

John D. Rockefeller IV
Governor



L. Clark Hansbarger, M.D.
Director

State of West Virginia

DEPARTMENT OF HEALTH
CHARLESTON 25305

NOTICE OF PUBLIC HEARING


Pursuant to Section five, Article three, Chapter twenty-nine-A of the Code of West Virginia, one thousand nine hundred thirty-one, as amended, the West Virginia Department of Health shall convene a public hearing at 10 a.m. on November 22, 1983, in the first floor conference room (room 14) of the P & G Building, 2019 Washington Street, East, Charleston, West Virginia for the purpose of taking evidence pertaining to the filing of proposed Birthing Center Licensure Regulations, West Virginia Department of Health Legislative Rules, Chapter 16-2E, Series I (1984).

Any citizen or other interested party may appear in person to present evidence. Any citizen or other interested party may submit written evidence to the Regulatory Services Program of the West Virginia Department of Health, by mail to 1800 Washington Street, East, Charleston, West Virginia 25305 or in person at Room 7, second floor, P & G Building, 2019 Washington Street, East, Charleston, West Virginia 25305 not later than 4:30 p.m., November 22, 1983. All comments written or oral, will be made part of the public record of comments received and will be considered as a part of the public hearing. The Department requests that parties wishing to comment make an effort to submit written copies of their comments in order to facilitate review of said comments.

The issues to be heard shall be limited to the actual information contained in the proposed and abovementioned regulations. Copies of the regulations may be obtained from the address heretofore appearing or by telephoning 304-348-0534 or from the Office of the Secretary of State, Capitol Complex, Charleston, West Virginia 25305, telephone 304-345-4000.

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE Oct 19, 1983
Administrative Law Division


L. Clark Hansbarger, M. D.
Director of Health

Entered

FISCAL NOTE FOR PROPOSED RULES

Rule No. 16-2E, Series I(1984) Subject Birthing Centers

Type of Rule: Legislative Interpretive Procedural

Agency Health Department Address 1800 Washington Street, East
Charleston, WV 25305

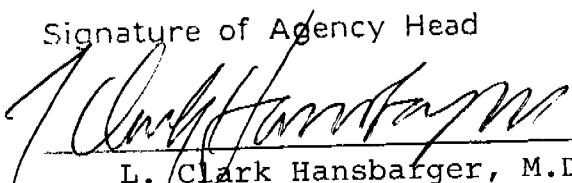
Authorized Representative _____ Phone _____

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ see below	\$	\$
Personal Services					
Current Expense					
Repairs and Alterations					
Equipment					
Others					

2. Explanation of above estimates. Although this is a new rule, the Department expects to be able to absorb the cost of administering this program into its ongoing budget. At the present time, there are only two birthing centers actually in operation. No more than two or three additional are anticipated to request licensure over the next two years.

3. Date October 19, 1983 Agency Health Department

Signature of Agency Head


L. Clark Hansbarger, M.D.
Director

Signature of Authorized Representative

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE Oct 19, 1983
Administrative Law Division

STATEMENT OF ECONOMIC IMPACT OF PROPOSED RULES OR REGULATIONS

Agency Health Department

Rule No. 16-2E, Series I (1984)

Subject Birthing Centers

1. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None. See preceding page.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

Staffing and programmatic requirements of the proposed regulation will have minimal, if any, impact on existing centers. Fire safety requirements may have cost implications. Cost data are not available.

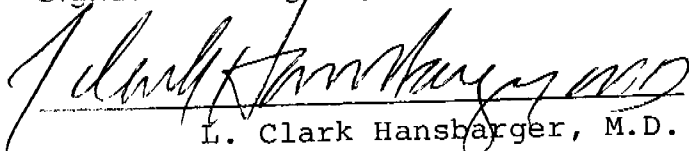
C. Economic Impact on Citizens/Public at Large.

None.

Date October 19, 1983

Agency Health Department

Signature of Agency Head


L. Clark Hansbarger, M.D.
Director

Signature of Authorized Representative

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A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE Oct 19, 1983
Administrative Law Division

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE 10/19/83

Administrative Law Division

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH

Birthing Center Licensure

Chapter 16-2E
Series I
(1984)

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH

Birthng Center Licensure

Chapter 16-2E
Series I
(1984)

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WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH

Chapter 16-2E
Series I
(1984)

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE

THIS DATE Oct 19, 1983
Administrative Law Division

Subject: Birthing Center Licensure

Section 1. General

1.1. Scope - These legislative rules establish rules and procedures for the licensing of birthing centers for the purpose of providing an alternate method of giving birth. The rules are designed to ensure adequate care and accommodations for clients of birthing centers while not hampering the development of such centers.

