases of communicable diseases shall comply with the Control of Communicable Diseases Code, the Control of Sexually Transmissible Infections Code, and the Control of Tuberculosis Code.

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- e) The ASTC shall consider, select and implement nationally recognized infection control guidelines in developing its infection control program, including the Centers for Disease Control and Prevention publication "Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings", "Guidelines for Disinfection and Sterilization in Healthcare Facilities" or "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care"; or the Association of periOperative Registered Nurses (AORN) publication "Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Centers".
- 1) When patients have a communicable disease, or present signs and symptoms suggestive of communicable disease, precautionary measures shall be taken to avoid cross-infection to personnel, other patients and the public.
  - 2) If an ASTC treats a patient who has a communicable disease, the ASTC shall provide appropriate facilities and equipment for isolation.
  - 3) Policies and procedures for handling infectious cases shall include orders to the medical, nursing and non-professional staff concerning isolation technique.
  - 4) The ASTC shall require that all persons who care for patients with or suspected of having a communicable disease, or whose work brings them in contact with materials that are potential conveyors of communicable disease, comply with the ASTC's infection control program to avoid transmission of the disease agent.
- f) The ASTC shall develop and implement comprehensive interventions to prevent and control extensively drug-resistant organisms (XDROs), including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), and certain gram-negative bacilli (GNB), that take into consideration guidelines of the Centers for Disease Control and Prevention for the management of XDROs in health care settings, including the "Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings" and "Guidelines for Hand Hygiene in Health-Care Settings".
- g) The ASTC shall comply with 42 CFR 416.43 and 416.51 in developing and maintaining an infection control program. Documentation that the ASTC considered, selected and implemented nationally recognized infection control

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guidelines in developing its infection control program shall be made available to the Department upon request.

- h) The ASTC shall develop, implement, monitor and enforce a hand hygiene program.
  - 1) The ASTC shall assess the current practice and compliance, assess current hand hygiene products, solicit input from clinical staff, and develop a hand hygiene program for all staff.
  - 2) All staff (including contractual and medical) shall be educated in the hand hygiene program during initial orientation and at least annually. This education shall be documented.
  - 3) The program shall have clear goals that require quantitative, time-specific improvement targets.
  - 4) The ASTC shall develop and implement ongoing measurement tools to assure compliance with the program.
  - 5) The results of the monitoring shall be incorporated in the clinical statistical data required in Section 205.620.
- i) Contaminated material shall be handled and disposed of in a manner designed to prevent the transmission of the infectious agent.
- j) Thorough hand hygiene shall be required after touching any contaminated or infected material.
- k) Whenever the Control of Communicable Diseases Code and the Control of Tuberculosis Code require the submission of laboratory specimens for the release of a patient from isolation or quarantine, the specimens shall be submitted to the laboratories of the Illinois Department of Public Health or other laboratory licensed by the Department for the specific tests required.
- l) The ASTC shall establish a systematic plan of checking and recording cases of infection, known or suspected, that develop in the ASTC. The cases shall also be reported to the governing body. The ASTC shall investigate health care associated infections to determine the causative organism and its possible sources. The findings and recommendations shall be reported to the medical staff and

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administration for corrective action.

- m) Policies and procedures related to this Section, and including, but not limited to, the following items, shall be developed:
- 1) The isolation of patients with specific and suspected infectious diseases and protective isolation of appropriate patients.
  - 2) In-service education programs on the control of infectious diseases.
  - 3) Policies and procedures for isolation techniques appropriate to the diagnosis of the patient, and protective routines for personnel and visitors.
  - 4) The recording and reporting of all infections of clean surgical cases to the administration and procedures for the investigation of cases.

(Source: Added at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART F: RECORDS AND REPORTS

**Section 205.610 Clinical Records and Reports**

- a) The ASTC shall maintain accurate~~Accurate~~ and complete clinical records ~~shall be maintained~~ for each patient, and all entries in the clinical record shall be made at the time the surgical procedure is performed and when care, treatment, medications, or other medical services are given. The record shall include, but not be limited to, the following:
- 1)a) Patient~~patient~~ identification;:-
  - 2)b) Admitting~~admitting~~ information including patient history, physical examination findings, diagnosis or need for medical services;:-
  - 3)e) Pre-counseling~~pre-counseling~~ notes;:-
  - 4)d) Signed~~signed~~ informed consent;:-
  - 5)e) Confirmation~~confirmation~~ of a pregnancy (when an abortion is performed);:-

