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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #05-93

DIGEST

Adds 410 IAC 27 to establish rules pertaining to the operation and management of birthing centers as well as establishing minimum licensing qualifications and establishing requirements for sanitation standards, staff qualifications, necessary emergency equipment, procedures to provide emergency care, quality assurance standards, and infection control, to prescribe the operating policies, supervision, and maintenance of medical records, to establish procedures for the issuance, renewal, denial, and revocation of licenses while addressing the form and content of the license and the collection of an annual license fee, and to address procedures and standards for inspections. Effective 30 days after filing with the Secretary of State.

410 IAC 27

SECTION 1. 410 IAC 27 IS ADDED TO READ AS FOLLOWS:

ARTICLE 27. BIRTHING CENTERS

Rule 1. Definitions

410 IAC 27-1-1 Applicability

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 27-1-1)*

410 IAC 27-1-2 “Authenticate” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. “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; or**
- (3) a unique identifier such as a number or computer key.**

(Indiana State Department of Health; 410 IAC 27-1-2)

410 IAC 27-1-3 “Birthing center” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-18-2-36.5; IC 16-21-1

Sec. 3. “Birthing center” has the meaning set forth in IC 16-18-2-36.5. *(Indiana State Department of Health; 410 IAC 27-1-3)*

410 IAC 27-1-4 “Center” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 4. “Center” means a birthing center. *(Indiana State Department of Health; 410 IAC 27-1-4)*

410 IAC 27-1-5 “Certified nurse midwife” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 25-23-1-13.1

Sec. 5. “Certified nurse midwife” means a person licensed to practice as a nurse midwife under IC 25-23-1-13.1. (Indiana State Department of Health; 410 IAC 27-1-5)

410 IAC 27-1-6 “Commissioner” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 6. “Commissioner” means the state health commissioner or the state health commissioner’s designee. (Indiana State Department of Health; 410 IAC 27-1-6)

410 IAC 27-1-7 “Council” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 7. “Council” has the meaning set forth in IC 16-18-2-84(1). (Indiana State Department of Health; 410 IAC 27-1-7)

410 IAC 27-1-8 “Department” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 8. “Department” means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 27-1-8)

410 IAC 27-1-9 “Division” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 9. “Division” means the division of acute care of the department. (Indiana State Department of Health; 410 IAC 27-1-9)

410 IAC 27-1-10 “Governing body” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 10. “Governing body” means:

(1) board of trustees;

(2) governing board;

(3) board of directors; or

(4) other body or individual responsible for governing a birthing center.

(Indiana State Department of Health; 410 IAC 27-1-10)

410 IAC 27-1-11 “Health care provider” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 11. “Health care provider” has the meaning set forth in IC 16-18-2-163. (Indiana State Department of Health; 410 IAC 27-1-11)

410 IAC 27-1-12 “Health care worker” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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 27-1-12)*

410 IAC 27-1-13 “Licensed health professional” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 13. “Licensed health professional” has the meaning set forth in IC 25-23-1-27.1. *(Indiana State Department of Health; 410 IAC 27-1-13)*

410 IAC 27-1-14 “Medical staff” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 14. “Medical staff” means physicians and certified nurse midwives appointed by the governing body or contracted with by the governing body and responsible to the governing body 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 27-1-14)

410 IAC 27-1-15 “Pharmacist” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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 27-1-15)*

410 IAC 27-1-16 “Physician” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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 27-1-16)*

410 IAC 27-1-17 “Registered nurse” defined

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 17. “Registered nurse” means an individual licensed under IC 25-23-1. *(Indiana State Department of Health; 410 IAC 27-1-17)*

Rule 2. License Requirements

410 IAC 27-2-1 License

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 4-21.5-3-5; IC 16-21-2-14

Sec. 1. (a) A license must be obtained from the state health commissioner under IC 4-21.5-3-5 before:

(1) establishing;

(2) conducting;

(3) operating; or

(4) maintaining;

a birthing center. A birthing center may not operate without a license issued by the commissioner.

- (b) A license to operate a birthing center:
 - (1) expires one (1) year after the date of issuance;
 - (2) is not assignable or transferable; and
 - (3) is issued only for the premises named in the application.

(c) A license is valid for only one (1) location. Multiple centers may not be operated under one (1) license.

(d) Upon closure of the center, the license shall be returned to the division. *(Indiana State Department of Health; 410 IAC 27-2-1)*

410 IAC 27-2-2 Review of physical plant plans

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) The department will not issue a provisional license to operate a birthing center until the center has obtained final plan approval from the sanitary engineering program of the department.

(b) Before the start of the construction, addition, or renovation project, the center shall request and obtain plan approval from the sanitary engineering program of the department. To request plan approval, the center must file with the department a request for plan review on a form approved by the department and have the following available for review:

- (1) Detailed architectural and operational plans for construction.
- (2) Functional program narrative.
- (3) 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.
- (4) Working drawings, project manuals, and specifications.

(c) After receiving plan approval, the center shall:

- (1) inform the sanitary engineering program of any changes or modifications to the plans approved by the department; and
- (2) provide appropriate architectural and operational plans to the department for those changes or modifications.

After reviewing any changes or modifications and upon a determination of compliance with physical plant rules under this article, a final plan approval will be issued by the sanitary engineering program. *(Indiana State Department of Health; 410 IAC 27-2-2)*

410 IAC 27-2-3 Application for initial license

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. (a) To obtain a license to operate a birthing center, an application for a license to operate a birthing center must be submitted to the division. The application may be submitted simultaneously with the request for plan review before construction. At the latest, however, the application must be received by the department at least forty-five (45) days before the anticipated opening of the center. At least forty-five (45) days before the opening of the center, the applicant must inform the division of the anticipated date of opening.

(b) The initial license application includes the following:

- (1) An application for a license to operate a birthing center on a form prescribed by the division.
- (2) Documents required by the application for a license to operate a birthing center.
- (3) The appropriate license fee.

