

Document: Final Rule

Source: January 1, 2001, Indiana Register, Volume 24, Number 4

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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

LSA Document #00-13(F)

DIGEST

Amends 410 IAC 15-2.1-11, 410 IAC 15-2.4-1, 410 IAC 15-2.6-1, and 410 IAC 15-2.7-1 concerning the ambulatory outpatient surgical center rules to clarify the definition of health care provider, clarify requirements for certification and dietary services, and to correct the items incorporated by reference. Effective 30 days after filing with the secretary of state.

410 IAC 15-2.1-11 **410 IAC 15-2.6-1**
410 IAC 15-2.4-1 **410 IAC 15-2.7-1**

SECTION 1. 410 IAC 15-2.1-11, AS ADDED AT 23 IR 781, SECTION 1, IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-2.1-11 “Health care provider” defined

Authority: IC 16-21-1-7

Affected: IC 16-18-2-163; IC 16-21-1

Sec. 11. “Health care provider” means a provider as defined in ~~IC 34-18-2-14~~ **IC 16-18-2-163**. (*Indiana State Department of Health; 410 IAC 15-2.1-11; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; filed Nov 13, 2000, 11:17 a.m.: 24 IR 990*)

SECTION 2. 410 IAC 15-2.4-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-2.4-1 Governing body; powers and duties

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 1. (a) The governing body shall function as the supreme authority of the center. The governing body shall assume full legal responsibility for determining, implementing, and monitoring policies governing the center’s total operation and for ensuring that these policies are followed so as to provide quality health care in a safe environment. The governing body is legally responsible for the conduct of the center as an institution. The governing body shall do the following:

(1) Ensure that the center:

(A) meets all rules and regulations for licensure and **for certification, if applicable;** and

(B) makes available to the commissioner or representatives of the department upon request all reports, records, minutes, documentation, information, and files required for licensure.

(2) Adopt bylaws and function accordingly.

(3) Review the bylaws at least triennially.

(4) Maintain a liaison with the medical staff.

(5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up.

(b) The governing body is responsible for conduct of the medical staff activities related to the center. The governing body shall: ~~do the following:~~

(1) Determine, with the advice and recommendations of the medical staff and in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(2) Ensure ~~the following:~~ **that:**

(A) The requests of practitioners for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff.

- (B) Reappointments are acted upon at least biennially.
 - (C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications.
 - (D) This process occurs within a reasonable period of time, as specified by the medical staff bylaws.
 - (3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.
 - (4) Ensure that the medical staff is accountable and responsible to the governing body for the quality of care provided to patients.
 - (5) Ensure that criteria for selection for medical staff membership are individual character, competence, education, training, experience, and judgment.
 - (6) Ensure that the granting of medical staff membership or professional privileges in the center is not solely dependent upon certification, fellowship, or membership in a specialty body or society.
 - (7) Ensure all patients are admitted to the center only upon the recommendation of a practitioner with admitting privileges for the purpose of performing surgical procedures and services.
 - (8) Ensure surgical procedures are performed only by a physician, dentist, or podiatrist who is privileged to perform such procedures according to medical staff by laws, regulations, and/or policies and procedures.
 - (9) Ensure surgical procedures performed are limited to procedures authorized by the governing body and not requiring a stay longer than twenty-four (24) hours.
- (c) The governing body is responsible for managing the center. The governing body shall: ~~do the following~~:
- (1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer.
 - (2) Delineate in writing the responsibility and authority of the chief executive officer.
 - (3) Require the chief executive officer or a designee to attend meetings of the governing body and its committees and act as its representative at medical staff meetings.
 - (4) Require that the chief executive officer designate in writing an administrative officer to serve during his or her absence.
 - (5) Require that the chief executive officer develop and implement policies and programs for the following:
 - (A) Ensuring the employment of personnel, in accordance with state and federal rules, whose qualifications are commensurate with anticipated job responsibilities.
 - (B) Ensuring that during the center's operational hours that staffing requirements are met for quality patient care and that employees do not provide services in an adjacent office, clinic, hospital, or other facility at the same time.
 - (C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.
 - (D) Ensuring that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available upon request.
 - (E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.
 - (F) Establishing criteria for each manager, including, but not limited to, the following:
 - (i) Definition of educational requirements.
 - (ii) Experience requirements.
 - (iii) Professional certification, licensing, or registration, where appropriate.
 - (G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel who provide direct patient care.
 - (H) A post offer physical examination and employee health monitoring in accordance with the ~~center's center~~ infection control program.
 - (I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.
 - (J) Establishing a policy and procedure for communication with physicians concerning a patient emergency.
 - (K) Establishing criteria to determine the delineation of privileges.
 - (L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.
 - (M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.
 - (N) Coordinating, reporting, and complying with authorized local, regional, and state planning groups and other center services suppliers so that effective data collection can be maintained.
 - (O) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.