1.2. Authority - These legislative rules are issued under the authority of Chapter 16, Article 2E, Section 3 and are related to Chapter 16, Article 2E, Section 1 et seq. of the West Virginia Code of 1931, as amended.

1.3. Filing Date - These legislative rules were promulgated on the *** day of ***, and were filed on the *** day of *** in the Secretary of State's office.

1.4. Effective Date - These legislative rules became effective on the *** day of ***.

Section 2. Supersession and Repeal of Former Regulations - [Reserved]

Section 3. Application and Enforcement

3.1. Application - These legislative rules shall apply to any person, partnership, association or corporation and any local governmental unit or

any division, department, board or agency thereof establishing, conducting, managing or operating a birthing center.

3.2. Exceptions

3.2.1. A birthing service or center operated as a service within a hospital shall be licensed under hospital licensure regulations as promulgated under Chapter 16, Article 5B of the West Virginia Code of 1931, as amended.

3.3. Enforcement - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

Section 4. Definitions

4.1. Applicant - The person who submits an application for an original or a renewal license to operate a birthing center or birthing service.

4.2. Birthing Center - A type of facility which is a building, house or the equivalent organized to provide facilities and staff to support a birthing service for pregnant clients. A birthing center should be an adaptation of a home environment to a short-stay ambulatory health care facility where low risk births are planned to occur away from the mother's usual residence following normal uncomplicated pregnancy.

4.3. Birthing Service - The prenatal, intrapartum, and post partum care provided for individuals with uncomplicated pregnancy, labor and vaginal birth and newborn care during the recovery period.

4.4. Client - A woman, fetus, or newborn receiving care and services provided by a birthing center during pregnancy, childbirth and recovery.

4.5. Clinical Staff - Physicians, nurse-midwives, midwives and nurses appointed by the governing body of the birthing center to practice within the birthing center.

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4.5. Clinical Staff - Physicians, nurse-midwives, midwives and nurses appointed by the governing body of the birthing center to practice within the birthing center.

4.6. Department - The West Virginia department of health.

4.7. Director - The director of the West Virginia department of health or his lawfully appointed designee.

4.8. Gender - The pronoun "he" shall denote both the masculine and feminine gender. The use of any word denoting the masculine gender shall be taken to apply to both females and males.

4.9. Governing Body - The individual, agency, group or corporation, appointed, elected or otherwise designated in which the ultimate responsibility and authority for the conduct of the birthing center is vested.

4.10. License - The document issued by the director which constitutes the authority to receive patients and perform services included within the scope of these regulations.

4.11. Licensed or Registered or Certified - When applied to a person means that the person to whom the term is applied is duly licensed or registered or certified to practice a profession by the proper authority within the State of West Virginia and when applied to a facility means that the facility is duly licensed by the department of health.

4.12. Low Risk Maternal Client - An individual who is in general good health who participates in ongoing prenatal care and a maternity health education program, and who has no major medical, psychological or sociological problems, and who has had no significant obstetrical complications which are likely to recur, and who is anticipated to have a medically, psychologically and sociologically uncomplicated course of pregnancy and labor, including a vaginal birth, and who is expected to accomplish birth without the use of general anesthesia.

4.13. Nurse-Midwife - An individual licensed in West Virginia as a nurse-midwife.

4.14. Recovery - That period of time starting at the birth and ending with the discharge of a client from the birthing center or the period of time between the birth and the time a client leaves the premises of the birthing center.

4.15. Support Person - The individual selected or chosen by a maternal client to provide support and assistance during the process of labor and childbirth.

Section 5. State Administrative Procedures

5.1. General Licensure Provisions

5.1.1. No person, partnership, association, corporation, or any local governmental unit or any division, department, board or agency thereof may operate a birthing center in the State of West Virginia without first obtaining a license under these rules.

