

INTRODUCTION

The Rhode Island Department of Health has legal and professional responsibilities for the health, welfare and safety of the citizens of Rhode Island.

These rules and regulations are promulgated pursuant to the authority set forth in section 23-1-1 of the General Laws of Rhode Island, as amended. The purpose of these rules and regulations is to_safeguard the health, safety and welfare of women undergoing a termination of pregnancy. To assure quality care, the regulations focus on major areas of public health concern and define the facilities required for acceptable practice, consistent with the most recent *Guidelines for Women's Health Care* of the American College of Obstetricians and Gynecologists.

These regulations do not predetermine the result of professional judgement as to the wisdom and propriety of the service which must remain the province of the physician or other licensed health care practitioner acting within his/her scope of practice. These regulations shall supersede all previous rules_and regulations pertaining to the termination of pregnancy promulgated by the Department of Health and filed with the Secretary of State.

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PART I: **Definitions**

Section 1.0 *Definitions*

Wherever used in these regulations, the following terms shall be construed as follows:

- 1.1 "Fetal death", as defined in subsection 23-3-1(3) of the General Laws of Rhode Island, as amended, means death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such expulsion or extraction the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles.
- 1.2 "Gestation" means the duration of the pregnancy computed from the first day of the last menstrual period, or based upon clinical judgment of the examining physician (or other licensed health care practitioner acting within his/her scope of practice) when that date is unreliable.
- 1.3 "Gestational age" means the estimated age of the fetus based upon anatomical characteristics of the fetus.
- 1.4 *"Physician"* means a person authorized or licensed to practice medicine or osteopathy pursuant to Chapter 37 of Title 5.
- 1.5 "Termination of a pregnancy" or "Termination" shall mean administering to a woman any medicine, drug, substance, or thing whatever, or the employment upon her of any instrument or other means whatever, with intent to procure or induce the miscarriage of such woman. (The term "abortion" is not used in these regulations, since it applies to both spontaneous and induced fetal loss).

PART II: Requirements for Pregnancy Terminations

Section 2.0 *General Provisions*

- 2.1 Pursuant to the provisions of section 23-1-19 of the General Laws of Rhode Island, as amended, the Director of Health is authorized to enter, examine or survey at any reasonable time such places as he/she considers necessary, which perform the services of these rules and regulations.
- 2.2 Prior to the end of the fourteenth (14th) week of gestation (counted from the first day of the last normal menses), termination of pregnancy may be performed outside the hospital or freestanding ambulatory surgical center, when hospital emergency back-up services are available and other provisions of these regulations are observed.
- 2.3 From the beginning of the fifteenth (15th) week of gestation through the end of the eighteenth (18th) week of gestation (counted from the first day of the last normal menses), termination procedures utilizing surgical techniques or methods shall be performed only in a licensed hospital, licensed freestanding ambulatory surgical center, licensed physician office setting providing surgical treatment ("office operatory"), and/or in an outpatient setting meeting the criteria required for a freestanding surgical facility, and in accordance with other provisions of these rules and regulations.
- 2.4 After the beginning of the nineteenth (19th) week of gestation (counted from the first day of the last normal menses), a procedure utilizing surgical techniques or methods shall be performed in a hospital, and/or a licensed freestanding ambulatory surgical center. Provided, however, consistent with the provisions of section 11-23-5 of the Rhode Island General Laws, as amended, the procedure shall be performed in the final trimester only when necessary to preserve the life or health of the mother.
- 2.5 A patient shall not be compelled to undergo, a physician or other licensed health care practitioner acting within his/her scope of practice shall not be compelled to perform, or a person shall not be compelled to assist at, termination of pregnancy.
- 2.6 The principles for a signed statement of "informed consent", including an operative permit as required for other medical-surgical procedures, shall apply.

Section 3.0 Requirements for Facilities Utilizing Surgical Techniques or Methods

- 3.1 Where inhalation anesthesia is utilized, a licensed freestanding ambulatory surgical center or a licensed physician office setting providing surgical treatment ("office operatory") shall comply with the safety standards cited in the *Rules and Regulations for Licensing of Freestanding Ambulatory Surgical Centers (R23-17-FASC)* of reference 1 herein; a hospital shall comply with the safety standards cited in the *Rules and Regulations for Licensing of Hospitals* of reference 2 herein.
- 3.2 Furthermore all facilities utilizing surgical techniques or methods shall provide the following:
 - 3.2.1 Facilities for registration, interviewing, counseling, history taking, medical evaluation and examination, equipped with suitable furnishings and accommodations, including waiting and dressing rooms and other appurtenances for the privacy, physical comfort and convenience of patients and personnel;
 - 3.2.2 An adequately staffed and equipped procedure room(s) sufficient in number and size to

accommodate expected caseload, personnel and equipment including the following:

- a. Dressing room and scrub-up facilities suitably located to procedure room(s);
- b. Utility room with facilities for sterilization of supplies, except when sterile supplies are received from a central supply service;
- c. All necessary instruments and supplies for the performance of appropriate surgical procedure;
- d. All necessary equipment for resuscitation and emergency treatment of complications (e.g., hemorrhage, cardiac arrest, shock, anaphylactic reactions and respiratory complications);
- e. An adequate supply of drugs, Rh immune globulin, electrolyte solutions and plasma volume expanders, immediately available at all times for emergency use; and
- f. Environmental controls for the protection of the health, safety and welfare of patients and personnel.
- 3.2.3 A recovery room(s) adequate in size and appropriately equipped and staffed in which the patient(s) will be observed until sufficiently recovered from the procedure and the anesthesia and can be safety discharged by the physician or other licensed health care practitioner acting within his/her scope of practice.
- 3.2.4 Provisions shall be made for the prompt and safe transfer of patients for the back-up services referred to in sections 2.2 and 2.3 above.
- 3.2.5 Facilities not on the ground floor shall be served by an elevator capable of accommodating a standard stretcher.
- 3.2.6 Space and equipment shall be provided to permit the production, storage, retrieval and reproduction of records.