(c) 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. *(Indiana State Department of Health; 410 IAC 27-2-3)*

410 IAC 27-2-4 Review and approval of initial license application

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 16-21-2-11

Sec. 4. (a) Upon receipt of a completed application for a birthing center license, the department will review the application and accompanying documentation to determine that the applicant has met the requirements of IC 16-21-2-11(a)(1) and IC 16-21-2-11(a)(2).

(b) Upon determination by the commissioner that the applicant has failed to comply with this article, the commissioner may:

- (1) request additional information concerning the application;**
- (2) conduct a further investigation to determine whether a provisional license should be granted; or**
- (3) deny the application.**

(c) Upon determination by the commissioner that the applicant has complied with the provisional licensing requirements for a birthing center under this article, the commissioner will:

- (1) provisionally approve the application for a birthing center license; and**
- (2) issue a provisional license to operate a birthing center.**

The provisional license expires ninety (90) days after issue.

(d) After the opening of the center and before the expiration of the provisional license, the department will conduct a licensing survey to ensure that the center is operating in compliance with this article.

(e) If the center is found on the initial licensing survey to be in compliance with this article, the commissioner will issue a full license to operate a birthing center. If the center is not found to be in compliance with this article, the commissioner may extend the provisional license for up to ninety (90) days. If the provisional license is extended, a revisit survey will be conducted or additional documentation will be requested, or both, before the end of the provisional period to ensure compliance with this article. If the center is found to be in compliance with this article, the commissioner will issue a full license to operate a birthing center. If the center is not found to be in compliance with this article after the extended provisional period, the commissioner may:

- (1) request additional information concerning the application;**
- (2) conduct a further investigation to determine whether a provisional license should be granted; or**
- (3) deny the application.**

(Indiana State Department of Health; 410 IAC 27-2-4)

410 IAC 27-2-5 Denial of license

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 27-13-1

Sec. 5. The commissioner may deny a license to operate a birthing center for any of the following reasons:

- (1) If the licensee or licensees are not of reputable and responsible character.**
- (2) If the birthing center is not in compliance with the minimum standards for a birthing center adopted under this article.**
- (3) For violation of any of the provisions of IC 16-21 or this article.**
- (4) For permitting, aiding, or abetting the commission of any illegal act in the center.**
- (5) For knowingly collecting or attempting to collect from:**
 - (A) a subscriber (as defined in IC 27-13-1-32); or**
 - (B) an enrollee (as defined in IC 27-13-1-12);****of a health maintenance organization (as defined in IC 27-13-1-19) any amounts that are owed by the health maintenance organization.**
- (6) If conduct or practices of the center are found to be detrimental to the patients of the birthing center.**
- (7) If the application for a license to operate a birthing center or supporting documentation provided inaccurate statements or information.**

(Indiana State Department of Health; 410 IAC 27-2-5)

410 IAC 27-2-6 Renewal of license

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 6. (a) In order to renew its birthing center license, the center shall file an application for the renewal of a birthing

center license with the division at least one (1) month before the expiration of the current license.

(b) The renewal application includes the following:

- (1) An application for the renewal of a license to operate a birthing center on a form prescribed by the division.
- (2) Documents required by the application for the renewal of a license to operate a birthing center.
- (3) The appropriate license fee.

(c) Upon determination by the commissioner that the applicant has met the licensing requirements for a birthing center, the commissioner will approve the application for the renewal of a license to operate a birthing center and issue a license. *(Indiana State Department of Health; 410 IAC 27-2-6)*

410 IAC 27-2-7 Posting of license

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 7. A license issued under this article must be conspicuously posted on the premises in an area open to patients. *(Indiana State Department of Health; 410 IAC 27-2-7)*

410 IAC 27-2-8 Enforcement actions

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-3; IC 27-13-1

Sec. 8. (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 the 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 article.
- (2) Permitting, aiding, or abetting the commission of any illegal act in an institution.
- (3) Knowingly collecting or attempting to collect from:
 - (A) a subscriber (as defined in IC 27-13-1-32); or
 - (B) an enrollee (as defined in IC 27-13-1-12);

of a health maintenance organization (as defined in IC 27-13-1-19) any amounts that are owed by the health maintenance organization.

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

(Indiana State Department of Health; 410 IAC 27-2-8)

410 IAC 27-2-9 Probationary license

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 9. A probationary license may be:

- (1) issued for a period of three (3) months; and
- (2) reissued;

but not more than three (3) probationary licenses may be issued during a twelve (12) month period. The issuance of a probationary license results in the automatic expiration of any other license held under this article. *(Indiana State Department of Health; 410 IAC 27-2-9)*

Rule 3. Surveys

410 IAC 27-3-1 Survey procedures

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 1. (a) The birthing center shall fully cooperate with surveys conducted by representatives of the department. Upon arrival of department surveyors at the center, the center may immediately contact the department to confirm the identity of the surveyors. Upon confirmation by the department of the survey and surveyors, the center shall immediately admit the surveyors to the center and not delay the survey.

(b) Documents, registers, reports, records, and minutes of the birthing center must be made available to the department upon request for inspection and copying.

(c) Documents, registers, reports, records, and minutes required to be maintained by the birthing center include, but are not limited to, the following:

- (1)** Documents showing ownership and a copy of articles of incorporation (if incorporated).
- (2)** All documents pertaining to quality assurance and improvement of patient care and medical care.
- (3)** Personnel records.
- (4)** Medical records.
- (5)** Reports under IC 16-21-2-6.
- (6)** Policies and procedures of the birthing center.

(d) If the governing body of the center is an individual responsible for governing the birthing center, the center is not required to prepare and maintain the documents referenced in this subsection. If the governing body is not an individual with sole authority and responsibility for the center, the center must prepare and maintain the following documents, registers, reports, records, and minutes to include, but not be limited to:

- (1)** The constitution and bylaws of the governing body.
- (2)** Minutes of meetings of the governing body and committees thereof.

(e) Documents, registers, reports, records, and minutes must be complete and up-to-date. *(Indiana State Department of Health; 410 IAC 27-3-1)*

410 IAC 27-3-2 Licensing surveys

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) The department will conduct a licensing survey of each birthing center at least once every two (2) years. The licensing survey is conducted to ensure that the birthing center is operating in compliance with this article.

