**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES**

**Chapter 03 Freestanding Major Medical Equipment Facilities**

**Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland**

*10.05.03.01*

**.01 Definitions.**

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

B. Terms Defined.

(1) Freestanding Facility Operating Major Medical Equipment.

(a) "Freestanding facility operating major medical equipment" means a facility using major medical equipment.

(b) "Freestanding facility operating major medical equipment" does not include any freestanding ambulatory care facilities or service owned or operated by a hospital and regulated under COMAR 10.07.01.

(2) "JCAHO" means the Joint Commission on Accreditation of Healthcare Organizations, a private organization that creates standards, surveys, and accredits hospitals and health-related facilities.

(3) "Major medical equipment" means:

(a) All cardiac catheterization equipment necessary to perform heart catheterization;

(b) A computed tomography (CT) scanner;

(c) A lithotriptor;

(d) Radiation therapy equipment, including a linear accelerator; or

(e) A magnetic resonance imager (MRI).

(4) "Supervisor" means a physician who is licensed by the Board of Physician Quality Assurance and who has expertise in the operation of major medical equipment.

*10.05.03.02*

**.02 License Requirements.**

A. A facility operating major medical equipment shall meet all general licensing requirements for a facility as provided in COMAR 10.05.01 and all requirements of this chapter.

B. An owner of mobile major medical equipment shall obtain a license under this chapter.

C. A facility operating major medical equipment that is engaged exclusively in biomedical research is not required to be licensed under this chapter if:

(1) Charges for any health care service provided with the equipment will not be paid by any patient or third-party payor; and

(2) The capital costs associated with the equipment and any related construction or renovation are not included in patient charges.

*10.05.03.03*

**.03 Licensing Procedure.**

A. A person desiring to establish or operate a facility that operates major medical equipment shall submit an application for licensure.

B. The following information for each piece of equipment shall accompany the application:

(1) Manufacturer and model of the equipment;

(2) Address where the equipment is to be located; and

(3) Qualifications of the licensed physician who will be supervising the use of the equipment.

C. The applicant or licensee shall submit a nonrefundable fee of $700 with an application for:

(1) Initial licensure; or

(2) License renewal.

*10.05.03.04*

**.04 Inspections by the Secretary.**

A. The Secretary may verify compliance with licensing requirements through on-site random sample record reviews. Unless there is an immediate threat to the health and safety of patients or employees, the Secretary shall notify the licensee 5 days before conducting an on-site inspection.

B. For the purpose of verifying compliance, the Secretary shall have access to:

(1) The facility or office where the equipment is located;

(2) Patients' medical records, including image or scan records;

(3) Quality assurance records, including peer review documentation;

(4) Records documenting in-service training on use of the equipment;

(5) Records verifying personnel training;

(6) Equipment quality control and inspection records;

(7) Radiation safety reports;

(8) Records of referrals and evidence of appropriate use of equipment;

(9) Policies and procedures that ensure safe operation of equipment; and

(10) Qualifications of personnel:

(a) Permitted to supervise use of the major medical equipment,

(b) Permitted to operate the major medical equipment, and

(c) Responsible for maintenance of the major medical equipment.

*10.05.03.05*

**.05 Personnel.**

A. Operators of Magnetic Resonance Imager (MRI) Equipment. Operators of MRI equipment shall demonstrate competency to successfully and safely complete magnetic resonance procedures.

B. Operators of Radiation-Producing Equipment. The licensee shall ensure that operators of radiation-producing equipment are qualified in accordance with Health Occupations Article, 14-306 and 14-606, Annotated Code of Maryland.

C. Students and Graduate Technologists. This regulation does not prohibit students or graduate technologists from operating equipment, if the students or technologists are directly monitored by a supervisor.

*10.05.03.05*

*10.05.03.06*

**.06 Quality Assurance Program.**

A. A facility operating major medical equipment shall develop and implement:

(1) A quality assurance program in compliance with the guidelines outlined in COMAR 10.05.01.08; and

(2) Additional quality assurance requirements of this regulation.

B. Scope. The quality assurance program shall apply to all personnel supervising or operating major medical equipment.

C. Appropriate Use.

(1) The administrator shall develop a procedure to monitor referral and appropriate use for each procedure performed using the major medical equipment, ensuring that:

(a) Referrals are consistent with the health care practitioner's scope of practice as defined in the Health Occupations Article, Annotated Code of Maryland;

(b) The supervisor of major medical equipment is available to a referring health care practitioner to discuss appropriate use; and

(c) If the supervisor of major medical equipment questions the appropriateness of a requested procedure, the supervisor shall contact the referring health care practitioner for additional information relating to the appropriateness of using the equipment.

(2) When considering appropriate use, the supervisor of major medical equipment shall consider the patient's risks for undergoing specific testing, and the effectiveness of the particular equipment modality to aid in diagnosis.

D. The supervisor of the major medical equipment shall monitor the quality assurance program to determine the effectiveness of the delivery of services.

*10.05.03.07*

**.07 Operating Standards for Safety.**

A. A person may not operate major medical equipment unless the operator uses safety measures to protect the patient and the operator in accordance with the requirements of this chapter.

B. The administrator shall ensure that all equipment:

(1) Is manufactured according to the requirements of 21 CFR 800-----1299, which is incorporated by reference;

(2) Is appropriately labeled and includes an operating manual;

(3) Is considered safe and effective and approved for marketing by receipt of an FDA classification or a letter of approval according to 21 CFR 800-----1050.10, which is incorporated by reference; and

(4) Meets all applicable standards for equipment adopted by the Division of Radiation Control of the Department of the Environment.

C. Safe Operation of Equipment. To ensure safe operation of the equipment, the administrator shall:

(1) Develop safety and performance testing procedures;

(2) Maintain records of inspection and test results;

(3) Develop procedures for identifying equipment malfunctions;

(4) Provide instruction and training for equipment operators;

(5) Develop policies and procedures that include the following safety rules:

(a) Proper safety precautions against fire, explosion, and electrical or mechanical hazards,

(b) Guidelines for the management of patients developing emergency situations while undergoing testing, and

(c) Safety precautions for equipment that emits radiation and magnetic fields;

(6) Develop protocols and procedures to ensure that patients, operators, and individuals are not exposed to unnecessary hazards; and

(7) Ensure that operators are familiar with the most current safety procedures.

*10.05.03.08*

**.08 Medical Records.**

A. A facility operating major medical equipment shall comply with all requirements of COMAR 10.05.01.09 and the requirements of this regulation.

B. A facility operating major medical equipment shall maintain a medical record for each patient on whom a test is performed and make the information available to the Secretary on request.

C. Each patient's medical record shall include the following information:

(1) Symptoms exhibited by the patient;

(2) Suspected diagnosis before the test or procedure; and

(3) Nature of findings.