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Document No. 4669
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-7-110 et seq. and 44-41-10 et seq.

61-12. Standards for Licensing Abortion Clinics.

Preamble:

Regulation 61-12 has not been substantively updated since 1996. This amendment is necessary to update definitions, references, and codification. The amendment may also revise requirements for obtaining licensure, compliance for licensure, accident and incident reporting requirements, abortion reporting, inspections and violations, complaint reporting, patient rights, infection control, inservice training, record maintenance and retention, personnel requirements, fire and life safety requirements, and construction design requirements. The Department also intends to add language to incorporating current provider-wide exceptions and memoranda applicable to abortion clinics. The Department may also include stylistic changes, which may include corrections for clarity and readability, grammar, punctuation, codification, and overall improvement of the text of the regulation.

A Notice of Drafting was published in the *State Register* on April 22, 2016.

Section-by-Section Discussion of Proposed Amendments

The title was amended for regulatory consistency and clarity.

Statutory authority for this regulation was added under the title of the regulation and before the table of contents.

TABLE OF CONTENTS

The table of contents was updated to reflect amended sections.

61-12.100. DEFINITIONS AND LICENSE REQUIREMENTS (formerly 61-12.PART I)
Section title was amended for clarity.

61-12.101. Definitions
The definitions of 101.C Administrator, 101.D Administering Medication, 101.H Controlled Substance, 101.I Consultation, 101.M Health Assessment, 101.O Inspection, 101.P Investigation, 101.Q Legally Authorized Healthcare Provider, 101.R License, 101.T Licensed Nurse, 101.W Nonlegend Medication, 101.X Physical Examination, 101.BB Procedure Room, 101.DD Quality Improvement Program, 101.EE Recovery Area, 101.FF Repeat Violation, 101.GG Responsible Party, 101.HH Revocation of License, 101.II Staff Member, and 101.JJ Suspension of License were added. The definitions of 101.B Abortion Clinic, 101.E (formerly 101.C) Allied Health Professional, 101.N (formerly 101.K) In Loco Parentis, 101.S (formerly 101.L) Licensee, 101.V (formerly 101.N) Minor, 101.Y (formerly 101.O) Physician, 101.Z (formerly 101.P) Pregnancy, 101.AA (formerly 101.Q) Probable Gestational Age of the Embryo or Fetus, 101.KK (formerly 101.S) Trimester, and 101.LL (formerly 101.T) Viability have been amended. The definitions of 101.I Fire Safety Authority and 101.J Hospital have been deleted. The remaining definitions were renumbered to adjust the codification.

61-12.102.A. License

Section 102.A was amended to delineate the scope of licensure and to prohibit facilities from providing care or services prior to the effective date of licensure.

61-12.102.B. Compliance
New Section 102.B was added to require that all facilities comply with licensing standards as well as applicable local, state, and federal laws, codes, and regulations.

61-12.102.C. Compliance with Structural Standards
New Section 102.C was added to allow facilities licensed at the time of promulgation of these regulations to continue utilizing the previously-licensed structure without modification.

61-12.102.D. Licensed Capacity
New Section 102.D was added to require facilities to obtain authorization from the Department when the number of procedure rooms exceeds the licensed capacity.

61-12.102.E. Issuance and Terms of License (formerly 61-12.102.B)
Section 102.E (formerly 102.B) was relocated and amended to clarify the licensure terms and provisions relating to multiple facilities and license placement within the facility.

61-12.102.F. Facility Name (formerly 61-12.102.J)
Section 102.F was relocated from former Section 102.J and delineates the requirements for facility names.

61-12.102.G. Application (formerly 61-12.Chapter 9)
Section 102.G was relocated from former Chapter 9 and clarifies the requirements of the license application.

61-12.102.H. Licensing Fees (formerly 61-12.102.E)
Section 102.H (formerly 102.E) was relocated and amended to delineate licensure fees, require that the fees be made payable by check or money order, and to allow the Department to charge a fee for plan reviews, construction inspections, and licensing inspections. Section 102.H (formerly 102.E) also requires that the renewal license fee include the renewal license fee plus any outstanding inspection fees.

61-12.102.I. Late Fee
Section 102.I was added to require a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, for failure to submit a renewal application after the licensure expiration date. Section 102.I further adds that continual failure to submit complete and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

61-12.102.J. License Renewal (formerly 61-12.102.H)
Section 102.J (formerly 102.H) was amended to require that where a license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved. Sections 102.J.1 and 102.J.2 were relocated from former Section 102.K and requires that a facility shall request issuance of an amended license by application to the Department prior to change of facility ownership or change of facility location and further requires that changes to the facility name or address shall be accomplished by application or by letter from the licensee.

61-12.102.K. Exceptions to Licensing Standards (formerly 61-102.L)
Section 102.K was relocated from former Section 102.L and clarifies the exceptions to these standards.

61-12.102.C. Effective Date and Terms of License

This section has been deleted as its requirements have been incorporated elsewhere.

61-12.102.D. Separate Licenses
This section has been deleted as unnecessary.

61-12.102.F. Inspections
This section has been deleted as its requirements have been incorporated elsewhere.

61-12.102.G. Initial License
This section has been deleted as unnecessary.

61-12.102.I. Noncompliance
This section has been deleted as unnecessary.

61-12.200. ENFORCEMENT OF REGULATIONS
New Section 200 was added outline procedures for enforcement of the regulation.

61-12.201. General
Section 201 was added to allow the Department to utilize inspections, investigations, consultations, and other documentation to enforce the regulation.

61-12.202. Inspections and Investigations
Section 202.A requires that facilities be inspected prior to initial licensing. Section 202.B states that facilities are subject to inspection or investigation at any time without prior notice by authorized individuals. Section 202.C delineates the requirements of facility accessibility for inspectors. Section 202.D describes the written plan of correction for facilities that are found noncompliant. Section 202.E outlines the confidentiality requirements of reports of inspections or investigations. Section 202.F was added to delineate existing inspection fees.

61-12.300. ENFORCEMENT ACTIONS (formerly 61-12.103)
New section title was added to clarity and consistency.

61-12.301. General (formerly 61-12.103)
Section 301 was relocated from the introductory paragraph of former Section 103.

61-12.302. Violation Classifications
Sections 302.A (formerly 103.A), 302.B (formerly 103.B), 302.C (formerly 103.C), 302.D (formerly 103.D), and 302.E (formerly 103.E) were amended to adjust the codification and delineate the different classes of violations. Section 302.F (formerly 103.F) was amended to update the monetary penalty ranges and conform to codification. Former Section 103.G was deleted as unnecessary.

61-12.400. POLICIES AND PROCEDURES (formerly 61-12.PART II)
Section title amended for clarity and consistency and to update codification. Section 400.A (formerly 201.A) was amended to requiring facilities to develop policies and procedures and delineates the requirements thereof. Section 400.B (formerly 201.B) delineates the required policies for the abortion procedure.

61-12.500. STAFF
New Section 500 title was added for clarity and consistency.

61-12.501. General

Section 501.A requires that the facility have appropriate staff in numbers and training to meet the needs and conditions of the patients at all times. Section 501.B requires that the facility assign duties and responsibilities to all staff members and volunteers in writing. Section 501.C requires that the facility maintain a written employment application for all employees.

61-12.502. Administrator (formerly 61-12.202)
Former Section 202 was rewritten and separated out for easier readability. Section 502.A requires that the facility have an administrator to ensure regulatory compliance. Section 502.B requires that there be a staff member designated in writing to act in the absence of the administrator. Section 502.C delineates the requirements for changing administrators.

61-12.503. Facility Staff
Section 503.A was relocated from former Section 205.A. Section 503.B was relocated from former Section 205.E. Section 503.C was relocated from former Section 205.B.

61-12.504. Physicians
Section 504.A was relocated from former Section 205.C.1. Section 504.B (formerly 205.C.3) requires that a physician sign the discharge order and be readily accessible and available until the past patient has been discharged. Section 504.C was relocated from former Section 205.C.2. Section 504.D was relocated from former Section 205.F.

61-12.505. Nursing Staff
Section 505.A was relocated from former Section 205.D.2. Section 505.B was added to require that the nursing staff be assigned duties consistent with their scope of practice as determined through their licensure and education. Section 505.C was relocated from former Section 205.D.3.

61-12.506. Inservice Training
Section 506.A was added to require that training for the tasks each staff member performs shall be conducted. Section 506.B was added to delineate the specific required training and to require documentation thereof. Section 506.C requires that all licensed nurses possess a valid CPR certificate within three (3) months from the first day on the job in the facility. Section 506.D requires that there be a registered nurse or allied health professional with a valid advanced cardiac life support credential on duty in the facility whenever patients are present. Section 506.E requires that all new staff members have documented orientation to the facility within twenty-four (24) hours of their first day on the job in the facility.

61-12.507. Health Status
Section 507.A requires that all staff members having patient contact have a health assessment within twelve (12) months prior to initial patient contact. Section 507.B requires that the health assessment include a tuberculin skin test. Section 507.C allows for copies of health assessment records when a staff member works at multiple facilities owned by the same licensee.

61-12.600. REPORTING
New Section 600 was added to delineate the facility's reporting requirements.

61-12.601. Accidents and/or Incidents
Section 601.A requires the facility to report and maintain a record of each accident and/or incident for six (6) years. Section 601.B requires the facility to submit an online report of the accident and/or incident to the Department within five (5) days of the occurrence and includes a non-exhaustive list of the accidents and/or incidents requiring reporting. Section 601.C delineates the information required to be reported. Section 601.D requires the facility to report each accident and/or incident resulting in unexpected death or

serious injury to the next of kin or responsible party, as well as to the Department, within twenty-four (24) hours.

61-12.602. Abortions and Fetal Deaths
Section 602.A was relocated from former Section 403.A.1 and amended to require that abortions be reported to the Bureau of Vital Statistics within seven (7) days after the abortion. Section 602.A.1 delineates the information required to be reported. Section 602.A.2 delineates the penalties for failing to report abortions. Section 602.B (formerly 403.A.2) was amended to require that fetal deaths be reported pursuant to the standards in Regulation 61-19, Vital Statistics.

61-12.603. Communicable Diseases
New Section 603 was added to require that all cases of reportable diseases be reported to the appropriate county health department in accordance with Regulation 61-20, Communicable Diseases.

61-12.604. Facility Closure
Section 604.A was added to requires facilities to notify the Department in writing prior to the permanent closure of a facility and to require the facility to notify the Department within ten (10) days of closure of the provisions for the maintenance of the facility records. Section 604.B was added to delineate the requirements of facilities temporarily closing.

61-12.605. Zero Census
New Section 605 requires that when there have been no patients in the facility for a period of ninety (90) days or more, the facility shall notify the Department in writing that there have been no patients no later than the one hundredth (100th) day following the date of the last procedure.

61-12.700. PATIENT RECORDS (formerly 61-12.CHAPTER 4)
Section 700 was relocated from former CHAPTER 4 and retitled for clarity and consistency.

61-12.701. Consent of the Patient (formerly 61-12.206)
Section 701.A was relocated from former Section 206. Section 701.B was added to allow for consent to be waived if a physician determines that a medical emergency exists involving the life of or a grave or physical injury to the woman or the pregnancy is a result of incest.

61-12.702. Abortion Performed Upon Minors (formerly 61-12.207)
Section 702 was relocated from former Section 207.

61-12.703. Content (formerly 61-12.401)
Section 703.A was relocated from former Section 401 and amended to delineate the general requirements of records in the facility. Section 703.B (formerly 401.A) was amended to delineate the specific entries required for records of patients in the facility. Section 703.B.1.d (formerly 401.A.1) was amended to require a unique medical record identifying number instead of a social security number. Section 703.C was relocated from former Section 401.C.

61-12.704. Dissemination of Information (formerly 61-12.208)
Section 704 was relocated from former Section 208.

61-12.705. Authentication of Patient Records
Section 705.A requires that each document generated be separately authenticated. Section 705.B delineates the accepted methods of authentication. Section 705.C delineates the requirements for using electronic or computer-generated signature codes for authentication purposes. Section 705.D outlines the requirements for utilizing rubber stamp signatures.

61-12.706. Record Maintenance (formerly 61-12.402)
Section 706 was relocated from former Section 402 and was rewritten and separated out for easier readability. Section 706.A delineates the storage requirements for records. Section 706.B requires that a transfer summary accompany patients when being transferred to an emergency facility. Section 706.C delineates confidentiality requirements for records. Section 706.D refers to requirements for records from third party contractors. Section 706.E allows facilities to determine the storage medium for records. Section 706.F delineates records requirements upon patient discharge. Section 706.G delineates record retention requirements. Section 706.H states that patient records are property of the facility and shall not be removed without a court order.

61-12.800. CARE, TREATMENT, PROCEDURES, AND SERVICES (formerly 61-12.PART III)
Section 800 was relocated from former PART III and retitled for clarity and consistency.

61-12.801. General
Section 801.A requires that care, treatment, procedures, and/or services be performed safely in accordance with orders from physicians or other legally authorized healthcare providers. Section 801.B requires that the facility comply with all current federal, state, and local laws and regulations. Section 801.C requires a written agreement when the facility engages outside sources for facility services.

61-12.802. Limitations of Services Offered by Abortion Facilities (formerly 61-12.302)
Section 802.A (formerly 302.A) was amended to require that Abortion Facilities only perform abortions on patients who are within eighteen (18) weeks from the first day of their last menstrual period unless the Abortion Facility is also licensed by the Department as an Ambulatory Surgical Facility. Section 802.B requires that an Abortion Facility also licensed by the Department as an Ambulatory Surgical Facility perform abortions in accordance with Chapter 41, Title 44 of the South Carolina Code of Laws.

61-12.803. Anesthesia Services
Section 803.A requires that anesthesia be administered pursuant to state law by a qualified anesthesiologist or an individual legally authorized to administer anesthesia. Section 803.B requires that a patient be attended by a physician after being administered anesthesia until the patient may be safely placed under post-procedure supervision by the nursing staff.

61-12.804. Laboratory Services (formerly 61-12.304)
Section 804.A (formerly 304.A) was amended to require that each facility provide or make arrangements for obtaining laboratory services required in connection with the procedure to be performed. Section 804.B (formerly 304.A.2) was amended to require that facilities conducting laboratory tests involving human specimens obtain a CLIA certificate. Section 804.C (formerly 304.B) was amended to require that prior to the procedure, laboratory tests for hematocrit or hemoglobin, and determination of Rh factor shall be administered. Section 804.D (formerly 304.C) was amended to require that testing for chlamydia and gonorrhea, syphilis serology, and papanicolaou be administered. Section 804.E was relocated from former Section 304.D. Section 804.F was relocated from former Section 304.F. Section 804.G was relocated from former Section 304.H.

61-12.900. MEDICATION MANAGEMENT (formerly 61-12.303)
Section 900 was relocated from former Section 303 and retitled for clarity and consistency.

61-12.901. General
Section 901.A requires that medications be properly managed in accordance with local, state, and federal laws and regulations. Section 901.B delineates the requirements for nonlegend medications. Sections 901.C and 901.C.1 were relocated from former Section 303.E.1 and delineate the requirements of the

facility physician with regard to controlled substances. Section 901.C.2 was relocated from former Section 303.E.2. Section 901.C.3 requires reporting theft or loss of controlled substances. Section 901.D was relocated from former Section 303.A and delineates the requirements of the emergency kit or cart. Section 901.E was relocated from former Section 303.A.2 and requires that applicable reference materials published within the previous year be available at the facility.