(b) The division will notify the center of the results of the licensing survey in writing.

(c) The center may request the department to accept an accreditation or certification survey instead of a licensing survey. The division may accept an accreditation or certification survey report from a nationally-recognized accreditation or certification agency, association, or organization that is determined by the division to have survey standards consistent with this article. Upon request by the center, the department will review the accreditation or certification survey report for the facility. If the department finds that, based on the accreditation report, the center was found to have substantially complied with the standards referenced in this subsection, the department will accept the accreditation report as a licensing survey. If, based on the accreditation report, the center failed to significantly comply with the standards referenced in this subsection, the department may:

- (1)** request a plan or correction; or
- (2)** conduct a licensing survey.

If the department accepts accreditation or certification surveys as a licensing survey, the department will conduct at least one (1) licensing survey in a four (4) year period. *(Indiana State Department of Health; 410 IAC 27-3-2)*

410 IAC 27-3-3 Complaint surveys

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. (a) In accordance with division policy, the division shall investigate credible complaints received by the division that allege noncompliance with this article.

(b) Complaints will be assigned a priority for investigation in accordance with division policy.

(c) A licensing survey may be conducted simultaneously with and in addition to a complaint survey.

(d) The division shall notify the birthing center of the results of the complaint survey in writing. *(Indiana State Department of Health; 410 IAC 27-3-3)*

410 IAC 27-3-4 Plan of correction

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 4. (a) The birthing center must file an acceptable plan of correction with the division within ten (10) days of receipt of a survey report from the division that documents noncompliance with state rules.

(b) Unless the commissioner determines that there is a need for immediate release, the birthing center will have ten (10) days after notification of a noncompliance to submit to the division an acceptable plan of correction before the survey report is made available to the public. *(Indiana State Department of Health; 410 IAC 27-3-4)*

Rule 4. Governing Body

410 IAC 27-4-1 Powers and duties

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 1. (a) The governing body:

- (1)** shall function as the ultimate authority of the birthing center; and
- (2)** is responsible for the conduct and management of the center.

(b) If the governing body is an individual who has sole authority and responsibility for the center, that individual may also serve as the center administrator or medical director, or both, if qualified. A center administrator appointed by the governing body may also serve as the medical director if qualified.

(c) The governing body shall do the following:

(1) Assume responsibility for:

- (A)** determining;
- (B)** implementing; and
- (C)** monitoring;

policies governing the center's operation.

(2) Ensure that:

- (A)** center policies are followed so as to provide quality health care in a safe environment; and
- (B)** the center complies with:
 - (i)** this article; and
 - (ii)** IC 16-21.

(3) Review, at least quarterly, reports of management operations, including, but not limited to, the following:

- (A)** Quality assessment and improvement program.
- (B)** Patient services provided.
- (C)** Results attained.
- (D)** Recommendations made.
- (E)** Actions taken.
- (F)** Follow-up.

(4) Maintain documents, registers, and reports that show the following:

- (A)** Ownership.

- (B) Compliance with local, state, and federal laws and regulations.
 - (C) Adherence to center bylaws (if applicable) and center policies.
 - (5) Approve all appointments to or contracts with medical staff.
 - (6) Ensure the following:
 - (A) Maintenance of the physical plant.
 - (B) That the center is:
 - (i) equipped; and
 - (ii) staffed;
 - to meet the needs of the patients.
 - (7) Require for all services policies and procedures that are:
 - (A) updated as needed; and
 - (B) reviewed at least triennially.
 - (8) Establish a policy and procedure for communication with physicians concerning a patient emergency.
 - (9) Review and analyze each physician's services at specified intervals at regular meetings, including, but not limited to, the following:
 - (A) Appropriateness of diagnoses and treatments rendered related to a standard of care and anticipated or expected results.
 - (B) Performance evaluation based on clinical performance indicated in part by the results or outcome of surgical intervention.
 - (C) Scope and frequency of procedures.
 - (10) Establish a process for the following:
 - (A) Reporting physicians who fail to comply with state professional licensing law requirements as found in IC 25-22.5.
 - (B) Documenting actions against physicians who fail to comply with the center policies and procedures.
 - (11) Ensure physician coverage of emergency care that at least:
 - (A) provides a definition; and
 - (B) addresses a timely response.
- (d) If the governing body is not an individual responsible for the governing of the center, the governing body must do the following:
- (1) Adopt bylaws and operate in compliance with the bylaws.
 - (2) Review the bylaws at least triennially.
- (e) If the governing body is not an individual who is also serving as the medical director, the governing body shall do the following:
- (1) Designate a medical director who has the responsibility for the direction of:
 - (A) medical;
 - (B) nursing; and
 - (C) health-related;services to patients.
 - (2) Maintain a liaison with the medical director.
- (f) If the governing body is not an individual who is also serving as the center administrator, the governing body shall do the following:
- (1) Designate a center administrator who has the responsibility and authority to carry out the day-to-day operation of the center.
 - (2) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the center administrator.
 - (3) Delineate in writing the responsibility and authority of the center administrator.
 - (4) Require the following:
 - (A) That the center administrator or a designee:
 - (i) attend meetings of the governing body and its committees; and
 - (ii) act as its representative at medical staff meetings.
 - (B) That the center administrator:
 - (i) designate in writing an administrative officer to serve during his or her absence; and
 - (ii) develop and implement appropriate policies and programs.

(Indiana State Department of Health; 410 IAC 27-4-1)

410 IAC 27-4-2 Appointment and conduct of medical staff

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 25-23-1-19.4

Sec. 2. (a) The medical staff of the center consists of physicians and certified nurse midwives:

- (1) employed by;**
- (2) appointed to; or**
- (3) contracted with by;**

the center to provide medical services at the center. The medical staff must be composed of at least one (1) physician.