Section 4.0 **Program Requirements**

- 4.1 Provisions shall be made for the protection of the dignity, privacy and emotional concerns of the patient in a safe, considerate atmosphere.
- 4.2 All indicated counseling services shall be made available to patients for the prevention and management of personal problems before and after a termination procedure.
- 4.3 Verification of the diagnosis and duration of pregnancy and a medical history shall be obtained and a complete physical examination performed, including pelvic examination, with consideration of any medical, surgical or psychiatric conditions requiring special attention.
- 4.4 No less than the following laboratory procedures shall be conducted on each patient and reports shall be available prior to the performance of termination of pregnancy procedure: (1) pregnancy test; (2) hemoglobin or hematocrit; (3) blood and Rh typing; and (4) urinalysis.
 - 4.4.1 Other laboratory procedures such as Papanicolaou smear, and tests for sexually

transmitted diseases should be conducted in accordance with standard medical practice.

- 4.5 A medical record shall be established and maintained for each patient and shall contain no less than the following items:
 - a. reports of observations cited above in section 4.3;
 - b. laboratory findings;
 - c. plan of management, including reasons for termination of pregnancy, and procedure to be employed;
 - d. all observations of patient's condition during procedure and recovery; and
 - e. discharge, follow-up, and referral plans.
- 4.6 All tissue removed shall be considered as surgical specimens and shall be submitted for pathological examination and the report included in the patient record. Furthermore, for any termination after the eleventh (11th) week of gestation, the gestational age of the fetus shall be determined in accordance with current standards of medical practice.
- 4.7 Provisions shall be made for patient access to family planning services, including referral to specialized agencies.
- 4.8 Rh immune globulin shall be administered to every unsensitized Rh(d) negative woman who has a termination of pregnancy.

Section 5.0 *Personnel Requirements*

- 5.1 All termination procedures shall be performed only by a physician licensed under the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended, or other licensed health care practitioner acting within his/her scope of practice, provided, however, surgical terminations shall only be performed by a physician.
- 5.2 There shall be sufficient personnel to carry out all required functions including reception, counseling, pre- and post-operative nursing care, clerical work, housekeeping and maintenance.
- 5.3 Anesthesia shall be administered in accordance with the *Rules and Regulations for Licensing of Freestanding Ambulatory Surgical Centers (R23-17-FASC)* or the *Rules and Regulations for Licensing of Hospitals* as appropriate to the category of facility where the termination of pregnancy is performed.

PART III: Reporting and Severability

Section 6.0 Reporting Requirements

- 6.1 All live births, and all fetal deaths after 20 weeks of gestation, shall be reported in accordance with the current requirements of section 23-3-17 of the General Laws of Rhode Island, as amended, entitled "Fetal Death Registration."
- All fetal deaths, whether induced as consequence of a termination procedure or by spontaneous abortion shall be reported in accordance with subsection (b) of the above-cited law, which reads,

"All other fetal deaths, irrespective of the number of weeks uterogestation, shall be reported directly to the state Department of Health within seven (7) calendar days after delivery." Such reporting shall be made on authorized forms provided by the Department of Health.

Section 7.0 Severability

7.1 If any provision of these regulations or the application thereof to any facility or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end, the provisions of the regulations are declared to be severable.

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PART IV: References

- 1. Rules and Regulations for Licensing of Freestanding Ambulatory Surgical Centers (R23-17-FASC), Rhode Island Department of Health, May 1998, and subsequent amendments thereto.
- 2. Rules and Regulations for Licensing of Hospitals, Rhode Island Department of Health, September 1999 (E), and subsequent amendments thereto.
- 3. Rules and Regulations for the Licensing of Professional (Registered), Certified Registered Nurse Practitioners, Certified Registered Nurse Anesthetists and Practical Nurses and Standards for the Approval of Basic Nursing Education Programs (R5-34-NUR/ED), Rhode Island Department of Health, December 1998, and subsequent amendments thereto.
- 4. Rules and Regulations for the Licensure and Discipline of Physicians (R5-37-MD/DO), Rhode Island Department of Health, September 1998, and subsequent amendments thereto.
- 5. "Vital Records," Chapter 23-3 of the Rhode Island General Laws, as amended.
- 6. *Guidelines for Women's Health Care*, The American College of Obstetricians and Gynecologists, 409 12th St., S.W., Washington, D.C., 20024-2188, 1996.
- 7. Rules and Regulations for the Licensing of Midwives (R23-13-MID), Rhode Island Department of Health, November 1998, and subsequent amendments thereto.
- 8. Rules and Regulations for the Registration of Physician Assistants (R5-54-PA), Rhode Island Department of Health, February 1994, and subsequent amendments thereto.