ARTICLE 15. HOSPITAL LICENSURE RULES

Rule 1. Hospital Operation, Management, Construction, Equipment Requirements (Repealed)

(Repealed by Indiana State Department of Health; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1280; errata filed Jan 5, 1995, 4:20 p.m.: 18 IR 1290)

Rule 1.1. Definitions

410 IAC 15-1.1-1 Applicability

Authority: IC 16-21-1-7; IC 16-21-1-8; IC 16-21-1-9
Affected: IC 16-19-3; IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article except as otherwise indicated. *(Indiana State Department of Health; 410 IAC 15-1.1-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-2 "Ambulatory outpatient surgical center" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1

Sec. 2. "Ambulatory outpatient surgical center" means a center as defined in IC 16-18-2-14. *(Indiana State Department of Health; 410 IAC 15-1.1-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-2.5 "ASA Class I patient" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2.5. "ASA Class I patient" means a normal, healthy patient. *(Indiana State Department of Health; 410 IAC 15-1.1-2.5; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-3 "Authenticate" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. "Authenticate" means the author or responsible individual has reviewed the clinical content of the order and validated an entry in the record by:

(1) a full signature, including first initial, last name, and discipline;
(2) written initials if full signature appears on the same page;
(3) a unique identifier such as a number or computer key; or
(4) a signature stamp.

(Indiana State Department of Health; 410 IAC 15-1.1-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-3.3 "Biologics" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.3. "Biologics" means a biological product, such as:

(1) a globulin;
(2) a serum;
(3) a vaccine;

(4) an antitoxin;
(5) blood; or
(6) an antigen;
used in the prevention or treatment of disease. *(Indiana State Department of Health; 410 IAC 15-1.1-3.3; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-3.7 "Burn" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 3.7. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:
(1) Fire.
(2) Heat.
(3) Chemicals.
(4) Electricity.
(5) Radiation.
(6) Gases.
(Indiana State Department of Health; 410 IAC 15-1.1-3.7; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-4 "Commissioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. "Commissioner" means the state health commissioner or the state health commissioner's designee. *(Indiana State Department of Health; 410 IAC 15-1.1-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-5 "Council" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-84; IC 16-21-1

Sec. 5. "Council" means the body defined in IC 16-18-2-84(1). *(Indiana State Department of Health; 410 IAC 15-1.1-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-6 "Department" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 15-1.1-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-7 "Division" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. "Division" means the division of acute care of the department. *(Indiana State Department of Health; 410 IAC 15-1.1-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-8 "Donor" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. "Donor" means an individual as defined in IC 29-2-16-1 *[IC 29-2-16 was repealed by P.L.147-2007, SECTION 21, effective July 1, 2007.]*. *(Indiana State Department of Health; 410 IAC 15-1.1-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-8.5 "Elopement" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 8.5. "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so. *(Indiana State Department of Health; 410 IAC 15-1.1-8.5; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-9 "Executive board" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-18-2-120; IC 16-21-1

Sec. 9. "Executive board" means the board as defined in IC 16-18-2-120. *(Indiana State Department of Health; 410 IAC 15-1.1-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-10 "Governing board" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-1

Sec. 10. "Governing board" means the body defined in IC 16-18-2-149. *(Indiana State Department of Health; 410 IAC 15-1.1-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-11 "Health care provider" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 11. "Health care provider" means a provider as defined in IC 27-12-2-14 *[IC 27-12 was repealed by P.L.1-1998, SECTION 221, effective July 1, 1998.]*. *(Indiana State Department of Health; 410 IAC 15-1.1-11; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-12 "Health care worker" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1-6

Sec. 12. "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a hospital. *(Indiana State Department of Health; 410 IAC 15-1.1-12; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-13 "Hospital" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-18-2-179

Sec. 13. "Hospital" means an organization as defined in IC 16-18-2-179. *(Indiana State Department of Health; 410 IAC 15-1.1-13; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-13.1 "Hyperbilirubinemia" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.1. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate. *(Indiana State Department of Health; 410 IAC 15-1.1-13.1; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-13.2 "Hypoglycemia" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.2. "Hypoglycemia" means a physiologic state in which:
(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and
(2) physiological or neurological, or both, dysfunction begins.
(Indiana State Department of Health; 410 IAC 15-1.1-13.2; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-13.3 "Immediately postoperative" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.3. "Immediately postoperative" means within twenty-four (24) hours after either of the following:
(1) Induction of anesthesia (if surgery or other invasive procedure is not completed).
(2) Completion of surgery or other invasive procedure.
(Indiana State Department of Health; 410 IAC 15-1.1-13.3; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-13.4 "Informed consent" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.4. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure. *(Indiana State Department of Health; 410 IAC 15-1.1-13.4; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-13.5 "Intended use" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "Intended use" means the use of a device as described on the label and associated materials provided by the device's manufacturer. *(Indiana State Department of Health; 410 IAC 15-1.1-13.5; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-*

410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-13.6 "Joint movement therapy" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.6. "Joint movement therapy" means all types of manual techniques, to include:
(1) mobilization (movement of the spine or a joint within its physiologic range of motion);
(2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
(3) any other type of manual musculoskeletal therapy;
regardless of their precise anatomic and physiologic focus or their discipline of origin. *(Indiana State Department of Health; 410 IAC 15-1.1-13.6; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-13.7 "Kernicterus" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 13.7. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. *(Indiana State Department of Health; 410 IAC 15-1.1-13.7; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-14 "Licensed health professional" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-27.1

Sec. 14. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. *(Indiana State Department of Health; 410 IAC 15-1.1-14; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-14.2 "Low-risk pregnancy" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 14.2. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:
(1) Essential hypertension.
(2) Renal disease.
(3) Collagen-vascular disease.
(4) Liver disease.
(5) Preeclampsia.
(6) Cardiovascular disease.
(7) Placenta previa.
(8) Multiple gestation.
(9) Intrauterine growth retardation.
(10) Smoking.
(11) Pregnancy-induced hypertension.
(12) Premature rupture of membranes.
(13) Other previously documented condition that poses a high risk of pregnancy-related mortality.
(Indiana State Department of Health; 410 IAC 15-1.1-14.2; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-15 "Medical staff" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-2-7

Sec. 15. "Medical staff" means a group as defined in IC 16-21-2-7. *(Indiana State Department of Health; 410 IAC 15-1.1-15; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-15.5 "Neonates" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 15.5. "Neonates" means infants in the first twenty-eight (28) days of life. *(Indiana State Department of Health; 410 IAC 15-1.1-15.5; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-16 "Pharmacist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-26-13

Sec. 16. "Pharmacist" means an individual licensed under IC 25-26-13. *(Indiana State Department of Health; 410 IAC 15-1.1-16; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-17 "Physician" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-22.5-5

Sec. 17. "Physician" means an individual licensed under IC 25-22.5-5. *(Indiana State Department of Health; 410 IAC 15-1.1-17; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-18 "Practitioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-1-9-2

Sec. 18. "Practitioner" means an individual as defined in IC 25-1-9-2. *(Indiana State Department of Health; 410 IAC 15-1.1-18; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-19 "Registered nurse" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1

Sec. 19. "Registered nurse" means an individual licensed under IC 25-23-1. *(Indiana State Department of Health; 410 IAC 15-1.1-19; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-19.5 "Rural hospital" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 19.5. "Rural hospital" means, for purposes of designation as a critical access hospital, a hospital located in a city or town with a population not greater than twenty thousand (20,000). *(Indiana State Department of Health; 410 IAC 15-1.1-19.5; filed Jan 30, 2007, 9:53 a.m.: 20070221-IR-410060427FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA) NOTE: Agency cited as 410 IAC 15-1.1-20, which was renumbered by the Publisher as 410 IAC 15-1.1-19.5.*

410 IAC 15-1.1-20 "Serious disability" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 20. "Serious disability" means either of the following:

(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
    (A) not present on admission and requiring continued treatment; or
    (B) for which there is a high probability of long term or permanent lifestyle change at discharge.
(2) Unintended loss of a body part.

(Indiana State Department of Health; 410 IAC 15-1.1-20; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.1-21 "Sexual assault" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1; IC 35-42-4; IC 35-46-1-3

Sec. 21. "Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3. *(Indiana State Department of Health; 410 IAC 15-1.1-21; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-22 "Surgery or other invasive procedure" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 22. For purposes of this rule, 410 IAC 15-1.4-2.2, and 410 IAC 15-2.4-2.2, "surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. Such procedures include, but are not limited to:

(1) Open or percutaneous surgical procedures.
(2) Percutaneous aspiration.
(3) Selected injections.
(4) Biopsy.
(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
(6) Laparoscopies.
(7) Endoscopies.
(8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters. *(Indiana State Department of Health; 410 IAC 15-1.1-22; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.1-23 "Toxic substance" defined

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 23. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.

(Indiana State Department of Health; 410 IAC 15-1.1-23; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

Rule 1.2. Compliance with Rules

410 IAC 15-1.2-1 Compliance with rules

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) All hospitals shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.

(b) Components required for licensure as a hospital are the following:

(1) Governing board.
(2) Quality assessment and improvement program.
(3) Dietary service.
(4) Infection control program.
(5) Laboratory service.
(6) Medical record service.
(7) Medical staff.
(8) Nursing service.
(9) Pharmaceutical service.
(10) Physical environment service.
(11) Plant maintenance service.
(12) Radiologic service.

(c) Optional services, not required for licensure, shall comply with all rules for that service.

(d) The hospital shall have a plan to address the internal review and reporting of unusual occurrences and disasters. This plan shall cover, but not be limited to, the following:

(1) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.
(2) Chemical poisoning occurring within the hospital resulting in a negative patient outcome.
(3) Unexplained loss of or theft of a controlled substance.
(4) Missing patient whose whereabouts are unknown for over twenty-four (24) hours.

(e) The hospital shall report the following incidents to the division:

(1) Verbal reports within twenty-four (24) hours of occurrence on:
    (A) murder, suicide, or kidnapping of patient occurring after admission;
    (B) reportable infection outbreaks or food poisonings as required by federal, state, and local law; and
    (C) a disruption, exceeding four (4) hours, in the continued safe operation of the hospital or in the provision of patient care, caused by internal or external disasters, strikes by health care workers, or unscheduled termination of vital services.
(2) Written reports on occurrences listed in subdivision (1), if requested, shall be submitted to the division within a reasonable period of time and document all information required by the department, including, but not limited to, the following:
    (A) An explanation of the circumstances surrounding the incident.
    (B) Summaries of all findings, conclusions, and recommendations associated with the review of the incident.
    (C) A summary of actions taken to resolve identified problems, to prevent recurrence of the incident, and to improve overall patient care.
(3) This subsection does not replace other reporting requirements. Copies of these required reports will be acceptable in satisfying subdivision (2).

(f) In the event of flood, fire, or other disaster, the governing board, or the governing board's designee, or the commissioner shall close all or that part of the hospital as may be necessary to ensure the safety and well-being of patients. The commissioner shall approve reopening. *(Indiana State Department of Health; 410 IAC 15-1.2-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

Rule 1.3. Licensure Requirements

410 IAC 15-1.3-1 Issuance of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The hospital shall file an application for licensure on a yearly basis with the division, prior to the expiration of the current license.

(b) A license is not transferable or assignable and shall be issued only for the premises named in the application.

(c) If multiple buildings are licensed under a single license, the licensee shall operate these buildings as a single integrated system as follows:

(1) All buildings or portions of buildings under a single license shall be governed by a single governing body and under administrative control of a single administrator.

(2) All hospital facilities operating under a single license shall have a single medical staff.

(d) Reapplication shall be filed when a change of fifty percent (50%) or greater ownership occurs.

(e) An application for license from a newly constructed hospital shall be obtained from the division and submitted after the physical plant plans have been approved under 410 IAC 15-1.5-8. Upon receipt of a design release from the state building commissioner, an application shall be submitted to the division on the form provided, along with the documents required by the application form.