5.1.2. Neither an original nor a renewal license shall be issued under these rules for a project reviewable under Chapter 16, Article 2D of the West Virginia Code of 1931, as amended unless the state health planning and development agency has issued a finding, after a final conformance review, that the completed project conforms to the terms of the certificate of need decision issued for the project. Evidence of compliance shall be supplied with licensure applications.

5.1.3. A license shall be valid only for the premises and persons named and described in the application, shall not be transferable or assignable and shall be surrendered to the director upon written demand stating the cause for the demand.

5.1.4. If the ownership of a birthing center with a valid unexpired license changes, the new owner shall apply for a new license. The application of the new owner for a license shall have the effect of a valid license for three months from the date the application is received by the director.

5.1.5. A license shall state: (a) the specific name of the birthing center to which it applies; (b) the date of issuance; and (c) the expiration date. A birthing center name change shall be shown in the next license issued.

5.1.6. The license shall be posted in a conspicuous and public place of the birthing center.¹

5.1.7. Neither the name of the birthing center nor any advertising of the center's services shall suggest or claim any services other than those given on the application and for which the center is licensed.

5.2. Initial License

5.2.1. An applicant shall submit a completed application to the director, on a form prescribed by the director, not less than thirty days and not more than sixty days prior to the date proposed for commencement of operation. Information required may include affirmative evidence of ability to comply with these rules and regulations. A nonrefundable fee of ten dollars (\$10) shall be submitted with the application for an initial license.

5.2.2. An initial license shall be issued only after the director inspects the birthing center and only if he finds that:

(a) the birthing center substantially complies with these rules and regulations; and

(b) the applicant is a person responsible and suitable to operate, direct or participate in the operation of a birthing center by virtue of financial capacity and appropriate business or professional experience.

5.2.3. An initial license issued after the effective date of these rules and regulations shall be valid for a period of one year from the date of issuance.

5.3. Renewal License

5.3.1. An applicant for a renewal license shall submit a completed application to the director on a form prescribed by the director not less than thirty days and not more than ninety days prior to the scheduled expiration date of the current license. A nonrefundable fee of ten dollars (\$10) shall be submitted with the license renewal application.

5.3.2. The director shall issue a renewal license when he finds the facility in compliance with these regulations and the licensee submits a completed application and the correct renewal fee.

5.3.3. A renewal license shall be valid for a period of one year from the date of issuance.

5.4. Provisional License

5.4.1. If the director finds that an applicant for a renewal license is not in substantial compliance with the requirements of these regulations the director may, in his discretion, issue a provisional license.

5.4.2. A provisional license may be issued only when the director finds that: (a) the care given in the birthing center is adequate to meet client needs; and (b) the birthing center has demonstrated improvement in and potential for substantial compliance within the term of the license for which renewal is requested.

5.4.3. A provisional license shall not be issued for a period greater than twelve months; shall not be renewed; and shall not be issued to a facility with uncorrected violations of these regulations which would pose an imminent danger to the health and safety of any client.

5.5. Inspections

5.5.1. The director shall conduct at least one unannounced inspection annually of a licensed birthing center to determine compliance with the provisions of these regulations.

5.5.2. The director shall have the right to enter the premises of a facility which he has reason to believe is being operated or maintained as a birthing center without a license.

5.5.3. If the owner or person in charge of a licensed birthing center or of an unlicensed facility which the director has reason to believe is being operated as a birthing center refuses entry pursuant to these regulations, the director shall take action to secure a lawful warrant authorizing inspection.

5.5.4. If the director finds on the basis of the inspection that a facility is operating as a birthing center without a license, the facility shall apply within ten days for a license in accordance with the provisions of these regulations.

5.5.5. Failure to apply for a license shall be subject to the penalties established by Chapter 16, Article 2E, Section 5 of the West Virginia Code of 1931, as amended.

5.5.6. A report of any inspection made pursuant to these regulations shall be made in writing and shall be maintained on file by the director.

5.5.7. Inspection reports shall specifically list each deficiency in the birthing center's compliance with statutes and rules and regulations.

5.5.8. The director shall send a copy of a report of an inspection to the birthing center.

5.6. Plans of Correction

5.6.1. A birthing center found on the basis of an inspection to have deficiencies in compliance with these rules and regulations shall develop a plan of correction and submit it to the director within thirty days of receipt of the inspection report.