(b) The medical director must:

- (1) be a physician licensed to practice in the state of Indiana; and**
- (2) provide oversight of certified nurse midwives under IC 25-23-1-19.4.**

(c) If the medical staff consists of more than one (1) physician:

- (1) the medical director:**
 - (A) shall serve as coordinator of the medical staff; and**
 - (B) conduct meetings of the medical staff at least every six (6) months;**
- (2) minutes of meetings of the medical staff and committees thereof shall be maintained; and**
- (3) a current roster of members of the medical staff shall be maintained.**

(d) In appointing or contracting with medical staff, the governing body shall ensure the following:

- (1) That appointments to or contracts with medical staff are acted upon with the advice and recommendation of the medical director.**
- (2) That reappointments to and contracts with medical staff are reviewed and acted upon at least biennially.**
- (3) That criteria for selection for medical staff include the following:**
 - (A) Individual character.**
 - (B) Competence.**
 - (C) Education.**
 - (D) Training.**
 - (E) Experience.**
 - (F) Judgment.**
- (4) That the appointment of or contracting with medical staff is not solely dependent upon:**
 - (A) certification;**
 - (B) fellowship; or**
 - (C) membership;****in a specialty body or society.**

(e) The governing body is responsible for the conduct of the medical staff activities related to the birthing center. The governing body shall ensure the following:

- (1) That the medical staff is accountable and responsible to the governing body for the quality of care provided to patients.**
- (2) That services are performed only by qualified staff approved by the governing body to perform such services.**
- (3) That services performed in the center are limited to services authorized by the governing body.**

(f) The governing body is responsible for assuring that quality patient care is provided. In accordance with center policy, the governing body shall ensure that a qualified licensed physician who is a member of the medical staff is responsible for the care and treatment of each patient.

(g) The governing body is responsible for services delivered in the center by contractors for medical services. The governing body shall ensure the following:

- (1) 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) That the services performed under a contract are:**

- (A) provided in a safe and effective manner; and
 - (B) included in the center's quality assessment and improvement program.
 - (3) That the center maintains a list of all contracted services, including the scope and nature of the services provided.
- (Indiana State Department of Health; 410 IAC 27-4-2)*

Rule 5. Administration and Policies

410 IAC 27-5-1 Administration

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. The center administrator is responsible for day-to-day operations of the birthing center to include, but not be limited to, the following functions:

- (1) Employing qualified staff:
 - (A) commensurate with assigned duties and responsibilities; and
 - (B) in accordance with the employee's licensure, certification, experience, and competence.
- (2) Ensuring that sufficient staff is present to provide quality patient care.
- (3) Annual implementation of internal and external disaster and emergency preparedness plans with documentation of outcome.

(Indiana State Department of Health; 410 IAC 27-5-1)

410 IAC 27-5-2 Required policies and procedures

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) The center shall develop, implement, and maintain the following:

- (1) Written medical staff policies.
- (2) Written procedures for the following:
 - (A) Emergencies.
 - (B) Initial treatment.
 - (C) Transfer.

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

- (1) Timely assessment.
- (2) Basic life support.
- (3) Appropriate transfer.

(c) The center shall develop, implement, and maintain the following:

- (1) Policies that cover health care worker practice problems, including, but not limited to, the following:
 - (A) Impaired health care workers.
 - (B) Criminal history.
 - (C) Disciplinary action.
- (2) A written plan to address the internal review of unusual occurrences and disasters. This plan must cover, but not be limited to, the following:
 - (A) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.
 - (B) Unexplained loss of or theft of a controlled substance.
 - (C) Deaths occurring within the center.

(Indiana State Department of Health; 410 IAC 27-5-2)

Rule 6. Quality Assessment and Improvement

410 IAC 27-6-1 Quality assessment and improvement

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The birthing 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.
 - (B) Transfer.
 - (C) Infection control.
 - (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.
- (4) Medical and medication errors.

(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 27-6-1)*

Rule 7. Medical Records

410 IAC 27-7-1 Medical records; storage; administration

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The birthing center must do the following:

- (1) Create and maintain a medical record on each patient.
- (2) Have a written policy that ensures responsibility for and maintenance of medical records as follows:
 - (A) The center must establish and implement the following:
 - (i) Policies and procedures to assure that the care and services provided to each patient are appropriately documented.
 - (ii) A system to assure that medical records are readily available in accordance with center policy and systematically organized to facilitate the compilation and retrieval of information.
 - (B) The policy must provide safeguards to assure protection of the medical records from the following:
 - (i) Fire.
 - (ii) Water.
 - (iii) Other sources of damage.
 - (C) All original medical records or legally reproduced medical records must be maintained by the center for a period of at least seven (7) years or the applicable statute of limitation, whichever is longer. Original medical records must be maintained in the center for at least two (2) years. Records over two (2) years old may be kept off-site but must be retrievable within forty-eight (48) business hours.

(b) A medical record must be maintained with documentation of service rendered for each patient of the center as follows:

- (1) Medical records:
 - (A) are documented accurately and in a timely manner;
 - (B) are readily accessible; and
 - (C) 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:
 - (A) ensures the integrity of the authentication; and
 - (B) 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 that allows for timely retrieval of records by:

- (A) identification data;
- (B) diagnosis;
- (C) treatment rendered;
- (D) physician;
- (E) condition on discharge; and
- (F) transfer to hospital;

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 medical records.

(c) A written or electronic register must be kept of all patients treated that provides the following:

- (1) Identification data.
- (2) Treatment rendered.
- (3) Attending physician.
- (4) Condition on discharge.
- (5) Transfers to hospital facility.
- (6) Other data deemed necessary by the center.

(Indiana State Department of Health; 410 IAC 27-7-1)

410 IAC 27-7-2 Content of the medical record

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) The medical record must contain sufficient information to do the following:

- (1) Identify the patient.
- (2) Document tests, examinations, and procedures performed.
- (3) Document accurately the course of the patient's stay in the center and the results.

(b) All entries in the medical record must be as follows:

- (1) Legible.
- (2) Complete.
- (3) Made by authorized individuals as specified in center and medical staff policies.
- (4) Authenticated and dated in accordance with this article.

