

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BUREAU OF HEALTH CARE SERVICES

FREESTANDING SURGICAL OUTPATIENT FACILITIES

(By authority conferred on the department of licensing and regulatory affairs by sections 2226(d), 2233, 20115, 20145, 20161, 20171, and 21015 of 1978 PA 368, MCL 333.2226(d), 333.2233, 333.20115, 333.20145, 333.20161, 333.20171, and 333.20155, section 9 of 1965 PA 380, MCL 16.109, and Executive Reorganization Nos. 2003-1 and 2011-4, MCL 445.2011, and 445.2030)

R 325.3801 Definitions; A.

Rule 1. As used in these rules:

(a) "Act" means 1978 PA 368, being §§333.1001 et seq.

(b) "Anesthesia" means a state of loss of feeling or sensation and is normally used to denote the loss of sensation to pain purposely induced by the use of a specific gas or drug to permit the performance of surgery or other painful procedure.

(c) "Anesthesiologist" means a physician who specializes in the field of anesthesiology and who may or may not be a diplomate of his or her specialty board.

(d) "Anesthetic" means a drug, gas, or other agent used to abolish the sensation of pain. There are 3 classifications as follows:

(i) "General anesthetic" means an anesthetic agent that produces a temporary loss of consciousness by the administration of a gas; oral, intramuscular, and intravenous drugs; or a combination of these methods.

(ii) "Local anesthetic" means a drug whose action is limited to an area of the body around the site of its application.

(iii) "Spinal," "epidural," or "caudal" anesthetic means the injection of an appropriate local type of anesthetic into the spinal canal, epidural area, to produce a local loss of sensitivity to the body areas at and below the sensory nerve distribution at the level of injection.

(e) "Anesthetist" means a person who is qualified to administer anesthetic. In common usage, the term applies to nurses and lay persons who have had special training and experience under medical auspices in the administration of anesthetics.

History: 1979 AC; 2001 AACCS.

R 325.3802 Definitions; C to S.

Rule 2. As used in these rules:

(a) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.

(b) "Department" means the department of licensing and regulatory affairs.

(c) "Director" means the director of the department.

(d) "Freestanding surgical outpatient facility" or "facility" means a facility as defined in section 20104(5) of the code, MCL 333.20104(5), and includes, but is not limited to, a facility that includes a private practice office that performs 120 or more

surgical abortions per year and that publicly advertises outpatient abortion services. Characteristics of a freestanding surgical outpatient facility include, but not limited to, patient encounters with a physician, dentist, podiatrist, or other provider primarily for the purpose of performing surgical procedures or related diagnosis, consultation, observation, and postoperative care, and the owner or operator makes the facility available to other physicians, dentists, podiatrists, or providers who comprise its professional staff.

(e) "Hospital" means a facility defined in section 20106(5) of the code.

(f) "Nurse" means an individual who is currently licensed or registered as a nurse by the state.

(g) "Physician" means a person licensed to practice medicine or osteopathy in this state.

(h) "Pregnancy termination facility" means a facility, including, but not limited to, a private practice office that performs 120 or more surgical abortions per year and that publicly advertises outpatient abortion services.

(i) "Private practice office" means an office of a physician, dentist, podiatrist, or other provider whose patients are limited to those of the individual licensed professional maintaining and operating the office or the combined patients of individually licensed professionals practicing together in a legally constituted professional corporation, association, or partnership, and sharing office space. The office is maintained and operated by the licensed professional in accordance with usual practice patterns according to the type of practice. Patient encounters in the office are for the purpose of diagnosis and treatment and are not limited primarily to the performance of surgical procedures and related care.

(j) "Publicly advertises" means to advertise using directory or internet advertising including yellow pages, white pages, banner advertising, or electronic publishing.

(k) "Surgery" means the treatment of human beings by a physician, by the use of 1 or more of the following procedures:

(i) Cutting into any part of the body by surgical scalpel, electro-cautery, or other means for diagnosis or the removal or repair of diseased or damaged tissue, organs, tumors, or foreign bodies.

(ii) Reduction of fractures or dislocations of a bone, joint, or bony structure.

(iii) Repair of malformations or body defects resulting from injury, birth defects, or other causes that require cutting and manipulation or suture.

(iv) Instrumentation of the uterine cavity, including the procedure commonly known as dilatation and curettage, for diagnostic or therapeutic purposes.

(v) Any instrumentation of or injection of any substance into the uterine cavity of a woman for the purpose of terminating a pregnancy.

(vi) Human sterilization procedures.

(vii) Endoscopic procedures.

History: 1979 AC; 2001 AACCS; 2013 AACCS.