5.6.2. A plan of correction shall specify a reasonable time within which the birthing center shall correct each violation cited in the report, which time shall be the shortest possible time within which the birthing center reasonably can be expected to correct the violation.

5.6.3. The time stated shall be subject to approval or modification by the director. In determining whether to approve the time submitted by the facility, the director shall consider the following factors: (a) the seriousness of the violation; (b) the availability of required equipment or personnel; (c) the estimated time required for delivery and installation of required equipment; and (d) any other relevant circumstances.

5.6.4. A plan of correction submitted by a birthing center shall be approved, modified or rejected by the director. The director shall notify the birthing center within ten (10) days as to whether a plan of correction has been approved, modified or rejected. If the director rejects or modifies the plan, the reasons for the action shall be stated. When the director rejects a plan of correction, a reasonable time for submission of a revised plan may be allowed.

5.6.5. Upon the failure by a birthing center with deficiencies to submit a plan of correction which is approved by the director or to correct any deficiency within the time specified in an approved plan of correction, the director may initiate legal action available to him in accordance with the West Virginia Code of 1931, as amended, and these rules and regulations.

5.7. Complaint Investigation

5.7.1. Any person may register a complaint with the director alleging violation of applicable laws or rules and regulations by the birthing center. A complainant shall state the substance of the complaint and shall identify the birthing center involved.

5.7.2. The director may conduct either an announced or an unannounced inspection of the birthing center to determine the validity of the complaint. The department shall provide the birthing center with notice of the substance of the complaint only at the time of the inspection. The director shall conduct such other investigations as may be necessary to determine the validity of the complaint.

5.7.3. The director shall notify the complainant and the birthing center in writing of the results of the investigation no later than twenty (20) working days after completing an investigation of a complaint.

5.7.4. Upon written request, the director will send the complainant a description of the corrective action the birthing center will be required to take and of any disciplinary action to be taken.

5.7.5. The name of a complainant or of any person named in a complaint shall be safeguarded by the director and shall not be disclosed without the individual's prior written authorization. Before any complaint is

disclosed to a birthing center or to the public pursuant to these regulations, any information in the complaint which could reasonably identify the complainant or a client shall be deleted. If a complaint becomes the subject of a judicial proceeding, nothing in these rules and regulations shall be construed to restrict disclosure of information which would otherwise be disclosed in a judicial proceeding.

5.8. Availability of Reports and Records

5.8.1. The director shall make available for public inspection and upon written request may provide copies of the following documents: (a) inspection reports; (b) reports of investigations conducted in response to complaints; and (c) any other reports filed with or issued by the director pertaining to the compliance of a facility with applicable laws, rules and regulations. A fee may be charged to cover the cost of research and copying. Applications for initial and renewal license shall be held confidential.

5.8.2. The director shall treat a report of inspection of a birthing center as public information from the time a written plan of correction is submitted.

5.8.3. If the birthing center does not submit a written plan of correction within the time specified by the director pursuant to Section 5.7 of these regulations, reports pertaining to the birthing center shall be made public at the expiration of the specified time.

5.8.4. Other records and reports shall be treated as public information from the time they are issued by the director.

5.8.5. Nothing contained in this Section shall be construed to require or permit the public disclosure of confidential medical, social, personal or financial records of any client.

5.8.6. Before releasing a report or record deemed public information the director shall delete any confidential information which could reasonably permit identification of clients or of complainants or of any other information required to be held confidential under these rules and regulations.

Section 6. Physical Facilities

6.1. Life Safety - The birthing center shall be in compliance with the National Fire Protection Association, National Fire Codes and the Fire Prevention Code known as the Fire Safety Code, as adopted by the West Virginia fire commission and the additional promulgated fire safety regulations as filed by the state fire commission.

6.2. General Construction

6.2.1. There shall be drainage, sewerage disposal, hot and cold running water supply, and electricity which shall meet state and local laws and rules and regulations. Evidence of compliance shall be available in the birthing center and shall, upon written request, be submitted to the director.

6.2.2. Local building codes and zoning restrictions shall be observed. Evidence of compliance shall be available in the birthing center and shall, upon written request, be submitted to the director.

6.3. Food Service - Any catered food service or on-premises food service provided by the facility shall be in compliance with West Virginia Food Service Sanitation Regulations promulgated by the West Virginia Board of Health.