61-12.902. Medication Orders
Section 901.A requires that medications be administered only upon orders of a physician or other legally authorized healthcare provider. Section 902.B delineates the requirements for medication orders. Section 902.C prohibits medications and medical supplies ordered for a specific patient being provided to or administered to any other patient.

61-12.903. Administering Medication (formerly 61-12.303.B)
Section 903.A delineates the requirements of the medication administration record. Section 903.B delineates the requirements of records and record retention for stock controlled substances.

61-12.904. Pharmacy Services
Section 904 requires that facilities maintaining stocks of legend medications for use within the facility obtain and maintain a valid, current, nondispensing drug outlet permit.

61-12.905. Medication Storage (formerly 61-12.303.C)
Section 905.A delineates the general requirements for medication storage. Section 905.B delineates the refrigeration requirements for medications requiring refrigeration. Section 905.C requires that medications be properly stored and safeguarded to prevent access by unauthorized persons. Section 905.D requires that refrigerated medications adhere to temperatures as established by the U.S. Pharmacopeia. Section 905.E prohibits medications from being stored with poisonous substances. Section 905.F requires a review of medication storage areas by the consultant pharmacist at least monthly.

61-12.906. Disposition of Medications
Section 906.A prohibits retention of expired, damaged, or deteriorated medications and delineates the disposal requirements thereof. Section 906.B requires destruction records to be retained for at least two (2) years.

61-12.1000. RIGHTS AND ASSURANCES (formerly 61-12.209)
Section 1000.A requires the facility to comply with all relevant federal, state, and local laws and regulations concerning discrimination. Section 1000.B requires the facility to develop and post conspicuously a grievance or complaint procedure for patients. Section 1000.C requires that care, treatment, procedures, and/or services provided shall be delineated in writing and patients made aware of such as verified by the signature of the patient or responsible party. Section 1000.D delineates the required patient rights. Section 1000.E requires that the Statement of Rights of Patients be posted in a conspicuous place in the facility.

61-12.1100. EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS
New section title added for clarity and consistency.

61-12.1101. Emergency Services (formerly 61-12.305)
Section 1101.A (formerly 305.B) requires appropriate equipment to render emergency resuscitative and life support procedures pending transfer to a hospital. Section 1101.B (formerly 305.C) requires that the facility inform the local ambulance service of the nature of problems which may result from abortions.

61-12.1102. Disaster Preparedness (formerly 61-12.502)

Section 1102 was relocated from former Section 502 and amended to require that a facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

61-12.1103. Emergency Call Numbers
Section 1103.A requires the facility to post emergency call data for the fire and police departments, ambulance service, and the Poison Control Center in a conspicuous place. Section 1103.B requires that other emergency call information be available, including the contact information of staff members to be notified in case of emergency.

61-12.1200. INFECTION CONTROL AND ENVIRONMENT (formerly 61-12.CHAPTER 6)
Section was retitled for clarity and consistency and renumbered to adjust the codification.

61-12.1201. Staff Practices
Section 1201.A requires the facility to ensure that staff uses preventive measures and practices in compliance with applicable guidelines of entities listed therein. Section 1201.B requires that when a patient has a communicable disease, a physician or other legally authorized healthcare provider shall ensure that the facility has the capability to provide adequate care. Section 1201.C requires the facility to designate a person to coordinate tuberculosis screening of personnel and any other tuberculosis control activities.

61-12.1202. Vaccinations
Section 1202.A requires that all direct care staff be vaccinated with the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. Section 1202.B requires the influenza vaccination annually for all direct care staff unless the vaccine is contraindicated or the individual is offered the vaccine and declines. Section 1202.C requires vaccination or evidence of immunity for measles, rubella, and varicella, unless the vaccine is contraindicated or the individual is offered the vaccine and declines.

61-12.1203. Live Animals
Section 1203 prohibits live animals in the facility, but offers an exception for patrol dogs, guide dogs, or other service animals accompanying individuals with disabilities.

61-12.1204. Sterilization Procedures (formerly 61-12.602)
Section 1204.A (formerly 602.C) was amended to require that the accuracy of instrumentation and equipment be tested at least quarterly and periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained. Section 1204.B (formerly 602.D) requires that the dates of sterilization and expiration be marked on all supplies sterilized in the facility. Section 1204.C (formerly 602.A) requires that the facility provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures. Section 1204.D requires cleaning and disinfection of equipment shall be accomplished.

61-12.1205. Tuberculosis Risk Assessment
Section 1205.A was added to require facilities to conduct an annual tuberculosis risk assessment in accordance with CDC guidelines. Section 1205.B was added to require that a risk classification be part of the risk assessment in determining the need for an ongoing TB screening program for staff and the frequency of screening.

61-12.1206. Staff Tuberculosis Screening (formerly 61-12.204.B)
Section 1206 was relocated from former Section 204.B and amended to delineate the current tuberculosis screening requirements for staff pursuant to CDC guidelines.

61-12.1207. Housekeeping (formerly 61-12.604)
Section 1207.A (formerly 604.A) was amended to require that the facility and its grounds be uncluttered, clean, and free of vermin and offensive odors. Section 1207.B delineates the requirements for interior housekeeping. Section 1207.C delineates the requirements for exterior housekeeping.

61-12.1208. Infectious Waste
Section 1208.A was added to require that facilities register as an infectious waste generator as outlined in Regulation 61-105, Infectious Waste Management. Section 1208.B (formerly 605.D) was amended to require that accumulated waste, including all contaminated dressings, be managed and disposed of in a manner compliant with OSHA standards and in accordance with R.61-105.

61-12.1209. Clean and Soiled Linen and Surgical Clothing (formerly 61-12.603)
Section 1209.A (formerly 603.A) was amended to delineate the requirements for clean, sanitary linen and surgical clothing. Section 1209.B (formerly 603.B) delineates the requirements for storage and collection of soiled linen and surgical clothing.

61-12.1300. QUALITY IMPROVEMENT PROGRAM
Section 1300.A was added to require the facility to establish and implement a written plan for a quality improvement program for patient care. Section 1300.B requires an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services. Section 1300.C requires that evaluation of patient care be criteria-based. Section 1300.D requires a quarterly review of five percent (5%) of medical records of patients. Section 1300.E requires an evaluation by patients of care and services provided by the facility. Section 1300.F requires the administrator to review findings of the program to ensure that effective corrective actions have been taken. Section 1300.G requires the program to identify and establish indicators of quality care. Section 1300.H requires that the results of the program be submitted to the licensee for review at least annually.

61-12.1400. MAINTENANCE (formerly 61-12.503)
Section 1400 was relocated from former Section 503 and renumbered to adjust the codification.

61-12.1401. General (formerly 61-12.503.A)
Section 1401 was relocated from former Section 503.A and amended to require the facility to document preventative maintenance and comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

61-12.1402. Equipment Maintenance (formerly 61-12.503.B)
Section 1402 was relocated from former Section 503.B.

61-12.1500. FIRE PROTECTION AND PREVENTION (formerly 61-12.PART VII)
Section was relocated from former PART VII and renumbered to adjust the codification. Former Section 702 was deleted as it is no longer necessary.

61-12.1501. Firefighting Equipment and Systems (formerly 61-12.701)
Section 1501.D (formerly 701.D) was amended to require that fire extinguishers be installed in accordance with the codes and standards referenced in Section 1602. Sections 1501.D.2 (formerly 701.D.2), 1501.F.1 (formerly 701.F.1), and 1501.H (formerly 701.H) were amended to conform to drafting standards.

61-12.1502. Gas Storage (formerly 61-12.703)

Section 1502 was relocated from former Section 703 and amended to require that gases be handled and stored in accordance with the provisions of the codes and standards referenced in Section 1602.

61-12.1503. Fire and Disasters
Section 1503.A requires that the Department be notified immediately regarding any fire in the facility, followed by a complete written report, but not to exceed seventy-two (72) hours from the occurrence of the fire. Section 1503.B requires that an evacuation plan be posted in prominent places and staff members be trained as part of their responsibilities to guide patients to the designated exits. Section 1503.C requires the facility to notify the fire department and the fire code official immediately when a required fire protection system is out of service.

61-12.1600. DESIGN AND CONSTRUCTION (formerly 61-12.PART VIII)
Section 1600 was relocated from former PART VIII and renumbered to adjust the codification.

61-12.1601. General (formerly 61-12.801)
Section 1601 (formerly 801) was amended for clarity and consistency.

61-12.1602. Codes and Standards (formerly 61-12.802)
Section 1601.A (formerly 802.A) was amended to require that facility design and construction comply with applicable provisions of these regulations and the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. Former Section 802.B was deleted as it is no longer necessary.

61-12.1603. Submission of Plans and Specifications (formerly 61-12.803)
Section 1603.A.1 (formerly 803.A.1) was amended to require that plans and specifications for new buildings, additions, or major alterations be prepared by an architect registered in South Carolina and shall bear his or her seal. Section 1603.B.1 (formerly 803.B.1) was amended to accepted drafting standards. Section 1603.B.2 (formerly 803.B.2) was amended to require that preliminary submissions include a code analysis and life safety plan. Section 1603.D (formerly 803.D) was amended for grammar. Section 1603.E (formerly 803.E) was amended to delineate the existing inspection fees required during the construction phase of a project and includes a chart of all existing construction-related inspection fees. The remaining items were renumbered to adjust the codification.

61-12.1604. Licensure of Existing Structures (formerly 61-12.804)
Section 1604 (formerly 804) was amended to one paragraph for clarity and consistency. Section 1604 (formerly 804) was amended to update a section reference and to require that, if required, plans submitted shall be in accordance with Section 1603.

61-12.1700. PHYSICAL PLANT
New section title was added for clarity and consistency.

61-12.1701. Physical Facilities (formerly 61-12.807)
Section 1701.A was added to require an adequate number of examination and procedure rooms in the facility. Section 1701.B requires that each procedure room be provided a suitable gynecological procedure table with adjustable examination lighting. Section 1701.C requires an area to be provided for use by nurses in preparing medications for patients and keeping medical records. Section 1701.D requires the facility to have an adequate number of recovery rooms. Section 1701.E requires a room for temporary storage of soiled linen and waste in covered containers. Section 1701.F requires an area to accommodate sterilization procedures. Section 1701.G requires a suitable dressing room space for physicians and nursing staff. Section 1701.H requires procedure and recovery rooms to be located on an exit access corridor. Section 1701.I requires an elevator in facilities occupying multi-storied buildings. Section

1701.J requires fixed or portable work surface areas in each procedure room. Section 1701.K requires that doors accessing the facility and procedure rooms be at least thirty-six (36) inches wide and corridors at least forty-eight (48) inches wide. Section 1701.N (formerly 807.O) was amended for drafting standards and to require that cleaning materials and supplies be stored in a safe manner and all harmful agents be locked away. Section 1701.P (formerly 807.Q) was amended for drafting standards. Former Sections 807.S and 807.T have been deleted as unnecessary. Section 1701.V (formerly 807.Y) was amended to require that interior finish materials comply with the codes and standards referenced in Section 1602. The remaining items have been renumbered to adjust the codification.

61-12.1702. Heating and Ventilation (formerly 61-12.807.L)
Section 1702.A (formerly 807.L.1) was amended to require that lighting, heating, and ventilation systems comply with the codes and standards referenced in Section 1602. Section 1702.B was relocated from former Section 807.L.3.

61-12.1703. Water Supply and Plumbing (formerly 61-12.808)
Section 1703.A (formerly 808.A) was amended for drafting standards. Section 1703.B.1 (formerly 808.B.1) was amended to refer to the codes and standards referenced in Section 1602.

61-12.1704. Emergency Power and Lighting Requirements (formerly 61-12.809)
Section 1704.C was added to allow a battery backup with a duration of ninety (90) minutes to satisfy the remaining requirements of Section 1704.

61-12.1705. Location (formerly 61-12.806)
Section 1705 was relocated from former Section 806.

Former 61-12.PART IX. PREREQUISITES FOR INITIAL LICENSURE
Former PART IX has been deleted as these requirements have been incorporated elsewhere in the regulation.

61-12.1800. SEVERABILITY
Section 1800 was added to allow the regulation to remain valid should it be determined that a portion of the regulation be invalid or unenforceable.

61-12.1900. GENERAL (formerly 61-12.PART X)
Section 1900 was relocated from former PART X and amended for grammar.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit written comments on the proposed regulation by writing to Gwen C. Thompson by mail at Bureau of Health Facilities Licensing, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina 29201; by facsimile at (803) 545-4212; or by email at HealthRegComm@dhec.sc.gov. Comments may also be submitted electronically on the Public Comments for Health Regulations page at the following address: http://www.scdhec.gov/Agency/RegulationsAndUpdates/PublicComments/. To be considered, comments must be received no later than 5:00 p.m. on October 24, 2016, the close of the public comment period. Comments received shall be submitted in a Summary of Public Comments and Department Responses for the Board of Health and Environmental Control's consideration at the public hearing.

Interested persons may also make oral and/or written comments on the proposed amendments of R.61-12 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly scheduled meeting on December 8, 2016. The Board will conduct the public hearing in the Board Room,

Third Floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, South Carolina 29201. The Board meeting commences at 10:00 a.m., at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda published by the Department twenty-four (24) hours in advance of the meeting at the following address: http://www.scdhec.gov/Agency/docs/AGENDA.pdf. Persons desiring to make oral comments at the hearing are asked to limit their statements to five (5) minutes and, as a courtesy, are asked to provide written copies of their presentation for the record. Due to admittance procedures at the DHEC Building, all visitors should enter through the Bull Street entrance and register at the front desk.

Copies of the proposed amendments for public comment as published in the State Register on September 23, 2016, may be obtained online in the DHEC Regulation Development Update at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/. Click on the Health Facilities Regulations topic and scan down to the proposed amendments of R.61-12. A copy can also be obtained by contacting Gwen Thompson at the above address or by email at thompsgw@dhec.sc.gov.

Preliminary Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any inherent requirements of this regulation. There are no external costs anticipated.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness is based on an analysis of the factors listed in S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-12, *Standards for Licensing Abortion Clinics*.

Purpose: The purpose of these amendments to R.61-12 is to revise and clarify standards pertaining to abortion clinics. These proposed amendments provide updates to the definitions, requirements for obtaining and maintaining licensure, accident and/or incident reporting requirements, record maintenance and retention, patients' rights, emergency procedures and disaster preparedness, infection control and sanitation, personnel requirements, design and construction, and fire and life safety. In addition, provisions have been amended for general clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation.

Legal Authority: 1976 Code Sections 44-41-10, et seq, and 44-7-110, et seq.