R 325.3803 Terms defined in code

Rule 3. Terms defined in the code have the same meanings when used in these rules.

History: 2001 AACCS.

R 325.3811 Licenses; requirements; applications.

Rule 11. (1) A freestanding surgical outpatient facility shall not be established, maintained, or operated without first obtaining a license. The term "freestanding surgical outpatient facility" or other similar term shall not be used on unlicensed places.

(2) An application for a license for a facility shall be made on forms authorized and provided by the department. The application shall include the identity of the owner of the facility.

(3) An application for a license for a facility shall be made and signed by the individual desiring to establish, conduct, or maintain a licensed facility, or by the authorized representative of an individual, co-partnership, corporation, or association desiring to establish, conduct, or maintain a facility. The application shall include a statement of the intended purpose of the facility by specifying the types of surgery to be performed in it. When appropriate, the name of the facility may include a brief statement of the services provided, for example, hand surgery, general surgery, industrial surgery. The brief designation may appear under the name of the facility on an external sign of the building visible to the public if a sign is used.

(4) The owner or governing body may designate a qualified administrator of a facility, who may be the authorized representative, and delegate to the administrator the responsibility for the day-to-day operation in compliance with licensing requirements and such additional policies or regulations as the owner or governing body may adopt.

(5) An authorized representative shall be authorized to make application and amendments to the application to provide the department with all information necessary to the department's determination made in connection with issuance of the license and to enter into agreements with the department

in connection with the issuance of the license. A certificate of appointment or other written evidence of the authority vested in the authorized representative shall be attached to the application.

(6) In matters relating to licensing, the department may continue to deal with the authorized representative until notified, in writing, that a new authorized representative has been appointed with equal power, and the former authorized representative is no longer authorized to act.

(7) The department may use any appropriate means of notice and may direct notices of any administrative action pursuant to licensing of a facility to the applicant or the authorized representative either personally or by mail at the address of the facility.

History: 1979 AC; 2001 AACCS.

R 325.3812 Licenses, permits; issuance.

Rule 12. (1) If the department determines that a facility complies with the act and these rules, then the department shall issue a license.

(2) The director may issue a provisional license or temporary unrenewable permit in accord with the act and these rules.

(3) The department, upon issuing a provisional license or denying a license, shall give the applicant or the authorized representative written notice of the action and the reasons therefor.

History: 1979 AC; 2001 AACCS.

R 325.3813 Licenses; permits; transferability; notice of change; display.

Rule 13. (1) A license, provisional license, or temporary unrenewable permit is not transferable between owners or from 1 location to another.

(2) The applicant or authorized representative shall give written notice to the department within 5 business days of any change in information as submitted in the application pursuant to which a license, provisional license or temporary unrenewable permit was issued.

(3) The current license, provisional license, or temporary unrenewable permit shall be posted in a conspicuous public area of the facility.

History: 1979 AC.

R 325.3815 Construction and major alterations of physical facilities.

Rule 15. (1) The owner or governing body of a proposed freestanding surgical outpatient facility shall submit plans of the proposed facility to the department for review and approval before beginning any construction project, including modernization, addition to, or conversion of, an existing structure. The purpose of the review is to ensure that the proposed facility is designated and constructed in accordance with applicable rules.

(2) A facility shall not be constructed nor major alterations undertaken without first obtaining a construction permit from the department.

(3) A major alteration is any extensive structural alteration of an existing building area involving significant changes in the interior configurations or intended use by the moving of partitions of a number of rooms and involving an expenditure in excess of \$50,000.00. Removal of the partitions between 2 adjacent rooms to provide additional room space is not a major alteration unless all of the following occur:

(a) It costs more than \$50,000.00.

(b) Multiple changes are to be made for a changed use of an entire wing or area.

(c) Extensive plumbing and electrical wiring changes are required.

(4) The department may modify or waive 1 or more of the requirements of these rules regarding construction or equipment standards, or both, for a pregnancy termination facility if both of the following provisions apply:

(a) The freestanding surgical outpatient facility was in existence and operating on December 31, 2012.

(b) The department makes a determination that the existing construction or equipment, or both, within the facility is adequate to preserve the health and safety of the patients and employees of the facility or that the construction or equipment standards, or both, can be modified to adequately preserve the health and safety of the patients and employees of the facility without meeting the specific requirements of these rules.

History: 1979 AC; 2001 AACCS; 2013 AACCS.

R 325.3816 Compliance with other laws, codes, and ordinances.

Rule 16. A facility shall comply with applicable state laws and shall furnish such evidence as the department may require to show compliance with the applicable local laws, codes, and ordinances.