(c) All patient records must document and contain, at a minimum, the following:

- (1) Patient identification and demographics.
- (2) Complete:
 - (A) social;
 - (B) family;
 - (C) medical;
 - (D) reproductive;
 - (E) nutrition; and
 - (F) behavioral;

history.

- (3) Initial physical examination, laboratory tests, and evaluation of risk status.
- (4) Appropriate referral on ineligible clients with report of findings on initial screening.
- (5) Continuous periodic prenatal examination and evaluations of risk factors.
- (6) Instruction and education to include, but not be limited to, the following:
 - (A) Nutritional counseling.

- (B) Self care and changes in pregnancy.
- (C) Understanding of findings of examinations, studies, and laboratory tests.
- (D) Preparation for labor.
- (E) Sibling preparation, if applicable.
- (F) Preparation for early discharge.
- (G) Newborn assessment and care.
- (7) Preadmission diagnostic studies if performed.
- (8) History, physical examination, and risk assessment on admission to the center.
- (9) Monitoring of progress in labor and assessment of maternal and newborn reaction to labor in accordance with accepted professional standards.
- (10) Consultation, referral, and transfer for maternal and neonatal problems that elevate risk status.
- (11) Newborn assessment including the following:
 - (A) Apgar scores.
 - (B) Maternal-newborn interaction.
 - (C) Prophylactic procedures.
 - (D) Accommodation to extra-uterine life.
 - (E) Blood glucose when clinically indicated.
- (12) Maternal assessments during recovery.
- (13) Summary of labor.
- (14) Discharge summary to include mother and infant.
- (15) Discharge plan and instructions.
- (16) Any allergies and abnormal drug reactions.
- (17) Evidence of appropriate informed consent for procedures and treatments consistent with state law.
- (18) Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient.
- (19) A copy of the transfer form if the patient was referred to a hospital or other facility.

(Indiana State Department of Health; 410 IAC 27-7-2)

Rule 8. Personnel

410 IAC 27-8-1 Personnel policies and records

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) Each facility shall maintain current and accurate personnel records for all employees. Personnel records shall:

- (1) be maintained for each employee of the center; and
- (2) include personal data to include:
 - (A) education;
 - (B) experience;
 - (C) date of employment;
 - (D) a copy of current license when required;
 - (E) evidence of participation in job-related educational and training activities; and
 - (F) health records of employees that relate to post offer and subsequent:
 - (i) physical examinations;
 - (ii) tests; and
 - (iii) immunizations.

(b) If the center administrator is not the governing body, the center must establish employment criteria for the center administrator to include, but not be limited to, the following:

- (1) Definition of educational requirements.
- (2) Experience requirements.
- (3) Professional certification, licensing, or registration requirements where appropriate.

(c) Each center must do the following:

- (1) Maintain 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.

(2) Ensure that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required:

(A) maintain current license, registration, or certification; and

(B) keep documentation of same.

(Indiana State Department of Health; 410 IAC 27-8-1)

410 IAC 27-8-2 Employee health monitoring

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) The center shall do the following:

(1) Develop, implement, and maintain a written policy for the control of communicable disease in compliance with applicable federal and state laws.

(2) Monitor employee health in accordance with the center's infection control program.

(3) Ensure that all employees, staff members, and contractors having direct patient contact are evaluated at least annually for tuberculosis. Any person having a positive finding on a tuberculosis evaluation may not work in the center unless approved by a physician to work. The center may perform its own tuberculosis evaluation or utilize reliable medical records from a qualified health care provider. Tests for tuberculosis performed by the center must meet Centers for Disease Control guidelines. An evaluation for tuberculosis may be performed using a PPD (Mantoux) skin test, chest radiograph, or other tuberculosis testing procedure approved by the Centers for Disease Control. The center must maintain documentation of tuberculosis evaluations showing that any person working in the center and having direct patient contact has had a negative finding on a tuberculosis examination within the previous twelve (12) months.

(Indiana State Department of Health; 410 IAC 27-8-2)

410 IAC 27-8-3 Orientation and training requirements

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. (a) The center must do the following:

(1) Develop, implement, and maintain a policy and procedure for the orientation of new employees, contractors, and agency personnel providing direct care and services to patients.

(2) Orientate all new employees, including contract and agency personnel, to applicable center and personnel policies.

(b) The center shall ensure cardiopulmonary resuscitation (CPR) competence for adults and neonates 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. *(Indiana State Department of Health; 410 IAC 27-8-3)*

Rule 9. Medical Staff

410 IAC 27-9-1 Organization of medical staff

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The medical staff of the center is:

(1) accountable to the governing body of the center; and

(2) responsible to the governing board for the quality of medical care and services provided to patients.

(b) The medical director must do the following:

(1) Examine credentials of candidates for appointment, reappointment, or contracting to the medical staff.

(2) Make recommendations to the governing body on the appointment or reappointment of medical staff.

(c) The medical staff must develop and maintain policies and procedures for the provision of medical services. The policies must provide for and the medical staff must ensure the following:

(1) An appropriate and timely medical history and physical examination is performed.

(2) All physician and certified nurse midwife orders:

(A) are in writing or acceptable computerized form; and

(B) must be authenticated by a responsible licensed health professional as allowed by center policies not to exceed thirty (30) days.

(3) There is a provision for personnel authorized to take a verbal order.

(Indiana State Department of Health; 410 IAC 27-9-1)

Rule 10. Patient Care and Nursing Services

410 IAC 27-10-1 Patient care

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) All patient care services must:

(1) meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice;

(2) be under the direction of a qualified person or persons; and

(3) require that:

(A) the patient care services rendered are:

(i) reviewed and analyzed at regular meetings of patient care personnel; and

(ii) used as a basis for evaluating the quality of services provided; and

(B) personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.

(b) Written patient care policies and procedures must be available to personnel and must include, but not be limited to, the following:

(1) A provision that labor shall not be induced, stimulated, or augmented with chemical agents during the first or second stage of labor.

(2) A provision that the center clearly delineate the medical and social risk factors that exclude women from the low-risk intrapartum group, which must include, but are not limited to, the following:

(A) Maternal characteristics:

(i) clients under sixteen (16) years of age and over forty (40) years of age; and

(ii) parity four (4) or more.