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- 6) ~~f)~~ ~~Signed~~ signed physician orders;:-
  - 7) ~~g)~~ ~~Laboratory~~ laboratory test reports, pathologist's report of tissue, and radiologist's report of ~~imaging studie~~; ~~sx-rays~~:-
  - 8) ~~h)~~ ~~An~~ anesthesia record;:-
  - 9) ~~i)~~ ~~The~~ operative record;:-
  - 10) ~~j)~~ ~~Medication~~ medication and medical treatments;:-
  - 11) ~~k)~~ ~~Recovery~~ recovery room progress notes;:-
  - 12) ~~l)~~ ~~Physician~~ physician and ~~nurse~~ nurses' progress notes;:-
  - 13) ~~m)~~ ~~The patient's~~ condition at time of discharge;:-
  - 14) ~~n)~~ ~~Patient~~ patient instructions; ~~and~~:-
  - 15) ~~o)~~ ~~Post-counseling~~ post-counseling notes.
- b) The ASTC shall comply with the Department's rules titled Pregnancy Termination Report Code.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 205.620 Statistical Data**

- a) Each ambulatory surgical treatment center shall collect, compile and maintain the following clinical statistical data at the facility to be made available to the Department during a survey or inspection, or upon the Department's request:
- 1) ~~The~~ the total number of surgical cases treated by the ~~ASTC~~ center;
  - 2) ~~The~~ the number of each specific surgical procedure performed;
  - 3) ~~The~~ the number and type of complications reported, including the specific procedure associated with each complication;
  - 4) ~~The~~ the number of patients requiring transfer to a ~~licensed~~ hospital for

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treatment of complications. ~~The List the~~ procedure performed and the complication that prompted each transfer shall be listed; ~~and~~

5) ~~The the~~ number of deaths, including the specific procedure that was performed; ~~and~~

6) The results of the monitoring of the ASTC's hand hygiene program in Section 205.550(h).

b) ~~The This~~ clinical statistical data shall be collected, compiled and maintained quarterly, with reports completed no later than January 31, April 30, July 31 and October 31 for the preceding quarter.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

SUBPART H: LICENSURE PROCEDURES

**Section 205.860 Hearings**

a) Applicants and licensees may appeal certain actions of the Department under the Act and this Part. *If a facility desires to contest any Department action, it shall send a written request for a hearing to the Department within 10+en days after of receipt of the notice of the contested action.* Following receipt of a request for a hearing, the Department shall conduct a hearing to review the contested action. (Section 10c(c) of the Act)

b) Hearings conducted pursuant to the Act and this Part shall be conducted in accordance with the following:

1) Sections 10c, 10f, and 10g of the Act.

2) Article 10 Sections 10 through 18 of the Illinois Administrative Procedure Act ~~(Ill. Rev. Stat. 1991, ch. 127, pars. 1010 through 1018 et seq.)~~.

3) The Department's rules ~~titled of the Department entitled~~ "Rules of Practice and Procedure in Administrative Hearings" ~~(77 Ill. Adm. Code 100)~~.

c) Applicants and licensees have a right to administrative review of actions and decisions of the Department by the courts under the Administrative Review Law ~~(Ill. Rev. Stat. 1989, ch. 110, par. 3-101 et seq.)~~.

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(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

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

**Section 205.1370 Support Service Areas**

- a) ~~A control station shall be located to permit visual surveillance of all traffic that enters the surgical area. Personnel who have a communicable disease shall be excluded from the surgical area.~~ ~~A control station shall be located to permit visual surveillance of all traffic that enters the operating suite.~~
- b) ~~The ASTC shall provide sterilizing~~ Sterilizing facilities with high-speed autoclaves conveniently located in a clean workroom to serve all procedure rooms ~~shall be provided. Alternate provisions, approved by the governing body.~~ ~~Approved alternate provisions~~ may be made for replacement of sterile instruments during surgery.
- c) A drug distribution station shall be provided for storage and preparation of medication to be administered to patients.
- d) Scrub stations with knee, foot or elbow actuated faucets or with automatic electronic actuated faucets shall be provided near the entrances to, but outside of, the procedure rooms. Scrub facilities shall be arranged to minimize splatter on nearby personnel or supply carts.
- e) A soiled workroom for the exclusive use of the surgical suite staff shall be provided. The soiled workroom shall contain a work counter, a sink equipped for ~~hand washing~~ handwashing, a waste receptacle, and a linen receptacle. This room may be used for cleaning anesthesia equipment.
- f) Fluid waste disposal facilities shall be conveniently located with respect to the general procedure rooms.
- g) ~~Clean workroom~~ A clean workroom or a clean supply room is required when clean materials are assembled within the surgical suite prior to use. A clean workroom shall contain a work counter, sink equipped for hand washing ~~handwashing~~, and space for clean and sterile supplies. A clean supply room shall be provided when the narrative program defines a system for the

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storage and distribution of clean and sterile supplies that would not require the use of a clean workroom.