History: 1979 AC; 2001 AACCS.

R 325.3817 Rescinded.

History: 1979 AC; 2001 AACCS.

R 325.3818 Rescinded.

History: 1979 AC; 2001 AACCS.

R 325.3819 Rescinded.

History: 1979 AC; 2001 AACCS.

R 325.3820 Prohibitions

Rule 20. (1) The use of the words "state approved" or similar words is prohibited. The word "licensed" may be used by a licensed facility.

(2) The use of the word "hospital" or words having similar meaning is prohibited in reference to a facility, except to identify a facility owned and operated by a licensed hospital by including, if desired, the name of the parent hospital in the name or by a modifying phrase or a clause as a subtitle of the facility's name.

History: 1979 AC.

R 325.3822 Disaster and emergency procedures.

Rule 22. (1) A facility shall have a written plan of procedure to be followed in case of fire, explosion, or other emergency.

(2) A disaster plan shall specify persons to be notified, location of alarm signals and fire extinguishers, evacuation routes, emergency procedures for patient care, and assignment of specific tasks.

(3) Personnel shall be assigned and trained to perform specific task.

History: 1979 AC.

R 325.3825 Patient care.

Rule 25. (1) A facility shall be planned, staffed, equipped, and operated with the individual patient's welfare and safety to be of paramount concern.

(2) The feelings, sensibilities, and comfort of the patient shall be fully respected and given meticulous attention by all personnel.

(3) A person cared for in a facility shall be seen by, and be under the care of, a currently licensed physician.

History: 1979 AC.

R 325.3826 Surgical procedures; medications.

Rule 26. (1) A surgical procedure performed in a facility shall be done by a licensed physician. A licensed podiatrist or licensed dentist may also perform surgical procedures in a facility under the direction of a physician and in accord with written facility policies and procedures adopted by the governing body or owner.

(2) A qualified physician shall be present on the premises of a facility through the postoperative period of a patient's stay in the facility.

(3) Medications, diagnostic procedures, and treatments customarily given or performed by nurses or other qualified personnel shall be given only upon written order of the responsible physician, except under either of the following:

(a) In emergencies, verbal orders of the physician for medications or treatments may be carried out with subsequent notation of such care being entered in the patient's record and signed by the physician.

(b) Standing orders for specific tests and pre- and postoperative care may be established and honored when provided in writing and approved by the medical staff or physician owner or operator of the facility.

History: 1979 AC; 2001 AACS; 2013 AACS.

R 325.3827 Admission and registration.

Rule 27. (1) A person referred, or applying, for care in a facility shall be received and treated in a kindly and sympathetic manner.

(2) An applicant for care shall be registered promptly with the procurement of the identification, vital and financial information essential to the initiation of requisite medical and business records and any required departmental reports.

History: 1979 AC.

R 325.3828 Informed consents.

Rule 28. (1) Except as provided by subrule (2) of this rule, the owner or governing body shall adopt and enforce a policy which will require that informed consents will be obtained from a patient or, in case of an unemancipated minor, the responsible

relative or guardian before the performance of surgical procedures, and shall require that signed written consent forms be placed in each patient's chart.

(2) The owner or governing body of a pregnancy termination facility shall adopt and enforce a policy which will require that informed consents be obtained in compliance with section 17015 of the code, MCL 333.17015. In the case of an unemancipated minor, informed consents will also be obtained in compliance with 1990 PA 211, MCL 722.901, et seq.

History: 1979 AC; 2001 AACCS.

R 325.3831 Records.

Rule 31. (1) Medical records shall be initiated and kept on all patients receiving any type of surgical care.

(2) A facility shall maintain administrative records to include as a minimum:

(a) Records of surgical procedures performed each day. These shall be maintained in chronological sequence in a permanent bound register or logbook.

(b) Monthly statistical summary of numbers of surgical procedures performed, appropriately classified according to standard nomenclature.

(c) Narcotics register.

(d) Transfers to a hospital for post-surgical care and case outcome.

History: 1979 AC.

R 325.3832 Transportation services.

Rule 32. A facility shall have adequate transportation services immediately available, or have protocols established for accessing 911 emergency transportation services, for emergency patients requiring transfer to a hospital. A facility shall be located not more than 30 minutes normal travel time from the hospital with which written emergency admission arrangements are made. When indicated, a physician or nurse from the facility shall accompany the patient to provide emergency care en route.

History: 1979 AC; 2001 AACCS; 2013 AACCS.

R 325.3833 Counseling and referrals for subsequent care.

