

ASF and Abortion Clinic Regulation Requirement Comparison

DEFINITIONS

- Abortion clinic regulation defines “abortion clinic” as any facility, other than a hospital licensed by DHEC and certified by DHEC to be a suitable facility for the performance of abortion, in which any second trimester or five or more first trimester abortions per month are performed.
- ASF regulation defines “Ambulatory Surgical Facility” as a “facility organized and administered for the purpose of performing surgical procedures and/or endoscopy for which patients are scheduled to arrive, receive surgery, and be discharged on the same day.” The definition further states that “The owner or operator shall make the facility available to other providers who comprise an organized professional staff, *i.e.*, an open medical staff,” and “This definition does not apply to any facility used as an office or clinic for the private practice of licensed healthcare professionals.”
 - Note: ASF regulation states that an ASF license shall not be required for, nor shall such a license be issued to, the following:
 - ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of the hospital regulation); or
 - private practices, defined as an individually-licensed physician or group of licensed physicians who practice together at a certain location/address in a legally-constituted professional corporation, association, or partnership; patient encounters in the office or clinic are for the purpose of diagnosis and treatment, and not limited primarily to the performance of surgery and related care, treatment, procedures, and/or services.

LICENSE FEES

- Abortion clinic regulation requires initial and annual license fee of \$500.
- Abortion clinic regulation does not speak to late fees for license applications, but a proviso in the appropriations act applicable to health licensing fees in general provides that failure to submit a license renewal application or fee to the department by the license expiration date shall result in a late fee of \$75 or 25% of the licensing fee amount, whichever is greater, in addition to the licensing fee.
- ASF regulation requires initial and annual license fee of \$150 per operating/procedure room or \$600, whichever is greater.
- ASF regulation provides that failure to submit renewal application after license expiration date may result in late fee of 25% of license fee, in addition to the license fee.

INSPECTION FEES

- ASF regulation states that DHEC may charge fees for plan reviews, construction inspections, and licensing inspections. Charging ASF inspection fees is authorized by SC Code Section 44-7-270.
- Pursuant to DHEC’s inspection fee schedule, ASF routine inspections are \$350 annually plus \$45 per operating, endoscopy, and procedure room; ASF follow-up inspections are \$200 plus \$45 per room.
- Abortion clinic regulation does not address inspection fees. Charging abortion clinic inspection fees is also authorized by SC Code Section 44-7-270.
- Pursuant to DHEC’s inspection fee schedule, abortion clinic routine inspections are \$350 annually plus \$25 per procedure room; abortion clinic follow-up inspections are \$200 plus \$25 per procedure room.

ENFORCEMENT

- Abortion clinic regulation has monetary penalty range of \$0 to \$5,000 per violation, depending upon class level and frequency of the violation over a 3-year period of time.
- ASF regulation has monetary penalty range of \$100 to \$10,000 per violation, depending upon class level and frequency of the violation over a 2-year period of time.

STAFFING

- ASF regulation requires facilities to have a medical director of the facility who is a physician.

- ASF regulation requires a physician shall be physically present or available within 30 minutes until all patients have departed the premises.
- Abortion clinic regulation requires facilities to have a physician or ultrasound technician with requisite training conduct ultrasonography if conducted in the clinic.
- Abortion regulation requires 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.

INSERVICE TRAINING

- ASF regulation requires emergency procedures and disaster preparedness training and fire response training within 24 hours of first day of job.
- Abortion clinic regulation requires fire protection training but does not require it within 24 hours, and there is no requirement emergency procedures and disaster preparedness training apart from fire protection training.

LIMITS ON ABORTION PROCEDURES

- Abortion clinic regulation states abortions shall only be performed in abortion clinics on patients who are within 18 weeks from first day of LMP.
- Abortion clinic regulation states abortions beyond 18 weeks shall be performed in a hospital.
- Abortion clinic regulation states abortions beyond 18 weeks may be performed in an ASF also licensed as abortion clinic up to 26 weeks after first day of LMP.
- Abortion clinic regulation requires abortion clinics performing abortions beyond 14 weeks to meet additional requirements:
 - (1) physicians shall be board-certified or a candidate for board certification;
 - (2) physicians shall have admitting privileges at a local ob/gyn hospital;
 - (3) laryngoscopes, endotracheal tubes, and defibrillator; and
 - (4) lab tests and procedures including white blood count, sickle cell, and ultrasonogram.
- ASF regulation states that as a term of licensure, abortions shall not be performed in an ASF unless it is also licensed as an abortion clinic pursuant to the abortion clinic regulation.

