

DRAFT REGULATIONS, FOR INFORMAL PUBLIC COMMENT.

- *In making comments, please reference both the specific section of the regulations and the specific concern.*

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 12 ADULT HEALTH

10.12.01 Surgical Abortion Facilities

Authority: Health-General Article, §20-209, Annotated Code of Maryland

BEGIN NEW

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Department" means the Department of Health and Mental Hygiene.

(2) "Facility" means a surgical abortion facility.

(3) Health Professional.

(a) "Health professional" means an individual who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, to provide health care services.

(b), "Health professional" does not include those individuals who are licensed to practice medicine, dentistry, or podiatry under the Health Occupations Article, Annotated Code of Maryland.

(4) "Physician" means an individual licensed to practice medicine in this State under Health Occupations Article, Title 14, Annotated Code of Maryland.

(5) “Regular service” means that surgical abortion procedures are performed onsite on a routine basis.

(6) “Surgical abortion facility” means an outpatient facility that provides surgical termination of pregnancy services as a regular service except if the facility is regulated by the Department under:

(a) Health General Article, Title 19, Subtitle 2, Annotated Code of Maryland;

(b) Health General Article, Title 19, Subtitle 3A, Annotated Code of Maryland; or

(c) Health General Article, Title 19, Subtitle 3B.01 (B), Annotated Code of Maryland.

.02 License Required.

A. A person may not establish or operate a surgical abortion facility without obtaining a license from the Secretary.

B. License Period. A license is valid for 3 years from the date of issuance, unless suspended or revoked by the Secretary.

C. A license issued under this chapter is not transferable.

.03 Licensing Procedure.

A. A person desiring to operate a facility shall:

(1) Be in compliance with all applicable federal and State laws and regulations;

(2) File an application on a form provided by the Department; and

(3) Submit a written description of its quality assurance program as required by Regulation .16 of this chapter.

B. Based on information provided to the Department by the applicant and the Department's own investigation, the Secretary shall:

(1) Approve the application unconditionally;

(2) Approve the application conditionally; or

(3) Deny the application, if the applicant:

(a) Has been found liable for or has been convicted of:

(i) Fraud or a felony that relates to Medicaid or Medicare, or

(ii) A crime involving moral turpitude; or

(b) Considering the factors identified in Regulation .19B, does not comply with the regulations in this Chapter.

C.. Denial of License for Prior Revocation or Consent to Surrender License.

(1) The Secretary may deny a license to:

(a) A corporate applicant if the corporate entity has an owner, director, or officer:

(i) Whose conduct caused the revocation of a prior license, or

(ii) Who held the same or similar position in another corporate entity which had its license revoked; or

(b) An individual applicant:

(i) Whose conduct caused the revocation of a prior license, or

(ii) Who held a position as owner, director, or officer in a corporate entity which had its license revoked; or

(iii) An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.

(2) The Secretary shall also consider the factors identified in Regulation .19B of this chapter when deciding whether to deny a license.

D. A person aggrieved by a decision of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

E. Renewal of License.

(1) At least 60 days before a license expires, the licensee shall submit a renewal application to the Secretary.

(2) The Secretary shall renew the license for an additional 3-year period for a licensee that meets the requirements of this chapter.

.04 Inspections by the Department.

A. Open for Inspection. A licensed facility or an entity proposing to operate such a facility shall be open during normal business hours, or any other times that the facility is serving patients, for inspection by the Department and by any other agency designated by the Department to:

(1) Verify compliance with this chapter; and

(2) Investigate a complaint concerning patient care and safety.

B. Noncompliance. If the Department determines that a facility fails to meet any provision of this chapter, the Department shall:

(1) Advise the facility of the exact nature of the violation; and

(2) Require that the facility specify what corrective action it is taking and monitor the facility to ensure that it takes corrective action.

C. If the complaint concerns the performance of a health care practitioner or standards of practice, the Department shall refer the complaint to the board that licenses, certifies, or otherwise authorizes the health care practitioner to provide services under the Health Occupations Article, Annotated Code of Maryland.

D. Records and Reports. The facility shall make its records and reports available to the Department onsite at the facility during an inspection.

.05 Administration.