6.4. General Maintenance

6.4.1. The birthing center shall establish and implement a written

program of preventive maintenance to ensure that all essential mechanical, electrical and client care equipment is in safe operating condition.

6.4.2. Stairwells and corridors shall be kept free from obstruction at all times.

6.4.3. The interior and the grounds of the birthing center shall be kept in sanitary, safe and presentable condition and shall be free from accumulated rubbish and other health hazards of a similar nature.

6.4.4. Effective measures shall be taken to minimize the presence of insects, rodents and vermin. Pesticides shall not be applied in any way that constitutes a hazard to clients, staff or any other persons.

6.4.5. Maintenance and housekeeping services may be provided by another organization,

6.4.6. All floor surfaces, wall surfaces, water closets, lavatories, tubs and showers shall be kept clean and in good repair.

6.4.7. The birthing center shall adopt and implement written policies and procedures to provide for the handling of equipment and medical supplies in a manner which ensures the utilization of clean and sterile supplies and equipment in client care. Clean and sterile supplies and equipment shall be segregated from those that are soiled.

6.4.8. The birthing center shall adopt and implement written policies and procedures to ensure the provision of clean linens and the segregation of clean linens from those which are soiled.

6.4.9. The birthing center shall adopt and implement written policies and procedures to provide for the collection and disposition of refuse and liquid waste in a manner to prevent the creation of unsafe or unsanitary conditions.

Section 7. Governance and Management

7.1. The birthing center shall identify to the director the governing body or person so functioning which has the overall authority and responsibility for the operation and management of the birthing center.

7.2. The birthing center shall adopt and implement written policies and procedures which shall include at a minimum:

(a) the health care and safety of clients within or on the premises of the birthing center;

(b) the operation of the facility;

(c) services provided by the facility;

(d) the health and safety of facility staff within or on the premises of the birthing center;

(e) personnel policies and procedures, including job descriptions and educational and training requirements;

(f) orientation, training and education programs for staff; and

(g) other policies and procedures required by these rules and regulations.

7.3. Staff shall have access to the policies and procedures.

7.4. The birthing center shall establish and maintain a current written plan for the facility which shall be reviewed at least once every two years. Such plan shall include:

(a) a description of services to be provided;

(b) a description of clients to be served;

(c) an organizational plan which includes all positions and delineates responsibilities, authority, and relationships of positions within the birthing center; and

(d) linkages to other services and levels of care within the health care system. The review shall be documented in writing.

7.5. Clients shall be enrolled or admitted for birthing services only after evaluation by the clinical staff.

7.6. The governing body shall appoint an administrator or director who has the responsibility for implementing the policies and procedures of the birthing center and for the administrative operation of the center.

7.7. No birthing center which offers such services shall deny acceptance to a prospective client on grounds of race, color, religion, or national origin.

7.8. No client shall be segregated, given separate treatment, restricted in the enjoyment of any advantage or privilege enjoyed by other clients of the birthing center or provided with any aid, care services or other benefits which are different or are provided in a different manner from those provided to other clients of the on the grounds of race, color, religion or national origin.

Section 8. Clinical Staffing

8.1. There shall be sufficient, qualified staff available to perform the services offered by the birthing center. In evaluating the numbers and qualifications of staff, the director shall consider the following criteria: (a) the number and type of clients of the center; (b) the type of services provided by the center; (c) the education, training and experience of the staff as it relates to their job responsibilities; (d) any specific requirements of these regulations; (e) professional credentials; and (f) state professional licensure requirements. All staff and any consultants or volunteers pro-

viding services under the auspices of the birthing center who are required by state law to be licensed, registered or certified shall have valid licenses, registrations or certificates, copies of which licenses, registrations or certificates shall be on file with the facility.

8.2. A physician certified by the American Board of Obstetrics and Gynecology or who is otherwise qualified and authorized by training and experience as a practitioner in obstetrics shall participate in the development of and the review of clinical policies and procedures of the birthing center.

8.3. All policies and procedures relating to client care shall be approved and reviewed on a yearly basis by a physician meeting the requirements of 8.2 of these rules and regulations.

8.4. A physician certified by the American Board of Obstetrics and Gynecology or a physician who is otherwise qualified and authorized by training and experience and who is recognized by peers in the community as an experienced, competent practitioner in obstetrics shall be immediately available by telephone twenty-four hours a day. The birthing center shall provide written evidence of physician availability.

