

**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS**

**BUREAU OF COMMUNITY AND HEALTH SYSTEMS**

**LICENSING HEALTH FACILITIES OR AGENCIES**

(By authority conferred on the department of licensing and regulatory affairs by sections 20115, 20131, 20132, 20141, 20171, 21419, 21521, 21523, 21561, 21562, 21563, 21615, 21741, and 21795 of the public health code, 1978 PA 368, MCL 333.20115, 333.20131, 333.20132, 333.20141, 333.20171, 333.21419, 333.21521, 333.21523, 333.21561, 333.21562, 333.21563, 333.21615, 333.21741, and 333.21795, and Executive Reorganization Order Nos. 1994-1, 1996-1, 1997-4, 2003-1, 2009-20, 2011-4 and 2015-1, MCL 333.26322, 330.3101, 333.26324, 445.2011, 333.26366, 445.2030 and 400.227)

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## PART 1: GENERAL PROVISIONS

### **R 325.45101 Applicability.**

Rule 101. (1) Rules 325.45103 to 325.45323 are applicable to all of the following:

- (a) Freestanding surgical outpatient facility.
- (b) Hospice.
- (c) Hospital.
- (d) Nursing care facility.

(2) Rules 325.45331 to 325.45343 are only applicable to a freestanding surgical outpatient facility.

(3) Rules 325.45345 to 325.45367 are only applicable to a hospice.

(4) Rules 325.45369 to 325.45375 are only applicable to a hospital.

(5) Rules 325.45377 to 325.45385 are only applicable to a nursing care facility.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45102 Application; rules; standards of care.**

Rule 102. The application of these rules, R 325.45101 to R 325.45385, by a health facility or agency and by the department shall be done in accordance with the services offered by the health facility or agency and relevant standards of care.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45103 Definitions; A to F.**

Rule 103. (1) As used in these rules:

(a) “Anesthesia” means a state of loss of feeling or sensation and is normally used to denote the loss of sensation to pain that is purposely induced using a specific gas or drug to permit the performance of surgery or other painful procedure.

(b) “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.

(c) “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, or 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 a local anesthetic into the spinal canal epidural area to produce a loss of sensitivity to the body areas at and below the sensory nerve distribution at the level of the injection.

(d) “Anesthetist” means a person who is qualified to administer anesthetic.

(e) “Applicant” means a person applying to the department for a health facility or agency license.

(f) “Article 15” means article 15 of the code, MCL 333.16101 to 333.18838.

(g) “Article 17” means article 17 of the code, MCL 333.20101 to 333.22260.

(h) “Attending physician” means that term as defined in section 20102(4) of the code, MCL 333.20102.

(i) “Authorized representative” means that term as defined in section 20102(5) of the code, MCL 333.20102.

(j) “Bereavement services” means emotional, psychosocial, or spiritual support services provided to the family before or after the death of the patient to assist the family in coping with issues related to grief, loss, or adjustment.

(k) “Building change” means alterations to an existing building involving a change in the interior configuration or intended use, including alterations to the mechanical, electrical, or plumbing systems. This term does not include routine maintenance or replacement with comparable mechanical, electrical, or plumbing equipment that does not alter the current physical structure.

(l) “Business day” means a day other than a Saturday, Sunday, or any legal holiday.

(m) “Change of ownership” means the transfer of a health facility or agency from 1 owner to another if the licensee changes. This term does not include a transfer of a health facility or agency from 1 owner to another if the licensee does not change.

(n) “Code” means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(o) “Complainant” means an individual who files a complaint with the department alleging that a person has violated the code, an order issued under the code, or administrative rules promulgated thereunder.

(p) “Correction notice” means a notice from the department to a health facility or agency specifying violations of the code or these rules, corrective action to be taken, and the period in which the corrective action is to be completed.

(q) “County medical care facility” means that term as defined in section 20104 of the code, MCL 333.20104.