(B) Past obstetrical history:

(i) all hypertensive disorders of pregnancy;

(ii) previous delivery other than spontaneous or low forceps;

(iii) cesarian section; and

(iv) infant greater than four thousand five hundred (4,500) grams.

(C) Associated conditions:

(i) scarred uterus;

(ii) vaginal plastic surgery;

(iii) adrenal disease;

(iv) cardiovascular disease except mild asymptomatic Class 1 without hemodynamic abnormality;

(v) collagen disease;

(vi) renal disease (albuminuria, hematuria, casts);

(vii) acute or chronic liver disease;

(viii) diabetes mellitus;

(ix) gestational diabetes;

(x) genetic disorder;

(xi) hematologic disease;

(xii) hypertension;

(xiii) neurological disorder;

(xiv) hyperthyroidism; and

(xv) venereal and related diseases.

(D) Prenatal course of current pregnancy:

- (i) anemia (less than ten (10) grams hemoglobin concentration and not responding to therapy);
- (ii) uterine bleeding except for threatened abortion in first trimester;
- (iii) any presentation except vertex position at thirty-seven (37) weeks or beyond;
- (iv) intrauterine fetal growth retardation or fetus small for gestational age;
- (v) preeclampsia;
- (vi) known multiple gestation;
- (vii) premature labor at less than thirty-seven (37) weeks;
- (viii) prolonged rupture of membranes for:
 - (aa) fourteen (14) hours without regular contractions; or
 - (bb) twenty-four (24) hours with contractions unless delivery is imminent;
- (ix) prolonged pregnancy of forty-two (42) weeks or more;
- (x) polyhydramnios; or
- (xi) significant isoimmunization against Rh or other antigen, which may affect the fetus.

(3) A provision that the center clearly delineates the medical and social risk factors that exclude women from the low-risk intrapartum group but that may be waived by the medical director on an individual basis, including, but not limited to, the following:

(A) Maternal characteristics:

- (i) height less than sixty (60) inches; and
- (ii) weight less than one hundred (100) pounds and greater than two hundred (200) pounds.

(B) Past obstetrical history:

- (i) habitual abortion of:
 - (aa) more than two (2) consecutive spontaneous or induced abortions;
 - (bb) postpartum hemorrhage; and
 - (cc) third stage problem or problems, for example, severe lacerations, inverted uterus, or retained placenta;
- (ii) preeclampsia;
- (iii) previous second stage labor greater than two (2) hours;
- (iv) premature baby of thirty-seven (37) weeks or less than two thousand five hundred (2,500) grams;
- (v) respiratory distress;
- (vi) congenital abnormality;
- (vii) known genetic disorders;
- (viii) any neonatal death;
- (ix) fetal death; or
- (x) significant birth injury.

(C) Associated conditions:

- (i) gastrointestinal disorders, for example, regional ileitis or ulcerative colitis;
- (ii) pulmonary disease not requiring treatment, for example, asthma or chronic bronchitis;
- (iii) psychiatric;
- (iv) thrombophlebitis;
- (v) alcohol abuse;
- (vi) drug abuse;
- (vii) smoking greater than one (1) pack per day; or
- (viii) urinary tract surgery.

(D) Failure of the women to register with the center before the end of the first trimester.

(4) A provision that a reliable method of patient identification must be used.

(5) A provision for the care of the infant, which shall include, but is not limited to, the following:

- (A) Resuscitation of the newborn.
- (B) Prophylactic treatment of the eyes.
- (C) Documented physical examination of the newborn before discharge.
- (D) The collection of blood for newborn screenings.
- (E) Referral for any abnormalities or problems.
- (F) Procedures for the detection of Rh and ABO isoimmunization.

(6) A provision for instruction or instructions to be given to the patient or the patient's legal representative regarding follow-up care and transportation needed by the patient on discharge to include at least the following:

- (A) Signs and symptoms of possible complications.
- (B) Activities allowed and activities to be avoided.

(C) Hygienic and other postdischarge procedures to be followed.

(D) The center's emergency phone numbers available on a twenty-four (24) hour basis.

(E) Follow-up appointment, if indicated;

(7) A provision to maintain a written system of documentation of patients who report postdischarge complications and the center's interventions. The interventions must be documented in the medical record.

(8) A provision that facilities, reusable equipment, and supplies must be thoroughly cleaned or sterilized, or both, following use according to center policies and procedures.

(Indiana State Department of Health; 410 IAC 27-10-1)

410 IAC 27-10-2 Nursing services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) Personnel with appropriate training must be available at all times to handle possible emergencies involving patients of the center.

(b) A registered nurse must serve as head nurse supervising health care personnel.

(c) All registered nurses and licensed practical nurses must be currently licensed in Indiana.

(d) An experienced registered nurse must supervise all health care personnel, including, but not limited to, registered nurses, licensed practical nurses, and other birth attendants as follows:

(1) Licensed practical nurses may do the following:

(A) Serve as scrub personnel under the supervision of a qualified registered nurse.

(B) 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.

(2) Birthing attendants shall be directly supervised by a qualified registered nurse.

(e) A registered nurse must be in attendance from the time a patient is admitted to the center until the patient and neonate are either discharged or transferred.

(f) All nursing personnel must meet annual inservice requirements as established by center, federal, and state requirements.

(g) A registered nurse must assign 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.

(h) Chemical agents may be administered within the individual licensed health professional's scope of practice to inhibit labor, as a temporary measure, until referral or transfer is complete. *(Indiana State Department of Health; 410 IAC 27-10-2)*

Rule 11. Infection Control Program

410 IAC 27-11-1 Infection control administration

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The center must do the following:

(1) Provide a safe and healthful environment that minimizes infection exposure and risk to the following:

(A) Patients.

(B) Health care workers.

(C) Persons who accompany patients.

(2) Maintain a written infection control policy that provides for an active and effective center-wide infection control program. The policy must include a system designed for the:

(A) identification;

(B) surveillance;

(C) investigation;

(D) control; and
(E) prevention;
of infections and communicable diseases in patients and health care workers.