Plan for Implementation: Upon approval by the General Assembly and publication in the *State Register* as a final regulation, a copy of R.61-12, which includes these latest amendments, will be available electronically on the Department's Laws and Regulations website under the Health Regulations category at: http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/. Subsequently, this regulation will be published in the South Carolina Code of Regulations. Printed copies will be available for a fee from the Department's Freedom of Information Office. The Department will also send an email to stakeholders, affected services and facilities, and other interested parties.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-12 has not been substantively updated since 1996. Therefore, many of the procedures, practices, and terms are outdated and/or no longer applicable. The amendments further clarify and improve reporting requirements, patients' rights, personnel requirements, record maintenance and retention, infection control and sanitation, inservice training, and emergency procedures and disaster preparedness. Additionally, amendments to design and construction, and fire and life safety are needed to comply with current codes and procedures.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these amendments. There are no anticipated additional costs to the regulated community. Amendments to R.61-12 improve patient rights and assurances, personnel requirements, inservice training, accident and/or incident reporting requirements, update emergency procedures and disaster preparedness planning, and update design, construction, and fire and life safety measures to comply with current procedures and codes.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-12 seek to support the Department's goals relating to the protection of public health through the anticipated benefits highlighted above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the revision is not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

Statement of Rationale:

The Department proposes amending R.61-12, *Standards for Licensing Abortion Clinics*. The amendments update R.61-12 to incorporate best practices while ensuring protection of public health. The amendments address issues regarding licensure requirements, personnel requirements, inservice training, emergency procedures and disaster preparedness planning, accident and/or incident reporting ambiguities, lessen the burden regarding design and construction requirements, and update the design, construction, and fire and life safety to current codes and standards.

~~Indicates Matter Stricken~~
Indicates New Matter

Text:

61-12. Standards for Licensing Abortion ~~Clinics~~Facilities.

Statutory Authority: 1976 Code Sections 44-41-10 et seq. and 44-7-110 et seq.

TABLE OF CONTENTS

~~SECTION 701. Fire-Fighting Equipment and Systems.~~
~~SECTION 702. Alarms.~~
~~SECTION 703. Gas Storage.~~

~~PART VIII. DESIGN AND CONSTRUCTION.~~
~~SECTION 801. General.~~
~~SECTION 802. Local and State Codes and Standards.~~
~~SECTION 803. Submission of Plans and Specifications.~~
~~SECTION 804. Licensure of Existing Structures.~~
~~SECTION 805. Minor Alterations in Licensed Facilities.~~
~~SECTION 806. Location.~~
~~SECTION 807. Physical Facilities.~~
~~SECTION 808. Water Supply and Plumbing.~~
~~SECTION 809. Emergency Power and Lighting Requirements.~~

~~PART IX. PREREQUISITES FOR INITIAL LICENSURE.~~

~~PART X. GENERAL.~~
SECTION 100 – DEFINITIONS AND LICENSE REQUIREMENTS
101. Definitions
102. License Requirements

SECTION 200 – ENFORCEMENT OF REGULATIONS
201. General
202. Inspections and Investigations

SECTION 300 – ENFORCEMENT ACTIONS
301. General
302. Violation Classifications

SECTION 400 – POLICIES AND PROCEDURES

SECTION 500 – STAFF
501. General
502. Administrator
503. Facility Staff
504. Physicians
505. Nursing Staff
506. Inservice Training
507. Health Status

SECTION 600 – REPORTING
601. Accidents and/or Incidents
602. Abortions and Fetal Deaths
603. Communicable Diseases
604. Facility Closure
605. Zero Census

SECTION 700 – PATIENT RECORDS
701. Consent of the Patient
702. Abortion Performed Upon Minors

1603. Submission of Plans and Specifications
1604. Licensure of Existing Structures

SECTION 1700 – PHYSICAL PLANT
1701. Physical Facilities
1702. Heating and Ventilation
1703. Water Supply and Plumbing
1704. Emergency Power and Lighting Requirements
1705. Location

SECTION 1800 – SEVERABILITY

SECTION 1900 - GENERAL

~~PART I~~
~~DEFINITIONS AND REQUIREMENTS FOR LICENSURE~~
SECTION 100 - DEFINITIONS AND LICENSE REQUIREMENTS

~~SECTION 101. Definitions.~~**101. Definitions**

~~—~~For the purposes of these regulations, the following definitions apply:

A. Abortion. The use of an instrument, medicine, drug, or other substance or device with intent to terminate the pregnancy of a woman, known to be pregnant, for reasons other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

B. Abortion ~~Clinic~~Facility. Any facility, other than a hospital ~~as defined in Section 101.J, in which any second trimester or five or more first trimester abortions per month are performed~~which has been licensed by the Department as legally suitable to perform abortions.

C. Administrator. The staff member designated by the licensee to have the authority and responsibility to manage the facility and be charge of all functions and activities of the facility.

D. Administering Medication. The direct application of a single dose or multi-dose of medication to the body of a patient by injection, ingestion, or any other means.

~~C~~E. Allied Health Professional. A person other than a physician who possesses specialized training and skill acquired by completing certain courses of study or intensive job-related training and, where applicable, has been duly licensed or registered by appropriate licensing or certification agencies. All allied health professionals must be supervised by a physician and/or registered nurse.

~~D~~F. Conception. The fecundation of the ovum by the spermatozoa.

~~E~~G. Consent. A signed and witnessed voluntary agreement to the performance of an abortion.

H. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, or V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.

I. Consultation. A visit by Department representatives to provide information to the licensee in order to facilitate compliance with these regulations.

~~F~~J. Department. The South Carolina Department of Health and Environmental Control.

~~G~~K. Emancipated Minor. A minor who is or has been married or has by court order been freed from the care, custody, and control of her parents.

~~H~~L. Fetal Death. 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 voluntary muscles.

~~I. Fire Safety Authority. The State Fire Marshal, or his designee, who performs facility fire and safety inspections.~~

M. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other legally authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature.

~~J. Hospital. An institution licensed for hospital operation by the Department in accordance with the provisions of Article 3, Chapter 7, Title 44, of the S.C. Code of Laws, 1976, as amended, and that has also been certified by the Department to be a suitable facility for the performance of abortion.~~

~~K~~N. In Loco Parentis. Any person over the age of eighteen (18) who has placed ~~him/herself~~himself or herself in the position of a lawful parent by assuming obligations that are incidental to the parental relationship and has so served for a period of sixty (60) days.

O. Inspection. A visit by Department representative(s) for the purpose of determining compliance with this regulation.

P. Investigation. A visit by Department representative(s) to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

Q. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific treatments, care, or services to patients, such as an advanced practice registered nurse or physician assistant.

R. License. A certificate issued by the Department to an Abortion Facility to provide care, treatment, procedures, surgery, and/or services.

~~L~~S. Licensee. ~~The person, partnership, corporation, association, organization, or professional entity on whom rests the ultimate responsibility and authority for the conduct of the abortion clinic~~The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, surgery, and/or services at an Abortion Facility and with whom rests the ultimate responsibility for compliance with this regulation.

T. Licensed Nurse. An individual currently licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse.

~~M~~U. Medical Emergency. That condition which, on the basis of the physician's good faith judgment, so complicates a pregnancy as to necessitate an immediate abortion to avert the risk of her death or for which a delay will create serious risk of substantial and irreversible impairment of major bodily functions.

~~N~~V. Minor. A female under the age of seventeen (17).

W. Nonlegend Medication. A mediation that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

X. Physical Examination. An examination of a patient by a physician or other legally authorized healthcare provider that addresses those issues identified in Section 703.B of this regulation.

~~O~~Y. Physician. ~~A person licensed to practice medicine in this State~~A person licensed to practice medicine in the state of South Carolina by the South Carolina Board of Medical Examiners.

~~P~~Z. Pregnancy. The condition of a woman carrying a fetus or embryo within her body as the result of conception.

~~Q~~AA. Probable Gestational Age of the Embryo or Fetus. In the judgment of the attending physician based upon the attending physician's examination and the woman's medical history, with reasonable probability, the gestational age of the embryo or fetus at the time the abortion is planned to be performed. This examination shall be in accordance with The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services to calculate gestational age from the first date of the last menstrual period as follows:

Calculation	Weeks of Gestational Age								
Conception	8	10	12	14	16	18	20	22	24
LMP	10	12	14	16	18	20	22	24	26

~~What, in the judgment of the attending physician, based upon the attending physician's examination and the woman's medical history, is with reasonable probability, the gestational age of the embryo or fetus at the time the abortion is planned to be performed. This estimate must be guided by recommendations found in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services, i.e., calculated from the first day of the last menstrual period.~~

BB. Procedure Room. A room in which abortion procedures are performed.

~~R~~CC. Products of Conception. Fetal and embryonic tissues resulting from implantation in the uterus.

DD. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, procedures, and/or services, identify the ways to improve its performance, and take actions that result in higher quality of care, treatment, procedures, and/or services for the facility's patients.

EE. Recovery Area. An area used for the recovery of patients.

FF. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a thirty-six (36) month period. The time period determinant of repeat violation status is not interrupted by ownership changes.

GG. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator, or person with a health care power of attorney or other durable power of attorney.

HH. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

II. Staff Member. An adult who is a compensated employee of the facility on either a full- or part-time basis.

JJ. Suspension of License. An action by the Department requiring a facility to cease operation for a period of time or to require a facility to cease admitting patients until such time as the Department rescinds that restriction.

~~S~~KK. Trimester. A ~~12-week~~twelve (12) week period of pregnancy.

1. First. The first twelve (12) weeks of pregnancy commencing with conception rather than computed on the basis of the menstrual cycle.

2. Second. That portion of a pregnancy following the ~~12th~~twelfth week and extending through the ~~24th~~twenty-fourth week of gestation.

3. Third. That portion of pregnancy beginning with the ~~25th~~twenty-fifth week of gestation.

~~4. All other references in this regulation to gestational age will refer to that calculated from the first day of the last menstrual period as used in The American College of Obstetricians and Gynecologists Standards for Obstetric-Gynecologic Services. The following is furnished to provide clarification of gestational age:~~

~~Calculation Weeks of Gestational Age~~

~~Conception~~	~~8~~	~~10~~	~~12~~	~~14~~	~~16~~	~~18~~	~~20~~	~~22~~	~~24~~
~~LMP~~	~~10~~	~~12~~	~~14~~	~~16~~	~~18~~	~~20~~	~~22~~	~~24~~	~~26~~

~~T~~LL. Viability. That stage of human development when the fetus is potentially able to live outside of the mother's womb with or without the aid of artificial life support systems. ~~(~~Section 44-41-10(l) of the ~~S.C.~~South Carolina Code of Laws further states that "for the purposes of this chapter, a legal presumption is hereby created that viability occurs no sooner than the twenty-fourth week of pregnancy." The "twenty-fourth week," as stated in the ~~S.C~~South Carolina Code of Laws, is based on computation from date of conception, ~~i.e.~~for example, the twenty-sixth week from the first day of the last menstrual period.~~)~~

~~SECTION 102 License Requirements.~~**102. License Requirements (II)**

A. License. ~~It shall be unlawful to operate an abortion clinic within South Carolina without possessing a valid license issued annually by the Department~~No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself, such as advertise or market, as an abortion facility in South Carolina without first obtaining a license from the Department. No such party shall provide care, treatment, procedures, surgery, and/or services to patients prior to the effective date of licensure. Upon the Department's determination that such party provides

care, treatment, procedures, and/or services without a Department-issued license, the party shall cease operation immediately and ensure safety, health, and well-being of the patients. Current or previous violations of the South Carolina Code of Laws and/or Department regulations may jeopardize the issuance of a licensed or licensed of another facility or addition to an existing facility owned or operated by the violating licensee. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a licensed to the proposed facility or an amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities licensed at the time of promulgation of these regulations shall be allowed to continue utilizing the previously-licensed structure without modification.

D. Licensed Capacity. No facility that has been licensed for a set number of procedure rooms shall exceed that number of procedure rooms or establish new care, treatment, procedures, and/or services without first obtaining authorization from the Department. (I)

~~B~~E. Issuance and Terms of License. ~~A license is issued pursuant to the provisions of Section 44-41-10 et seq., of the S.C. Code of Laws of 1976, as amended, and these standards, and shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.~~

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety, or the well-being of any occupant of the facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, such as interstate highways, shall not be considered as dividing unless otherwise adjoining or contiguous property.

6. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

7. A facility shall provide only the care, treatment, procedures, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide pursuant to the definition in Section 101.A of this regulation.

~~C. Effective Date and Term of License. A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection has occurred.~~

~~D. Separate Licenses. Separate licenses are required for facilities not maintained on the same premises.~~

~~E. Licensing Fees. The initial and annual license fee shall be $500.00 for each licensed facility. Such fee shall be made payable to the Department. Fees are non-refundable.~~

~~F. Inspections. Each facility shall be inspected prior to initial licensure and at least annually thereafter by authorized representatives of the Department.~~

~~1. All licensed facilities are subject to inspection at any time.~~

~~2. Department inspectors shall have access to all properties and areas, objects, records and reports, and shall have the authority to make photocopies of those documents required in the course of inspections or investigations. (II)~~

~~G. Initial License. A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide care to patients until it has been issued an initial license. When it is determined that the facility is in compliance with the requirements of these standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued. Chapter 9 of this regulation sets forth the prerequisites for initial licensure. (I)~~

~~H. License Renewal. Applicants for an annual license renewal shall file an application with the Department, pay a license fee, and undergo a licensing inspection.~~

~~I. Noncompliance. When noncompliance(s) with the licensing standards exists, the applicant or licensee shall be notified by the Department of the violation(s) and required to provide information as to how and when each violation will be corrected and how future occurrences may be prevented.~~

~~J. Facility Name. No proposed abortion clinic shall be named, nor may any existing abortion clinic have its name changed to, the same or similar name as any other abortion clinic licensed in the State. If it is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.~~

F. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in South Carolina. The Department shall determine if names are similar. If the facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

G. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two (2) of its officers; or in the care of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of

the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or partnerships shall be registered with the South Carolina Secretary of State's Office. The following documentation shall be submitted to the Department with the application prior to initial licensing:

1. Notice of Completion (NOC) from the Department's Division of Health Facilities Construction (DHFC);

2. Copy of executed rental or lease agreement (if the proposed licensee is renting or leasing real property);

3. Documentation from the South Carolina Secretary of State's Office, such as, articles of incorporation, certificate of existence, articles of organization, certificate of authenticity, or partnership agreement, as applicable;

4. Business license or letter from the appropriate governing authority stating no business license is required;

5. Zoning letter of approval signed by the zoning authority;

6. Facility floor plan, with dimensions; and

7. Proof of ownership, such as, a copy of the bill of sale, mortgage, or deed, if applicable.

H. Licensing Fees. The initial and renewal license fee shall be five hundred dollars ($500.00) for each licensed facility. The renewal license fee shall include the renewal license fee plus any outstanding inspection fees. Such fees shall be made payable by check or money order to the Department and is not refundable.

I. Late Fee. Failure to submit a renewal application after the license expiration date may result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

J. License Renewal. To renew a license, an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, which is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership; or

b. Change of facility location from one geographic site to another.

2. Changes in facility name or address, as notified by the post office, shall be accomplished by application or by letter from the licensee.