~~2) An autoclave shall be incorporated into the clean workroom.~~

- h) Anesthesia storage facilities shall be provided. Flammable anesthetics are prohibited.
- i) Medical gas supply storage with space for reserve nitrous oxide and oxygen cylinders shall be provided, with all tanks properly secured.
- j) A storage~~Storage~~ area for equipment and supplies used in the surgical suite shall be provided. The area shall provide protection against dust, moisture, insects, vermin, and temperature and humidity extremes.
  - 1) Restricted area: traffic is restricted to authorized personnel and patients. No street clothing shall be worn in the restricted area. Health care workers shall wear facility-laundered surgical attire. Head and facial hair shall be contained within a protective covering. Cloth head coverings shall be laundered by the facility and changed daily. Additional garments shall be completely contained or covered within the surgical attire. Masks shall be worn in restricted areas where open sterile supplies or equipment are present or scrubbed persons are located.
  - 2) Semi-restricted area: traffic is restricted to authorized personnel and patients. No street clothing shall be worn in the semi-restricted area. Health care workers wear facility-laundered surgical attire. Head and facial hair shall be contained within a protective covering. Cloth head coverings shall be laundered by the facility and changed daily. Additional undergarments shall be completely contained or covered within the surgical attire. Masks are not required in this area. Patients shall wear attire appropriate for their surgical procedure and shall wear hair covering if applicable.
- k) Staff and personnel facilities shall be provided for male and female personnel (orderlies, technicians, nurses, and doctors) working within the surgical suite. The areas shall contain a lounge area, lockers, toilets, lavatories equipped for hand washing~~handwashing~~, and space for changing clothes. These areas shall be arranged to provide a one-way traffic pattern so that personnel entering from outside the surgical~~sterile~~ area can change, ~~gown~~, and move directly into the



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sterile area in facility-laundered surgical attire. ~~Space for removal of scrub suits and foot covers shall be designed so that personnel using it will avoid physical contact with clean personnel.~~

- l) The ASTC shall provide change~~Change~~ areas where patients can change from street clothes into hospital gowns in privacy; and be prepared for surgery; ~~shall be provided~~. This shall include lockers, toilets, clothing change or gowning areas, and space for the administration of medications.
- m) The stretcher storage area shall be out of the direct line of traffic.
- n) A janitor's closet containing a floor receptor or service sink; and storage space for housekeeping supplies and equipment; shall be provided exclusively for the surgical ~~area~~suite.
- o) Traffic patterns in the surgical area shall be designed to facilitate movement of the patients and personnel into, through and out of defined areas, including restricted and semi-restricted areas. Traffic flow shall be tailored to the types of procedures offered in the ASTC.
- p) Signage shall clearly delineate the traffic flow and surgical attire requirements.
- q) The movement of clean and sterile items shall be separated from contaminated or dirty items by space, time or traffic patterns.
- r) All jewelry shall be removed prior to the surgical scrub. Jewelry shall not be worn in the operating room, except that anesthesia personnel may wear a watch.
- s) Additional personal protective equipment shall be worn when exposure to blood or other potentially infectious material is anticipated.
- t) Whenever surgical attire or personal protective equipment is soiled, it shall be removed and discarded prior to leaving the surgical area.
- u) The sterile gown and gloves used when participating in surgical procedures shall be removed and discarded.
- v) The unsterile gloves worn when participating in surgical procedures shall be removed and discarded prior to leaving the operating room.

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- w) The use of single-use coverall suits shall be determined by ASTC policy.
- x) Shoe covers shall be worn when it can reasonably be anticipated that splashes or spills may occur. If shoe covers are worn, they shall be changed whenever they become torn, wet or soiled; or daily, whichever comes first. They shall be removed and discarded before leaving the surgical area.
- y) The use of cover gowns for covering the surgical attire when outside of the surgical area shall be determined by ASTC policy. Surgical attire worn into the institution from outside shall be changed before entering the operating room. Persons exiting the facility shall don facility-laundered surgical attire upon return to the surgical area.

(Source: Amended at 38 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)