A. Administrator. Each facility shall have an administrator, who is responsible for the daily operation of the facility, including but not limited to:

- (1) In consultation with the facility staff, developing and implementing the facility's policies and procedures, including procedures for the accountability of personnel involved in patient care;;
- (2) Organizing and coordinating the administrative functions of the facility;
- (3) Coordinating the provision of services that the facility provides;
- (4) Training the staff on the facility's policies and procedures, and with applicable federal, State, and local laws and regulations; and
- (5) Ensuring that all personnel:
 - (a) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties;
 - (b) Are licensed or certified by an appropriate occupational licensing board to practice in this State, if required by law; and
 - (c) Perform or delegate duties and responsibilities in accordance with standards of practice as defined by the Health Occupations Article, Annotated Code of Maryland.

B. Policies and Procedures. The facility shall have policies and procedures concerning the following:

- (1) The scope and delivery of services provided by the facility either directly or through contractual arrangements;
- (2) Personnel practices;

- (3) Postoperative recovery, if applicable;
- (4) The transfer or referral of patients who require services that are not provided by the facility;
- (5) Infection control for patients and staff;
- (6) Pertinent safety practices, including the control of fire and mechanical hazards;
- (7) Preventive maintenance for equipment to ensure proper operation and safety; and
- (8) The services and procedures specified in Regulations .07—.12 of this chapter.

C. The administrator shall ensure that all:

- (1) The facility's policies and procedures are reviewed by staff at least annually and are revised as necessary;
- (2) The facility's policies and procedures are available at all times for staff inspection and reference; and
- (3) Appropriate personnel implement all policies and procedures as adopted.

D. The facility shall have job descriptions on file for all personnel.

.06 Personnel.

A. Qualifications of Physicians and Facility Staff. A facility shall ensure that all physicians and other health professionals who are employees or contractual staff have been appropriately trained and licensed or certified under the Health Occupations Article, Annotated Code of Maryland.

B. Credentialing of Physicians. The facility shall collect, review, and document the following information concerning a physician licensed under the Health Occupations Article, Title 14, Annotated Code of Maryland:

- (1) The physician's education;
- (2) The professional experience of the physician, including:
 - (a) Any board certification or specialty training of the physician, and

- (b) Any post-graduate training;
- (3) Any license or registration to practice a health occupation ever held by the physician, including DEA registration;
- (4) Any hospital where the physician was appointed or employed during the last 10 years, including:
 - (a) The name of the hospital,
 - (b) The term of appointment or employment, and
 - (c) Privileges held and any disciplinary action taken, including suspension, revocation, limitation, or voluntary surrender;
- (5) The physician's professional liability insurance for the last 5 years, including:
 - (a) The physician's present carrier,
 - (b) The physician's current limits of coverage,
 - (c) The physician's current types of coverage, and
 - (d) Restrictions on the physician's coverage;
- (6) Any claim that has been made against the physician in the practice of a health occupation in the last 5 years, and the status of the claim;
- (7) Any physical or mental condition that currently impairs the physician's ability to exercise privileges;
- (8) Any complaint or report, permitted to be disclosed by law, which has been filed with any state licensing or disciplinary body, or comparable body of the armed forces; and
- (9) Data provided by the National Practitioner Data Bank.

C. For a physician who has privileges in a licensed Maryland hospital, the administrator may verify, through the hospital, the credentials described in §B of this regulation.

D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes:

- (1) An update of the information required in §B of this regulation; and
- (2) An assessment of the physician's performance pattern based on an analysis of:
 - (a) Complaints filed with the facility,
 - (b) Malpractice claims filed,
 - (c) Utilization, quality, and risk data,
 - (d) Adherence to policies, bylaws, and procedures, and
 - (e) Physician practice patterns as reviewed through the facility's quality assurance program.

E. Credentialing of Health Professionals.

(1) Direct Hires.

(a) The facility shall collect, review, and verify evidence of the following information for all licensed or certified allied health professionals that are employed by the facility:

- (i) A current license or certificate to practice in this State; and
- (ii) Malpractice insurance, if required by the facility.

(b) The administrator shall approve the delineation of services to be provided by the health professional.

(2) Nondirect Hires. When a licensed physician uses a health practitioner to provide services at the facility, and that person is not employed by the facility, the licensed physician who employs the health practitioner is responsible for verifying the information required in §E(1) of this regulation.

.07 Surgical Abortion Services.