~~K. Change of License. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:~~

~~1. Change of ownership by purchase or lease;~~

~~2. Change of facility's name or address.~~

~~L. Exceptions to Licensing Standards. The Department may make exception(s) to these standards where it is determined that the health and welfare of the community require the services of the facility and that the exception(s), as granted, will have no significant adverse impact on the health, safety, or welfare of the facility's patients.~~

K. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

SECTION 200 - ENFORCEMENT OF REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections and Investigations

A. An inspection by the Department shall be conducted prior to initial licensing of a facility and subsequent inspections conducted at least annually thereafter as deemed appropriate by the Department. (I)

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department. (I)

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (I)

D. An Abortion Facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences, actual and similar; and

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by S.C. Code Sections 44-7-310 and -315.

F. In accordance with S.C. Code Section 44-7-270, the Department may charge a fee for inspections. The fee for initial and annual routine inspections shall be three hundred fifty dollars ($350.00) plus twenty-five dollars ($25.00) per procedure room. The fee for follow-up inspections shall be two hundred dollars ($200.00) plus twenty-five dollars ($25.00) per procedure room.

~~SECTION 103 Penalties.~~

SECTION 300 - ENFORCEMENT ACTIONS

~~When it determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice, may deny, suspend, or revoke licenses, or assess a monetary penalty. Under such conditions, the following shall apply:~~

301. General

When the Department determines that an Abortion Facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, and/or revoke its license.

302. Violation Classifications

Violations of the standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or ~~welfare~~well-being of the ~~patients~~persons ~~of~~in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation ~~shall~~ exists after expiration of ~~said~~this time ~~shall~~may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a ~~direct or immediate relationship to~~negative impact on the health, safety or well-being of the ~~facility's patients~~persons in the facility. The citation of a Class II violation ~~shall~~may specify the time within which the violation is required to be corrected. Each day such violation ~~shall~~ exists after expiration of ~~said~~this time ~~shall~~may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation ~~shall~~ exists after expiration of ~~said~~this time ~~shall~~may be considered a subsequent violation.

D. ~~Class I and II violations are indicated by notation after each applicable section, i.e., (I) or (II). Violations of sections that are not annotated in that manner denote Class III violations~~The notations "(I)" or "(II)," placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. ~~In arriving at a decision to penalize a facility, the Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or well-being; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations~~In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations. (I)

F. When a decision is made to ~~assess~~impose monetary penalties, the following schedule ~~will~~shall be used as a guide to determine the dollar amount:

~~Frequency of violation of standard within a 24 month period: MONETARY PENALTY RANGES~~

~~FREQUENCY CLASS I CLASS II CLASS III~~

~~1st $ 200 – 1000 $ 100 – 500 $ 0~~

~~FREQUENCY CLASS I CLASS II CLASS III~~

~~2nd 500 – 2000 200 – 1000 100 – 500~~
~~3rd 1000 – 5000 500 – 2000 200 – 100~~
~~4th 5000 1000 – 5000 500 – 200~~
~~5th 5000 5000 1000 – 500~~
~~6th 5000 5000 5000~~

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	**CLASS I**	**CLASS II**	**CLASS III**
1st	$500-1500	$300-800	$100-300
2nd	1000-3000	500-1500	300-800
3rd	2000-5000	1000-3000	500-1500
4th	5000	2000-5000	1000-3000
5th	5000	5000	2000-5000
6th and more	5000	5000	5000

~~G. Any facility that is dissatisfied with Department decisions may request a hearing pursuant to the Administrative Procedures Act.~~

~~PART II~~
~~ADMINISTRATION AND MANAGEMENT~~
SECTION 400 - POLICIES AND PROCEDURES (II)

~~SECTION 201 Licensee. (II)~~

~~A. The licensee of each facility has the ultimate responsibility for the overall operation of the facility. Every facility shall be organized, equipped, staffed and administered to provide adequate care for each person admitted.~~

A. Policies and procedures addressing each section of this regulation regarding admissions criteria, care, treatment, pre-operative and abortion procedures and/or services, patient rights, provisions for the education of patients as appropriate in pre-procedure care, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. The licensee or administrator shall annually review all policies and procedures and such review shall be documented. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically.

B. The policy for the abortion procedure shall address:

1. Intravenous fluids (IVs);

2. Fluids;

3. Analgesia and/or anesthesia. General anesthesia shall be administered only by a certified registered nurse anesthetist, anesthesiologist, or dentist anesthetist or physician anesthetist;

4. Management of infectious waste from generation to disposal, pursuant to the requirements of Regulation 61-105, Infectious Waste Management;

5. Post-procedure care and recovery room procedures to include emergency care;

6. Provisions for the education of the patient, family and others, as appropriate in pre- and post-procedure care;

7. Plans for follow-up of the patient after discharge from the facility, to include arrangements for a post-procedure visit, and specific instructions in case of emergency;

8. Management and appropriate referral of high-risk conditions;

9. Transfer of patients who, during the course of pregnancy termination, are determined to need care beyond that of the facility;

10. Infection control and sanitation procedures to include duties and responsibilities of the infection control committee that shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling, and preventing infections in the facility; and

11. Registration of live birth, death, and fetal death records, pursuant to the requirements of Regulation 61-19, Vital Statistics, when applicable.

~~B. Policies and procedures for operation of the facility shall be formulated and reviewed annually by the licensee of the facility. They shall include but not be limited to:~~

~~1. Purpose of the facility, to include scope and quality of services;~~

~~2. Ensuring compliance with all relevant federal, state, and local laws that govern operations of the facility;~~

~~3. Personnel policies and procedures, to include inservice training requirements;~~

~~4. The person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible;~~

~~5. Provision for annual review and evaluation of the facility's policies, procedures, management and operation;~~

~~6. Provision for a facility-wide quality improvement program to evaluate patient care. The program shall be ongoing, have statistical summaries, and have a written plan of implementation.~~

~~7. Patient rights and grievance procedures;~~

~~8. Functional safety and maintenance policies and procedures;~~

~~9. Incident reporting;~~

~~10. Consent must be informed, shall be obtained prior to the procedure, and shall include evidence of an explanation by a physician or allied health professional of the services offered and potential risks. Documentation of the informed consent must be filed in the patient's record.~~

SECTION 500 - STAFF

501. General (II)

A. An Abortion Facility shall have appropriate staff in numbers and training to meet the needs and conditions of the patients at all times. Training and qualifications for the tasks each staff member performs shall be in compliance with all professional standards and applicable federal and state laws.

B. The Abortion Facility shall assign duties and responsibilities to all staff members and volunteers in writing, and shall be in accordance with the Abortion Facility's policy and the staff member's capability. The assigned duties and responsibilities shall be maintained, reviewed, and revised as changes occur. A copy shall be provided to the employee and volunteer. (I)

C. The Abortion Facility shall maintain a written employment application for all employees. The Abortion Facility shall maintain accurate and current information regarding all staff members of the facility, to include at least a home address, phone number, and health, work, and training background. (I)

~~SECTION 202 Administrator. (II)~~**502. Administrator (II)**

~~An administrator shall be selected by the licensee and shall have the ability and authority to manage and administer the facility. Any change in the position of the administrator shall be reported immediately by the licensee to the Department in writing. An individual shall be appointed in writing to act in the absence of the administrator.~~

A. Each Abortion Facility shall have an administrator who shall be capable of meeting the responsibilities of operating the facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations.

B. The Abortion Facility shall have a staff member designated, by name or position, in writing, to act in the absence of the administrator.

C. The licensee shall notify the Department via telephone or email within seventy-two (72) hours of any change of administrator status. The licensee shall provide the Department in writing within ten (10) days the name of the newly-appointed administrator, documented qualifications as required by Section 502.A, and the effective date of the appointment.

~~SECTION 203 Administrative Records.~~

~~The following administrative documents and references shall be on file in the facility:~~

~~A. Current policies and procedures concerning the operation of the facility; (II)~~

~~B. Current memorandums of agreement and credentialing documentation.~~

~~C. A current copy of these regulations;~~

~~D. Annual elevator safety inspections, if applicable;~~

~~E. Annual heating, ventilation, and air conditioning inspection report.~~

503. Facility Staff (II)

A. Physicians, nurses, and Allied Health Professionals shall constitute the Abortion Facility staff.

B. Allied Health Professionals, working under appropriate direction and supervision, shall be employed to work only within areas where their competency has been established.

C. The Abortion Facility staff shall meet at least quarterly to review and analyze their facility experiences. Staff shall maintain minutes of such meetings.

~~SECTION 204 Personnel. (II)~~

~~Each facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients.~~

~~A. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate licensure, if applicable, and health and personal background of each employee.~~

~~B. Prior to performing job duties, all employees, to include volunteers who have direct patient contact within the clinic, shall have tuberculin skin testing conducted unless a previously positive reaction is documented in millimeters. The intradermal (Mantoux) method, using five tuberculin units of stabilized~~

purified protein derivative (PPD) is to be used. For employees/volunteers who have no documentation of a negative PPD result during the preceding 12 months, then the two-step procedure (one PPD test with negative result followed one to three weeks later by another PPD test) is required to establish a reliable baseline. If employees/volunteers have complete documentation of a negative PPD during the preceding 12 months (may be a single PPD or a two-step PPD), then a single PPD is acceptable to establish the baseline for current employment.

1. Persons with negative tuberculin skin tests who have direct contact with patients shall have an annual tuberculin skin test.

2. There is no need to perform an initial or routine chest X-ray on employees or volunteers with negative tuberculin tests who are asymptomatic.

3. Personnel with a positive reaction to the skin test shall have no patient contact until certified non-contagious by a physician.

4. Employees and volunteers with reactions of 10mm and over to the pre-employment tuberculin test, those new employees/volunteers who have previously documented positive reactions, those with newly converted skin tests and those with symptoms suggestive of TB (e.g., cough, weight loss, night sweats, fever, etc.), shall be given a chest X-ray to determine whether TB disease is present. If TB disease is diagnosed, appropriate treatment shall be given and contacts examined.

5. Personnel who are known or suspected to have TB shall be required to be evaluated by a physician and will not be allowed to return to work until they have been certified non-contagious by the physician.

6. Preventive treatment of personnel with new positive reactions is essential, and shall be considered for all infected employees/volunteers who have patient contact, unless specifically contraindicated. Routine annual chest X-rays of persons with positive reactions do not prevent TB and therefore are not a substitute for preventive treatment nor are required.

a. Employees and volunteers who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of TB.

b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest X-ray. These individuals must be informed of their lifelong risk of developing and transmitting TB to individuals in the institution and in the community. They shall be informed of symptoms which suggest the onset of TB, and the procedure to follow should such symptoms develop.

7. Post-exposure skin tests should be provided for tuberculin-negative employees/volunteers within 12 weeks after termination of contact for any suspected exposure to a documented case of pulmonary TB.

8. A person shall be designated in writing at each facility to coordinate TB screening of personnel and any other TB control activities.

C. All professional and allied health professional staff members shall be currently certified with American Red Cross or American Heart Association CPR and capable of recognizing symptoms of distress. A professional or allied health professional staff member who is legally qualified to perform advanced cardiac life support must be present while patients are undergoing abortion procedures/ recovery in the facility. (I)

~~D. No employee or volunteer of the facility, while afflicted with any infected wounds, boils, sores, or an acute respiratory infection, or any other contagious disease or illness, shall work in any capacity in which there is a likelihood of such person transmitting disease to other individuals.~~

~~E. Each facility shall have and execute a written orientation program to familiarize each new staff member with the facility and its policies and procedures, to include, as a minimum, fire safety and other safety measures, medical emergencies, and infection control.~~

~~F. Inservice training programs shall be planned and provided for all employees and volunteers to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually:~~

~~1. Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as handwashing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members;~~

~~2. Fire protection, to include evacuating patients, proper use of fire extinguishers, and procedures for reporting fires:~~

~~3. Confidentiality of patient information and records, and protecting patient rights;~~

~~4. Licensing regulations.~~

~~G. Job Descriptions.~~

~~1. Written job descriptions that adequately describe the duties of every position shall be maintained.~~

~~2. Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.~~

~~3. Job descriptions shall be reviewed at least annually, kept current and given to each employee and volunteer when assigned to the position and when revised.~~

~~H. A personnel file shall be maintained for each employee and for each volunteer. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. The file shall contain a current job description that reflects the individual's responsibilities and work assignments, and documentation of the person's orientation, in-service education, appropriate licensure, if applicable, and TB skin testing.~~

504. Physicians (I)

A. Abortions shall be performed only by physicians who are licensed to practice medicine in South Carolina and properly qualified by training and experience to perform pregnancy termination procedures.

B. A physician shall sign the discharge order and be readily accessible and available until the last patient has been discharged.

C. The Abortion Facility shall have:

1. At least one (1) obstetrics and gynecology (OB/GYN) board-certified physician on staff who has admitting privileges at one (1) or more local hospitals with OB/GYN services to ensure his or her availability to the staff and patients during all operating hours; or

2. A signed written agreement with at least one (1) OB/GYN board-certified physician with admitting privileges at one (1) or more local hospitals with OB/GYN services to ensure his or her availability to the staff and patients during all operating hours.

D. If ultrasonography is conducted in the Abortion Facility, the procedure shall be conducted by a physician or by an ultrasound technician who shall have documented evidence of completion of a training course in ultrasonography.

~~SECTION 205 Clinical Staff (II)~~

~~A. Physicians, nurses, and allied health professionals shall constitute the clinical staff.~~

~~B. The clinical staff shall meet at least quarterly to review and analyze their clinical experiences; minutes shall be maintained of such meetings.~~

~~C. Physicians. (I)~~

~~1. Abortions shall be performed only by physicians who are licensed to practice medicine in this State and who are properly qualified by training and experience to perform pregnancy termination procedures.~~

~~2. The facility shall enter into a signed written agreement with at least one physician board-certified in obstetrics and gynecology (if not one on staff) who has admitting privileges at one or more local hospitals with OB/GYN services to ensure his/her availability to the staff and patients during all operating hours.~~

~~3. A physician must remain on the premises until all patients are stable, and are ready for discharge. A physician must sign the discharge order and be readily accessible and available until the last patient has been discharged.~~

~~D. Nursing.~~

~~1. Nursing care shall be under the supervision of a registered nurse currently licensed in this State.~~

~~2. A registered nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period and until discharge by the attending physician.~~

~~3. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.~~

~~E. Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.~~

~~F. If ultrasonography is conducted in the clinic, the procedure shall be conducted by a physician or by an ultrasound technician who shall have documented evidence of completion of a training course in ultrasonography.~~

~~SECTION 206 Consent of the Patient. (I)~~

~~A physician shall not perform an abortion without first obtaining a signed and dated consent of the pregnant woman pursuant to the provisions of Section 44-41-30 of the S.C. Code of Laws, 1976, as amended.~~

~~SECTION 207 Abortion Performed Upon Minors. (I)~~

~~No person may perform an abortion upon a minor unless consent is obtained pursuant to the provisions of Section 44-41-31 of the S.C. Code of Laws, 1976, as amended.~~

~~SECTION 208 Dissemination of Information. (I)~~

~~Clinics must comply with the Woman's Right to Know Act, Section 44-41-310 et seq., of the S.C. Code of Laws, 1976, as amended, and maintain an adequate supply of current printed material from the Department which has not been altered in content.~~

~~SECTION 209 Patients' Rights (II)~~

~~A. The facility shall have written policies and procedures to assure the individual patient the right to dignity, privacy, safety, and to register complaints with the Department. These patients' rights shall be approved by the licensee.~~

~~B. Each facility shall display in a conspicuous place a copy of the patients' rights. In addition, a copy signed by the patient shall be included in the medical record.~~

505. Nursing Staff (I)

A. At least one (1) registered nurse shall be on duty in the Abortion Facility to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period and until discharge by the attending physician.