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

(c) The center must designate a person qualified by training or experience as responsible for the following:

- (1) Ongoing infection control activities.
- (2) The development and implementation of policies governing control of infections and communicable diseases.

(d) The center administrator must do the following:

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

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

(1) The infection control committee must meet at least quarterly. Membership must include, 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 (c).
- (B) The medical director.
- (C) A representative from the nursing staff (if the center employs a licensed nurse).
- (D) Representatives 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:
 - (i) identifying;
 - (ii) reviewing; and
 - (iii) 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 that are pertinent to infection control.

These include, but are not limited to, the following:

- (i) Sanitation, including proper disposal of removed tissue.
- (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 system for patients with communicable diseases.
- (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.

(Indiana State Department of Health; 410 IAC 27-11-1)

410 IAC 27-11-2 Sterilization

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) 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 (to include 410 IAC 1-4, Universal Precautions). 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:**
 - (i) loading;**
 - (ii) operating;**
 - (iii) cleaning; and**
 - (iv) maintaining;****sterilizers.**
 - (C) Instructions for:**
 - (i) cleaning;**
 - (ii) packaging;**
 - (iii) storing;**
 - (iv) labeling; and**
 - (v) dispensing of;****sterile supplies.**
 - (D) The 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 to include, but not be limited to, the following:**
 - (A) Records of recording thermometers or a daily record of the sterilizing cycle:**
 - (i) date;**
 - (ii) time;**
 - (iii) temperature;**
 - (iv) pressure; and**
 - (v) contents;****for each sterilizer load.**
 - (B) Results of biological indicators used in testing the sterilizing processes.**

(b) Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood or other potentially infectious materials must be cleaned then decontaminated in accordance with acceptable standards of practice and applicable state laws and rules (to include 410 IAC 1-4, Universal Precautions). (*Indiana State Department of Health; 410 IAC 27-11-2*)

410 IAC 27-11-3 Laundry

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. The center, whether it operates its own laundry or uses outside laundry service, must 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 must be available in each room where clean or soiled linen is processed and handled.

(Indiana State Department of Health; 410 IAC 27-11-3)

Rule 12. Emergency Care

410 IAC 27-12-1 Emergency care

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. The center must have the following:

(1) A readily accessible written protocol for the following:

(A) Managing medical emergencies that occur within the center.

(B) The transfer of patients requiring further emergency care to a hospital capable of providing obstetrical and neonatal services.

(2) Separate and readily accessible emergency carts or trays for mothers and newborns.

(Indiana State Department of Health; 410 IAC 27-12-1)

Rule 13. Anesthesia and Birthing Services

410 IAC 27-13-1 Anesthesia services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The center must provide adequate anesthesia services to meet the needs of the patient, within the scope of the services offered, in accordance with acceptable standards of practice, under the direction of a licensed physician with specialized training or experience in the administration of anesthetics.

(b) Anesthesia services in a center are limited to local anesthesia.

(c) The medical staff shall write and implement policies and procedures that include, but are not limited to, the following:

(1) Safety rules to be followed relating to the administration of anesthesia.

(2) Safety training required of personnel.

(d) Anesthesia must only be administered by a member of the medical staff who is one (1) of the following:

(1) A qualified physician with appropriate:

(A) training;

(B) experience; and

(C) privileges.

(2) A licensed health care professional authorized to administer a specific form of anesthesia or otherwise authorized to administer topical or local anesthesia by state law or rule.

(3) A registered nurse acting:

(A) under the direction; and

(B) in the immediate presence;

of a physician.

(Indiana State Department of Health; 410 IAC 27-13-1)

410 IAC 27-13-2 Birthing services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 2. (a) Delivery shall be performed by a:

(1) certified nurse midwife; or

(2) physician.

(b) A physician must either be:
(1) present in the facility; or
(2) immediately available by telecommunications to the staff;
when there is a patient in the center.

(c) A physician or certified nurse midwife must remain in the center until the mother and neonate are either discharged or transferred. In addition to a physician or certified nurse midwife, a second employee who is CPR competent shall be present at each birth.

(d) Surgical services must be organized 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 limited to episiotomy and episiotomy repair.
- (2) Surgical services are under the direction of a physician qualified by experience and training.
- (3) Surgical services must develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care.

(Indiana State Department of Health; 410 IAC 27-13-2)

410 IAC 27-13-3 Equipment

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. There must be sufficient patient care equipment and space to assure the safe, effective, and timely provision of the available services to patients, which includes, but is not limited to, the following:

- (1) A heat source for infant examination or resuscitation.
- (2) Transfer incubator or isolette or demonstrated capability of immediate availability of a transfer incubator.
- (3) Blood pressure equipment.
- (4) Thermometers.
- (5) Fetoscope/doptone.
- (6) Intravenous equipment.
- (7) Sterilizer.
- (8) Resuscitation equipment.
- (9) Oxygen equipment for maternal and neonate uses.
- (10) Instruments for delivery, episiotomy, and repair.
- (11) Other supplies and equipment specified by the medical staff.

(Indiana State Department of Health; 410 IAC 27-13-3)

Rule 14. Dietary Services

410 IAC 27-14-1 Dietary services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) If nourishment and other dietary needs of the patients are provided in the center, the center must comply with 410 IAC 7-24.

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

(c) If prepackaged single service nourishments are provided, refrigeration storage of nourishments and other food products must be separate from refrigeration storage for pharmaceuticals. *(Indiana State Department of Health; 410 IAC 27-14-1)*

Rule 15. Laboratory Services

410 IAC 27-15-1 Laboratory services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) The center must provide, or make available, those pathology and medical laboratory services and consultations 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:

- (1) upon the written request of individuals and licensed health professionals authorized by law; and**
- (2) with governing body approval.**

(c) The center must 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.

(d) Laboratory supervisory and testing personnel qualifications must be:

- (1) consistent with the work assignments; and**
- (2) in compliance with 42 CFR 493.**

(e) All nursing and other center personnel performing laboratory testing must have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.