A. Surgical abortion procedures shall be performed in a safe manner by qualified physicians.

B. An administrator shall develop and implement policies, procedures, and protocols for the provision of surgical abortion services including but not limited to:

- (1) Personnel;
- (2) Pre-operative testing and examinations;
- (3) Surgical procedures;
- (4) Post-anesthesia care and observation;
- (5) Discharge planning;
- (6) Emergency services;
- (7) Informed consent; and
- (8) Safety.

C. Before conducting a surgical procedure, a physician or other qualified health care practitioner shall conduct a history and physical examination.

D. If the assessments required by §C of this regulation are performed before the day of surgery, on the day of surgery a qualified health care practitioner shall reassess and document any change in the patient's clinical status that could have an effect on the surgical procedure to be performed and the anesthesia to be used.

E. Discharge. Before discharge from the facility, the patient shall be evaluated by an appropriately trained licensed health care provider. This evaluation shall be documented in the patient's record.

.08 Anesthesia Services.

A. Anesthetics shall be administered by appropriately trained and licensed health care providers as defined in §C of this regulation.

B. If anything other than an unsupplemented local anesthetic is needed to accomplish a surgical procedure, there shall be a pre-anesthesia evaluation and the anesthetic risk to the patient shall be documented in the patient's medical record.

C. General anesthesia shall be administered only by a:

(1) Qualified anesthesiologist;

(2) Physician qualified to administer anesthesia; or

(3) Certified registered nurse anesthetist in accordance with Health Occupations Article, §8-205, Annotated Code of Maryland, and COMAR 10.27.06.

.09 Emergency Services.

A. Basic Life Support. Licensed personnel employed by the facility shall have certification in basic life support. A licensed staff individual trained in basic life support shall be on duty whenever there is a patient in the facility.

B. The facility shall have at least one clinical staff member available by phone 24 hours a day to respond to emergency situations.

C. When sedation is administered, the facility shall have at least the following emergency equipment available to the procedure rooms:

(1) Oxygen;

(2) Mechanical ventilatory assistance including airways and manual breathing bag;

(3) Automated external defibrillator (AED);

(4) Cardiac monitoring equipment;

(5) Suction equipment; and

(6) Emergency medical equipment and supplies specified by the medical staff.

D. When general anesthesia is administered, a facility shall have laryngoscopes and endotracheal tubes available in the procedure room.

.10 Hospitalization.

A. The surgical abortion facility shall have an effective procedure for the transfer of patients to a hospital when care beyond the capabilities of the facility is required.

B. Procedures for emergency transfer to a hospital shall include, at a minimum:

- (1) Written protocols and procedures related to emergency transfer procedures;
- (2) A mechanism for notifying the hospital of a pending emergency case;
- (3) A mechanism for arranging appropriate transportation to the hospital;
- (4) Protocols for transmitting a copy of the patient's medical record to the hospital; and
- (5) Appropriate training for staff in the facility's written protocols and procedures.

.11 Pharmaceutical Services.

A. The surgical abortion facility shall:

- (1) Provide drugs under the direction of an authorized prescriber; and
- (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice.

B. Administration of Drugs.

- (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.
- (2) Staff shall report adverse reactions to the patient's health care practitioner and document these reactions in the patient's medical record.
- (3) Orders given orally for drugs shall be followed by a written order which is signed by the authorized prescriber.

.12 Laboratory Services.

A. The administrator shall develop and implement policies and procedures for obtaining routine and emergency laboratory services to meet the needs of the patient. Policies and procedures shall include:

- (1) Turn-around time;
- (2) Review of laboratory reports; and
- (3) Documentation of laboratory results.

B. Laboratory facilities shall be approved under the Clinical Laboratory Improvement Act (CLIA) and be licensed by the State under COMAR 10.10.03.

C. The facility shall include laboratory reports in the patient's medical records.

.13 Medical Records.

A. The facility shall maintain a complete, comprehensive, and accurate medical record for a patient.

B. A patient's medical record shall include at least the following:

- (1) Patient identifier;
- (2) Significant medical history and results of a physical examination;
- (3) Documentation of care or services provided;
- (4) Evidence of consent; and
- (5) Discharge diagnosis.

C. The facility shall:

- (1) Send a copy of the medical record with the patient on referral to another health care provider or on transfer to a hospital;
- (2) If appropriate, use the medical record when instructing the patient and the family; and

(3) Comply with all disclosure requirements as set forth in Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland.