Rule 33. (1) When procedures having present or future social implications for a patient are performed, such as human sterilizations or pregnancy terminations, or when indicated in other situations, a facility shall make available and offer appropriate counseling, interpretation, and referral for subsequent indicated care. To accomplish this, a facility shall:

(a) Provide through physicians, qualified nurses, social workers, or specially trained and qualified counselors for appropriate assistance and counseling as needed.

(b) Maintain liaison with and make indicated referrals to community counseling, family planning, or other social and health service agencies to help assure appropriate and adequate subsequent care of the patient.

(c) Provide such counseling or assistance without coercion.

(2) Counselors, other than a responsible physician, should consult with the physician concerning results of counseling and the initiation of any referrals that seem necessary.

(3) An appropriate method for providing information to and receiving information from legitimate referral sources shall be established, including adequate mechanisms for the scheduling and fulfilling of advance appointments requested by a referral source.

History: 1979 AC.

R 325.3834 Medical supervision and administrative management.

Rule 34. (1) The medical care provided in a facility shall be under the direction of a qualified licensed physician.

(2) There shall be a designated responsible person in overall administrative charge of a facility who may be the owner, a co-owner, or person employed by the owner to fulfill this responsibility. If qualified, the person may also be the medical director who shall be responsible for the medical direction of the facility as well as for the nonprofessional administrative activities, or a suitably qualified nonmedical administrator may be employed to assume nonprofessional administrative and business management responsibility.

History: 1979 AC.

R 325.3835 Physician qualifications; records.

Rule 35. (1) A physician, podiatrist, or dentist performing surgery in a facility shall possess adequate qualifications acquired by special training and experience to evaluate the medical, podiatric or dental conditions, potential risks, recognize and adequately treat emergency complications encountered in any procedure undertaken, and perform the procedure in accordance with the usual standards of medical, podiatric, or dental practice.

(2) The facility shall maintain a record of the educational training and experience background of each person granted privileges to perform surgery in a facility.

(3) Except as provided by subrule (4) of this rule, a qualified anesthesiologist or anesthetist shall be on the staff and, when medically indicated, participate in the selection of the most appropriate anesthetic agent to be used and be present to supervise or actually administer the anesthetic when procedures are undertaken which require such participation.

(4) A pregnancy termination facility shall secure the services of an anesthesiologist or anesthetist for an abortion procedure when a patient requires unconscious sedation through the use of a general anesthetic.

History: 1979 AC; 2001 AACS.

R 325.3836 Medical policies; rules.

Rule 36. (1) In a hospital-owned and operated facility, the medical staff rules, regulations, and policies adopted by the hospital for such care shall prevail.

(2) In a nonhospital-owned and operated facility, comparable written medical staff rules, regulations, and policies shall be developed and adopted by the medical staff.

History: 1979 AC.

R 325.3837 Medical consultations.

Rule 37. Consultation and assistance in any needed medical specialty field shall be readily available and used as indicated before and, when necessary, following a surgical procedure. If there is any doubt concerning the patient's medical status, appropriate consultation shall be required and written reports of the consultants' findings and recommendations shall be entered in the patient's clinical record. A facility shall maintain a current record of the identities of consultants serving the facility.

History: 1979 AC; 2013 AACCS.

R 325.3838 Medical reviews.

Rule 38. The conduct of the work of a facility shall be regularly and frequently reviewed by the appropriate medical staff committee (tissue, medical audit or utilization, medical records) in a hospital operated facility to assure maintenance of high standards and quality of care. In other facilities, comparable arrangements acceptable to the director for impartial medical surveillance and review of the quality of care provided shall be made.

History: 1979 AC.

R 325.3839 Scrub procedures; policy.

Rule 39. A facility shall have a written policy adopted by the medical staff to provide for adequate handwashing and surgical scrub-up procedures between patient examinations when actual contact with a patient occurs and between surgical operative procedures in accord with generally accepted standards for sanitation and surgical scrub-up cleanliness.

History: 1979 AC.

R 325.3840 Nurse qualifications.

Rule 40. (1) Nursing care in a facility shall be under the direction of a currently registered professional nurse who possesses additional qualifications acquired by training and experience essential to the proper and safe conduct of the surgical

procedure undertaken and nursing care attention to the postoperative observation and needs of the patients.

(2) A registered professional nurse who possesses the special skills and experience necessary to supply or supervise all nursing care needs of patients in preparation for and during the surgical procedure and the recovery period until discharge by the responsible physician, shall be on duty.

(3) A licensed practical nurse with special training and experience, working under appropriate supervision and direction, may be used to complement the registered professional nursing staff to perform duties within the scope of his competence and restrictions of the nursing practice act.