B. Nursing staff shall be assigned duties consistent with their scope of practice as determined through their licensure and educational preparation.

C. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.

506. Inservice Training (I)

A. Staff members shall receive training in accordance with tasks performed in order to provide the care, treatment, procedures, and/or services delineated in Section 800.

B. Documentation of all inservice training shall be signed and dated by both the individual providing the training and the individual receiving the training. The following training shall be provided by appropriate resources, such as licensed, registered, or certified persons, books, electronic media, or otherwise, to all staff members in the context of their job duties and responsibilities, prior to patient contact and at a frequency determined by the facility, but at least annually unless otherwise specified by certificate, for example, cardiopulmonary resuscitation (CPR):

1. Cause, effect, transmission, prevention, and elimination of infections, to include management and care of persons with contagious and/or communicable disease, for example, hepatitis, tuberculosis, or HIV infection;

2. Occupational Safety and Health Administration (OSHA) standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within twenty-four (24) hours of their first day on the job in the facility (see Section 1100);

5. Fire response training within twenty-four (24) hours of their first day on the job in the facility;

6. Aseptic techniques such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies; and

7. The requirements of this regulation.

C. All licensed nurses shall possess a valid cardiopulmonary resuscitation (CPR) certificate within three (3) months from the first day on the job in the facility. A staff member with a valid CPR certificate (American Red Cross, American Heart Association Adult CPR training, or the National Safety Council Adult CPR training) shall be on duty whenever patients are in the facility.

D. A registered nurse or allied health professional who possesses a valid advanced cardiac life support credential shall be on duty in the facility whenever patients are in the facility.

E. All new staff members shall have documented orientation to the organization and environment of the facility, specific duties and responsibilities of staff members and direct care volunteers, and patients' needs within twenty-four (24) hours of their first day on the job in the facility.

507. Health Status (I)

A. All staff members who have contact with patients shall have, within twelve (12) months prior to initial patient contact, a health assessment as defined in Section 101.M.

B. The health assessment shall include a tuberculin skin test as described in Section 1206.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be acceptable at each Abortion Facility. (II)

SECTION 600 – REPORTING

601. Accidents and/or Incidents (II)

A. The Abortion Facility shall report a record of each accident and/or incident occurring at the Abortion Facility or on the facility grounds. A facility's record of each accident and/or incident shall be documented, reviewed, investigated, and if necessary, evaluated in accordance with facility policies and procedures, and retained by the facility for six (6) years.

B. The Abortion Facility shall submit an online report of the accident and/or incident to the Department within five (5) days of the occurrence. Accidents and/or incidents requiring reporting include, but are not limited to:

1. Abuse, neglect, or exploitation (confirmed);

2. Abuse, neglect, or exploitation (suspected);

3. Criminal event against patient;

4. Death, other than fetal death;

5. Fall resulting in fracture of bone or joint;

6. Hospitalization as a result of accident or incident;

7. Post-procedure complications arising as a result of an abortion procedure;

8. Adverse reaction to medication;

9. Severe hematoma;

10. Severe laceration; or

11. Attempted suicide onsite.

C. Reports submitted to the Department shall contain, at a minimum: facility name, facility license number, type of accident or incident, date accident or incident occurred, number of patients directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident or incident, internal investigation results if cause unknown, a brief description of the accident or incident including the location of occurrence, and treatment of injuries. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: name(s) of patient(s), staff, and/or visitor(s), and the injuries and treatment associated with each patient, staff member, and/or visitor.

D. The Abortion Facility shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or responsible party for the affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours. The facility shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email, or facsimile of each accident and/or incident resulting in unexpected death or serious injury. The Abortion Facility shall submit an online report of the accident and/or incident to the Department within five (5) days.

602. Abortions and Fetal Deaths (II)

A. The Abortion Facility shall report any abortion performed in South Carolina pursuant to S.C. Code Section 44-41-450 on the standard form for reporting abortions to the Department's Bureau of Vital Statistics within seven (7) days after the abortion is performed.

1. The Abortion Facility shall include in the report, at a minimum, the requirements set forth in S.C. Code Section 44-41-460.

2. Any Abortion Facility that fails to submit a report by the end of thirty (30) days following the due date shall be subject to a late fee of one thousand dollars ($1000) for each additional thirty (30) day period or portion of a thirty (30) day period the report is overdue. Additional penalties for Abortion Facilities are set forth in S.C. Code Section 44-41-460(D).

B. The Abortion Facility shall report live births, deaths, and fetal deaths pursuant to the standards in Regulation 61-19, Vital Statistics.

603. Communicable Diseases (I)

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with Regulation 61-20, Communicable Diseases.

604. Facility Closure

A. Prior to the permanent closure of an Abortion Facility, the Department shall be notified in writing on the intent to close and the effective closure date. Within ten (10) days of the closure, the Abortion Facility shall notify the Department of the provisions for the maintenance of records. On the date of closure, the current original license shall be returned to the Department.

B. In instances where an Abortion Facility temporarily closes, the Department shall be given written notice within a reasonable time in advance of closure. At a minimum, this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the Abortion Facility prior to its reopening. If the Abortion Facility is closed for a period longer than one (1) year, and there is a desire to reopen, the Abortion Facility shall reapply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

605. Zero Census

In instances when there have been no patients in the Abortion Facility for any reasons, for a period of ninety (90) days or more, the Abortion Facility shall notify the Department in writing no later than the one hundredth (100th) day following the date of the last procedure. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the Abortion Facility prior to any new admissions and/or readmissions to the facility. The Abortion Facility shall still apply and pay the licensing fee to keep the license active despite being at zero census or temporarily closed. If the Abortion Facility has no patients for a period longer than one (1) year, and there is a desire to reopen, the Abortion Facility shall reapply to the Department shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new Abortion Facility.

SECTION 700 – PATIENT RECORDS

701. Consent of the Patient (I)

A. A physician shall not perform an abortion without first obtaining the signed and dated consent of the pregnant woman pursuant to the provisions of S.C. Code Section 44-41-30. The consent shall include evidence of an explanation by a physician or allied health professional of the services offered and potential risks.

B. Consent shall be waived if:

1. A physician determines that a medical emergency exists involving the life of or grave physical injury to the pregnant woman; or

2. The pregnancy is the result of incest.

702. Abortion Performed Upon Minors (I)

No person shall perform an abortion upon a minor unless consent is obtained pursuant to the provisions of S.C. Code Section 44-41-31.

703. Content (II)

A. The Abortion Facility shall initiate and maintain an organized record for each patient, to include a distinction of patients who are minors. The record shall contain: sufficient, documented information to identify the patient; the person responsible for each patient; and the description of the care, treatment, procedures, and/or services provided. All entries shall be indelibly written, authenticated by the author, and dated.

B. Specific entries or documentation shall include at a minimum:

1. A face sheet with patient identification data, to include but not be limited to;

a. Name;

b. Address;

c. Telephone number;

d. Unique medical record identifying number;

e. Date of birth;

f. Consenting parent or legal guardian's name when the patient is a minor;

g. If married and living with husband, husband's name; and

h. Name, address, and telephone number of the person to be notified in the event of an emergency.

2. Signed consent for the procedure;

a. When the patient is a minor, photo identification for the consenting parent is required, along with the minor's birth certificate; and

b. If married and living with her husband, the consent of her husband.

3. Date of initial examination;

4. Date of abortion;

5. Referring and attending physicians' names and phone numbers, if applicable;

6. Complete medical history to include medications currently being taken;

7. Prior to the procedure, a physical examination, to the extent necessary to determine the health status of the patient, and identification of any preexisting conditions or complications, within fifteen (15) days of the procedure, including detailed findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period. The examination shall also include the following laboratory tests and/or procedures;

a. Ultrasonogram;

b. White blood count and determination of blood type, if applicable; and

c. Sickle cell, if applicable.

8. Arrangements made for consultation or referral services, if applicable;

9. Results of diagnostic tests and/or examinations, for example, x-ray, electrocardiography, clinical laboratory, pathology, consultations, and ultrasound;

10. Pre-procedure diagnosis;

11. Management and appropriate referral of high-risk conditions, if applicable;

12. Counselor's notes;

13. Physician's orders;

14. Complete record of abortion procedure to include;

a. Vital signs, such as, temperature, pulse, respiration, and blood pressure, prior to and following the procedure;

b. Name of procedure performed;

c. Anesthetic agent utilized;

d. Name of attending physician performing the procedure;

e. Names of facility assistants in attendance, to include other physicians, physician's assistants, anesthetists, nurses, or specially-trained technicians; and

f. Signature of physician performing the procedure.

15. Nurses' notes;

16. Progress notes to include a post-anesthesia note if general anesthesia is utilized;

17. Attending physician's description of gross appearance of tissue removed;

18. Final diagnosis;

19. Condition on discharge;

20. Post-procedure orders and follow-up care, discharge summary, including conditions at discharge or transfers, instructions for self-care and instructions for obtaining postoperative emergency care;

21. Documented verification that the patient has been presented printed materials as required by the Woman's Right to Know Act at S.C. Code Section 44-41-310;

22. Documented verification of patient rights; and

23. In the case of an unemancipated minor or mentally incompetent person, a copy of the court order or written consent authorizing the abortion.

C. The attending physician shall complete and sign the medical record within seventy-two (72) hours following discharge.

704. Dissemination of Information (I)

Abortion Facilities shall comply with the Woman's Right to Know Act, S.C. Code Sections 44-41-310 et seq., and maintain an adequate supply of current printed materials from the Department which has not been altered in content.

705. Authentication of Patient Records

A. Each document generated by a user shall be separately authenticated.

B. Written signatures or initials and electronic signatures or computer-generated signature codes are acceptable as authentication.

C. In order for an Abortion Facility to employ electronic signatures or computer-generated signature codes for authentication purposes, staff shall be identified who are authorized to authenticate patient records utilizing electronic or computer-generated signatures.

1. At a minimum, the Abortion Facility shall provide authentication safeguards to ensure confidentiality, including, but not limited to, the following:

a. Each user shall be assigned a unique identifier that is generated through a confidential code;

b. The Abortion Facility shall certify in writing that each identifier is kept strictly confidential. This certification shall include a user's commitment to terminate his or her use of an assigned identifier if it is determined that the identifier has been misused, meaning that the user has allowed another person(s) to use his or her personally-assigned identifier, or that the identifier has otherwise been inappropriately utilized; and

c. The user shall certify in writing that he or she is the only person with access to the identifier and the only person authorized to use the signature code.

2. The authentication system shall include a verification process to ensure that the content of authenticated entries are accurate. The verification process shall include, at a minimum, the following provisions:

a. Blanks, gaps, obvious contradictory statements, or other documentation that require the attention of the authorized user shall be considered authenticated until reviewed and corrected by the user and a revised report issued; and

b. Opportunity shall be provided for the use of electronic or computer-generated signature upon written notice to the individual responsible for the maintenance of patient records.

D. The use of rubber stamp signatures is acceptable under the following conditions:

1. The individual whose signature the rubber stamp represents shall be the only individual who has possession of and utilizes the stamp;

2. The individual places in the administrative offices of the facility a signed statement indicating that he or she is the only individual who has possession of and shall utilize the stamp; and

3. Rubber stamp signatures are not permitted on orders for medications listed as controlled substances pursuant to Regulation 61-4, Controlled Substances.

706. Record Maintenance

A. The Abortion Facility shall have accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary to include, at a minimum, the diagnosis and medication administration record, shall accompany the patient to the receiving emergency facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the Abortion Facility's patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The Abortion Facility shall have a written policy designating the persons allowed to access confidential patient information. (II)

D. Records generated by organizations or individuals contracted to the Abortion Facility for care, treatment, procedures, and/or services shall be maintained by the Abortion Facility that has admitted the patient. Appropriate information shall be provided to ensure continuity of care.

E. The Abortion Facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by Abortion Facility staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within thirty (30) days and filed in an inactive or closed file maintained by the licensee. Prior to the closing of an Abortion Facility for any reason, the licensee shall arrange for the preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G. An Abortion Facility shall maintain all records of patients for at least six (6) years following the discharge of the patient. Other documents required by the regulation, for example, fire drills, shall be retained at least twelve (12) months or until the next Department inspection, whichever is longer.

H. Patient records are the property of the Abortion Facility, and the original patient record shall not be removed without a court order. (II)

~~PART III~~
~~PATIENT CARE~~
SECTION 800 – CARE, TREATMENT, PROCEDURES, AND SERVICES

~~SECTION 301 Policies and Procedures. (II)~~

~~Abortion clinics shall not serve patients whose needs exceed the resources and/or capabilities of the clinic. The facility shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients, to include but not limited to:~~

~~A. Admission criteria;~~

~~B. Physician and nurse responsibilities for the services offered;~~

~~C. Specific details regarding the pre-operative procedures performed, to include:~~

~~1. History and physical examination, to include verification of pregnancy, estimation of gestational age, identification of any preexisting conditions or complications;~~

~~2. Special examinations, lab procedures, and/or consultations required, to include ultrasonography required when gestational age is clinically estimated to be equal to or more than 14 weeks from the first day of the last menstrual period as established by the physician's performance of a bimanual physical examination. Policies and procedures should also indicate that ultrasound is recommended when gestational age is equal to or more than 12 weeks from the first day of the last menstrual period as established by the performance of a bimanual physical examination or if the physical examination and clinical evidence is inconclusive as to the gestational age.~~

~~D. The actual abortion procedure, to include the use of:~~

~~1. IV's;~~

~~2. Fluids;~~

~~3. Analgesia/anesthesia. General anesthesia shall be administered only by a certified registered nurse anesthetist, anesthesiologist, or dentist anesthetist or physician anesthetist.~~

~~4. Tissue examination/disposal.~~

~~E. Post-procedure care/recovery room procedures to include emergency care;~~

~~F. Provisions for the education of patient, family and others, as appropriate in pre-and post-procedure care;~~

~~G. Plans for follow-up of patient after discharge from the facility, to include arrangements for post-operative visit, and specific instructions in case of emergency;~~

~~H. Management and appropriate referral of high-risk conditions;~~

~~I. Transfer of patients who, during the course of pregnancy termination are determined to need care beyond that of the facility;~~

~~J. Infection control and sanitation procedures to include duties and responsibilities of the infection control committee that shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility;~~

~~K. Registration of fetal death or death certificates, when applicable.~~

801. General (I)

A. Care, treatment, procedures, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers, and precautions shall be taken for patients with special conditions.

B. The Abortion Facility shall operate in compliance with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, and/or services, and protection.