(f) The center must 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 27-15-1*)

Rule 16. Pharmaceutical Services

410 IAC 27-16-1 Pharmaceutical services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. The center must 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:

(A) designated professional person with prescriptive authority; or

(B) 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:

(i) handling;

(ii) storing;

(iii) labeling;

(iv) dispensing; and

(v) administration according to established center policies and acceptable standards of practice.

(B) Reporting of adverse reactions and medication errors to the:

(i) licensed health professional responsible for the patient; and

(ii) appropriate committee;

and documented in the patient's record.

(C) 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.

(D) Instructions to the patient on the use of take-home medication is the responsibility of the:

(i) prescribing physician; or

(ii) certified nurse midwife.

(4) A formulary.

(5) A list of available emergency drugs.

(Indiana State Department of Health; 410 IAC 27-16-1)

Rule 17. Physical Plant; Maintenance; Equipment; Environment; Safety

410 IAC 27-17-1 Physical plant

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 22

Sec. 1. (a) The center must 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 must provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the fire prevention and building safety commission (IC 22, 675 IAC 22), Indiana fire prevention codes (675 IAC 22), and Indiana building codes (675 IAC 13).

(b) 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 license of an existing center shall comply with the following:

(1) This article.

(2) All building, fire safety, and handicapped accessibility codes and rules adopted and administered by the office of the state building commissioner.

(Indiana State Department of Health; 410 IAC 27-17-1)

410 IAC 27-17-2 Specifications of physical plant

Authority: IC 16-21-1-7; IC 16-21-2-2.5

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

Sec. 2. (a) The center must comply with the freestanding birthing center guidelines as stated in the 2001 edition of the national "Guidelines for Design and Construction of Hospital and Health Care Facilities", (Guidelines) section 9.7 except corridors may be less than forty-four (44) inches wide but in no case less than thirty-six (36) inches wide

(b) Water supply and sewage disposal services must be obtained from municipal or community services.

(c) Centers operating before the effective date of this rule are exempted from the requirements of this section. *(Indiana State Department of Health; 410 IAC 27-17-2)*

410 IAC 27-17-3 Maintenance of physical plant

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 3. 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:

(A) insects;

(B) rodents; or

- (C) other vermin.
- (2) No condition may be created or maintained that may result in a hazard to:
 - (A) patients;
 - (B) the public; or
 - (C) 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 one (1) of the following:
 - (i) Acceptable standards of practice.
 - (ii) The manufacturer's recommended maintenance schedule.
 - (C) Operational and maintenance control records must be as follows:
 - (i) Established and analyzed at least triennially.
 - (ii) Readily available on the premises.
 - (D) Maintenance and repairs must be carried out in accordance with applicable codes, rules, standards, and requirements of the following:
 - (i) Local jurisdictions.
 - (ii) The state fire marshal.
 - (iii) The department.

(Indiana State Department of Health; 410 IAC 27-17-3)

410 IAC 27-17-4 Maintenance of equipment

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 4. All patient care equipment must be in good working order and regularly serviced and maintained as follows:

- (1) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following:
 - (A) Acceptable standards of practice.
 - (B) The manufacturer's recommended maintenance schedule.
- (2) There must be evidence of preventive maintenance on all patient care equipment.
- (3) Appropriate records must be:
 - (A) kept pertaining to equipment maintenance, repairs, and electrical current leakage checks; and
 - (B) analyzed at least triennially.
- (4) Defibrillators, if present, must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.

(Indiana State Department of Health; 410 IAC 27-17-4)

410 IAC 27-17-5 Environment

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 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:

- (1) 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:
 - (A) Asepsis.
 - (B) Cross-contamination prevention.
 - (C) Safe practice.
- (2) Refuse, biohazards, infectious waste, and garbage must be:
 - (A) collected;
 - (B) transported;
 - (C) sorted; and

(D) disposed of;
by methods that will minimize nuisances or hazards in compliance with federal, state, and local laws and rules.
(Indiana State Department of Health; 410 IAC 27-17-5)

410 IAC 27-17-6 Safety

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 6. (a) 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 the following:

(A) Administration.

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

(A) Periodic equipment inspections.

(B) Insect, rodent, or other vermin control.

(C) Instructions for operating and maintaining the building or building portion and equipment.

(D) Chemical substance use and storage.

(E) Surgical waste and similar material disposal.

(F) General housekeeping precautions.

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

(A) Patient safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(5) 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.

(6) 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.

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

(b) The center must maintain adequate battery-powered lighting and sufficient equipment needed to provide for the:

(1) completion of services; and

(2) safety of patients and staff;

in the event of a power loss. (Indiana State Department of Health; 410 IAC 27-17-6)

Rule 18. Other Services

410 IAC 27-18-1 Other services

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) If the center provides other services not covered in specific sections of this article, 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 must be as follows:

(1) Under the direction of a qualified person or persons.

(2) Staffed in accordance with written center policies and in compliance with the applicable state and federal rules.

(Indiana State Department of Health; 410 IAC 27-18-1)

Rule 19. Incorporation by Reference

410 IAC 27-19-1 Incorporation by reference

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1

Sec. 1. (a) When used in this article, references to the following publications 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) **42 CFR 493 (October 1, 2004).**

(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.

(c) All incorporated material is available for public review at the department. *(Indiana State Department of Health; 410 IAC 27-19-1)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on October 24, 2005 at 9:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Rooms 1 and 2, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on a proposed rule pertaining to the operation and management of birthing centers as well as establishing minimum licensing qualifications and establishing requirements for sanitation standards, staff qualifications, necessary emergency equipment, procedures to provide emergency care, quality assurance standards, and infection control. The rules will prescribe the operating policies, supervision, and maintenance of medical records. The rules will establish procedures for the issuance, renewal, denial, and revocation of licenses while addressing the form and content of the license and the collection of an annual license fee. The procedures and standards for inspections will also be addressed.

These rules are designed to meet the statutory mandate of IC 16-21-1-7 and IC 16-21-2-2.5. Requirements not expressly required by these statutes have not been imposed.

Copies of these rules are now on file at the Health Care Regulatory Services Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health