(f) Any full or partial replacement of the physical plant of a hospital, any addition or renovation to the physical plant of a hospital, or any acquisitions of additional buildings under the current license of an existing hospital, shall meet the provisions of 410 IAC 15-1.5-8. *(Indiana State Department of Health; 410 IAC 15-1.3-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; filed Jun 3, 1996, 9:00 a.m.: 19 IR 2876; errata filed Jun 10, 1996, 2:00 p.m.: 19 IR 2884; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.3-2 Posting of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. The license shall be conspicuously posted on the hospital premises in an area open to patients and public. A copy shall be conspicuously posted in an area open to patients and public on the premises of each separate hospital building of a multiple hospital building system. *(Indiana State Department of Health; 410 IAC 15-1.3-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.3-3 Suspension or revocation of license

Authority: IC 16-21-1-7
Affected: IC 4-21.5; IC 16-21-1

Sec. 3. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):

(1) Issue a letter of correction.

(2) Issue a probationary license.

(3) Conduct a resurvey.

(4) Deny renewal of a license.

(5) Revoke a license.

(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000).

(b) The commissioner may take action under subsection (a) on any of the following grounds:

(1) Violation of any of the provisions of this article.

(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.

(3) Conduct or practice found by the council to be detrimental to the welfare of the patients of an institution.

(c) IC 4-21.5 applies to an action under this section.

(d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.

(e) The state department shall appoint an appeals panel consisting of three (3) members as follows:
(1) One (1) member of the executive board.
(2) One (1) attorney admitted to the practice of law in Indiana.
(3) One (1) individual with qualifications determined by the state department.
(f) An employee of the department may not be a member of the panel.
(g) The panel shall conduct proceedings for review of an order issued by an administrative law judge under this rule. The panel is the ultimate authority under IC 4-21.5. *(Indiana State Department of Health; 410 IAC 15-1.3-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.3-4 Complaint investigation

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) The division shall investigate all complaints that come under the department's jurisdiction, regardless of the method of communication.
(b) The complaints will be assigned a priority based on the seriousness of the complaint, according to division policy, and the priority will dictate the immediacy of the investigation.
(c) The complaint investigations will be unannounced and may:
(1) occur at the time of the annual licensure inspection; and
(2) evolve into a full survey.
(d) The results of the investigation will be given in writing to the hospital.
(e) The hospital will have a reasonable period of time to respond in writing with an acceptable plan of correction for noncompliance with state rules noted as a result of the investigation before this information is made available to the public.
(f) The results will be reviewed and upon recommendation of the division forwarded to the commissioner for action under section 3 of this rule.
(g) The completed complaint and survey results will become part of the hospital's public file. *(Indiana State Department of Health; 410 IAC 15-1.3-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

Rule 1.4. Governing Board Responsibilities

410 IAC 15-1.4-1 Governing board

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The governing board is legally responsible for the conduct of the hospital as an institution. The governing board shall do the following:
(1) Function as the supreme authority of the hospital.
(2) Ensure that the hospital:
(A) meets all rules and regulations for licensure and certification, if applicable; and
(B) makes available to the commissioner upon request all reports, records, minutes, documentation, information, and files required for licensure.
(3) Adopt bylaws and function accordingly.
(4) Review the bylaws at least triennially.
(5) Maintain a liaison with the medical staff.
(6) Review, at least quarterly, reports of management operations, medical staff actions, and quality monitoring, including patient services provided, results attained, recommendations made, actions taken, and follow-up.
(7) Ensure that there is a hospital-wide, quality assessment and improvement program to evaluate the provision of patient care.
(b) The governing board is responsible for the conduct of the medical staff. The governing board shall do the following:
(1) Determine, with the advice and recommendation 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 that:

(A) the requests of practitioners, for appointment or reappointment to practice in the hospital, 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; and

(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. Governing board approval of medical staff bylaws and rules shall not be unreasonably withheld.

(4) Ensure that the medical staff is accountable and responsible to the governing board 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 hospital is not solely dependent upon certification, fellowship, or membership in a specialty body or society.

(c) The governing board is responsible for managing the hospital. The governing board shall do the following:

(1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer. These criteria would apply to all chief executive officers appointed after the effective date of this article.

(2) Appoint a qualified chief executive officer who is delegated the authority and responsibility for managing the hospital and report to the division the name of the chief executive officer within ten (10) days after the appointment.

(3) Delineate in writing the responsibility and authority of the chief executive officer.

(4) Require that the chief executive officer or designee attends meetings of the governing board and its committees and act as its representative at medical staff meetings.

(5) Require that the chief executive officer has designated in writing an administrative officer to serve during his or her absence.

(6) Require that the chief executive officer develops 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) Orientation of all new employees, including contract and agency personnel, to applicable hospital, department, service, and personnel policies.

(C) 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 within a reasonable period of time.

(D) 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.

(E) Establishing criteria for each service manager, department director, or supervisor that includes, but is not limited to, the following:

(i) Definition of educational requirements.

(ii) Experience requirements.

(iii) Professional certification, licensing, or registration, where appropriate.

(F) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and hospital policy for all health care workers, including contract and agency personnel, who provide direct patient care.

(G) Providing employee health services and a post offer physical examination in consultation with the infection control committee.

(H) Requiring all services to have written policies and procedures that are updated as needed and reviewed at least triennially.

(I) Establishing a policy and procedure for communicating with physicians concerning an inpatient emergency in accordance with 410 IAC 15-1.5-5(b)(3)(L).

(J) Maintaining a current roster of members of the medical staff and their service categories.

(K) Maintaining personnel records for each employee of the hospital 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 test or chest x-ray, as applicable.

(L) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-servicing in special procedures.

(M) Coordinating with local, regional, and state health planning groups and other hospital services providers so that effective disaster preparedness, emergency service communication, and transportation systems are established and maintained.

(N) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.

(O) Development, implementation, and monitoring of a safety management program under the direction of a safety officer, qualified by experience or education.

(P) Safe, appropriate, and adequate transport of patients.

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

(1) Ensure all patients are admitted to the hospital only by a licensed practitioner who has been granted admitting privileges in accordance with the credentialing process of the hospital.

(2) 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 or psychiatric problem that is present on admission or develops during hospitalization that does not specifically fall within the scope of practice or the medical staff privileges of the admitting practitioner.

(3) Provide the following for any patients requiring emergency care:

(A) In hospitals with at least one hundred (100) acute care staffed beds, a licensed physician on the premises at all times who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).

(B) In hospitals of less than one hundred (100) acute care staffed beds:

(i) a licensed physician on the premises as in clause (A); or

(ii) a licensed physician who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i) and who is on call at all times and immediately available by phone and then available on the premises within thirty (30) minutes, if necessary, and in accordance with hospital and medical staff policies.

(4) Ensure either of the following:

(A) If the hospital does provide community emergency services to the public, it shall provide that service in compliance with 410 IAC 15-1.6-2.

(B) If the hospital does not provide community emergency services to the public, it shall do the following:

(i) Have written medical staff policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(ii) Provide immediate lifesaving measures within the scope of services available to all persons who appear for emergency care which includes, but is not limited to, the following:

(AA) Timely assessment.

(BB) Stabilization.

(CC) Treatment prior to transfer.

(iii) Arrange for transfer of the patient, with copies of records of treatments provided, to another hospital which does provide appropriate clinical services.

(5) Ensure policies are established to cover physician limited practice problems that may include, but are not necessarily limited to, the following:

(A) Impaired physicians.

(B) Criminal checks.

(C) Disciplinary action.

(6) Ensure that the hospital does the following:

(A) Establish written protocols to identify potential organ and tissue donors.

(B) Has written policies and procedures for the facilitation of organ and tissue donations, including procurement.

(C) Inform families or authorized persons of potential organ and tissue donors of the option of donation on admission or at the time of death of a potential donor.

(D) Use discretion and sensitivity in contacts with potential organ donor families.

(E) Notify the appropriate procurement organization of potential organ donors.

(F) Establish membership in the organ procurement and transplantation network if the hospital performs transplants.

(e) The governing board is responsible for the overall institutional plan as follows:

(1) The institutional plan shall:

(A) be reviewed and updated annually; and

(B) be prepared, under the direction of the governing board, by a committee with representatives from:

(i) the governing board;

(ii) the administration, which includes, but is not limited to:

(AA) nursing;

(BB) finance; and

(CC) medical staff of the hospital.

(2) The plan shall include, but not be limited to, the programs and services provided and an annual operating budget prepared according to generally accepted accounting principles.

(f) The governing board is responsible for services delivered in the hospital whether or not they are delivered under contracts. The governing board shall ensure the following:

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

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

(3) That the hospital maintains a list of all contracted services, including the scope and nature of the services provided.

(Indiana State Department of Health; 410 IAC 15-1.4-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge planning.

(B) Infection control.

(C) Medication therapy.

(D) Response to emergencies as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).

(3) All medical and surgical services performed in the hospital with regard to appropriateness of diagnosis and treatments related to a standard of care and anticipated or expected outcomes.

(b) The hospital shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action shall be documented.

(2) The outcome of the action shall be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 15-1.4-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.4-2.2 Reporting serious adverse events

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following:

(1) A process for determining the occurrence of the following serious adverse events within the hospital:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) Retention of broken microneedles.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events that result from patient actions after admission to the hospital. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;

(EE) rate;

(FF) preparation; or

(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.

(BB) Acute fatty liver of pregnancy.

(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or Stage 4 pressure ulcers acquired after admission to the hospital. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the hospital.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excludes events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or

(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.

(iv) Patient death associated with a fall while being cared for in the hospital.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the hospital.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the hospital.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the hospital's quality assessment and improvement program shall be designed by the hospital to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the hospital in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the hospital's quality assessment and improvement program;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) identify the serious adverse event and the hospital, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) hospital employee involved;

or any other information.

(2) A potentially reportable serious adverse event may be identified by a hospital that receives a patient as a transfer from

another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a hospital identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying hospital shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The hospital's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each hospital. The department's public report will be issued no less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1), that:

(1) is determined to have occurred within the hospital between:

(A) January 1, 2006; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 15-1.4-2.2; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

Rule 1.5. Required Hospital Services

410 IAC 15-1.5-1 Dietetic services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The hospital shall have organized food and dietary services that are directed and staffed by adequate, qualified personnel, or a contract with an outside food management company that meets the minimum standards specified in this section.

(b) The food and dietetic service shall have the following:

(1) A full-time employee who:

(A) serves as director of the food and dietetic services; and

(B) is responsible for the daily management of the dietary services.

(2) A qualified dietitian, full-time, part-time, or on a consulting basis. If a consultant is used, he or she shall:

(A) submit periodic written reports on the dietary services provided; and

(B) provide the number of on-site dietitian hours commensurate with:

(i) the type of dietary supervision required;

(ii) the bed capacity; and

(iii) the complexity of the patient care services.

(3) Administrative and technical personnel competent in their respective duties.

(c) The dietary service shall do the following:

(1) Provide for liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(2) Correlate and integrate dietary care functions with those of other patient care personnel which include, but are not limited to, the following:

(A) Patient nutritional assessment and intervention.

(B) Recording pertinent information on the patient's chart.

(C) Conferring with and sharing specialized knowledge with other members of the patient care team.

(d) Menus shall meet the needs of the patients as follows:

(1) Therapeutic diets shall be prescribed by the practitioner responsible for the care of the patient.

(2) Nutritional needs shall be met in accordance with recognized dietary standards of practice and in accordance with the orders of the responsible practitioner.

(3) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel.

(Indiana State Department of Health; 410 IAC 15-1.5-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-2 Infection control

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.

(b) There shall be an active, effective, and written hospital-wide infection control program. Included in this program shall be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.

(c) The infection control program shall have a method for identifying and evaluating trends or clusters of nosocomial infections or communicable diseases.

(d) A person qualified by training or experience shall be designated as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.

(e) The chief executive officer, medical staff, and executive nurse shall do the following:

(1) Be responsible for the implementation of successful corrective action plans in affected problem areas.

(2) Provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.

(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:

(1) The infection control committee shall be a hospital or medical staff committee that meets at least quarterly, with membership that includes, but is not limited to, the following:

(A) The person directly responsible for management of the infection surveillance, prevention, and control program.

(B) A representative from the medical staff.

(C) A representative from nursing service.

(D) A representative from administration.

(E) Consultants from other appropriate services within the hospital, as needed.

(2) The chairman should be a person with interest or experience in infection control.

(3) The infection control committee responsibilities shall include, but not be limited to, the following:

(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the hospital.

(B) Recommending corrective action plans on identified problems, reviewing outcomes, and assuring resolution.