C. When engaging a source other than the Abortion Facility to provide services normally provided by the facility, for example, staffing, training, maintenance, or housekeeping, the Abortion Facility shall have a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. All tasks performed by the source shall comply with this regulation with respect to patient care, treatment, procedures, and/or services, confidentiality, and rights. (II)

~~SECTION 302 Limitation of Services Offered by Abortion Clinics (I)~~

~~A. Abortions performed in abortion clinics shall be performed only on patients who are within 18 weeks from the first day of their last menstrual period. Those beyond 18 weeks shall be performed in a hospital. A licensed ambulatory surgical facility that is also licensed as an abortion clinic may perform abortions on patients who are up to 26 weeks after the first day of their last menstrual period.~~

~~B. Clinics performing abortions beyond 14 weeks from the first day of the last menstrual period must meet the requirements of Section 309.~~

802. Limitations of Services Offered by Abortion Facilities (I)

A. Abortion Facilities shall only perform abortions on patients who are within eighteen (18) weeks from the first day of their last menstrual period unless the Abortion Facility is also licensed by the Department as an Ambulatory Surgical Facility.

B. An Abortion Facility also licensed by the Department as an Ambulatory Surgical Facility shall perform abortions in accordance with Chapter 41, Title 44 of the South Carolina Code of Laws.

~~SECTION 303 Pharmaceutical Services. (II)~~

~~Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state and local statutes and regulations.~~

A. Emergency Drugs:

1. Emergency Kit or Emergency Drugs. Each facility shall maintain an emergency kit or stock supply of drugs and medicines for the use of the physician in treating the emergency needs of patients. This kit or medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel. A listing of contents by drawer or shelf shall be placed on the cabinet or emergency cart to allow quick retrieval. Contents shall correspond with the inventory list. Drugs and equipment must be available within the facility to treat, as a minimum, the following conditions: (I)

a. Cardiac arrest;

b. Seizure;

c. Asthmatic attack;

d. Allergic reaction;

e. Narcotic toxicity;

f. Hypovolemic shock;

g. Vasovagal shock.

2. Drug Reference Sources. Each facility shall maintain reference sources for identifying and describing drugs and medicines.

B. Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility except by those authorized by law under orders of a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine.

C. Medicine Storage. Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to ±3 degrees Fahrenheit shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.

D. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be located in such a manner as to prevent contamination of medicines being prepared for administration.

E. Controlled Substances Registration.

1. If a stock of controlled drugs is to be maintained at the facility, a physician on the clinic staff shall obtain an individual practitioner South Carolina Controlled Substances Registration and a Drug Enforcement Administration (DEA) Registration as registrant for the facility. This physician shall be responsible for the proper safeguarding and handling of controlled substances within the facility, and shall

~~be certain that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control of the Department.~~

~~2. With a written power of attorney, this physician may grant permission to any other physician who possesses an individual practitioner South Carolina Controlled Substances Registration and a DEA Registration to administer, order for administration, or dispense any controlled substances maintained by the facility.~~

~~F. Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered.~~

~~G. Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)~~

803. Anesthesia Services (I)

A. Anesthesia shall be administered according to the South Carolina Code of Laws and the South Carolina Code of Regulations by a qualified anesthesiologist or an individual legally authorized to administer anesthesia.

B. After the patient has been administered a general anesthetic, a physician shall attend the patient until the patient may be safely placed under post-procedure supervision by the nursing staff. The nursing staff shall provide post-procedure supervision and attend the patient until she regains full consciousness or the effects of the anesthetic have sufficiently subsided for the patient to summon aid when needed.

~~SECTION 304 Laboratory Services. (II)~~

~~A. Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).~~

~~1. Facilities for collecting specimens shall be available on site.~~

~~2. If laboratory services are provided on site they shall be directed by a person who qualifies as a director under CLIA 88 and shall be performed in compliance with CLIA 88 standards.~~

~~B. Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests are required:~~

~~1. Urinalysis including albumin and glucose examination;~~

~~2. Hematocrit or hemoglobin;~~

~~3. Determination of Rh factor (including the Du variant when the patient is Rh negative); Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative.~~

~~C. Other laboratory tests to be administered:~~

~~1. Testing for Chlamydia and gonorrhea;~~

~~2. Syphilis serology shall be offered;~~

~~3. A Papanicolaou procedure shall be offered;~~

~~4. Referral for chest X-ray, if indicated;~~

~~5. Other tests as deemed appropriate by the physician.~~

~~D. Aspirated tissues shall be examined to verify that villi or fetal parts are present; if villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.~~

~~E. A written report of each laboratory test and examination shall be a part of the patient's record.~~

~~F. If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she should be administered fluids and transported immediately to a hospital that routinely performs crossmatches and transfuses patients.~~

~~G. All laboratory supplies shall be monitored for expiration dates, if applicable.~~

~~H. Products of conception resulting from the abortion procedure must be managed in accordance with requirements for pathological waste pursuant to Department R.61-105, Infectious Waste Management Regulations. All contaminated dressings and/or similar waste shall be properly disposed of in accordance with R.61-105.~~

804. Laboratory Services (II)

A. Abortion Facilities shall provide laboratory services or arrangements for obtaining laboratory services required in connection with the procedure to be performed.

B. Abortion Facilities shall obtain a Clinical Laboratories Improvement Amendments (CLIA) certificate from the Department's CLIA Program if they test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

C. The following pre-procedure laboratory tests shall be administered:

1. Hematocrit or hemoglobin; and

2. Determination of Rh factor, including the Du variant when the patient is Rh negative. Rh (D) immune globulin (human) shall be administered, prior to discharge, to patients who are determined to be Rh negative.

D. Other laboratory tests to be administered:

1. Testing for chlamydia and gonorrhea;

2. Syphilis serology; and

3. Papanicolaou.

E. Aspirated tissues shall be examined to verify that villi or fetal parts are present. If villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.

F. If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she shall be administered fluids and transported immediately to a hospital that routinely performs cross-matches and transfuses patients.

G. An Abortion Facility shall manage all products of conception resulting from the abortion procedure pursuant to the requirements of Regulation 61-105, Infectious Waste Management. An Abortion Facility shall manage and dispose of all infectious waste, including contaminated dressings, in accordance with R.61-105.

~~SECTION 305 Emergency Care. (I)~~

~~A. All staff and/or consulting physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services or shall have in place documented arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary.~~

~~B. Equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer of the patient to a hospital.~~

~~C. The facility shall inform, in writing, the local ambulance service which provides emergency care and transport of patients, of the location of the facility, and the nature of medical problems which may result from abortions.~~

~~SECTION 306 Equipment and Supplies. (II)~~

~~There shall be appropriate equipment and supplies maintained for the patients to include but not limited to:~~

~~A. A bed or recliner suitable for recovery;~~

~~B. Oxygen with flow meters and masks or equivalent; (I)~~

~~C. Mechanical suction; (I)~~

~~D. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways; (I)~~

~~E. Emergency medications, intravenous fluids, and related supplies and equipment; (I)~~

~~F. A clock with a sweep second hand;~~

~~G. Sterile suturing equipment and supplies;~~

~~H. Adjustable examination light;~~

~~I. Containers for soiled linen and waste materials with covers;~~

~~J. Refrigerator;~~

~~K. Appropriate equipment for the administering of general anesthesia, if applicable.~~

~~SECTION 307 Consultation. (II)~~

~~Arrangements shall be made for consultation or referral services in the specialties of obstetrics/gynecology, anesthesiology, surgery, psychiatry, psychology, clinical pathology and pathology, clergy, and social services, as well as any other indicated field, to be available as needed.~~

~~SECTION 308 Quality Improvement. (II)~~

~~A. The facility shall establish and implement a written plan for a quality improvement program for patient care. The plan shall specify the individual responsible for coordinating the quality improvement program and shall provide for ongoing monitoring of staff and patient care services.~~

~~B. There shall be an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.~~

~~C. Evaluation of patient care throughout the facility shall be criteria based, so that certain actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified.~~

~~D. The quality improvement process shall incorporate quarterly review of a minimum of five per cent of medical records of patients undergoing procedures during a given quarter, but not less than five records shall be reviewed.~~

~~E. The quality improvement process shall include evaluation by patients of care and services provided by the facility. If the families of patients are involved in the care and services provided by the facility, the quality improvement process shall include a means for obtaining input from families of patients.~~

~~F. The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including as a minimum, policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.~~

~~G. The quality improvement program shall identify and establish indicators of quality care, specific to the facility, that shall be monitored and evaluated.~~

~~H. The results of the quality improvement program shall be submitted to the licensee for review at least annually and shall include at least the deficiencies found and recommendations for corrections or improvements. Deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee.~~

~~SECTION 309 Requirements for Clinics Performing Abortions Beyond 14 Weeks. (I)~~

~~Clinics which perform abortions beyond 14 weeks from the first day of the last menstrual cycle shall, in addition to those requirements in all other sections of this regulation, have the following in place:~~

~~A. Physicians shall be board certified or a candidate for board certification in obstetrics and gynecology, general surgery, or family practice;~~

~~B. Physicians shall have admitting privileges at one or more local hospitals that have appropriate obstetrical/gynecological services;~~

~~C. Laryngoscopes, endotracheal tubes, and defibrillator;~~

~~D. Laboratory tests/procedures shall include:~~

~~1. White blood count and determination of blood type;~~

~~2. Sickle cell, when indicated;~~

~~3. Ultrasonogram.~~

SECTION 900 – MEDICATION MANAGEMENT (I)

901. General

A. An Abortion Facility shall manage, secure, store, and administer all medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid in accordance with local, state, and federal laws and regulations. This includes the securing, storing, and administering of medications, medical supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. An Abortion Facility may retain nonlegend medications available without a prescription and label such medications as stock in the Abortion Facility for administration as ordered by a physician or other legally authorized healthcare provider.

C. Abortion Facilities using controlled substances shall obtain a controlled substances registration from the Department's Bureau of Drug Control and a controlled substances registration from the federal Drug Enforcement Administration (DEA). The registrations shall be displayed in a conspicuous location within the Abortion Facility.

1. The Abortion Facility physician shall be responsible for the proper safeguarding and handling of controlled substances within the Abortion Facility, and shall be certain that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately to the Bureau of Drug Control of the Department.

2. With a written power of attorney, the Abortion Facility physician may grant permission to any other physician who possesses an individual practitioner South Carolina Controlled Substances Registration and a DEA Registration to administer, order for administration, or dispense any controlled substances maintained by the Abortion Facility.

3. Operation of any Abortion Facility registered with the Department's Bureau of Drug Control and the DEA shall include reporting any theft or loss of controlled substances to local law enforcement and to the Bureau of Drug Control within three (3) working days of the discovery of the loss or theft. Operation of any Abortion Facility permitted by the South Carolina Board of Pharmacy shall include reporting the loss or theft of drugs or devices within three (3) working days of the discovery of the loss or theft.

D. Each Abortion Facility shall maintain, upon the advice and written approval of the physician or consultant pharmacist, an emergency kit or cart of lifesaving medicines and equipment for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of patients.

1. The kit or cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The exterior of each emergency medication kit or cart shall have displayed the following information:

a. "For Emergency Use Only"; and

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit or cart is opened, the Abortion Facility shall be restock and reseal the kit or cart within three (3) days to prevent risk of harm to a patient.

4. Medications used from the kit or cart shall be replaced pursuant to orders from a physician or other legally authorized healthcare provider according to Abortion Facility policy.

5. Contents of each section of the kit or cart shall be listed and maintained on or in the kit or cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained by the Abortion Facility for a period of two (2) years.

a. An Abortion Facility shall have drugs and equipment available within the Abortion Facility to treat, at a minimum, the following conditions:

1. Cardiac arrest;

2. Seizure;

3. Asthmatic attack;

4. Allergic reaction;

5. Narcotic toxicity;

6. Hypovolemic shock; and

7. Vasovagal shock.

b. Appropriate equipment and supplies shall be available to include, but not be limited to,:

1. Oxygen with flow meters and masks or equivalent;

2. Mechanical suction;

3. Resuscitation equipment to include, at a minimum, resuscitation bags and oral airways;

4. Sterile suturing equipment and supplies;

5. Laryngoscopes;

6. Endotracheal tubes; and

7. Defibrillator.

E. An Abortion Facility shall have applicable reference materials published within the previous year available at the Abortion Facility to provide staff members with adequate information concerning medications.

902. Medication Orders

A. Medications, including oxygen, shall be administered in the Abortion Facility to patients only upon orders of a physician or other legally authorized healthcare provider.

B. All orders, including verbal, shall be received only by licensed nurses or legally authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the Abortion Facility's policies and procedures, but no later than seventy-two (72) hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

903. Administering Medication

A. Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided the identification of the individual's initials is located within the record.

B. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two (2) years.

904. Pharmacy Services

Abortion Facilities that maintain stocks of legend medications and biologicals for patient use within the Abortion Facility shall obtain and maintain a valid, current, nondispensing drug outlet permit from the South Carolina Board of Pharmacy, displayed in a conspicuous location in the Abortion Facility, and have a consultant pharmacist on-call during Abortion Facility operating hours.

905. Medication Storage

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety, and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to plus or minus two (2) degrees Fahrenheit shall be maintained in these refrigerators.

C. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage, and shall be locked when not under direct observation by a licensed healthcare provider. Controlled substances shall be stored under double lock and key, and in accordance with applicable state and federal regulations. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

D. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia, thirty-six to forty-six (36–46) degrees Fahrenheit, or according to the recommendations of the manufacturer. Food and drinks shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

E. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications; and

3. Separately from food.

F. Review of medication storage areas shall be conducted by the consultant pharmacist or his or her designee on at least a monthly basis. Records of such reviews shall be retained by the Abortion Facility for at least two (2) years.

906. Disposition of Medications

A. Medications, medical supplies, and those items necessary for the rendering of first aid shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When non-controlled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and a witness. The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of Regulation 61-4, Controlled Substances.

B. Destruction records shall be retained by the Abortion Facility for at least two (2) years.

SECTION 1000 – RIGHTS AND ASSURANCES (II)

A. The Abortion Facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, for example, Title VII, Section 601 of the Civil Rights Act of 1964, and ensure that there is no discrimination with regard to source of payment in the recruitment or location of patients, acceptance or provision of services to patients or potential patients, provided that payment offered is not less than the cost of providing services.

B. The Abortion Facility shall develop and post in a conspicuous place in a public area of the Abortion Facility a grievance or complaint procedure to be exercised on behalf of patients that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

C. Care, treatment, procedures, and/or services provided by the Abortion Facility, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

D. Patient rights shall be guaranteed, prominently displayed, and the Abortion Facility shall inform the patient of these rights to include, at a minimum,:

1. The care, treatment, procedures, and/or services to be provided;

2. Informed consent for care, treatment, and/or services;

3. Freedom from mental and physical abuse and exploitation;

4. Privacy while being treated and while receiving care;

5. Respect and dignity in receiving care, treatment, procedures, and/or services;

6. Confidentiality and privacy of records. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. The Abortion Facility shall establish policies to govern access and duplication of the patient's record;

7. The right to conduct private telephone conversations with family and friends. When restrictions are necessary because of therapeutic or practical reasons, these reasons shall be documented, explained to the patient and family and reevaluated at least monthly; and

8. The right to be fully informed, as evidenced by the patient's written acknowledgement of these rights, of all rules and regulations regarding patient conduct and responsibilities.