History: 1979 AC.

R 325.3841 Ancillary personnel.

Rule 41. Ancillary personnel participating in patient care who are adequately trained and working under appropriate direction or supervision may be employed to assist within the areas of their competence in the conduct of the work of the facility.

History: 1979 AC.

R 325.3842 Supplies, equipment, and processing.

Rule 42. (1) Supplies of appropriate drugs, medications, fluids, electrolyte solutions (including plasma volume expanders), sterile linens (gowns, drapes, towels, and so forth), gloves, dressings, bandages and so forth shall be maintained in sufficient quantities for regular and emergency use. The drug storage, dispensing, and administration system shall comply fully with applicable state laws and rules.

(2) Such surgical instruments, accessory and operating room lights, and resuscitation equipment as are appropriate for the types of surgery and surgical risks which may be encountered in a facility shall be provided and maintained in clean and sterile condition.

(3) Adequate supplies of linens shall be maintained, sufficient to provide for all indicated changes after 1 use.

(4) There shall be appropriate provision for the satisfactory laundering of linens and garments.

History: 1979 AC.

R 325.3843 Beverages and nourishments.

Rule 43. Hot and cold beverages and appropriate light nourishments shall be provided and offered to patients, especially for those patients kept for observation for periods longer than the 3-hour minimum observation period specified in R 325.3868(1). These shall be stored and served in an appealing and sanitary manner.

History: 1979 AC.

R 325.3844 Housekeeping.

Rule 44. (1) The building, supplies, equipment, and furnishings shall be maintained in a clean, sanitary, safe, and usable condition.

(2) A facility shall have a housekeeping manual stating frequency and procedure for cleaning various areas in the facility. These procedures shall be followed to assure a sanitary environment.

(3) The building, equipment, fixtures, and operation shall comply with applicable local and state fire, safety, and sanitation codes.

History: 1979 AC.

R 325.3845 Laboratory services.

Rule 45. (1) Provision shall be made for the performance of indicated services by a laboratory that is licensed or exempt from licensing, and provides competent personnel and adequate equipment to make accurate determinations. Written documents of the arrangements shall be available for inspection.

(2) While laboratory services to be performed on a particular patient are matters of medical judgment, it is expected that those tests appropriate to the individual case will be performed and results recorded in the patient's clinical record. A facility shall adopt and maintain written policies specifying such minimal laboratory procedures as are required for specific types of surgical procedures.

(3) A facility shall provide for the services of a qualified pathologist to be available to it for the pathological examination and reportings of findings of all surgical specimens removed at the facility which in the judgment of the surgeon require pathological examination. Tissues not examined by a pathologist shall be described and identified in the clinical record by the operating surgeon.

History: 1979 AC.

R 325.3846 X-ray services.

Rule 46. (1) In a facility offering services which ordinarily require diagnostic x-ray examinations, appropriate arrangements shall be made to assure their availability.

(2) Depending on the volume and urgency of x-ray needs, the facility shall do 1 of the following:

(a) Arrange with a nearby radiology service operated by a qualified radiologist for the provision of the examination.

(b) Provide appropriate x-ray equipment with necessary staff within the facility. In such installations, the service shall be maintained under the direction of a physician qualified for the responsibility and shall include protection of patients and personnel from overexposure to radiation or electric shock.

(3) A report of a finding on an x-ray examination made shall be entered in the patient's record.

(4) Radiographic equipment shall be maintained in accord with existing law and rules.

History: 1979 AC.

R 325.3847 Medical records.

Rule 47. (1) Medical records shall be originated on all patients undergoing surgery, signed by the responsible physician, indexed, and so filed as to assure their ready access and future availability. The medical files shall be maintained in accordance with a written retention policy. In a hospital operated facility, the recordkeeping shall be incorporated into the hospital medical records system, including and subject to its established retention policies.

(2) Medical records shall contain, at a minimum, all of the following:

(a) Patient identification, including name, address, marital status, and birthdate.

(b) Medical history.

(c) Physical examination.

(d) Medical orders signed by the responsible physician.

(e) Laboratory findings.

(f) Special examination findings, for example, x-ray or electrocardiogram.

(g) Preoperative and final diagnosis.

(h) Nurses' notes which include a recording of vital signs, pre-and postoperatively, color, appearance, and other relevant observations with such frequency postoperatively as to document the patient's stabilized condition at time of discharge.

(i) Record of the sedation and anesthetic used by product name and dosage, identity of anesthetist if other than the surgeon, procedure, and any pertinent information concerning results or reactions.

(j) Written consultation reports signed by the consultant.