(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:

(i) Sanitation.

(ii) Universal precautions, including infectious waste management.

(iii) Cleaning, disinfection, and sterilization.

(iv) Aseptic technique, invasive procedures, and equipment usage.

(v) Reuse of disposables.

(vi) An isolation system.

(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.

(viii) An employee health program to determine the communicable disease history of new personnel as required by state and federal agencies.

(ix) Requirements for personal hygiene and attire appropriate for work settings.

(x) A program of food preparation and storage for all personnel involved in food handling which includes, but

is not limited to, the following:

(AA) Storage of employee food in patient refrigerators.

(BB) Medications in nutrition refrigerators.

(CC) Refrigerator and freezer temperature monitoring.

(xi) A program of linen management for personnel involved in linen handling.

(Indiana State Department of Health; 410 IAC 15-1.5-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-3 Laboratory services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) The hospital shall have, or make available, those pathology and medical laboratory services and consultation to meet the needs of patients served as determined by the medical staff which include the following:

(1) Emergency laboratory services shall be available twenty-four (24) hours a day as determined by the medical staff.

(2) The laboratory performs tests and examines specimens on the written request of individuals and practitioners allowed to order such evaluations and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.

(3) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the medical and nursing staff.

(4) Frozen section shall be provided where surgical procedures are performed which require immediate pathological examination.

(b) The hospital shall assure that all laboratory services provided to its inpatients and outpatients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.

(c) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic examination only and which require both macroscopic and microscopic examinations. Categories of specimens removed during surgical procedures which are determined to require only macroscopic examination shall be specified in the laboratory policies and the medical staff rules. The medical staff and a pathologist shall determine the qualified licensed health professional responsible for macroscopic examination.

(d) Laboratory supervisory and testing personnel qualifications shall be consistent with the work assignments and in compliance with 42 CFR 493.

(e) All nursing and other hospital personnel performing out-of-laboratory testing shall have annually updated performance certification maintained in the employee file for the procedures being performed.

(f) If sufficient or suitable outside facilities are not provided by undertakers or others, the hospital shall have a morgue or a low temperature body holding room. Policies covering appropriate refrigeration requirements and length of holding bodies shall be approved by the medical staff. If autopsies are performed in the hospital, there shall be a refrigerated storage unit designed for holding bodies, along with hand washing facilities and other necessary personal hygiene facilities available.

(g) The hospital shall maintain a minimum supply of blood and blood products or have an agreement with licensed blood sources which are in compliance with state law to obtain blood and blood products as quickly as needed.

(h) If donor blood is drawn in the hospital, the blood center shall be:

(1) in compliance with state law;

(2) appropriately licensed or registered by the Food and Drug Administration (FDA); and

(3) in compliance with 21 CFR 640 and 21 CFR 606.

(Indiana State Department of Health; 410 IAC 15-1.5-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1268; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-4 Medical record services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) The medical record service has administrative responsibility for the medical records that shall be maintained for

every individual evaluated or treated within those services that come under the hospital's license.

(b) The organization of the medical record service shall be appropriate to the scope and complexity of the services provided as follows:

(1) The service shall be directed by a registered health information administrator (RHIA) or a registered health information technician (RHIT). If a full-time or part-time RHIA or RHIT is not employed, then a consultant RHIA or RHIT shall be provided to assist the person in charge. Documentation of the findings and recommendations of the consultant shall be maintained.

(2) The medical record service shall be provided with the necessary direction, staffing, and facilities to perform all required functions in order to ensure prompt completion, filing, and retrieval of records.

(c) An adequate medical record shall be maintained with documentation of service rendered for each individual who is evaluated or treated as follows:

(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.

(2) A unit record system of filing should be utilized. When this is not possible, a system shall be established by the hospital to retrieve when necessary all divergently located record components.

(3) The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry shall be authenticated promptly in accordance with the hospital and medical staff policies.

(4) Medical records shall be retained in their original or legally reproduced form as required by federal and state law.

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the hospital policies.

(6) The hospital shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure in order to support continuous quality assessment and improvement activities.

(7) The hospital shall ensure the confidentiality of patient records which includes, but is not limited to, the following:

(A) A procedure for releasing information from or copies of records only to authorized individuals in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.

(d) The medical record shall contain sufficient information to:

(1) identify the patient;

(2) support the diagnosis;

(3) justify the treatment; and

(4) document accurately the course of treatment and results.

(e) All entries in the medical record shall be:

(1) legible and complete;

(2) made only by individuals given this right as specified in hospital and medical staff policies; and

(3) authenticated and dated promptly in accordance with subsection (c)(3).

(f) All inpatient records, except those in subsection (g), shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) The medical history and physical examination of the patient done within the time frames as prescribed by the medical staff rules and section 5(b)(3)(M) of this rule.

(3) A statement of the diagnosis or impressions drawn from the admission history and physical examination.

(4) Diagnostic and therapeutic orders.

(5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.

(6) Clinical observations, including results of therapy, documented in a timely manner.

(7) Progress notes.

(8) Operative note in accordance with 410 IAC 15-1.6-9(c)(7).

(9) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(10) Nursing notes, nursing plan of care, and entries by other health care providers that contain pertinent, meaningful observations and information.

(11) Reports of pathology and clinical laboratory examinations, radiology and nuclear medicine examinations or treatment, anesthesia records, and any other diagnostic or therapeutic procedures and their results.

(12) Documentation of complications and unfavorable reactions to drugs and anesthesia.

(13) A discharge summary authenticated by the physician. A final progress note may be substituted for the discharge summary in the case of a normal newborn infant and uncomplicated obstetric delivery. The final progress note should include any instruction given to the patient and family.

(14) Final diagnosis.

(g) A short stay record form used for inpatients hospitalized for less than forty-eight (48) hours, observation patients, ambulatory care patients, and ambulatory surgery patients shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Medical history and description of the patient's condition and pertinent physical findings.

(3) Diagnostic and therapeutic orders.

(4) Care based on identified standard of care and standard of practice.

(5) Data necessary to support the diagnosis and the treatment given, with reports of procedures and tests, and their results, clinical observations, including the results of therapy, and anesthesia given, if applicable.

(6) Operative note in accordance with 410 IAC 15-1.6-9(c)(7), if applicable.

(7) Final progress note, including instructions to the patient and family with dismissal diagnosis and disposition of patient.

(8) Authentication by the physician and other responsible personnel in attendance.

(h) Outpatient records shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Diagnostic and therapeutic orders.

(3) Description of treatment given, procedures performed, and documentation of patient response to intervention, if applicable.

(4) Results of diagnostic tests and examinations done, if applicable.

(i) Emergency service records shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Time of arrival, means of arrival, time treatment is initiated, and time examined by the physician, if applicable.

(3) Pertinent history of illness or injury, description of the illness or injury, and examination, including vital signs.

(4) Diagnostic and therapeutic orders.

(5) Description of treatment given or prescribed, clinical observations, including the results of treatment, and the reports of procedures and test results, if applicable.

(6) Authentication by the practitioner or licensed health professional who rendered treatment or prescribed for the patient in accordance with hospital policy.

(7) Instruction given to patient on release, prescribed follow-up care, signature of patient or responsible other, and name of person giving instructions.

(8) Diagnostic impression and condition on discharge documented by the practitioner, and disposition of the patient and time of dismissal.

(9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.

(Indiana State Department of Health; 410 IAC 15-1.5-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1269; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Jan 2, 2003, 10:22 a.m.: 26 IR 1550; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-5 Medical staff

Authority: IC 16-21-1-7

Affected: IC 16-21-1; IC 25-22.5

Sec. 5. (a) The hospital shall have an organized medical staff that operates under bylaws approved by the governing board and is responsible to the governing board for the quality of medical care provided to patients. The medical staff shall be composed of two (2) or more physicians and other practitioners as appointed by the governing board and do the following:

(1) Conduct outcome oriented performance evaluations of its members at least biennially.

(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance

with hospital policy and applicable state and federal law.
(3) Make recommendations to the governing board on the appointment or reappointment of the applicant for a period not to exceed two (2) years.
(4) Maintain a file for each member of the medical staff which includes, but is not limited to, the following:
(A) A completed, signed application.
(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.
(C) A copy of their current Indiana license showing date of licensure and current number or an available certified list provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the medical licensing board.
(D) A copy of their current Indiana controlled substance registration showing number, as applicable.
(E) A copy of their current Drug Enforcement Agency registration showing number, as applicable.
(F) Documentation of experience in the practice of medicine.
(G) Documentation of specialty board certification, as applicable.
(H) Category of medical staff appointment and delineation of privileges approved.
(I) A signed statement to abide by the rules of the hospital.
(J) Documentation of current health status as established by hospital and medical staff policy and procedure and federal and state requirements.
(K) Other items specified by the hospital and medical staff.
(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules shall:
(1) be approved by the governing board;
(2) be reviewed at least triennially; and
(3) include, but not be limited to, the following:
(A) A description of the medical staff organizational structure. If the organization calls for an executive committee, a majority of the members shall be physicians on the active medical staff.
(B) Meeting requirements of the staff.
(C) A provision for maintaining records of all meetings of the medical staff and its committees.
(D) A procedure for designating an individual physician with current privileges as chief, president, or chairperson of the staff.
(E) A statement of duties and privileges for each category of the medical staff.
(F) A description of the medical staff applicant qualifications.
(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.
(H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing board.
(I) A process for appeals of decisions regarding medical staff membership and privileges.
(J) A process for medical staff performance evaluations based on clinical performances indicated in part by the results of quality assessment and improvement activities.
(K) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting appropriate enforcement actions against practitioners who fail to comply with the hospital and medical staff bylaws and rules.
(L) A provision for physician coverage of emergency care that addresses at least:
(i) a definition of emergency care to include, but not be limited to:
(AA) inpatient emergencies; and
(BB) emergency services emergencies; and
(ii) a timely response.
(M) A requirement that a complete physical examination and medical history be performed:
(i) on each patient admitted by a practitioner who has been granted such privileges by the medical staff;
(ii) within seven (7) days prior to date of admission and documented in the record with a durable, legible copy of the report and changes noted in the record on admission; or
(iii) within forty-eight (48) hours after an admission.

(N) A requirement that all physician orders shall be in writing or acceptable computerized form and shall be authenticated by the responsible individual in accordance with hospital and medical staff policies.

(O) A requirement that all verbal orders must be repeated and verified and that the repetition and verification be documented in the patient's medical record signed and dated by the authorized health care professional that took the order. If there is no repetition and verification of the verbal order the prescribing physician/practitioner shall authenticate and date the verbal order within forty-eight (48) hours.

(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.

(c) The medical staff should attempt to secure autopsies in all cases of unusual deaths and educational interest. There shall be the following:

(1) A mechanism for documenting in writing the following:

(A) That permission to perform an autopsy was obtained.

(B) The source of the permission.

(2) A system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

(Indiana State Department of Health; 410 IAC 15-1.5-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1271; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Jan 2, 2003, 10:22 a.m.: 26 IR 1551; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-6 Nursing service

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-11

Sec. 6. (a) The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. The service shall have the following:

(1) An organizational plan which delineates the responsibilities for patient care.

(2) A nurse executive who is:

(A) licensed under IC 25-23-1-11; and

(B) responsible for the following:

(i) The operation of the services, including, but not limited to, determining the types and numbers of nursing personnel and staff necessary to provide care for all patient care areas of the hospital.

(ii) Maintaining a current nursing service organization chart.

(iii) Maintaining current job descriptions with reporting responsibilities for all nursing staff positions.

(iv) Ensuring that all nursing personnel meet annual in-service requirements as established by hospital and medical staff policy and procedure, and federal and state requirements.

(v) Establishing the standards of nursing care and practice in all settings in which nursing care is provided in the hospital.

(b) The nursing service shall have the following:

(1) Adequate numbers of licensed registered nurses, licensed practical nurses, and other ancillary personnel necessary for the provision of appropriate care to all patients, as needed, to include the immediate availability of a registered nurse.

(2) The service shall have a procedure to ensure that hospital nursing personnel, including nurse registry personnel for whom licensure is required, have valid and current licensure.

(3) A registered nurse shall supervise and evaluate the care planned for and provided to each patient.

(4) The nursing staff shall develop and utilize an ongoing individualized plan of care based on standards of care for each patient.