MEDICATION

- Abortion clinic regulation states that drugs administered to patients must come from a physician order that is written and personally signed by the physician.
- ASF regulation allows authorized healthcare providers the authority to supply the orders too.
- Abortion clinic regulation does not have requirements for disposition of medications.
- ASF regulation has non-controlled legend medication and controlled substances destruction requirements, and requires the facility to retain records of destruction for two years or until DHEC's next inspection.

TB TEST

- Abortion clinic regulation requires TB tests using single or two-step PPD test.
- ASF regulation requires TB tests using two-step TST or BAMT.

LAB TESTS

- Abortion clinic regulation requires lab tests including a urine pregnancy test to be performed on patients before abortions, unless the physician identifies fetal heart beats or fetal movements in the physical examination. The abortion clinic regulation also requires the aspirated tissues to be examined to verify that villi or fetal parts are present.
- Abortion clinic regulation requires products of conception to be managed as pathological waste pursuant to the infectious waste regulation.
- ASF regulation does not provide specific lab tests that must be conducted on patients.

RADIOLOGY

- ASF regulation requires every facility to have capability to provide/obtain diagnostic radiology services in connection with surgery/procedure being performed.
- Abortion clinic regulation does not address this.

EMERGENCY CARE

- ASF regulation requires there to be at least one physician on staff who has admitting privileges at one or more hospitals.
- Abortion clinic regulation requires all staff and/or consulting physicians to have admitting privileges at one or more hospitals that have appropriate ob/gyn services or have documented transfer arrangements approved by DHEC.

ANESTHESIA EQUIPMENT

- Abortion clinic regulation only requires appropriate equipment for administering of general anesthesia.
- ASF regulation specifies requirements for anesthesia equipment including readily available, clean, operating properly, oxygen measuring component with alarm sensor, inspections prior to each use, and records of all maintenance for two years or until DHEC's next inspection.

AUTHENTICATION/UNIQUE IDENTIFIERS

- ASF regulation requires all user-generated documents to be separately authenticated and allows for electronic signatures and computer-generated signature codes by authorized staff. For facilities that employ the electronic-type signatures, the regulation requires authentication safeguards such as each user must be assigned a unique identifier generated through a confidential code.
- Abortion clinic regulation does not address any authentication.

REPORTING

- ASF regulation requires the facility to report accidents and incidents resulting in unexpected death or serious injury to responsible parties and DHEC within 24 hours and to file a report with DHEC within 5 days.
- Abortion clinic regulation requires the facility to report accidents and incidents involving a death, other than fetal death, to DHEC within the next work day and to report accidents and incidents involving serious injury to DHEC within 10 days.
- ASF regulation has provisions on facility closure and zero census. Abortion clinic regulation does not have these provisions.

PHYSICAL AREAS

Physical Requirement Category		ASF Regulation Requirement	Abortion Clinic Regulation Requirement
Surgical suite	Operating room	Yes	No
	Procedure room	Yes	Yes
	Work station	Yes	Yes*
	Scrub facilities	Yes	No
	Soiled workroom	Yes	Yes*
	Clean workroom	Yes	Yes*
	Sterilization room	Yes	Yes*
	Anesthesia area	Yes	No
	Staff changing area	Yes	Yes
Corridors sized for stretchers	Yes	No, except for exit access corridor	
Recovery area		Yes	Yes
Soiled utility room		Yes	Yes
Clean utility room		Yes	Yes*

Physical Requirement Category		ASF Regulation Requirement	Abortion Clinic Regulation Requirement
Life safety systems	Emergency power	Yes	Yes
	Emergency generator	Yes	No
	Fire alarm system	Yes	Yes
	Sprinkler system	Yes	No
	Nurse call system	Yes	Yes
*ASF regulation requires these rooms and areas to be separate rooms, but the abortion clinic regulation allows these rooms and areas to be separate areas within a single room.			