(k) Social or social service information relevant to the case.

(l) Surgeon's operative note including naming of procedure performed, physician performing surgery, anesthetic agent used, names of assistants (whether another physician, a nurse, or a specially trained technician), duration of procedure and any unusual problems or occurrences encountered, and surgeon's description of gross appearance of tissues removed.

(m) Physician's progress notes and discharge note. The physician's progress and discharge notes may be combined in the patient's clinical record.

(n) Summary of instructions given for follow-up observation and care as well as recording of all referrals for counseling, family planning, or other medical conditions requiring further attention.

(o) Identification of the physician who actually discharges the patient.

(3) Medical records shall be available for survey and review of content at any time by authorized members of the department.

(4) Medical records shall be maintained as confidential documents with the following exceptions:

(a) Information required under these rules.

(b) Information required by law.

(c) Information authorized for disclosure by written release by the patient.

(5) A facility in which pregnancy terminations are performed shall maintain records of the procedures and shall file reports and furnish statistical and such other information as may be required by the director of the department of community health. These shall be reported on forms provided by the director in accordance with definitions and notification procedures as he or she may specify. The report forms shall be signed in each instance by the physician performing the procedure. The report forms shall not require identification of the patient undergoing the procedure.

(6) Failure or refusal of a facility to file the notification of termination of pregnancy properly executed and personally signed by the responsible physician is sufficient cause for immediately beginning proceedings for revoking the license and closing the facility.

(7) Information submitted by a referral source shall become an integral part of the clinical record of the patient.

History: 1979 AC; 2013 AACCS.

R 325.3848 Medical records; storage.

Rule 48. Adequate space shall be provided for the storage of medical records so located as to assure their confidentiality and protect them from access by unauthorized persons. Additional work space in or adjacent to the medical records storage area shall be provided for the assembly, completion and review of medical records.

History: 1979 AC.

R 325.3851 Rescinded.

History: 1979 AC; 2001 AACCS.

R 325.3855 Plans and specifications.

Rule 55. (1) A floor plan of the facility with a description of rooms showing size, door locations, and fixed equipment shall be on file in the facility and at the department.

(2) Complete plans and specifications for new buildings, additions, major building changes, and conversion of existing facilities for use as a facility shall be submitted to the department for review and approval.

(3) Plans and specifications meeting the requirements of the law and these rules shall be approved by the department and a permit for construction issued.

(4) Construction of new buildings, additions, major building changes, and conversion of existing structures for use as a facility shall not begin until the plans and specifications have been approved by the department and a permit for construction issued.

(5) As provided by R 325.3868a, the department may waive a specific requirement of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2013 AACCS.

R 325.3856 Exterior.

Rule 56. (1) The premises of a facility shall be maintained in a safe and sanitary condition and in a manner consistent with the public health and welfare.

(2) At least 1 entrance to a facility shall provide safe and easy access for the physically handicapped.

(3) Exterior ramps and steps shall have a handrail on both sides.

(4) Sufficient light for an exterior ramp or steps shall be provided for the safety of persons using the facility.

(5) As provided by R 325.3868a, the department may waive a specific requirement of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2013 AACCS.

R 325.3857 Interior construction.

Rule 57. (1) A building shall be of safe construction and shall be free from hazards to patients, personnel, or visitors.

(2) Each area of a facility shall be provided with lighting adequate for the use to be made of the location and in compliance with generally recognized lighting standards.

(3) Each area of a facility shall be provided with a type and amount of ventilation commensurate with its use, to minimize the occurrence of transmissible disease, control odors, and contribute to the comfort of patients and personnel.

(4) Corridors, hallways, passageways, and doorways shall be kept free from obstruction at all times.

(5) Floors, walls, and ceilings shall be covered and finished in a manner that permits maintenance of a sanitary environment.

(6) Emergency electrical service shall be permanently installed in the facility to provide lighting in corridors, exits, procedure rooms, recovery rooms, congregate rooms, nurse stations, and other critical areas. In new construction or renovations, an emergency generator that has an automatic transfer switch or an alternative source of immediate electrical power acceptable to the department shall be provided for lighting and operation of equipment necessary to patient care.

(7) Patient examination, procedure, and recovery rooms shall have a minimum door width of 3 feet.

History: 1979 AC; 2001 AACCS; 2013 AACCS.

R 325.3858 Elevators.

Rule 58. (1) An elevator shall be provided where patient care is provided at different floor levels. The cab size of the elevator shall be sufficient to accommodate a stretcher and attendant.

(2) As provided by R 325.3868a, the department may waive a specific requirement of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2013 AACCS.