(5) A registered nurse shall assign the care of each patient to nursing personnel in accordance with the patient's need and the specialized qualifications and competence of the nursing staff available.

(6) All nursing personnel shall demonstrate and document competency in fulfilling assigned responsibilities.

(c) Drugs and biologicals shall be prepared for administration and administered as follows:

(1) By, or under the supervision of, a registered nurse or other qualified personnel.

(2) In accordance with current federal and state laws.

(3) In accordance with medical staff rules.

(4) In accordance with the signed written orders of the practitioner or practitioners responsible for the patient's care. When verbal or telephone orders are used, they shall be accepted only by personnel that are authorized to do so by the medical staff rules.

(5) In accordance with currently acceptable standards of practice.

(6) As specified under section 7 of this rule.

(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6).

(e) Emergency equipment and emergency drugs shall be available for use on all nursing units. *(Indiana State Department of Health; 410 IAC 15-1.5-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.5-7 Pharmaceutical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) The hospital shall have a pharmaceutical service that meets the needs of the patient and complies with requirements set forth by the Indiana board of pharmacy.

(b) The hospital shall have a pharmacy service directed by a pharmacist, as follows:

(1) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, coordinating, and implementing the written policies and procedures to ensure appropriate distribution, control, therapeutic monitoring, and accountability of all drugs used in the hospital.

(2) The pharmacy service shall be administered in accordance with accepted professional standards and federal and state laws.

(3) The pharmacy service shall have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.

(d) Written policies and procedures shall be developed and implemented that include the following:

(1) Establish a formulary system with specifications for the selection and procurement of all drugs and biologicals at reasonable costs and as approved by the medical staff.

(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:

(A) Separation of drugs designed for external use from drugs intended for internal use.

(B) Appropriate storage conditions.

(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or destruction.

(D) Documentation and accountability for an accurate accounting of controlled substances from the time of receipt in the institution through the administration to the patient or subsequent removal from general stock and reporting of all abuses and losses of controlled substances.

(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent.

(F) Availability of information relating to drug interactions and information on the following:

(i) Drug therapy.

(ii) Side effects.

(iii) Toxicology.

(iv) Dosage.

(v) Indications for use.

(vi) Routes of administration.

(3) Review the use of medications with the standards developed by the medical staff, which include stop orders for scheduled drugs and biologicals not specifically prescribed as to time or number of doses.

(4) Allow for adequate drug therapy monitoring procedures to exist.

(5) Minimize medication errors and document, monitor, evaluate, and report adverse drug reactions and medication errors.

(6) Provide for the maintenance of drug and poison information materials.

(Indiana State Department of Health; 410 IAC 15-1.5-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-8 Physical plant, maintenance, and environmental services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. (a) The hospital shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the hospital license as follows:

(1) The plant operations and maintenance service, equipment maintenance, and environmental service shall be:

(A) staffed to meet the scope of the services provided; and

(B) under the direction of a person or persons qualified by education, training, or experience.

(2) There shall be a safety officer designated to assume responsibility for the safety program.

(3) The hospital shall provide a physical plant and equipment that meet the statutory requirements and regulatory provisions of the state department of fire and building services, including 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.

(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:

(1) No condition in the facility or on the grounds shall be maintained that may be conducive to the harborage or breeding of insects, rodents, or other vermin.

(2) No condition shall be created or maintained that may result in a hazard to patients, public, or employees.

(3) There shall be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.

(4) There shall be a plan for emergency fuel and water supply.

(5) Provision shall be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals shall be available, along with training or instruction of the appropriate personnel, in the maintenance and operation of the fixed and movable equipment.

(B) Operational and maintenance control records shall be established and analyzed periodically. These records shall be readily available on the premises.

(C) Maintenance and repairs shall be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, the administrative building council, the state fire marshal, and the department.

(c) In new construction, renovations, and additions, the hospital site and facilities, or nonlicensed facilities acquired for the purpose of providing hospital services, shall meet the following:

(1) The 2001 edition of the national "Guideline for Construction and Equipment of Hospital and Medical Facilities" (Guidelines).

(2) All building, fire safety, and handicapped accessibility codes and rules adopted and administered by the state building commissioner shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.

(3) When renovation or replacement work is done within an existing facility, all new work or addition, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of National Fire Protection Association (NFPA) 101 (2000 Edition).

(4) Proposed sites shall be located away from detrimental nuisances, well drained, and not subject to flooding. A site survey and recommendations shall be obtained from the department prior to site development.

(5) Water supply and sewage disposal services shall be obtained from municipal or community services. Outpatient facilities caring for patients less than twenty-four (24) hours that do not provide surgery, laboratory, or renal dialysis services may be served by approved private on-site septic tank absorption field systems.

(6) Site utility installations for water, sprinkler, sanitary, and storm sewer systems, and wells for potable emergency water supplies, shall comply with applicable sections of Bulletin S.E. 13, "On-Site Water Supply and Waste-water Disposal for Public and Commercial Establishments", 1988 edition.

(7) As early in the construction, addition, or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:

(A) Functional program narrative as established in the Guidelines.

(B) Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.

(8) Prior to the start of construction, addition, or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the division of sanitary engineering of the department, as follows:

(A) Working drawings, project manual, and specifications shall be included.

(B) Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 2(f)(2) of this rule.

(C) All required approvals shall be obtained from the state building commissioner and final approval from the division of sanitary engineering of the department prior to issuance of the occupancy letter by the division.

(9) All backflow prevention devices shall be installed as required by 327 IAC 8-10 and the current edition of the Indiana plumbing code. Such devices shall be listed as approved by the department.

(10) Upon receipt of a design release from the state building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department, a licensure application shall be submitted to the division on the form approved and provided by the department.

(11) Documentation from the state building commissioner that the hospital is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division with the licensure application.

(12) Plans for constructing, expanding, or remodeling x-ray or gamma ray facilities shall be accompanied by an evaluation of the radiation protection features by a radiation qualified expert as required by 410 IAC 5. After completion of the x-ray or gamma ray installation and prior to use, a radiation safety survey shall be performed by a radiation qualified expert to ensure that the facility meets all applicable requirements of 410 IAC 5 and National Council on Radiation Protection and Measurements (NCRP) Reports Number 49 and 102.

(13) Outpatient facilities, rehabilitation facilities, psychiatric facilities, and mobile, transportable, and relocatable units that are included under the hospital license may comply with appropriate sections of the Guidelines. If not, they shall comply with the hospital section of the Guidelines.

(d) The equipment requirements are as follows:

(1) All equipment shall be in good working order and regularly serviced and maintained.

(2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows:

(A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.

(B) There shall be evidence of preventive maintenance on all equipment.

(C) Appropriate records shall be kept pertaining to equipment maintenance, repairs, and current leakage checks.

(3) Defibrillators shall be discharged at least in accordance with manufacturers' recommendations and a discharge log with initialed entries shall be maintained.

(4) Electrical safety shall be practiced in all areas.

(e) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, shall be kept clean and orderly in accordance with current standards of practice as follows:

(1) Environmental services shall be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:

(A) Asepsis.

(B) Cross-infection.

(C) Safe practice.

(2) Refuse and garbage shall be collected, transported, sorted, and disposed of by methods that will minimize nuisances or hazards.

(f) The safety management program shall include, but not be limited to, the following:

(1) An ongoing hospital-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the safety committee.

(2) A safety committee appointed by the chief executive officer that includes representatives from administration, patient services, and support services.

(3) The safety program that includes, but is not limited to, the following:

(A) Patient safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(D) Hazardous materials and wastes management in accordance with federal and state rules.

(E) A written fire control plan that contains provisions for the following:

(i) Prompt reporting of fires.

(ii) Extinguishing of fires.

(iii) Protection of patients, personnel, and guests.

(iv) Evacuation.

(v) Cooperation with firefighting authorities.

(F) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies.

(G) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(Indiana State Department of Health; 410 IAC 15-1.5-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1273; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1135; filed Apr 16, 2004, 10:30 a.m.: 27 IR 2718; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-9 Radiologic services

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 9. (a) The hospital shall have on-site, or available by arrangement, the diagnostic imaging services required by the needs of the patients served and within the scope of the service provided, that are in compliance with federal and state rules, as follows:

(1) If radiation emitting or nonionizing services, either diagnostic or therapeutic, are provided, the applicable requirements of this section apply. The services may include, but not be limited to the following:

(A) Mammography.

(B) Computerized tomography.

(C) Magnetic resonance imaging.

(D) Ultrasound.

(E) Catheterization lab.

(F) Interventional radiology.

(2) If therapeutic or diagnostic nuclear medicine services are provided, they shall comply with the applicable requirements of this section and with 410 IAC 15-1.6-4.

(b) The services that use ionizing radiation shall not compromise the health, safety, and welfare of patients or personnel in accordance with federal and state rules, as follows:

(1) Proper safety precautions shall be maintained against radiation hazards in accordance with the hospital's radiation and safety program as developed by the radiation safety officer. This includes, but is not limited to, the following:

(A) Adequate shielding for patients, personnel, and facilities.

(B) Procedures for monitoring:

(i) skin dosage;

(ii) radionuclide contamination;

(iii) quality control;

(iv) technique charts, where applicable; and

(v) handling of hazardous materials.

(C) Appropriate storage, use, and disposal of radioactive materials.

(2) Equipment shall be inspected, tested, and calibrated at least annually by qualified personnel with appropriate documentation reasonably available.

(3) Hazards and faulty equipment identified shall be promptly corrected in accordance with current standards of practice and applicable federal and state rules to include, but not be limited to, collimation and filtration, and evaluation of equipment

performance.

(4) Written preventive maintenance policies and procedures, in accordance with manufacturer's recommendations and hospital policy, shall be maintained and compliance shall be documented.

(c) Procedures and treatments are performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.

(d) A full-time, part-time, or consulting radiologist or physician qualified by education and experience in the service provided as determined by the medical staff shall do the following:

(1) Supervise the service provided.

(2) Ensure that only personnel use the equipment and administer procedures who:

(A) have been designated as qualified by the medical staff; and

(B) are allowed to do so in accordance with current standards of practice and state rules.

(3) Interpret those tests that are determined by the medical staff to require a radiologist's or appropriately credentialed physician's specialized knowledge.

(4) Be available for consultation for the quality and necessity of diagnostic imaging, nuclear medicine, and therapeutic procedures, if applicable.

(e) Records shall be maintained as follows:

(1) The radiologist or other practitioner shall authenticate reports of his or her interpretations.

(2) The hospital shall maintain the following for at least five (5) years:

(A) Copies of reports and printouts.

(B) Films, scans, and other image records.

(C) If clauses (A) and (B) are maintained in the medical record, these items shall be maintained in accordance with state and federal law.

(Indiana State Department of Health; 410 IAC 15-1.5-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1275; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.5-10 Utilization review and discharge planning services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 10. (a) The hospital shall have and implement a written plan, approved by the medical staff and governing body, that describes the utilization review program and governs its operation.

(b) The utilization review program shall address appropriate utilization of patient care resources.

(c) Concurrent review shall focus on those diagnoses problems, procedures, or practitioners with identified or suspected utilization-related problems.

(d) The hospital's utilization review program shall be reviewed and evaluated at least annually and be revised, as appropriate, to reflect the findings of the hospital's utilization review activities.

(e) To facilitate discharge as soon as an acute level of care is no longer required, the hospital shall have effective, ongoing discharge planning that:

(1) facilitates the provision of follow-up care;

(2) is initiated in a timely manner as established by written hospital policy;

(3) transfers or refers patients, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. The information shall include, but not be limited to, the following:

(A) medical history;

(B) current medications;

(C) activities status;

(D) nutritional needs;

(E) outpatient service needs;

(F) follow-up care needs; and

(4) utilizes available community and hospital resource to provide appropriate referrals or make available social, psychological, and educational services to meet the needs of the patient.

(f) If required by Medicare, the hospital has a current memorandum of understanding covering binding review that complies with federal peer review rules. *(Indiana State Department of Health; 410 IAC 15-1.5-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

Rule 1.6. Optional Hospital Services

410 IAC 15-1.6-1 Anesthesia services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) If the hospital furnishes anesthesia services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a qualified physician. The service is responsible for all anesthesia administered in the hospital.