8.5. A physician or nurse midwife shall be present at each birth. A second person, who is an employee or member of the clinical staff with resuscitation skills shall be immediately available during each birth.

8.6. The clinical staff shall develop and adopt rules and procedures, subject to the approval of the governing body, which shall include requirements for clinical staff membership, delineation of clinical privileges and responsibilities, and the organization of the clinical staff.

8.7. Qualified staff shall be present in the birthing center at all times

when clients are present. In evaluating the necessary qualifications, the director shall take into account the particular type of service scheduled and other factors as specified in these rules and regulations.

Section 9. Clinical Policies and Procedures

9.1. There shall be written policies, including detailed definitions of, screening criteria for, and procedures for identifying: (a) low-risk maternal clients who shall be eligible for birthing services offered by the birthing center; and (b) individuals who shall be ineligible for birthing services at the birthing center.

9.2. There shall be written policies and procedures, including detailed definitions or criteria for: (a) identification and transfer of clients who, during the course of pregnancy, are determined to be ineligible; and (b) identification and transfer of clients who, during the course of labor or recovery, are determined to be ineligible for continued care in the birthing center.

9.3. There shall be written plans and procedures for consultation, backup services, transfer and transport of a newborn or maternal client to a hospital where appropriate care is available.

9.4. Clinical policies and procedures shall be developed for routine and for emergency care of both the maternal and the fetus or newborn client until completion of care by the birthing center either through completion of the care program or through transfer to other levels of care.

9.5. The center shall provide written evidence of the availability of emergency transport services for clients.

9.6. There shall be provision for emergency admission of clients to a

hospital by at least one of the following methods: (a) the attending physician or the consultant physician on call shall have admitting privileges at the hospital to be utilized for emergency transfer; or (b) there shall be a written agreement with a hospital for emergency services and admissions. A hospital policy statement concerning emergency procedures and admissions may, at the director's discretion, be accepted as satisfying this requirement.

9.7. There shall be provision for the education, orientation and training of clients, family and support persons in pregnancy, childbirth and newborn care.

9.8. Procedures shall be adopted and implemented for the registration of births and the examination for and the reporting of congenital physical and mental impairments in infants in accordance with state law found at Chapter 16, Article 5, Section 12a of the West Virginia Code of 1931, as amended.

9.9. Prophylactic treatment of the eyes of the newborn shall be performed in accordance with Chapter 16, Article 3 of the West Virginia Code of 1931, as amended and any regulations promulgated thereunder.

9.10. The birthing center shall comply with state law relating to the testing for phenylketonuria, galactosemia and hypothyroidism as found at Chapter 16, Article 22, of the West Virginia Code of 1931, as amended, and any rules promulgated thereunder.

9.11. There shall be procedures for infection control which shall include consideration of housekeeping, cleaning, sterilization, sanitization and storage of supplies and equipment, and health of personnel.

9.12. Health records for personnel shall include documented evidence

of a tuberculosis screening if indicated by exposure or prevalence.

9.13. Employees with any communicable disease in an infectious stage shall not be on duty.

9.14. The birthing center shall adopt and implement a program for documented reviews of the quality of the management of the care of clients. Such program shall include: (a) regular staff meetings and case presentations; (b) midwifery audit; and (c) evaluation of routines for infection control, equipment maintenance and emergencies. Drills in emergency procedures shall be a component of the quality review program.

9.15. Clinical policies and procedures shall be organized and indexed and shall be readily available on site for staff use and inspection at all times.

Section 10. Pharmaceuticals

10.1. There shall be written prescriptions or orders signed by a practitioner legally authorized to prescribe for all drugs administered to clients within the birthing center.

10.2. There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

10.3. Written policies shall be established addressing the type, and intended use of any drug to be used by patients within the facility.

10.4. Anesthetic agents other than local anesthetics and pudendal blocks shall not be used.

10.5. Drugs shall be administered only by personnel or clinical staff licensed to administer drugs.

10.6. Drugs, medications and chemicals kept anywhere in the center

shall be clearly labeled with drug name, strength, and expiration date.

10.7. Drugs, chemicals, and medications shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons.

10.8. Drugs shall not be stored in a refrigerator used for food storage for clients and families.

10.9. Poisonous chemicals, caustic materials, or drugs shall show appropriate warning or poison labels and shall be stored separately from other drugs. Drugs for external use shall be separated from drugs for internal use.