R 325.3859 Public and personnel areas.

Rule 59. (1) Space shall be provided for adequate reception, waiting, interviewing, administrative, and business office functions.

(2) Space provided for admission, interviewing and consultation functions shall be so located as to provide privacy. This shall include adequate office space and furnishings for the social worker if one is employed by a facility and for counselors and outside agency workers, when indicated, to interview and advise patients in reasonable privacy.

(3) One or more rooms equipped with toilet and lavatory facilities shall be provided near the waiting and reception areas.

(4) Locker room space or other security resources shall be provided for employee's personal effects.

(5) In new construction or renovations, an approved type public drinking fountain shall be provided.

History: 1979 AC.

R 325.3860 Communications.

Rule 60. Adequate telephone communication and a nurse call system shall be provided for patient and staff use appropriate for the size of a facility and scope of services rendered.

History: 1979 AC.

R 325.3866 Clinical facilities.

Rule 66. (1) A facility shall have enough examination rooms to meet the volume of work to be accomplished, and each room shall provide a minimum of 70 square feet of usable floor space. In new construction or renovations, 80 square feet of usable floor space shall be provided.

(2) An examining room shall have a handwash lavatory within the room, which shall be equipped with a gooseneck inlet and wrist, knee, or foot controls.

(3) A change area shall be provided for patients and provision shall be made for the safe storage of their personal effects.

(4) A facility shall have enough operating or procedure rooms to meet the volume of work to be accomplished, and each room shall provide a minimum of 120 square feet of usable floor space. In new construction, 150 square feet of usable floor space shall be provided.

(5) Explosive anesthetic agents shall not be used in the rooms.

(6) A supply of oxygen and appropriate masks or other means of administration shall be available in each room.

(7) A room shall be designed to permit the transfer of a patient from the table to a stretcher and to permit sufficient clearance on either side and at the foot of the table with necessary equipment and supplies in place.

(8) A nurse call signal shall be provided from the procedure and examining room to a central control station.

(9) A scrub sink that has a gooseneck outlet shall be available in or adjacent to the procedure rooms.

(10) Single-use soap, scrub brushes, and towels shall be utilized in patient care areas.

(11) The room shall contain a suitable operating table and other equipment necessary for the types of procedures to be performed.

(12) Space for and sterilization equipment shall be provided to process all medical supplies that require sterilization between uses. Equipment shall be capable of accommodating the work load of the facility, and controls acceptable to the director shall be used to check effectiveness and assure sterilization.

(13) As provided by R 325.3868a, the department may waive a specific requirement of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2001 AACS.

R 325.3867 Medication and storage areas.

Rule 67. (1) A facility shall have enough medication work and storage areas to meet the volume of work to be accomplished.

(2) A shelf or desk shall be provided for the nurse's use in preparing and administering medications and recording information in patients' records and shall be within and readily accessible to all patient care areas for which that nursing station has responsibility.

(3) A medication storage and preparation area equipped with a sink that has a gooseneck inlet and hot and cold water and locked storage for medications shall be provided. This includes adequate space for the storage of medications, fluids, and electrolyte solutions in a safe and sanitary manner.

(4) Space shall be available for the storage of clean linens, equipment, supplies, wheelchairs and stretchers.

(5) A soiled utility room shall be available for temporarily holding waste materials and cleaning of items to be reused.

(6) A janitor's closet that has a service sink shall be available.

(7) As provided by R 325.3868a, the department may waive subrule (5) of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2001 AACS; 2013 AACS.

R 325.3868 Patient observation and recovery areas.

Rule 68. (1) Patient observation and recovery areas shall be provided in sufficient numbers to accommodate the patient load with a planned minimum of a 3-hour recovery period and longer when necessary for individual patients. The areas shall be comfortably

furnished and adequately equipped for the patient's safe postoperative observation and recovery.

(2) A facility shall provide at least 1 recovery room equipped for use by and observation of patients requiring recumbent care post-surgically. A minimum of 1 hospital-type bed or wheeled recovery room stretcher shall be provided for each 10 post-surgical patients to be cared for at any one time.

(3) Single bed/stretcher recovery rooms shall provide a minimum of 100 square feet of usable floor space.

(4) Multiple bed/stretcher recovery rooms shall provide a minimum of 80 square feet of floor space per bed or stretcher.

(5) A recovery room shall be designed to provide a minimum of 3 feet between beds or stretchers and 4 feet of clearance at the foot of the bed or stretcher.