(b) Anesthesia shall only be administered by those privileged by the medical staff who are:

(1) an anesthesiologist;

(2) a qualified physician with appropriate training, experience, and privileges;

(3) a dentist, oral surgeon, or a podiatrist who is qualified to administer anesthesia under state law; or

(4) a certified registered nurse anesthetist (CRNA) who is under the direction of the operating practitioner or of a qualified physician who is immediately available if needed.

(c) Anesthesia services shall be consistent with needs and resources, as follows:

(1) There shall be written policies and procedures on monitored anesthesia care (MAC), general anesthesia, and regional anesthesia which include, but are not limited to, the following:

(A) The delineation of preanesthesia and postanesthesia responsibilities.

(B) The completion, within forty-eight (48) hours prior to surgery, of a preanesthesia evaluation for each patient by an individual(s) qualified to administer anesthesia.

(C) The requirement of an intra-operative anesthesia record on each patient.

(D) The completion, within forty-eight (48) hours after surgery, of a postanesthesia follow-up report on each inpatient by the individual who administered the anesthesia.

(E) The completion of a postanesthetic evaluation for proper anesthesia recovery of each outpatient in accordance with written policies and procedures approved by the medical staff.

(F) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit by the practitioner in subsection (b) responsible for the patient's care in accordance with hospital policy.

(2) There shall be written policies and procedures on local anesthesia.

(3) There shall be intra-operative monitoring in accordance with current acceptable standards of practice.

(4) Anesthesia equipment shall be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.

(Indiana State Department of Health; 410 IAC 15-1.6-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-2 Emergency services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) If a hospital provides a community emergency service, the service shall meet the emergency needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a physician qualified by education or experience.

(b) The emergency service shall have the following:

(1) A scope of service that is clearly defined.

(2) Written policies and procedures governing medical care provided in the emergency service are established by and are a

continuing responsibility of the medical staff. The policies shall include, but not be limited to, the following:

(A) Provision for the care of the disturbed patient.

(B) Provision for immediate assessment of all patients presenting for emergency and obstetrical care.

(C) Provision for transfer of patients when care is needed which cannot be provided.

(3) Integration with other hospital services.

(4) Laboratory and x-ray services available at all times.

(5) Adequate qualified medical and nursing personnel available to meet the needs anticipated by the facility in accordance with 410 IAC 15-1.4-1 and 410 IAC 15-1.5-6, which includes, but is not limited to, the following:

(A) A registered nurse on duty and available to patients presenting with an emergency condition, on a twenty-four (24) hours per day, seven (7) day per week basis.

(B) A physician available at all times in accordance with 410 IAC 15-1.4-1(d)(3) and attending to patients with an emergency condition.

(6) A physician on-call roster available in the emergency service department which lists medical specialists in addition to scheduled medical staff.

(7) A patient control register.

(Indiana State Department of Health; 410 IAC 15-1.6-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-3 Nuclear medicine services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) If the hospital provides nuclear medicine services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and comply with applicable requirements of 410 IAC 15-1.5-9.

(b) Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice, and federal and state law, as follows:

(1) In-house preparation of radio-pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or physician.

(2) There is proper storage and disposal of radioactive material.

(3) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirements for laboratory services, in this article, with respect to the following:

(A) Management.

(B) Adequacy of facilities.

(C) Proficiency testing.

(D) Quality control.

(c) Equipment and supplies shall:

(1) be appropriate for the types of nuclear medicine services offered;

(2) be maintained in safe operating condition; and

(3) be inspected, tested, and calibrated at least annually by qualified personnel.

(d) The hospital shall maintain the following:

(1) Signed and dated reports of nuclear medicine interpretations, consultation, and procedures in accordance with applicable requirements of 410 IAC 15-1.5-9(e).

(2) Records of the receipt and disposition of radio-pharmaceuticals in accordance with federal and state rules.

(Indiana State Department of Health; 410 IAC 15-1.6-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-4 Outpatient care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) If the hospital provides outpatient care services, the service shall meet the needs of the patients, within the scope of the service offered, in accordance with acceptable standards of practice. The service shall be under the direction of a qualified person or persons.

(b) Outpatient care services shall be appropriately organized and integrated with inpatient services, as follows:

(1) Assign a qualified registered nurse to supervise the nursing care in outpatient care services.

(2) Have appropriate personnel available.

(3) Ensure a record is maintained in accordance with 410 IAC 15-1.5-4 and hospital policy.

(c) Outpatient care services may include, but are not limited to, the following:

(1) Observation care.

(2) Ambulatory care.

(3) Other care programs designated by the hospital.

(Indiana State Department of Health; 410 IAC 15-1.6-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-5 Psychiatric services

Authority: IC 16-21-1-7
Affected: IC 12-22-2-3; IC 16-21-1

Sec. 5. (a) If the hospital provides psychiatric services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.

(b) The service shall be under the direction of a physician qualified by training or experience.

(c) The service shall be staffed in accordance with hospital policies and with applicable state and federal rules.

(d) If the service provided includes a psychiatric unit exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25 and CFR Part 412, Subpart B, section 412.27 for the purposes of licensure.

(e) If the service provided includes a subacute short term stabilization program provided in a group home setting as provided for in IC 12-22-2-3, this article will apply with the exception of 410 IAC 15-1.5-8. *(Indiana State Department of Health; 410 IAC 15-1.6-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.6-6 Rehabilitation services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. (a) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, speech pathology, or other therapy services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a physician qualified by training or experience and supervised by a qualified person or persons.

(c) Available services shall be provided on the written request of individuals and practitioners allowed by law to order such services and as authorized by the governing body, and furnished in accordance with a written plan of treatment, if appropriate.

(d) The services shall have appropriate personnel available.

(e) If the services provided include an inpatient rehabilitation unit or the hospital itself is exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25, 42 CFR Part 412, Subpart B, section 412.29, and 42 CFR Part 412, Subpart B, section 412.30 for purposes of licensure. *(Indiana State Department of Health; 410 IAC 15-1.6-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-1.6-7 Respiratory care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) If the hospital provides respiratory care services, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The service shall be under the direction of a physician who is a pulmonologist or a physician qualified by training or experience, and supervised by a qualified person.

(c) The respiratory care service shall meet the following requirements:

(1) Have certified respiratory care practitioners or other personnel who meet the qualifications specified by the medical staff.

(2) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(d) Respiratory care services shall be:

(1) delivered in accordance with medical staff directives;

(2) documented in the medical record; and

(3) provided only on the orders of a physician or appropriately credentialed practitioner.

(e) If blood gases or other clinical laboratory tests are performed by the respiratory care service, 410 IAC 15-1.5-3 applies.

(Indiana State Department of Health; 410 IAC 15-1.6-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-8 Surgical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. (a) If the hospital provides inpatient or ambulatory surgical services, the services shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice and safety.

(b) The organization of the surgical services shall be appropriate, according to the scope of the services offered, as follows:

(1) The surgical service shall be under the direction of a physician qualified by experience and training.

(2) An experienced registered nurse shall supervise all nursing personnel in surgical services and postanesthesia care units (PACU), as follows:

(A) Licensed practical nurses, operating room technicians (ORTs), obstetrical technicians (OB Techs), and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.

(B) Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved written medical staff policies and procedures.

(c) Surgical services shall have policies governing surgical care designed to assure the achievement and maintenance of standards of medical practice and patient care, as follows:

(1) A mechanism shall be maintained which specifies the delineated surgical privileges of each practitioner.

(2) There shall be a history and physical workup in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting physician, which includes vital signs, allergies, and appropriate data.

(3) A properly executed informed consent form for the operation shall be in the patient's chart before surgery, except in extreme emergencies.

(4) The following equipment shall be available to the operating room suites and PACU:

(A) Cardiac monitor.

(B) Resuscitation equipment.

(C) Defibrillator.

(D) Aspirator.

(E) Oximeter.

(F) Tracheotomy set.

(5) There shall be adequate provision for immediate postoperative care.

(6) The operating room register shall be complete and up-to-date.

(7) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and authenticated by the surgeon.

(8) A list of tissues excluded from microscopic examination, if applicable, shall be maintained in surgery services.

(9) There shall be no explosive anesthetic agents, flammable, or potentially flammable, liquids or agents stored or used in the surgical services area.

(Indiana State Department of Health; 410 IAC 15-1.6-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

410 IAC 15-1.6-9 Other services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 9. (a) If the hospital provides other services not covered in specific sections of this article, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a qualified person or persons.

(c) The services shall be staffed in accordance with written hospital policies and comply with the applicable state and federal rules. *(Indiana State Department of Health; 410 IAC 15-1.6-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

Rule 1.7. Incorporation by Reference

410 IAC 15-1.7-1 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 below. The following publications are hereby incorporated by reference:

(1) Guidelines for Construction and Equipment of Hospital and Medical Facilities (2001 Edition). Copies are available from the American Institute of Architects, 1735 New York Ave. Northwest, Washington, D.C. 20006.

(2) Bulletin S.E. 13, "On-site Water Supply and Waste-water Disposal for Public and Commercial Establishments" (1988 Edition). Copies are available from the Indiana State Department of Health, 1330 West Michigan Street, P.O. Box 1964, Indianapolis, IN 46206-1964.

(3) 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 9101, Quincy, MA 02269-9904.

(4) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (2000 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9904.

(5) 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.

(6) 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.

(7) 42 CFR Part 412, Subpart B, Section 412.25, 42 CFR Part 412, Subpart B, Section 412.27, 42 CFR Part 412, Subpart B, Section 412.29, 42 CFR Part 412, Subpart B, Section 412.30 (October 1, 1993 Edition).

(8) 42 CFR Part 493 (October 1, 1993 Edition).

(9) 21 CFR Part 606 (April 1, 1994 Edition).

(10) 21 CFR Part 640 (April 1, 1994 Edition).

(b) Federal rules that 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 Indiana state

department of health. *(Indiana State Department of Health; 410 IAC 15-1.7-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1280; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1137; filed Apr 16, 2004, 10:30 a.m.: 27 IR 2720)*

Rule 2. Ambulatory Outpatient Surgical Centers, Operation, Building and Equipment (Repealed)

(Repealed by Indiana State Department of Health; filed Dec 1, 1999, 3:44 p.m.: 23 IR 796)

Rule 2.1. Definitions; Ambulatory Outpatient Surgical Centers

410 IAC 15-2.1-1 Applicability

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 15-2.1-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-2 "Ambulatory outpatient surgical center" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1

Sec. 2. "Ambulatory outpatient surgical center" means a center as defined in IC 16-18-2-14. *(Indiana State Department of Health; 410 IAC 15-2.1-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-3 "Authenticate" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. "Authenticate" means the author or responsible individual has reviewed the clinical content of the order and validated an entry in the record by:

(1) a full signature, including first initial, last name, and discipline;
(2) written initials if full signature appears on the same page;
(3) a unique identifier such as a number or computer key; or
(4) a signature stamp.

(Indiana State Department of Health; 410 IAC 15-2.1-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.1-4 "Center" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. "Center" means an ambulatory outpatient surgical center. *(Indiana State Department of Health; 410 IAC 15-2.1-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-5 "Commissioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 5. "Commissioner" means the state health commissioner or the state health commissioner's designee. *(Indiana State Department of Health; 410 IAC 15-2.1-5; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-6 "Council" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-84; IC 16-21-1

Sec. 6. "Council" means the body defined in IC 16-18-2-84(1). *(Indiana State Department of Health; 410 IAC 15-2.1-6; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-7 "Dentist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. "Dentist" means any person holding an unlimited license to practice dentistry in the state of Indiana. *(Indiana State Department of Health; 410 IAC 15-2.1-7; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-8 "Department" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 15-2.1-8; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-9 "Division" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 9. "Division" means the division of acute care of the department. *(Indiana State Department of Health; 410 IAC 15-2.1-9; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-10 "Governing body" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-1

Sec. 10. "Governing body" means:
(1) board of trustees;
(2) governing board;
(3) board of directors; or
(4) other body responsible for governing a center.
(Indiana State Department of Health; 410 IAC 15-2.1-10; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

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 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; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-12 "Health care worker" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 12. "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a center. *(Indiana State Department of Health; 410 IAC 15-2.1-12; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-13 "Licensed health professional" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-27.1

Sec. 13. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. *(Indiana State Department of Health; 410 IAC 15-2.1-13; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-14 "Medical staff" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 14. "Medical staff" means a group that is responsible to the governing board for the following:

(1) The clinical and scientific work of the center.