(P) Development, implementation, and monitoring of a safety management program to include, but not be limited to, the following:

- (i) Periodic equipment inspections.
- (ii) Insect, rodent, or other vermin control.
- (iii) Instructions for operating and maintaining the building or building portion and equipment.
- (iv) Chemical substances use and storage.
- (v) Surgical waste and similar material disposal.
- (vi) General housekeeping precautions.

(d) The governing body is responsible for assuring that quality patient care is provided. In accordance with center policy, the governing body shall do the following:

(1) Ensure a qualified licensed physician member of the medical staff is responsible for the care and treatment of each patient with respect to any medical problem that is present on admission or that develops during the surgical procedure that does not fall within the scope of practice or the medical staff privileges of the admitting practitioner.

(2) Ensure ~~the following:~~ **that:**

(A) The center develops, implements, and maintains written medical staff policies and procedures for emergencies, initial treatment, and transfer.

(B) The center provides immediate lifesaving measures within the scope of service available, to all persons in the center, to include, but not be limited to, the following:

- (i) Timely assessment.
- (ii) Basic life support.
- (iii) Proper transfer mode.

(3) Ensure that the center develops, implements, and maintains policies that cover physician limited practice problems, including, but not limited to, the following:

- (A) Impaired physicians.
- (B) Criminal history check.
- (C) Disciplinary action.

(4) Ensure that there is a center-wide, quality assessment and improvement program that evaluates the provision of patient care and outcome.

(e) The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:

(1) Ensure that a contractor of any service furnishes those services in such a manner as to permit the center to comply with all applicable statutes and rules.

(2) Ensure that the services performed under a contract are provided in a safe and effective manner and are included in the center's quality assessment and improvement program.

(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.

(4) Ensure that the center maintains a written transfer agreement with one (1) or more hospitals for immediate acceptance of ~~patients~~ **patient** who develop complications or require postoperative confinement, and that all physicians, dentists, and podiatrists performing surgery in the center maintain admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located.

(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.

(Indiana State Department of Health; 410 IAC 15-2.4-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; filed Nov 13, 2000, 11:17 a.m.: 24 IR 990)

SECTION 3. 410 IAC 15-2.6-1, AS ADDED AT 23 IR 795, SECTION 6, IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-2.6-1 Dietary services

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 1. (a) If nourishment and other dietary needs of the patients are provided in the center, the center shall comply with ~~410 IAC 7-15-1~~ **410 IAC 7-20**.

(b) If nourishments are to be prepared, a nourishment area with hand washing lavatory and refrigeration must be provided.

(c) If prepackaged single service nourishments are provided, refrigeration storage must be provided in the clean area. (*Indiana State Department of Health; 410 IAC 15-2.6-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795; filed Nov 13, 2000, 11:17 a.m.: 24 IR 992*)

SECTION 4. 410 IAC 15-2.7-1 IS AMENDED TO READ AS FOLLOWS:

410 IAC 15-2.7-1 Incorporation by reference

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed and are hereby incorporated by reference:

(1) Guidelines for Design and Construction of Hospitals and Health Care Facilities (1996-1997 Edition). Copies are available from the American Institute of Architects, 1735 New York Avenue Northwest, Washington, D.C. 20006. Local purchase may be made from the Architectural Center Bookstore, 47 South Pennsylvania Avenue, Indianapolis, Indiana 46204.

(2) National Fire Protection Association (NFPA) 99, Health Care Facilities (1993 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 1901, Quincy, Massachusetts 02260-9904.

(3) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (1985 Edition for Medicare/Medicaid certified nonaccredited hospitals, and the 1991 Edition for Medicare/Medicaid certified hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 1901, Quincy, Massachusetts 02269-9904.

(4) National Committee on Radiation Protection (NCRP) Reports, Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV: (September 15, 1976, Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(5) National Committee on Radiation Protection (NCRP) Reports, Number 102, "Medical X-ray, Electron Beam and Gamma Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)", June 30, 1989, Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

~~(6) 42 CFR 405, Subpart B, Section 412.25; 42 CFR 412, Subpart B, Section 412.27; 42 CFR 412, Subpart B, Section 412.29; 42 CFR 412, Subpart B, Section 412.30: (October 1, 1991, Edition):~~

~~(7) (6) 42 CFR 493 (Effective October 1, 1993, Edition).~~

~~(8) (7) 21 CFR 606 (April 1, 1994, Edition).~~

~~(9) (8) 21 CFR 640 (April 1, 1994, Edition).~~

(b) Federal rules which have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the department. (*Indiana State Department of Health; 410 IAC 15-2.7-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1658; filed Nov 13, 2000, 11:17 a.m.: 24 IR 992*)

LSA Document #00-13(F)

Notice of Intent Published: 23 IR 1125

Proposed Rule Published: August 1, 2000; 23 IR 2891

Hearing Held: August 22, 2000

Approved by Attorney General: October 25, 2000

Approved by Governor: November 8, 2000

Filed with Secretary of State: November 13, 2000, 11:17 a.m.

Incorporated Documents Filed with Secretary of State: None