(6) Comfortably furnished congregate rooms equipped with either reclining or lounge-type chairs or cots may be provided for the post-surgical observation of patients not needing bed or stretcher accommodations. Each congregate-type room shall provide a minimum of 50 square feet of usable floor space for each patient to be accommodated. A congregate room shall not contain accommodations for more than 12 patients.

(7) A toilet and lavatory shall be provided for each 6 recovery patients at a minimum. One or more bathing facilities are recommended.

(8) Corridors used for patient entry, egress, and surgical care areas in a facility shall have a minimum width of 6 feet.

(9) As provided by R 325.3868a, the department may waive a specific requirement of this rule as applied to a pregnancy termination facility.

History: 1979 AC; 2001 AACCS.

R 325.3868a Waiver of certain requirements.

Rule 68a. (1) In accordance with section 20115(4) of the code, MCL 333.20115(4), and pursuant to R 325.3815(4), the department may waive a specific requirement of R 325.3855, R 325.3856, R 325.3858, R 325.3866, R 325.3867(5), or R 325.3868 as applied to a pregnancy termination facility if it reasonably determines the facility construction, size, and equipment of a room, area, or equipment utilized for purposes of medication preparation or storage, sanitary storage, or facility maintenance are adequate to protect the health and safety of the patients and employees of the facility, or that the construction, equipment or maintenance standards can be modified to adequately preserve the health and safety of the patients and employees of the facility without meeting the specific requirements of these rules.

(2) A pregnancy termination facility shall submit a request for variance in writing at the time of application for a license.

(3) The decision of the department, including any qualification under which the variance is granted, shall be sent to the pregnancy termination facility and placed in the facility record.

(4) The variance may remain in effect for as long as the pregnancy termination facility continues to comply with the conditions of the variance or may be time-limited.

History: 2001 AACCS; 2013 AACCS.

R 325.3869 Capacities.

Rule 69. The numerical capacity of a facility shall be determined by the number of observation and recovery units provided. The post-surgical occupancy of a facility shall not exceed the determined capacity.

History: 1979 AC.

R 325.3871 Heating and electrical systems.

Rule 71. (1) A safe heating system shall be provided.

(2) A room used for patient care shall be maintained at a temperature of at least 70 degrees Fahrenheit with a maximum temperature of 78 degrees Fahrenheit as measured 3 feet above floor level.

(3) Duplex electrical outlets with a 3-wire system shall be provided in sufficient numbers to meet the needs of the areas served.

(4) Electrical equipment shall be maintained in good repair and properly grounded.

History: 1979 AC.

R 325.3872 Water supply system.

Rule 72. (1) A facility located in an area served by a public water system shall connect to and use that system.

(2) When a public water system is not available, the location and construction of a well and the operation of a private water system shall comply with the department rules "Minimum Standards for the Location and Construction of Certain Water Supplies," being R 325.1451 to R 325.1461 of the Michigan Administrative Code.

(3) There shall be no cross-connections between water systems that are safe for human consumption and those that are, or may become, unsafe for human consumption.

(4) Minimum water pressure available to each plumbing fixture shall exceed 20 pounds per square inch.

(5) The plumbing system shall supply an adequate amount of hot water at all times to meet the needs of each patient and the functioning of the various service areas.

(6) Hot water temperatures at fixture outlets shall be regulated to provide tempered water in range of 110 to 125 degrees Fahrenheit.

History: 1979 AC.

R 325.3873 Liquid wastes.

Rule 73. (1) Liquid wastes shall be discharged into a public sanitary sewage system when such a system is available.

(2) When a public sanitary sewage system is not available and a private liquid waste disposal system is used, the type, size, construction and alteration of, or major repairs to, the system shall be approved by the department.

(3) The liquid waste disposal system shall be maintained in a sanitary manner.

History: 1979 AC.

R 325.3874 Solid wastes.

Rule 74. (1) The collection, storage, and disposal of solid wastes, including garbage, refuse, and dressings, shall be accomplished in a safe and sanitary manner to minimize the danger of disease transmission and avoid creating a public nuisance or a breeding place for insects and rodents.

(2) Suitable containers for garbage, refuse, dressings, and other solid wastes shall be provided, emptied at frequent intervals, and maintained in a clean and sanitary condition.

(3) A facility shall have and enforce a written policy to govern storage, transportation, and disposal of surgical specimens. Surgical specimens not sent to a pathology laboratory shall be disposed of in a medically acceptable manner.

History: 1979 AC; 2013 AACCS.

R 325.3877 Miscellaneous storage.

Rule 77. (1) Hazardous and toxic materials shall be stored in a safe manner.

(2) A central general storage room shall be provided with space necessary to meet storage needs of the facility.

History: 1979 AC.