(2) Advice regarding professional matters and policies.

(3) Review of the professional practices in the center for the purposes of reducing morbidity and mortality and for the improvement of the care of patients in the center, including the following:

(A) The quality and necessity of care provided.

(B) The preventability of complications and deaths occurring in the center.

(Indiana State Department of Health; 410 IAC 15-2.1-14; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.1-15 "Pharmacist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-26-13

Sec. 15. "Pharmacist" means an individual licensed under IC 25-26-13. *(Indiana State Department of Health; 410 IAC 15-2.1-15; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-16 "Physician" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-22.5-5

Sec. 16. "Physician" means an individual licensed under IC 25-22.5-5. *(Indiana State Department of Health; 410 IAC 15-2.1-16; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-17 "Podiatrist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 17. "Podiatrist" means any person holding an unlimited license to practice podiatry in the state of Indiana. *(Indiana State Department of Health; 410 IAC 15-2.1-17; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-18 "Practitioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-1-9-2

Sec. 18. "Practitioner" means an individual as defined in IC 25-1-9-2. *(Indiana State Department of Health; 410 IAC 15-2.1-18; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-19 "Registered nurse" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1

Sec. 19. "Registered nurse" means an individual licensed under IC 25-23-1. *(Indiana State Department of Health; 410 IAC 15-2.1-19; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.1-20 "Supplier" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 20. "Supplier", for HCFA reimbursement only, means an agency for diagnosis and therapy, such as a laboratory, a clinic, and a physical therapist office, rather than sustained patient care. *(Indiana State Department of Health; 410 IAC 15-2.1-20; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

Rule 2.2. Compliance

410 IAC 15-2.2-1 Compliance with rules

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) All centers shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.

(b) Components required for licensure as a center are the following:

(1) Governing body.
(2) Quality assessment and improvement.
(3) Infection control program.
(4) Laboratory services.
(5) Medical records, storage, and administration.
(6) Medical staff, anesthesia, and surgical service.
(7) Patient care services.
(8) Pharmaceutical services.
(9) Physical plant, equipment maintenance, and environmental services.
(10) Radiology services.

(c) Optional services, not required for licensure, must comply with all rules for that service.

(d) The center shall develop, implement, and maintain a written plan to address the internal review and reporting of unusual occurrences and disasters. This plan must cover, but not be limited to, the following:

(1) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.
(2) Unexplained loss of or theft of a controlled substance.
(3) Deaths occurring within the center.

(Indiana State Department of Health; 410 IAC 15-2.2-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.2-2 Survey procedures

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 16-21-2-6

Sec. 2. (a) The center shall fully cooperate with licensure and complaint investigation inspections conducted by representatives of the department.

(b) The center shall maintain documents, registers, and reports which show ownership and compliance with local, state, and federal laws and regulations and adherence to bylaws and regulations of the facility.

(c) All documents in legally reproducible form must be maintained within the center for the period required by statutes of limitations and must be made available upon request for inspection, including copying by representatives of the department as follows:

(1) Items to include, but not be limited to, the following:

(A) Documents showing ownership and a certified copy of articles of incorporation (if incorporated).
(B) Constitution and bylaws of governing body.
(C) Minutes of meetings of governing body and committees thereof.
(D) Minutes of meetings of the medical staff and committees thereof.
(E) All documents pertaining to quality assurance and improvement of patient care and medical care.
(F) A current roster of members of the medical staff with designated privileges.
(G) Personnel records.
(H) Medical records.
(I) Reports pursuant to IC 16-21-2-6.

(2) A written or electronic register must be kept of all patients treated which provides identification data, treatment rendered, attending surgeon, condition on discharge, transfers to hospital facility, and such other pertinent data deemed needed by the center.

(3) Reports on patient services rendered must be submitted to the department as specified by the commissioner on forms provided by the department.

(d) The center must file an acceptable plan of correction with the division within ten (10) days of receipt of a survey report that documents noncompliance with state rules. *(Indiana State Department of Health; 410 IAC 15-2.2-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

Rule 2.3. Licensure Requirements; Ambulatory Outpatient Surgical Centers

410 IAC 15-2.3-1 Issuance of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The center shall file an application for licensure on a yearly basis with the division, prior to the expiration of the current license.

(b) A license is not transferable or assignable, and is issued only for the premises named in the application.

(c) If multiple buildings or sites (contracted, rented, or leased) are licensed under a single license, the licensee shall provide for these buildings as a single integrated system as follows:

(1) All buildings or portions of buildings under a single license must be governed by a single governing body and under the administrative control of a single chief executive officer.

(2) All facilities operating under a single license must have a single medical staff.

(d) All changes in ownership, name, and address must be reported in writing to the division. Reapplication must be filed when a change of fifty percent (50%) or greater ownership occurs.

(e) An application for licensure from a newly constructed center shall be obtained from the division and submitted on the form provided, along with the documents required by the application form, after the physical plant plans have been approved under 410 IAC 15-2.5-7 and upon receipt of a design release from the state building commissioner.

(f) Any full or partial replacement of the physical plant of a center, any addition or renovation to the physical plant of a center, or any acquisitions of additional buildings under the current license of an existing ambulatory surgical center shall meet the

provisions of 410 IAC 15-2.5-7.

(g) Upon closure of the center, the license shall be returned to the division. *(Indiana State Department of Health; 410 IAC 15-2.3-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.3-2 Posting of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The license must be conspicuously posted on the premises.

(b) A copy must be conspicuously posted in an area open to patients and the public on the premises of each separate building of a multiple building system. *(Indiana State Department of Health; 410 IAC 15-2.3-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.3-3 Suspension or revocation of license

Authority: IC 16-21-1-7
Affected: IC 4-21.5; IC 16-21-1

Sec. 3. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):

(1) Issue a letter of correction.
(2) Issue a probationary license.
(3) Conduct a resurvey.
(4) Deny renewal of a license.
(5) Revoke a license.
(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000) per violation.

(b) The commissioner may take action under subsection (a) on any of the following grounds:

(1) Violation of any provision of this rule.
(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.
(3) Conduct or practice found by the council to be detrimental to the welfare of the patients of an institution.

(c) IC 4-21.5 applies to an action under this section.

(d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.

(e) The department shall appoint an appeals panel consisting of three (3) members as follows:

(1) One (1) member of the executive board.
(2) One (1) attorney admitted to the practice of law in Indiana.
(3) One (1) individual with qualifications determined by the department.

(f) An employee of the department may not be a member of the panel.

(g) The panel shall conduct proceedings for review of an order issued by an administrative law judge under this rule. The panel is the ultimate authority under IC 4-21.5. *(Indiana State Department of Health; 410 IAC 15-2.3-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.3-4 Complaint investigation

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) The division shall investigate all complaints that come under the department's jurisdiction, regardless of the method of communication.

(b) The complaints will be assigned a priority for investigation according to division policy.

(c) The complaint investigation will be unannounced and may evolve into a full survey.

(d) The division shall notify the center of the results of the investigation in writing.

(e) The center will have ten (10) days after notification of a noncompliance to respond in writing with an acceptable plan of correction for noncompliance with state rules noted as a result of the investigation before this information is made available to the public.

(f) Upon recommendation of the division, the survey report will be forwarded to the commissioner for action under section 3 of this rule. *(Indiana State Department of Health; 410 IAC 15-2.3-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

Rule 2.4. Governing Body

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:

(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 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:

(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 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; errata filed May 4, 2001, 11:07 a.m.: 24 IR 2710; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 2. (a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge and transfer.

(B) Infection control.

(C) Medication errors.

(D) Response to patient emergencies.

(3) All services performed in the center with regard to appropriateness of diagnoses and treatments related to a standard of care and anticipated or expected outcomes.

(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 15-2.4-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 786; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.4-2.2 Reporting serious adverse events

Authority: IC 16-19-3-4; IC 16-21-1-7
Affected: IC 16-19-3; IC 16-21-1

Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following:

(1) A process for determining the occurrence of the following serious adverse events within the center:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;

or both

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) Retention of broken microneedles.

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;

(DD) time;
(EE) rate;
(FF) preparation; or
(GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.
(BB) Acute fatty liver of pregnancy.
(CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.

(v) Death or serious disability (kernicterus) associated with hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable due to the presence of eschar.

(vii) Patient death or serious disability due to joint movement therapy performed in the center.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

(AA) contains the wrong gas; or
(BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.

(iv) Patient death associated with a fall while being cared for in the center.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the center.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.

(2) A process for reporting to the department each serious adverse event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.

(b) Subject to subsection (e), the process for determining the occurrence of the serious adverse events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the serious adverse events listed in subsection (a)(1) within the center in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a serious adverse event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the center's quality assessment and improvement program;

(C) be submitted not later than six (6) months after the potential event is brought to the program's attention; and

(D) identify the serious adverse event and the center, but shall not include any identifying information for any:

(i) patient;
(ii) individual licensed under IC 25; or
(iii) center employee involved;

or any other information.

(2) A potentially reportable serious adverse event may be identified by a center that receives a patient as a transfer from another health care facility subject to a serious adverse event requirement or admits a patient subsequent to discharge from another health care facility subject to a serious adverse event requirement. In the event that a center identifies a potentially reportable event originating from another health care facility subject to a serious adverse event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a serious adverse reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The center's report of a serious adverse event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of such serious adverse events occurring within each center. The department's public report will be issued not less frequently than annually.

(e) Any serious adverse event listed in subsection (a)(1) that:

(1) is determined to have occurred within the center between:

(A) January 1, 2006; and
(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule. *(Indiana State Department of Health; 410 IAC 15-2.4-2.2; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

Rule 2.5. Required Ambulatory Outpatient Surgical Center Services

410 IAC 15-2.5-1 Infection control program

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.

(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.

(c) The infection control program must identify and evaluate trends or clusters of center generated infections or communicable diseases.

(d) The center shall designate a person qualified by training or experience as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.

(e) The chief executive officer, medical staff, and nursing manager shall:

(1) be responsible for the implementation of successful corrective action plans in affected problem areas and ensure that infection control policies are followed; and

(2) provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.

(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:

(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:

(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).

(B) A representative from the medical staff.

(C) A representative from the nursing staff.

(D) Consultants from other appropriate services within the center as needed.

(2) The infection control committee responsibilities must include, but are not limited to, the following:

(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the center.

(B) Recommending corrective action plans, reviewing outcomes, and assuring resolution of identified problems.

(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(D) Written reports of quarterly meetings.

(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:

(i) Sanitation.

(ii) Universal precautions, including infectious waste management.

(iii) Cleaning, disinfection, and sterilization.

(iv) Aseptic technique, invasive procedures, and equipment usage.

(v) Reuse of disposables.

(vi) A patient isolation system.

(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.

(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.

(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.

(x) A program of linen management.

(g) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer's recommendations and applicable state laws and rules, 410 IAC 1-4. Sterilization services must be directed by a qualified person or persons and must provide for the following:

(1) Biological indicators must be used to check sterilization processes at least monthly. Chemical sterilizing indicators must be used to check the sterilizing process of individual packs.

(2) Written policies and procedures must be available and followed by personnel responsible for sterilizing equipment and supplies, including, but not limited to, the following:

(A) Minimum time and temperature for processing various size bundles and packs.

(B) Instructions for loading, operating, cleaning, and maintaining sterilizers.

(C) Instructions for cleaning, packaging, storing, labeling, and dispensing of sterile supplies.

(D) Procedure for maintaining and recording the particular sterilizing cycle.

(E) Sterilization of heat labile reusable equipment.

(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not be limited to, the following:

(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.

(B) Results of biological indicators used in testing the sterilizing processes.

(h) Environmental surfaces and equipment not requiring sterilization which have been contaminated by blood or other potentially infectious materials shall be cleaned then decontaminated in accordance with acceptable standards of practice and applicable state laws and rules, 410 IAC 1-4.

(i) The center, whether it operates its own laundry or uses outside laundry service, shall ensure that the laundry process complies with a recognized laundry standard as follows:

(1) Clean linen must be separated from soiled linen at all times as follows:

(A) Contaminated linens must be clearly identified and bagged.