E. The Statement of Rights of Patients shall be posted in a conspicuous place in the Abortion Facility.

~~PART IV~~
~~MEDICAL RECORDS AND REPORTS~~

~~SECTION 401 Medical Records. (II)~~

~~Medical records shall be maintained for all patients examined or treated in the clinic. The records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. All information shall be centralized in the patient's medical record. All entries shall be legibly written or typed, dated and signed.~~

~~A. The record shall include as a minimum the following information:~~

~~1. A face sheet with patient identification data, to include but not be limited to: name, address, telephone number, social security number, date of birth, father's and mother's names when patient is a minor, husband's name, and name, address and telephone number of person to be notified in the event of an emergency;~~

~~2. Signed consent for the procedure;~~

~~3. Date of initial examination;~~

~~4. Date of abortion;~~

~~5. Referring and attending physicians' names and phone numbers, if applicable;~~

~~6. Complete medical history to include medications currently being taken;~~

~~7. Physical examination, to the extent necessary to determine the health status of the patient, within 15 days of the procedure, including detail of findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period;~~

~~8. Results of diagnostic tests and/or examinations, e.g., X-ray, electrocardiography, clinical laboratory, pathology, consultations, ultrasound;~~

~~9. Pre-operative diagnosis;~~

~~10. Counselor's notes;~~

~~11. Physician's orders;~~

~~12. Complete record of abortion procedure to include:~~

~~a. Vital signs, i.e., temperature, pulse, respiration, and blood pressure, prior to and following the procedure;~~

~~b. Name of procedure performed;~~

~~c. Anesthetic agent utilized;~~

~~d. Name of attending physician performing the procedure;~~

~~e. Names of clinical assistants in attendance, to include other physicians, physician's assistants, anesthetists, nurses, or specially trained technicians;~~

~~f. Signature of physician performing the procedure.~~

~~13. Nurses' notes;~~

~~14. Progress notes to include a post-anesthesia note if general anesthesia is utilized;~~

~~15. Attending physician's description of gross appearance of tissue removed;~~

~~16. Final diagnosis;~~

~~17. Condition on discharge;~~

~~18. Post-op orders and follow-up care;~~

~~19. Documented verification that the woman has been presented printed materials as required in the Woman's Right-to-Know Act;~~

~~20. In the case of an unemancipated minor or mentally incompetent person, a copy of the court order or written consent authorizing the abortion.~~

~~B. The attending physician must complete and sign the medical record within 72 hours following discharge.~~

~~SECTION 402 Records Storage.~~

~~All records shall be treated as confidential and shall be stored in a safe location for a minimum of 10 years. When records are stored in a location other than the clinic, and upon closure of the clinic, for any reason, the medical records shall be stored in a safe location for that minimum period, with the Department informed of that location. The medium in which the records are stored, e.g., optical disk, microfiche, is a facility decision.~~

~~SECTION 403 Reports. (II)~~

~~A. The following shall be reported to Vital Records and Public Health Statistics of this Department:~~

~~1. Any abortion performed, to be reported by the performing physician on the standard form for reporting abortions, within seven days after the abortion is performed;~~

~~2. A fetal death when the fetus has completed or passed the age or weight requiring a report, pursuant to the standards in Department R. 61-19, Vital Statistics.~~

~~B. A record of each accident or incident occurring in the facility which involves patients, staff, or visitors, including medication errors and adverse drug reactions, shall be prepared immediately. Accidents or incidents resulting in serious injury shall be reported, in writing, to the Department within 10 days of the occurrence; if a death occurs, other than a fetal death, it shall be reported to the Department not later than the next Department work day (Monday through Friday). Accidents and incidents that must be reported include, but are not limited to:~~

~~1. Those leading to hospitalization;~~

~~2. Those leading to death, other than a fetal death;~~

~~3. Adverse drug reactions.~~

SECTION 1100 – EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1101. Emergency Services (I)

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life support procedures pending transfer to a hospital.

B. The Abortion Facility shall inform the local ambulance services which provides emergency care and transport of patients the nature of medical problems which may result from abortion procedures.

1102. Disaster Preparedness (II)

An Abortion Facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

1103. Emergency Call Numbers (I)

A. The Abortion Facility shall post emergency call data in a conspicuous place and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center.

B. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

~~PART V~~
~~FUNCTIONAL SAFETY AND MAINTENANCE~~

~~SECTION 501 Policies and Procedures.~~

~~A. Written policies and procedures shall be developed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.~~

~~B. The policies and procedures shall include, but not be limited to:~~

~~1. Safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;~~

~~2. Provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;~~

~~3. Provisions for disseminating safety-related information to employees and users of the facility;~~

~~4. Provision for syringe and needle handling and storage.~~

~~5. Provisions for managing infectious waste from generation to disposal according to Regulation 61-105.~~

~~SECTION 502 Disaster Preparedness.~~

~~A. The facility shall have posted, in conspicuous places throughout the facility, a plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (I)~~

~~B. A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.~~

~~SECTION 503 Maintenance.~~

~~A. Facility Maintenance. A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.~~

~~B. Equipment Maintenance. When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, not less than annually, to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.~~

SECTION 1200 – INFECTION CONTROL AND ENVIRONMENT

1201. Staff Practices (I)

A. The Abortion Facility shall ensure that staff uses preventive measures and practices that are in compliance with applicable guidelines of the Bloodborne Pathogens Standards of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; the Department's Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings and Regulation 61-105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized healthcare provider shall ensure that the Abortion Facility has the capability to provide adequate care and prevent the spread of the disease, or transfer the patient to an appropriate healthcare provider if necessary.

C. The Abortion Facility shall designate, in writing, a person to coordinate tuberculosis screening of personnel and any other tuberculosis control activities.

1202. Vaccinations (I)

A. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case, the decision shall be documented. Each staff member who elects vaccination shall have completed the initial dose of the three (3) dose series within thirty (30) days of employment at the Abortion Facility.

B. All direct care staff shall have an annual influenza vaccination unless the vaccine is contraindicated or an individual is offered the vaccine and declines. In either case, the decision shall be documented.

C. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case, the decision shall be documented. Immunity to mumps is recommended.

1203. Live Animals

Live animals shall not be permitted in Abortion Facilities.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with disabilities.

1204. Sterilization Procedures (I)

A. An Abortion Facility shall have sterilizing equipment of appropriate type and of adequate capacity to properly sterilize instruments, operating room materials, and laboratory equipment and supplies. The

sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly. Periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

1. The Abortion Facility shall have documentation of each load run daily. A biological test of the autoclave shall be run daily and the results maintained in a log by the Abortion Facility.

2. Each separate package of instruments to be sterilized must have internal and external chemical indicators.

3. The accuracy of instrumentation and equipment shall be provided by periodic calibration and/or preventive maintenance as necessary, but not less than annually, and a log maintained by the Abortion Facility.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized in the Abortion Facility.

C. The Abortion Facility shall provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures.

D. Abortion Facility operations shall include cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use. A recognized method of monitoring disinfectant performance shall be employed. Disinfectants, for example, glutaraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings or tests and change dates of the disinfectant solution.

1205. Tuberculosis Risk Assessment (I)

A. All Abortion Facilities shall conduct an annual tuberculosis (TB) risk assessment in accordance with CDC guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, such as low risk or medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and patients and the frequency of screening. A risk classification shall be determined for the entire Abortion Facility. In certain settings, such as, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting, may have separate risk classifications.

1206. Staff Tuberculosis Screening (I)

A. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

B. Low Risk:

1. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for Mycobacterium tuberculosis (BAMT): All staff, within three (3) months prior to contact with patients, unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff

has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

2. Periodic TST or BAMT is not required.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to M. tuberculosis: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to twelve (8 to 12) weeks after that exposure to M. tuberculosis ended.

C. Medium Risk:

1. Baseline two-step TST or a single BAMT: All staff, within three (3) months prior to contact with patients, unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST, or the single BAMT, can be administered to serve as the baseline.

2. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease, including the staff responses, documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the administrator or director of nursing. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

3. Post-exposure TST or a BAMT for staff upon unprotected exposure to M. tuberculosis: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to twelve (8 to 12) weeks after that exposure to M. tuberculosis ended.

D. Baseline Positive or Newly Positive Test Result:

1. Staff with a baseline positive or newly positive test result for M. tuberculosis infection, such as TST or BAMT, or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, such as, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease, or evaluate an interpretable copy taken within the previous three (3) months. These staff members shall be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and shall be encouraged to follow the recommendations made by a physician with TB expertise, such as the Department's TB Control program.

2. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician or legally authorized healthcare provider, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician or legally authorized healthcare provider.

1207. Housekeeping (II)

A. The Abortion Facility and its grounds shall be uncluttered, clean, and free of vermin and offensive odors.

B. Interior housekeeping shall, at a minimum, include:

1. Cleaning each specific area of the Abortion Facility. Dry sweeping and dusting shall be prohibited in restricted areas as identified in facility policies and procedures; and

2. Cleaning of operating or procedure rooms in accordance with established written procedures after each operation or procedure.

C. Exterior housekeeping shall, at a minimum, include:

1. Cleaning of all exterior areas, for example, porches and ramps, and removal of safety impediments, such as snow and ice; and

2. Keeping the Abortion Facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

3. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform.

1208. Infectious Waste (I)

A. The Abortion Facility shall register as an infectious waste generator as outlined in Regulation 61-105, Infectious Waste Management.

B. Accumulated waste, including all contaminated dressings, shall be managed and disposed of in a manner compliant with OSHA Bloodborne Pathogens Standards and pursuant to the requirements of R.61-105.

1209. Clean and Soiled Linen and Surgical Clothing (II)

A. The Abortion Facility shall have a supply of clean, sanitary linen and surgical clothing available at all times at the Abortion Facility. In order to prevent contamination by dust or other airborne particles or organisms, clean linen and surgical clothing shall be stored and transported in a sanitary manner, such as, enclosed and covered. Linen and surgical clothing storage rooms shall be used only for the storage of linen and surgical clothing. Clean linen and surgical clothing shall not be stored with other items.

B. Soiled linen and surgical clothing.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing; and

2. Soiled linen and surgical clothing shall be kept in enclosed and/or covered containers.

SECTION 1300 – QUALITY IMPROVEMENT PROGRAM (II)

A. The Abortion Facility shall establish and implement a written plan for a quality improvement program for patient care. The plan shall specify the individual responsible for coordinating the quality improvement program and shall provide for ongoing monitoring of staff and patient care services.

B. The Abortion Facility shall have an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

C. Evaluation of patient care throughout the Abortion Facility shall be criteria-based, so that certain actions are taken or triggered when specific quantified, predetermined levels or outcomes or potential problems are identified.

D. The quality improvement process shall incorporate quarterly review of a minimum of five percent (5%) of medical records of patients undergoing procedures during a given quarter, but not less than five (5) records shall be reviewed.

E. The quality improvement process shall include evaluation by patients of care and services provided by the Abortion Facility. If the families of patients are involved in the care and services provided by the Abortion Facility, the quality improvement process shall include a means for obtaining input from families of patients.

F. The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including at a minimum, policy revisions, procedural changes, educational activities, and follow-up on recommendations, or that additional actions are no longer indicated or needed.

G. The quality improvement program shall identify and establish indicators of quality care, specific to the Abortion Facility that shall be monitored and evaluated.

H. The results of the quality improvement program shall be submitted to the licensee for review at least annually and shall include at least the deficiencies found and recommendations for corrections or improvements. Deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee.

SECTION 1400 – MAINTENANCE (II)

1401. General

The Abortion Facility equipment and building components, such as doors, windows, lighting fixtures, plumbing fixtures, shall be in good repair and operating condition. The Abortion Facility shall document preventative maintenance. The Abortion Facility shall comply with the applicable provisions of these regulations and the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

1402. Equipment Maintenance

When patient monitoring equipment is utilized, a written preventive maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with the manufacturer's specifications at periodic intervals, not less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. The Abortion Facility shall maintain records on each piece of equipment to indicate its history of testing and maintenance.

~~PART VI~~

INFECTION CONTROL AND SANITATION

SECTION 601 General.

Policies and procedures shall be established in writing to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

SECTION 602 Sterilization Procedures.

A. Adequate space shall be provided for storage, maintenance and distribution of sterile supplies and equipment.

B. Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled.

C. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features.

1. There must be documentation of each load run daily. A biological test of the autoclave shall be run daily and the results maintained on a log.

2. Each separate package of instruments to be sterilized must have internal and external chemical indicators.

3. The accuracy of instrumentation and equipment shall be provided by periodic calibration and/or preventive maintenance as necessary, but not less than annually, and a log maintained.

D. The policies and procedures shall indicate how the shelf life of a packaged sterile item is determined. Methods approved for use are:

1. Date of expiration being marked on the item; or

2. Event-related, i.e., day-to-day expiration, utilizing such wording as, "sterile unless the integrity of the package is compromised."

SECTION 603 Linen and Laundry.

A. An adequate supply of clean linen or disposable materials shall be maintained in order to insure change of linen on procedure tables between patients.

B. Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers.

C. A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

SECTION 604 Housekeeping.

A. General. A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings,

~~woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.~~

~~B. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.~~

~~C. Dry sweeping and dusting of walls and floors are prohibited.~~

~~SECTION 605 Refuse and Waste Disposal.~~

~~A. All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.~~

~~B. Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.~~

~~C. Immediately after emptying, containers for garbage shall be cleaned.~~

~~D. All waste meeting the definition of "infectious waste" as defined in Regulation 61-105 must be managed according to the requirements of that regulation.~~

~~SECTION 606 Outside Areas.~~

~~All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for insects, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.~~

~~PART VII~~
~~FIRE PROTECTION AND PREVENTION~~
SECTION 1500 – FIRE PROTECTION AND PREVENTION

~~SECTION 701 Fire-fighting Equipment and Systems.~~**1501. Firefighting Equipment and Systems (I)**

A. All ~~facilities~~Abortion Facilities located outside a fire protected area shall have a contract with the nearest fire department.

B. An evacuation plan shall be posted in prominent places and staff members shall be trained as part of their responsibilities to guide patients to the designated exits.

C. All fire protection and alarm systems and other fire-fighting equipment shall be inspected and tested at least once each year, and more often if necessary to maintain them in serviceable condition.

D. Fire extinguishers of the proper type shall be installed in accordance with ~~NFPA 10 (National Fire Protection Association) 10 requirements~~the codes and standards referenced in Section 1602 or as otherwise directed by fire authorities.

1. Fire extinguishers shall be kept in condition for instant use and shall be inspected monthly by ~~facility~~Abortion Facility staff with the date of inspection recorded on a tag affixed to the extinguisher.

2. Fire extinguishers shall be inspected and/or serviced annually by personnel licensed or certified to perform fire extinguisher servicing. Servicing~~/~~ and/or inspection records shall be kept on the fire extinguishers.

E. No portable electric, open flame, or unvented heaters shall be allowed in the ~~facility~~Abortion Facility.

F. Fire Drills.

1. A fire drill shall be conducted at least once every three (3) months. New ~~facilities~~Abortion Facilities shall conduct a fire drill within the first forty-eight (48) hours of operation. Each employee shall participate in a fire drill at least twice each year.

2. Records of drills shall be maintained to report the date, time, description, and evaluation of the drill, to include the names of participating staff and time for total evacuation.

G. Corridor Obstructions. All corridors and other means of egress or exit from the building shall be maintained clear and free of obstructions.

H. Corridor and Stairway Illumination. Corridors, stairs and other means of egress shall be lighted at all times with a minimum of one (1) foot-candle at finish floor level along the path of travel.