.14 Patients' Rights and Responsibilities

The administrator shall ensure that the facility develops and implements written policies and procedures concerning patients' rights and responsibilities, including but not limited to:

- A. The opportunity to participate in planning their medical treatment; and
- B. Confidentiality of medical records and the right to approve or refuse release of records to any individual outside the facility, except as provided by federal or State law.

.15 Physical Environment.

- A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services.
- B. A procedure room shall be designed and equipped to ensure that surgical abortion procedures conducted can be performed in a manner that ensures the safety of all individuals in the area.
- C. The facility shall have a separate recovery room and waiting area.
- D. The facility shall meet the requirements for handling, treatment, and disposal of special medical wastes as provided in COMAR 10.06.06.

.16 Quality Assurance Program.

- A. The administrator shall ensure that the facility develops and maintains a quality assurance program which includes:
 - (1) Monitoring and evaluation of the quality of patient care; and
 - (2) Identification, evaluation, and resolution of care problems.
- B. The facility shall conduct ongoing quality assurance activities and document the activities on a continuous basis, but not less than quarterly.

C. The administrator shall ensure that the facility develops a quality control procedure to monitor the safety and performance of all biomedical equipment.

D. The facility shall document the following information for all quality assurance activities:

(1) A description of identified problems;

(2) Findings;

(3) Conclusions;

(4) Recommendations;

(5) Actions taken;

(6) Results; and

(7) Follow-up.

.17 Emergency Suspension.

A. The Secretary may immediately suspend a license on a finding that the public health, safety, or welfare requires emergency action.

B. The Department shall deliver a written notice to the licensee:

(1) Informing the licensee of the emergency suspension;

(2) Giving the reasons for the action and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and

(3) Notifying the licensee of the licensee's right to request a hearing and to be represented by counsel.

C. The filing of a hearing request does not stay the emergency action.

D. When a license is immediately suspended, the licensee shall:

(1) Immediately return the license to the Department; and

(2) Stop providing services immediately.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

F. Hearing.

(1) The Office on Administrative Hearings shall:

(a) Conduct a hearing as set forth in Regulation .20 of this chapter; and

(b) Issue a proposed decision within 10 business days of the close of the hearing record.

(2) Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03.

G. Final Decision.

(1) The Secretary shall make a final decision in accordance with COMAR 10.01.03.

(2) If the Secretary's final decision does not uphold the emergency suspension, the licensee may resume operation.

.18 Revocation of License.

A. The Secretary, for cause shown, shall notify the licensee of the Secretary's decision to revoke the facility's license. The revocation shall be stayed if a hearing is requested.

B. The Secretary may revoke a license if the licensee:

(1) Has been convicted of:

(a) Fraud or a felony that relates to Medicaid or Medicare, or

(b) A crime involving moral turpitude; or

(2) Does not comply with the requirements of this chapter.

C. The Secretary shall consider the factors identified in Regulation .19B of this chapter when deciding whether to revoke a license.

D. The Secretary shall notify the licensee in writing of the following:

- (1) The effective date of the revocation;
- (2) The reason for the revocation;
- (3) The regulations with which the licensee has failed to comply that form the basis for the revocation;
- (4) That the licensee is entitled to a hearing if requested, and to be represented by counsel;
- (5) That the facility shall stop providing services on the effective date of the revocation if the licensee does not request a hearing;
- (6) That the revocation shall be stayed if a hearing is requested; and
- (7) That the licensee is required to surrender the license to the Department if the revocation is upheld.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

.19 Penalties.

A. Administrative Penalty. The Secretary may impose an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.

B. When considering whether to impose an administrative penalty and the amount of the penalty, the Secretary shall consider the following factors:

- (1) The number, nature, and seriousness of the violations;
- (2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;
- (3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;

(4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(5) Such other factors as justice may require.

C. A person aggrieved by the action of the Secretary under §A of this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

.20 Hearings.

A. A request for a hearing shall be filed with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted in accordance with State Government Article, §10-201 et seq., Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03.

C. The burden of proof is as set forth in COMAR 10.01.03.28.

D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.

E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.

F. The Secretary shall issued a final decision in accordance with COMAR 10.01.03.35.

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