(B) Clean linen must be covered during transit, and separate containers or carts must be provided for transporting thereof.

(2) Central clean linen storage space must be provided as follows:

(A) If commercial laundry services are utilized:

(i) a soiled linen collection room must be provided; and

(ii) a hand washing facility is required in each area where unbagged soiled linen is handled.

(B) If laundry is processed in the center:

(i) a laundry processing room must be provided;

(ii) clean linen storage and mending must be separated from soiled linen handling and storage; and

(iii) employee hand washing facilities shall be available in each room where clean or soiled linen is processed and handled.

(Indiana State Department of Health; 410 IAC 15-2.5-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 786; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.5-2 Laboratory services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The center shall provide, or make available, those pathology and medical laboratory services and consultation necessary to meet the needs of patients as determined by the medical staff.

(b) The laboratory performs tests, examines specimens, and reports the evaluation only upon the written request of individuals and practitioners authorized by law and with governing body approval.

(c) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the patient care staff.

(d) Frozen section shall be provided where surgical procedures are performed which require immediate pathological examination and if performed on site must meet 42 CFR 493 for high complexity pathology testing.

(e) The medical staff and a pathologist shall determine, as specified by medical staff rules and laboratory policy, what tissue specimen examination will be utilized on each specimen as follows:

(1) Microscopic examination only.

(2) Macroscopic examination only.

(3) Both microscopic and macroscopic examinations.

(f) The center shall assure that all laboratory services provided to its patients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.

(g) Laboratory supervisory and testing personnel qualifications must be consistent with the work assignments and in compliance with 42 CFR 493.

(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.

(i) The center shall maintain a minimum supply of blood and blood products in compliance with state and federal laws or have a written agreement with a licensed blood center or transfusion service that meets all state and federal laws pertaining to collection, storing, testing, and or transfusing.

(j) The center shall develop, implement, and maintain written quality control and quality assurance policies and procedures for complexity of testing performed that are consistent with and include all standards found in 42 CFR 493. *(Indiana State Department of Health; 410 IAC 15-2.5-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 788; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.5-3 Medical records, storage, and administration

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) The medical record service has administrative responsibility for the medical records that must be maintained for every patient of the center.

(b) The organization of the medical record service must be appropriate to the scope and complexity of the services provided as follows:

(1) The services must be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time and/or part-time RRA or ART is not employed, then a consultant RRA or ART must be provided to assist the

qualified person in charge. Documentation of the findings and recommendations of the consultant must be maintained.

(2) The medical record service must be provided with necessary direction, staffing, and facilities to perform all required functions in order to ensure prompt completion, filing, and retrieval of records.

(c) An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:

(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.

(2) A unit record system of filing should be utilized. When this is not practicable, a system must be established by the center to retrieve, when necessary, all divergently located record components.

(3) The center shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the center and medical staff policies.

(4) Medical records must be retained in their original or legally reproduced form as required by federal or state law.

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the center policies.

(6) The center shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure, physician, and condition on discharge, in order to support continuous quality assessment and improvement activities.

(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:

(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.

(d) The medical record must contain sufficient information to:

(1) identify the patient;

(2) support the diagnosis;

(3) justify the treatment; and

(4) document accurately the course of the patient's stay in the center and the results.

(e) All entries in the medical record must be as follows:

(1) Legible and complete.

(2) Made only by authorized individuals as specified in center and medical staff policies.

(3) Authenticated and dated in accordance with section 4(b)(3)(N) of this rule.

(f) All patient records must document and contain, at a minimum, the following:

(1) Patient identification.

(2) Appropriate medical history and results of a physical examination completed within the time frames in section 4(b)(3)(M) of this rule.

(3) Preoperative diagnostic studies recorded in the record before surgery, if performed.

(4) Any allergies and abnormal drug reactions.

(5) Entries related to anesthesia administration.

(6) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.

(7) Discharge diagnosis.

(8) Medical history, chief complaint, and physical examination, including copies of laboratory, x-ray consultations, and other special reports or summary of those same findings by the admitting physician.

(9) A written or dictated report describing techniques, findings, and tissue removed or altered.

(10) Signatures of physicians and health care workers who treated or cared for the patient.

(11) Condition on discharge, disposition of the patient, and time of dismissal.

(12) Final progress note, including instructions to the patient and family, with dismissal diagnosis.

(13) A copy of the transfer form, if the patient is referred to a hospital or other facility.

(g) All original medical records or legally reproduced medical records must be maintained by the center for a period of seven (7) years in accordance with subsection (c)(6) and (c)(7), must be readily accessible, in accordance with the center policy, and must

be kept in a fire resistive structure. *(Indiana State Department of Health; 410 IAC 15-2.5-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 788; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.5-4 Medical staff; anesthesia and surgical services

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1; IC 25-22.5

Sec. 4. (a) The medical staff of the center is accountable to the governing body of the center. The medical staff must be organized and operate under bylaws approved by the governing body. The medical staff is responsible to the governing board for the quality of medical care and surgical services provided to patients. The medical staff must be composed of one (1) physician, dentist, or podiatrist. The medical staff shall do the following:

(1) Conduct outcome-oriented performance evaluations of its member at least biennially.

(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with center policy and applicable state and federal law.

(3) Make recommendations to the governing body on the appointment or reappointment of the applicant for a period not to exceed two (2) years.

(4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following:

(A) A completed, signed application.

(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.

(C) A current copy of the individual's credentials as follows:

(i) Indiana license showing date of licensure and number or available data provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the appropriate licensing board.

(ii) Indiana controlled substance registration showing number as applicable.

(iii) Drug Enforcement Agency registration showing number as applicable.

(iv) Documentation of experience in the practice of medicine.

(v) Documentation of specialty board certification as applicable.

(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).

(D) Category of medical staff appointment and delineation of privileges approved.

(E) A signed statement to abide by the rules of the center.

(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.

(G) Other items specified by the center and medical staff.

(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules must be as follows:

(1) Be approved by the governing board.

(2) Be reviewed at least triennially.

(3) Include, at a minimum, the following:

(A) A description of the medical staff organization structure. If the organization calls for an executive committee, a majority of the members must be practitioners on the active medical staff.

(B) Meeting requirements of the medical staff to include, at a minimum, the following:

(i) Frequency, at least quarterly.

(ii) Attendance.

(C) A provision for maintaining records of all meetings of the medical staff and its committees.

(D) A procedure for designating an individual practitioner with current privileges as chief, president, or chairperson of the staff.

(E) A statement of duties and privileges for each category of the medical staff.

(F) A description of the medical staff applicant qualifications.

(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing body.

(I) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting enforcement actions against practitioners who fail to comply with the center and medical staff bylaws and rules.

(J) A requirement that each physician's services, dentist's services, and podiatrist's services are to be reviewed and analyzed at specified intervals at regular meetings, including, but not limited to, the following:

(i) Appropriateness of diagnoses and treatments rendered related to a standard of care and anticipated or expected results.

(ii) Performance evaluation based on clinical performance indicated in part by the results or outcome of surgical intervention.

(iii) Scope and frequency of procedures.

(K) A process for appeals of decisions regarding medical staff membership and privileges.

(L) A provision for physician coverage of emergency care which addresses at least the following:

(i) A definition of emergency care.

(ii) A timely response.

(M) A requirement that a medical history and physical examination be performed as follows:

(i) In accordance with medical staff requirements on history and physical examination consistent with the scope and complexity of the procedure to be performed.

(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.

(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.

(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.

(O) A provision for personnel authorized to take a verbal order.

(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.

(Q) A requirement for a center that permits patient care responsibilities by practitioners other than physicians, to have established policies and procedures, approved by the governing body, for overseeing and evaluating the nonphysician practitioners.

(R) A requirement that a physician shall be available to the center during the period any patient is present in the center.

(c) The anesthesia services of the center must meet the needs of the patient, within the scope of the services offered, in accordance with acceptable standards of practice, and must be under the direction of a licensed physician with specialized training or experience in the administration of anesthetics. The anesthesia service is responsible for all anesthesia administered in the center as follows:

(1) The medical staff shall write and implement policies and procedures and the governing body shall approve policies and procedures which include, but are not limited to, the following:

(A) A requirement that a licensed physician with specialized training or experience in the administration of an anesthetic supervise the administration of the anesthetic to a patient and remain present in the facility during the surgical procedure, except when only a local infiltration anesthetic is administered.

(B) The use of the following:

(i) Monitored anesthesia care (MAC).

(ii) General anesthesia.

(iii) Regional anesthesia.

(iv) Local anesthesia.

(v) Topical anesthesia.

(vi) Intravenous anesthesia.

(C) Personnel permitted to administer anesthesia. Anesthesia must only be administered by an individual privileged by the medical staff and who is a:

(i) qualified physician with appropriate training, experience, and privileges;

(ii) practitioner holding a current permit to administer a specific form of anesthesia or otherwise authorized to administer topical, local, regional, or general anesthesia by state law or rule; or

(iii) registered nurse acting under the direction of and in the immediate presence of the operating physician or other physician and who holds a certificate of completion of a course in anesthesia approved by the American Association of Nurse Anesthetists or a course approved by the appropriate licensing board.

(D) Safety rules to be followed.

(E) Safety training required of personnel.

(F) The delineation of preanesthesia, intra-operative, and postanesthesia responsibilities as follows:

(i) The completion, within forty-eight (48) hours before surgery, of a preanesthesia evaluation for each patient by an individual qualified to administer anesthesia for all types of anesthetics other than local and updated according to center policy (when more than forty-eight (48) hours) before surgery.

(ii) The completion by the practitioner administering anesthesia of intra-operative anesthesia monitoring and notations, to include vitals signs, on each patient in accordance with the center policy.

(iii) The completion of a postanesthetic evaluation for proper anesthesia recovery of each patient prior to discharge in accordance with written policies and procedures approved by the medical staff.

(iv) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit by the practitioner described in clause (C) as responsible for the patient's care in accordance with center policy.

(2) A requirement that anesthesia equipment must be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.

(3) A requirement that all anesthetic agents, flammable and/or potentially flammable liquids or agents, will be stored or used in the center in accordance with current standards of practice and as required by NFPA.

(d) Surgical services must be organized according to scope of the services offered, to meet the needs of the patient, in accordance with acceptable standards of practice and safety. Requirements for surgical services include the following:

(1) Surgical services are under the direction of a physician, dentist, or podiatrist qualified by experience and training.

(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:

(A) A mechanism must be maintained which specifies the delineated surgical privileges of each practitioner.

(B) A requirement that an appropriate history and physical workup must be in the chart of every patient before surgery. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting practitioner which includes, but is not limited to, vital signs, allergies, any significant risk factors, and date written.

(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:

(i) Emergency call system.

(ii) Oxygen.

(iii) Resuscitation equipment.

(iv) Defibrillator.

(v) Cardiac monitors.

(vi) Tracheostomy set.

(vii) Oximeter.

(viii) Suction equipment.

(ix) Other supplies and equipment specified by the medical staff.

(D) A requirement for adequate provision of immediate postoperative care.

(E) A requirement that the patient register is complete and up to date.

(F) A requirement for an operative report describing techniques, findings, and tissue removed or altered to be written or dictated immediately following surgery and authenticated by the surgeon in accordance with center policy and governing body approval.

(G) A requirement that a list of tissues excluded from microscopic examination, if applicable, be maintained in surgical

services.

(Indiana State Department of Health; 410 IAC 15-2.5-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 789; errata filed Dec 14, 1999, 23 IR 814; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.5-5 Patient care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 5. (a) All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services must be under the direction of a qualified person or persons. Patient care services must require the following:

(1) That the patient care services rendered are reviewed and analyzed at regular meetings of patient care personnel and used as a basis for evaluating the quality of services provided.

(2) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.

(3) That a registered nurse serves as head nurse supervising patient care services personnel.

(4) That all registered nurses and licensed practical nurses must be currently licensed in Indiana.

(5) That an experienced registered nurse supervise all nursing personnel, including, but not limited to, registered nurses, licensed practical nurses, and surgical technologists, in surgical areas and recovery unit(s) as follows:

(A) Licensed practical nurses and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.

(B) Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved medical staff policies and procedures.

(6) A registered nurse must be in attendance in the postanesthesia recovery room during its operational period when patients are present.