~~SECTION 702 Alarms.~~

~~A fire alarm system shall be provided in accordance with the provisions of NFPA 72. The fire alarm system shall be tested monthly and each detector tested annually. Records of all tests shall be retained for at least one year.~~

~~SECTION 703 Gas Storage.~~**1502. Gas Storage (I)**

~~—~~Gases~~,~~ ~~(~~flammable and nonflammable~~),~~ shall be handled and stored in accordance with the provisions of ~~applicable NFPA codes~~the codes and standards referenced in Section 1602.

1503. Fire and Disasters (II)

A. The Department shall be notified immediately via telephone, email, or facsimile regarding any fire in the Abortion Facility, followed by a complete written report, to include fire department reports, if any, to be submitted within a time period determined by the Abortion Facility, but not to exceed seventy-two (72) hours from the occurrence of the fire.

B. The Abortion Facility shall have an evacuation plan posted in prominent places and staff members shall be trained as part of their responsibilities to guide patients to the designated exits.

C. Where a required fire protection systems is out of service, the Abortion Facility shall notify the fire department and the fire code official immediately, and when required by the fire code official, the building shall either be evacuated or the Abortion Facility shall provide an approved fire watch for all occupants left unprotected by the shutdown until the fire protection system has returned to service, as applicable to the Department's Division of Health Facilities Construction (DHFC) Guidelines Manual.

~~PART VIII~~
~~DESIGN AND CONSTRUCTION~~
SECTION 1600 – DESIGN AND CONSTRUCTION

~~SECTION 801 General.~~**1601. General (II)**

~~—~~Every ~~facility~~Abortion Facility ~~must~~shall be planned, designed, and equipped to provide adequate facilities for the care and comfort of each patient.

~~SECTION 802 Local and State Codes and Standards.~~**1602. Codes and Standards (II)**

~~A. Facilities shall comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. Abortion clinics are categorized as a "business occupancy" as defined in the Standard Building Code~~Abortion Facility design and construction shall comply with applicable provisions of these regulations and the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal. No ~~facility~~Abortion Facility ~~will~~shall be licensed unless the Department has assurance that responsible local officials have approved the facility. Requirements of these regulations shall also be met.

~~B. The Department uses as its basic codes: the Standard Building Code, Standard Plumbing Code, Standard Mechanical Code, and National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the requirements set forth in this regulation are also met.~~

~~SECTION 803 Submission of Plans and Specifications.~~**1603. Submission of Plans and Specifications**

A. New Buildings, Additions or ~~Major~~ Alterations to Existing Buildings. (II)

1. When construction is contemplated either for new buildings, additions, or ~~major~~ alterations to existing buildings, the ~~facility~~Abortion Facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulation requirements that apply to that project. Plans and specifications shall be submitted to the Department for review. ~~Where the Standard Building Code or other regulations require fire rated walls or other fire rated structural elements, these~~These plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his~~/~~ or her seal.

2. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents require approval by the Department.

B. Preliminary submission shall include the following:

1. Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, ~~et cetera~~and other, properly designated; size, characteristics, and location of all existing public utilities, including information concerning water supply available for fire protection;

2. Code analysis and life safety plan; ~~Floor~~floor plans showing overall dimensions of buildings; locations, size, and purpose of all rooms; location and size of doors, windows, and other openings with

swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts, and chimneys; and

3. Outline specifications listing a general description of construction including interior finishes and mechanical systems.

C. Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout, if applicable.

D. ~~In~~If construction is delayed for a period exceeding twelve (12) months from the time of approval of final submission, a new evaluation and/or approval is required.

E. ~~One complete set of as-built drawings shall be filed with DHEC.~~The licensee shall pay the following inspection fees during the construction phase of the project. The plan review is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Fees	
Plan Review	
Total Project Cost	**Fee**
< $10,001.00	$750
$10,001 - $100,000	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Review	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

~~SECTION 804 Licensure of Existing Structures.~~**1604. Licensure of Existing Structures (II)**

~~—~~When an existing structure is contemplated for licensure it must meet the same building code requirements as a "new" ~~facility~~Abortion Facility (see Section ~~803.A~~1603.A). ~~If an expansion or renovation to an existing facility is contemplated, the~~The ~~facility~~Abortion Facility must contact the Division of Health Facilities Construction of this Department to discuss code and regulatory requirements that apply to that project. ~~The following shall be submitted to the Department:~~If required, plans shall be submitted in accordance with Section 1603.

~~A. If the physical dimensions of the building are affected, a plot plan in accordance with Section 803.B.1;~~

~~B. A floor plan in accordance with Section 803.B.2;~~

~~C. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.~~

NOTE: Those existing abortion clinics that have been identified by the Department, through submission of regular reports of abortions performed, may be licensed in their current buildings. However, upon initial licensure, these facilities will be required to submit a plan that will bring them into full compliance with this chapter within two years from date of licensure.

SECTION 805 Minor Alterations in Licensed Facilities.

When alterations that involve construction that may affect walls, ceilings, floors, or fire and life safety are contemplated, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards and determine if an architect need be involved.

SECTION 806 Location.

A. Transportation. The facility must be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have parking space to reasonably satisfy the needs of patients, staff, and visitors.

C. Communications. A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

SECTION 807 Physical Facilities.

A. An adequate number of examination/procedure rooms shall be provided. A procedure room shall be sized, shaped, and arranged to allow unfettered movement for all persons involved in the procedure.

B. Each procedure room shall be provided:

1. A suitable gynecological procedure table;

2. Equipment necessary to treat patients for hemorrhage, shock, cardiac arrest and other emergencies (an emergency "crash" cart in the immediate vicinity is acceptable); (I)

C. An area shall be provided for use by nurses in preparing medications for patients and keeping patient medical records. A room or cabinets shall be provided for storing medications and shall be kept locked except when medications are being prepared for administering. Narcotics shall be double-locked. An adequate supply of drugs shall be on hand at all times.

D. An adequate number of recovery room(s) or area(s) shall be provided. There shall be clear space on both sides and at the foot of each recovery bed/recliner to allow unencumbered movement by staff and patients.

1. There shall be a toilet room immediately accessible from the recovery area. This room shall contain a commode with grab bars or recessed hand holds and handwashing lavatory, operable without the use of hands, soap dispenser with soap, and paper towel dispensers with paper towels, or hot air dryer;

~~2. There shall be a signal system for each patient bath and toilet that shall include an audible alarm that can be heard and location identified by staff;~~

~~3. There shall be a readily accessible safe and sanitary storage area for patients' clothing and personal effects;~~

~~4. There must be provisions to afford privacy upon request of a patient, e.g., curtains, screens, private room.~~

~~E. A room for the temporary storage of soiled linen and waste in covered containers shall be provided. This room shall be provided with at least 10 air changes per hour with all air continuously exhausted to the outside.~~

~~F. There must be an area to accommodate the sterilization procedures as described in Section 602. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for abortion. The area shall be arranged to prevent cross traffic of clean and dirty material. Air flow in this area shall be from the "clean" area toward the "dirty" area.~~

~~G. Suitable dressing room space shall be provided for physicians and nursing staff. Scrub facilities shall be provided and located conveniently to the procedure room(s).~~

~~H. Procedure and recovery room(s) shall be located on an exit access corridor that provides unimpeded, rapid access to an exit of the building. This exit must accommodate emergency transportation vehicles and equipment.~~

~~I. In multi-storied buildings where the facility is not located on the floor of entry to/exit from the building, there must be at least one elevator that serves the clinic floor(s). The elevator must accommodate emergency transportation equipment.~~

~~J. Adequate fixed or portable work surface areas shall be maintained for use in each procedure room.~~

~~K. Doors providing access into the facility and procedure room(s) shall be at least 36 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least 48 inches wide.~~

SECTION 1700 – PHYSICAL PLANT

1701. Physical Facilities

A. The Abortion Facility shall have an adequate number of examination and procedure rooms. A procedure room shall be sized, shaped, and arranged to allow unfettered movement for all persons involved in the procedure.

B. Each procedure room shall have a suitable gynecological procedure table with adjustable examination lighting.

C. The Abortion Facility shall have an area for use by nurses in preparing medications for patients and keeping patient medical records. The Abortion Facility shall have a room or cabinets for storing medications that is kept locked except when medications are being prepared for administration. Narcotics shall be double-locked. An adequate supply of drugs shall be on hand at all times.

D. The Abortion Facility shall have an adequate number of recovery rooms or areas. There shall be clear space on both sides and at the foot of each recovery bed or recliner to allow unencumbered movement by staff and patients. (I)

1. There shall be a toilet room immediately accessible from the recovery area. This room shall contain a commode with grab bars or recessed hand-holds and handwashing lavatory, operable without the use of hands, soap dispenser with soap, and paper towel dispenser with paper towels, or hot air dryer;

2. There shall be a signal system for each patient bath and toilet that shall include an audible alarm that can be heard and location identified by staff;

3. There shall be a readily accessible safe and sanitary storage area for patients' clothing and personal effects; and

4. There shall be provisions to afford privacy upon request of a patient, for example, curtains, screens, or private room. (II)

E. A room for the temporary storage of soiled linen and waste in covered containers shall be provided. (II)

F. There shall be an area to accommodate the sterilization procedures as described in Section 1204. There shall be sufficient surgical instruments sterilized and available for each patient who presents herself for abortion. The area shall be arranged to prevent cross traffic of clean and dirty material. Air flow in this area shall be from the clean area toward the dirty area.

G. The Abortion Facility shall have suitable dressing room space for physicians and nursing staff. The Abortion Facility shall have scrub facilities located conveniently to the procedure room(s).

H. The Abortion Facility shall have procedure and recovery rooms; all located on an exit access corridor with unimpeded, rapid access to an exit of the building. The exit shall accommodate emergency transportation vehicles and equipment.

I. In multi-storied buildings where the Abortion Facility is not located on the floor of entry to or exit from the building, there shall be at least one (1) elevator that serves the Abortion Facility's floor(s). The elevator shall accommodate emergency transportation equipment. (II)

J. Adequate fixed or portable work surface areas shall be maintained for use in each procedure room.

K. Doors providing access into the Abortion Facility and procedure room(s) shall be at least thirty-six (36) inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. All corridors shall be at least forty-eight (48) inches wide.

~~L. Heating and ventilation.~~

~~1. Lighting, heating, and ventilation systems shall comply with local and state codes. There shall be approved equipment capable of maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.~~

~~2. The procedure room(s) and the recovery room(s) shall be provided a minimum of six air changes per hour. Air supplied to all areas shall be filtered through filters of at least 25 percent efficiency rating.~~

~~3. Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces that are not provided with operable windows or outside doors.~~

~~M~~L. The entrance shall be at grade level or above, be sheltered from the weather, and accommodate wheelchairs.

~~N~~M. There shall be adequate storage areas for supplies and other storage. Sterile supplies shall be stored separate from other supplies.

~~O~~N. One (1) or more janitor's closets shall be provided throughout the ~~facility~~Abortion Facility as required to maintain a clean and sanitary environment. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies. Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet for this purpose only.

~~P~~O. A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

~~Q~~P. There shall be at least two (2) exits remote from each other.

~~R~~Q. Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

~~S. Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.~~

~~T. All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.~~

~~U~~R. Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

~~V~~S. Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

~~W~~T. Wall bases in soiled equipment and material workrooms and other areas that are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

~~X~~U. Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

~~Y~~V. Interior finish materials shall comply with the ~~Standard Building Code~~ requirements ~~for "business occupancy."~~of the codes and standards referenced in Section 1602.

~~Z~~W. Adequate space shall be provided for reception, waiting, interviewing, administrative, and business office functions. Space provided for interviewing and admitting shall be located and designed to provide privacy.

1702. Heating and Ventilation (II)

A. Lighting, heating, and ventilation systems shall comply with the codes and standards referenced in Section 1602. There shall be approved equipment capable of maintaining a minimum temperature of seventy-two (72) degrees Fahrenheit and a maximum temperature of seventy-six (76) degrees Fahrenheit in patient areas.

B. Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces that are not provided with operable windows or outside doors.

~~SECTION 808 Water Supply and Plumbing.~~**1703. Water Supply and Plumbing (II)**

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the ~~facility~~Abortion Facility and shall be adequate in volume and pressure for all purposes including fire–fighting. Patient and staff handwashing lavatories shall be supplied with hot water that shall be thermostatically controlled to a temperature between one hundred (100) and one hundred twenty-five (125) degrees Fahrenheit.

B. Plumbing.

1. All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the ~~Standard Plumbing Code~~codes and standards referenced in Section 1602.

2. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. There shall be, at a minimum, an approved double-check assembly on the water supply to the ~~facility~~Abortion Facility.

~~SECTION 809 Emergency Power and Lighting Requirements.~~**1704. Emergency Power and Lighting Requirements**

A. The ~~facility~~Abortion Facility shall be equipped with automatic emergency power adequate to maintain the operation of lighting for procedure rooms, egress, fire detection equipment, and alarms. (I)

B. There shall be sufficient safe lighting for all activities, including suitable lighting for corridors. (II)

C. Battery backup with a duration of ninety (90) minutes is acceptable for the requirements listed in Sections 1704.A and 1704.B. (II)

1705. Location

A. Transportation. The Abortion Facility shall be served by roads that are passable at all times and adequate for the volume of expected traffic.

B. Parking. The Abortion Facility shall have parking space to reasonably satisfy the needs of patients, staff, and visitors.

C. Communications. The Abortion Facility shall have a telephone on each floor for patients and additional telephones or extensions, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose. (II)

~~Part IX. PREREQUISITES FOR INITIAL LICENSURE.~~

~~Prior to admission of patients to, and issuance of a license for new facilities or additional procedure rooms, the following actions must be accomplished:~~

~~A. Plans and construction must be approved by the Division of Health Facilities Construction of this Department.~~

~~B. The facility shall submit a completed application for license on forms that shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:~~

~~1. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of this Department (includes satisfactory laboratory reports of water samples).~~

~~2. Approval from the appropriate building official stating that all applicable local codes and ordinances have been complied with.~~

~~a. If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or~~

~~b. If the facility is located outside town or city limits, a written letter of agreement with the nearest fire department that will provide protection and respond in case of fire at the facility shall be obtained. This letter shall indicate that they have the equipment, personnel, and/or agreements with other departments to adequately respond to this type of facility.~~

~~3. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility meets the requirements of the Standard Building Code.~~

~~4. Certification by the contractor that only the carpeting described in B.3 above was installed in the facility.~~

~~5. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.~~

~~6. Certification by the owner or contractor that only materials described in B.5 above were installed.~~

~~7. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.~~

~~8. Certification by the contractor that only the materials described in 7 above were installed.~~

~~9. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.~~

~~10. Certification by the contractor that the automatic sprinkler system, if required or installed, has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.~~

~~11. Certification that all medical gas systems have been properly installed and tested.~~

~~C. The facility must register as an infectious waste generator as outlined in Regulation 61-105.~~

~~D. Required personnel must be employed, available, trained, and capable of performing their duties.~~

~~E. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.~~

~~F. The facility must pay the required licensing fee.~~

SECTION 1800 – SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

~~PART X GENERAL.~~

SECTION 1900 - GENERAL

Conditions ~~arising~~ that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.