10.10. The birthing center shall be in conformance with any applicable federal, state and local laws and regulations relating to drugs and to controlled substances.

Section 11. Records

11.1. The birthing center shall maintain a clinical record system, policies and procedures which provide for identification, security, confidentiality, control, retrieval and preservation of client care data and information.

11.2. There shall be a health record maintained for each maternal and newborn client to include:

- (a) personal and family history;
- (b) physical examination;
- (c) reports of relevant laboratory tests and screening procedures;
- (d) newborn and maternal status during the prenatal period, labor, birth, recovery and follow-up;
- (e) reports of any outside tests, examinations and treatments re-

quested by the birthing center during the course of care of the maternal and newborn client;

(f) all services provided to both the maternal and the newborn client;
and

(g) documentation and authentication by staff who order or who administer drugs or treatments or who make observations or assessments.

11.3. Entries in the client record shall be typewritten or written legibly in ink.

11.4. Documentation and record keeping shall include completion of birth or death certificates.

11.5. Records shall be retained for a period of twenty years.

Section 12. Client Rights

12.1. Clients shall be informed in writing of their rights and responsibilities.

12.2. Clients shall be clearly informed of the responsibilities of the birthing center for care of the client, including services to be provided and risks during pregnancy, labor, birth, recovery and follow-up. Information given shall include as one element the travel time to a hospital emergency facility.

12.3. Clients shall be clearly informed in writing of the costs of services to be provided and of any required services or procedures not included in the charges of the center.

12.4. Upon written request, the birthing center shall supply a client with an itemized statement detailing services provided and charges assessed at no additional cost to the client.

12.5. Clients shall be informed in writing that health department licensure requirements do not, by law, include any standards relating to acceptable site characteristics, physical environment or clinical equipment.

12.6. Clients shall have the right to participate in the development of their care plans.

12.7. Clients or their authorized agents or representatives shall have the right to examine their records at reasonable times and shall upon written request be provided with a copy or summary of their record within a reasonable period of time. The birthing center shall also comply with other provisions of state law found at Chapter 16, Article 29, Section 1 et seq. of the West Virginia Code of 1931, as amended, relating to client records. The birthing center shall have the right to charge a reasonable fee to cover the cost of reasonable expenses incurred in providing the copy.

Section 13. Penalties

13.1. Director's Authority

13.1.1. The director is authorized to suspend or revoke a birthing center license according to the provisions of Chapter 16, Article 2E, Section 2 of the West Virginia Code of 1931, as amended, if he finds upon inspection that there has been a substantial failure to comply with the provisions of these rules and regulations or with the laws of this state or with any order or final decision of the director.

13.2. The director may refuse to grant a license if he finds that the applicant has attempted to obtain the license by means of fraud or deceit.

13.3. The director may suspend or revoke a license if he finds that the license has been obtained by means of fraud or deceit.

13.4. When the director takes action pursuant to the suspension or revocation of a license issued under these rules and regulations, he shall comply with the requirements and procedures specified by Chapter 16, Article 2E, Section 2 of the West Virginia Code of 1931, as amended.

Section 14. Administrative Due Process

14.1. An applicant for a license or a licensee or any other person aggrieved by an order or other action by the director pursuant to these regulations or the laws of this State shall have the opportunity for a hearing by the director, upon written request to the director in a manner prescribed in and by the aforementioned Rules of Procedure for Contested Case Hearings and Declaratory Rulings (1981) promulgated by the Board of Health. The aforementioned Rules of Procedure are incorporated herein by reference.

14.2. A hearing pursuant to this Section shall be conducted in accordance with the pertinent provisions of Chapter 29A, Article 5 of the West Virginia Code of 1931, as amended and the aforementioned Rules of Procedure for Contested Case Hearings and Declaratory Rulings (1981).

14.3. The director's order shall be final unless vacated or modified by judicial review in accordance with the provisions of the law of this State.

Section 15. Severability - If any provisions of these rules or the application thereof to any person or circumstance shall be held invalid, such invalidity thereof shall not affect the provisions or application of these rules which can be given effect without the invalid provisions or application, and to this end the provisions of these rules are declared to be severable.