(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:

(1) Provision that a reliable method of patient identification must be used. Particular attention must be given to identification of infants, young children, and others unable to identify themselves.

(2) A requirement that side rails be provided on recovery carts and kept in the upright position when occupied by sedated patients.

(3) A provision for instruction(s) to be given to the patient, responsible adult, and/or family regarding follow-up care and transportation needed by the patient on discharge.

(4) A provision that facilities, reusable equipment, and supplies shall be thoroughly cleaned and/or sterilized following use according to center policies and procedures.

(5) A provision that all nursing personnel meet annual inservice requirements as established by center and federal and state requirements.

(6) A provision that a registered nurse assigns the care of each patient to patient care personnel in accordance with the patient's need and the specialized qualifications and competence of the patient care personnel available.

(Indiana State Department of Health; 410 IAC 15-2.5-5; filed Dec 1, 1999, 3:44 p.m.: 23 IR 792; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.5-6 Pharmaceutical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. The center shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Pharmaceutical services must have the following:

(1) A designated professional person with prescriptive authority, or a pharmacist, who is responsible for the control of drug stocks in the center.
(2) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.
(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:
(A) Drug handling, storing, labeling, and dispensing.
(B) Drug administration according to established center policies and acceptable standards of practice.
(C) Intravenous medications administration as it relates to sedation.
(D) Reporting of adverse reactions and medication errors to the practitioner responsible for the patient and the appropriate committee, and documented in the patient's record.
(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:
(i) Drug cabinets must be accessible only to authorized personnel.
(ii) Drug cabinets for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse must be permanently affixed compartments that are separately locked.
(iii) Drug carts with controlled drugs as designated in item (ii) must be securely affixed when not in use.
(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.
(4) A formulary.
(5) A list of available emergency drugs.

(Indiana State Department of Health; 410 IAC 15-2.5-6; filed Dec 1, 1999, 3:44 p.m.: 23 IR 792; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.5-7 Physical plant, equipment maintenance, and environmental services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) The center shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the center license as follows:
(1) The plant operations and maintenance service, equipment maintenance, and environmental services must be as follows:
(A) Staffed to meet the scope of the services provided.
(B) Under the direction of a person or persons qualified by education, training, or experience according to center policy approved by the governing body.
(2) The center shall provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the state department of fire and building services, 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.
(3) There must be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.
(4) In new construction, renovations, and additions, the center site and facilities, or nonlicensed facilities acquired for the purpose of providing center services, shall meet the following:
(A) The 2001 edition of the national "Guidelines for Design and Construction of Hospital and Health Care Facilities" (Guidelines).
(B) All building, fire safety, and handicapped accessibility codes, and rules adopted and administered by the state building commission shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.
(C) When renovation or replacement work is done within an existing facility, all new work or additions, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of NFPA 101 (2000 Edition).
(D) Water supply and sewage disposal services shall be obtained from municipal or community services.
(E) As early in the construction, addition, or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:
(i) Functional program narrative as established in the Guidelines.

(ii) Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.

(F) Prior to the start of construction, addition, or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the division of sanitary engineering of the department as follows:

(i) Working drawings, project manuals, and specifications shall be included.

(ii) Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 1(e)(2) of this rule.

(iii) All required approvals shall be obtained from fire and building services and final approval from the division of sanitary engineering of the department prior to issuance of the occupancy letter by the division.

(G) Upon receipt of a plan release from the fire and building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department, a licensure application shall be submitted to the division on the form approved and provided by the department.

(H) Documentation from the state building commissioner that the center is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division with the licensure application.

(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:

(1) No condition in the center or on the grounds may be maintained that may be conducive to the harboring or breeding of insects, rodents, or other vermin.

(2) No condition may be created or maintained that may result in a hazard to patients, public, or employees.

(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals must be available, along with training or instruction, or both, of the appropriate center personnel, in the maintenance and operation of fixed and movable equipment.

(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.

(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.

(D) Maintenance and repairs must be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, administrative building council, the state fire marshal, and the department.

(4) The patient care equipment requirements are as follows:

(A) There must be sufficient patient care equipment and space to assure the safe, effective, and timely provision of the available services to patients.

(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:

(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.

(ii) There must be evidence of preventive maintenance on all patient care equipment.

(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.

(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.

(5) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:

(A) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:

(i) Asepsis.

(ii) Cross-contamination prevention.

(iii) Safe practice.

(B) Refuse, biohazards, infectious waste, and garbage must be collected, transported, sorted, and disposed of by methods that will minimize nuisances or hazards according to federal, state, and local laws and rules.

(c) A safety management program must include, but not be limited to, the following:

(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.

(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.

(3) The safety program includes, but is not limited to, the following:

(A) Patient safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(4) A written fire control plan that contains provisions for the following:

(A) Prompt reporting of fires.

(B) Extinguishing of fires.

(C) Protection of patients, personnel, and guests.

(D) Evacuation.

(E) Cooperation with firefighting authorities.

(F) Fire drills.

(5) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with center policy and state and local regulations.

(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(Indiana State Department of Health; 410 IAC 15-2.5-7; filed Dec 1, 1999, 3:44 p.m.: 23 IR 793; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1133; filed Apr 16, 2004, 10:30 a.m.: 27 IR 2721; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

410 IAC 15-2.5-8 Radiology services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. (a) The center shall provide or make available diagnostic radiology services and reports required in connection with any surgery to be performed, necessary to meet the needs of the patients, as determined by the medical staff.

(b) Radiology services solely under arrangement must meet the needs of the patient and meet all state and federal requirements. If all radiology services are under arrangement, the remainder of this section does not apply.

(c) All centers shall comply with all regulations set forth in this rule and with 410 IAC 5, when radiology services are provided on-site by the center, including, but not limited to, the following:

(1) Radiology services must be supervised by a radiologist or radiation oncologist.

(2) All radiation therapy treatments, including all aspects of radium treatments, must be under the direct supervision of a radiation oncologist.

(3) If therapeutic or diagnostic nuclear medicine services are provided, they must comply with the applicable requirements of this section and with 410 IAC 15-1.6-3.

(4) All diagnostic radiographic procedures must be conducted by an individual meeting the requirements of 410 IAC 5-11.

(d) Written policies and procedures must be developed, implemented, and maintained and made available to personnel.

(e) Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:

(1) Proper safety precautions must be maintained against radiation hazards in accordance with the center's radiation and safety program(s).

(2) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.

(f) Procedures and treatments are performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the results of the evaluations to the extent permitted by law as authorized by the governing body.

(g) All radiologic equipment must be registered and inspected prior to use and then periodically, according to 410 IAC 5 and all other applicable state and federal statutes and rules.

(h) All radioactive materials must be registered and/or licensed under all applicable state and federal statutes and rules.

(i) The use of fluoroscopes must be limited to physicians or others authorized to operate in accordance with 410 IAC 5.

(j) Records of the results of all radiological procedures must be kept on file and recorded on the patient's chart. The center shall maintain the following for at least five (5) years:

(1) Copies of reports and printouts.

(2) Films, scans, and other image records.

(3) If subdivisions (1) and (2) are maintained in the medical record, these items shall be maintained in accordance with state and federal law.

(Indiana State Department of Health; 410 IAC 15-2.5-8; filed Dec 1, 1999, 3:44 p.m.: 23 IR 794; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1658; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)

Rule 2.6. Optional Ambulatory Surgical Center Services

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 7-24.

(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; errata filed Jan 21, 2005, 10:32 a.m.: 28 IR 1695; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

410 IAC 15-2.6-2 Other services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) If the center provides other services not covered in specific sections of 410 IAC 15-2.1 through 410 IAC 15-2.5, this rule, and 410 IAC 15-2.7, the services must meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a qualified person or persons.

(c) The services shall be staffed in accordance with written center policies and comply with the applicable state and federal rules. *(Indiana State Department of Health; 410 IAC 15-2.6-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

Rule 2.7. Incorporations by Reference

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 Hospital and Health Care Facilities (2001 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 (2000 Edition). 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 (NRCP) *[sic.]* 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 493 (Effective October 1, 1993, Edition).

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

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

(b) Federal rules that 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; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1134; filed Apr 16, 2004, 10:30 a.m.: 27 IR 2722; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661)*

Rule 3. Hospital Financial Disclosure

410 IAC 15-3-1 Definitions

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 1. As used in 410 IAC 15-3: "Ancillary service charges" means the difference between total service charges per stay and the daily service charges.

"Average patient length of stay by patient diagnosis" means the arithmetic mean of the total of all patient lengths of stay for a given patient diagnosis for each major payor category reported in days.

"Daily service charge" means the charge billed to a patient for a day of stay in a facility without any ancillary services provided.

"Discharges by patient diagnosis" means the count of discharges from a given fiscal period for each patient diagnosis/major payor category combination, where the primary payor has been used to determine assignment of each discharge to the appropriate major payor category.

"Major payor category" means categories of payors for Medicare, Medicaid, and all other payors (including, but not limited to, commercial insurance, Blue Cross, CHAMPUS, self-insured groups, HMOs and other prepaid groups, other government programs, individuals, and all others).

"Patient diagnosis" means the principal diagnosis recorded for billing purposes at the discharge of a patient.

"Preoperative preparation time by surgical procedure" means the average length of time in days between admit date and date of the first surgical procedure performed on the patient as counted based on the hospital's policy for daily charge purposes.

"Primary payor" means the first category of major payor categories which receives the bill for a patient stay.

"Surgical procedure" means a procedure reported as surgery for the purposes of billing. *(Indiana State Department of Health; 410 IAC 15-3-1; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-3-2 Fiscal reports; filing

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 2. (a) Each facility shall report the financial data required under IC 16-10-5-2(a) *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* by submitting a copy of audited financial statements and financial reports prepared for the hospital. Facilities audited by the Indiana state board of accounts may file a copy of that report as a means of satisfying this

requirement.

(b) Each facility shall report the patient utilization data required under IC 16-10-5-2(a) *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* using the diagnosis reported for billing purposes. These should be reported on the Hospital Financial Disclosure Report Forms contained in 410 IAC 15-3-6 or individual billing forms if approved by the board. *(Indiana State Department of Health; 410 IAC 15-3-2; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-3-3 Fiscal reports; extension of time for filing

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 3. (a) Each facility requesting an extension of time for filing the reports required under IC 16-10-5-2 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* beyond the 120 days after the end of the facility's fiscal year must make such request in writing to the board prior to the deadline for submitting the reports.

(b) The board shall act upon a request for an extension of time in which the report must be filed within 30 days of receiving the written request by the facility. Failure to act within the required period shall be deemed as a grant of the extension. *(Indiana State Department of Health; 410 IAC 15-3-3; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-3-4 Fiscal reports; additional information to be supplied

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 4. (a) The board shall notify, in writing, a facility of the need to submit further fiscal information as necessary to verify the accuracy of any information contained in the reports filed under these rules *[410 IAC 15-3]* by each facility.

(b) The board shall specify the period of time the facility has to supply the additional information. An extension of this time may be granted by the board upon written request by the facility. *(Indiana State Department of Health; 410 IAC 15-3-4; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-3-5 Commissioner's findings and recommendations

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 5. Each year, the state health commissioner or his designee shall make a compilation of the data obtained in these reports and report his findings and recommendations regarding changes in the financial status and patient utilization of facilities. *(Indiana State Department of Health; 410 IAC 15-3-5; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

410 IAC 15-3-6 Hospital financial disclosure report forms

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 6.

INDIANA HOSPITAL FINANCIAL DISCLOSURE REPORT FORM A

Hospital _____ Fiscal Year Start _____ End _____ Payor Category _____

Net Patient Revenue _____ Total Inpatient Days _____

Patient Days for Patients Aged: 0-14 _____; 15-64 _____; 65 and Over _____

	Patients Ages 0-14				Patients Ages 15-64				Patients Age 65 and Over			
Diagnosis (xxx.x)	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge
Total Discharges by Age Group												

INDIANA HOSPITAL FINANCIAL DISCLOSURE REPORT FORM B

Hospital _____ Fiscal Year Start _____ End _____ Payor Category _____

	Patients Ages 0-14			Patients Ages 15-64			Patients Age 65 and Over		
Diagnosis (xxx.x)	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time
Total Procedures by Age Group									

(Indiana State Department of Health; 410 IAC 15-3-6; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

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