(r) “Department” means the department of licensing and regulatory affairs.

(s) “Discharge” means that term as defined in section 21702(1) of the code, MCL 333.21702. In addition, as used in these rules, “discharge” means the voluntary or involuntary movement of a patient out of any type of health facility or agency.

(t) “Freestanding surgical outpatient facility” or “FSOF” means a facility as defined in section 20104(7) of the code, MCL 333.20104, and includes, but is not limited to, a private practice office that performs 120 or more surgical abortions per year and publicly advertises outpatient abortion services. Characteristics of a freestanding surgical outpatient facility include, but are not limited to, patient encounters with a physician, dentist, podiatrist, or other provider primarily for performing surgical procedures or related diagnosis, consultation, observation, and postoperative care, and the owner or operator may make the facility available to other physicians, dentists, podiatrists, or other providers who comprise its professional staff. This term does not include a private office of a physician, dentist, podiatrist, or other health professional 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, if the private office is maintained and operated by a licensed health professional in accordance with usual practice patterns according to the type of practice and patient encounters in the office are for diagnosis and treatment and are not limited primarily to the performance of surgical procedures and related care.

(2) Unless otherwise specified, a term defined in the code has the same meaning when used in these rules.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45105 Definitions; G to L.**

Rule 105. As used in these rules:

(a) “Governing body” means the person or persons who are legally responsible for the conduct of the health facility or agency, such as a board of directors or trustees. In the absence of an organized governing body, the owner, operator, or administrator shall carry out the functions of the governing body.

(b) “Health facility or agency” means that term as defined in section 20106(1) of the code, MCL 333.20106, with the following exceptions:

(i) An ambulance operation, aircraft transport operation, nontransport prehospital life support operation, or medical first response service.

(ii) A health maintenance organization.

(iii) A home for the aged.

(c) “Hospice” means that term as defined in section 20106(4) of the code, MCL 333.20106

(d) “Hospice administrator” means a person who is responsible to the hospice governing body, either directly or through the governing body’s chief executive officer, for the administrative operation of a hospice.

(e) “Hospice interdisciplinary care team” means a group composed of, at a minimum, a doctor of medicine or osteopathy, a registered professional nurse, a social worker, and a pastoral or other counselor. One hospice staff member may represent more than 1 of the required disciplines on the hospice interdisciplinary care team for which the individual is qualified to practice and is licensed, if required.

(f) “Hospice patient” means an individual in the terminal stage of an illness who has an anticipated life expectancy of 6 months or less and who has voluntarily requested admission and been accepted into a hospice.

(g) “Hospice residence” means that term as defined in section 21401(1)(b) of the code, MCL 333.21401.

(h) “Hospice staff” means the individuals who work for the hospice, including volunteers.

(i) “Hospital” means that term as defined in section 20106(5) of the code, MCL 333.20106.

(j) “Hospital long-term care unit” means that term as defined in section 20106(6) of the code, MCL 333.20106.

(k) “Involuntary transfer” means that term as defined in section 21702(3) of the code, MCL 333.21702.

(l) “License” means that term as defined in section 20108(2) of the code, MCL 333.20108.

(m) “License record” means any of the following documents:

(i) An application for a license.

(ii) A copy of a license.

(iii) Copies of reports of surveys and investigations made by or for the department.

(iv) Responses of an applicant or licensee to the department.

(v) Memoranda or other written communications with a licensee pertaining to the granting or denial of a license.

(n) “Licensed bed capacity” means the authorized and licensed bed complement of a health facility as shown on or included within its license.

(o) “Licensed practical nurse” means an individual who is licensed to practice nursing as a licensed practical nurse pursuant to part 172 of the code, MCL 333.17201 to MCL 333.17242.

(p) “Licensee” means that term as defined in section 20108(3) of the code, MCL 333.20108.

(q) “Long-term acute care hospital” means a specialty care hospital designed for patients with serious medical conditions that require intensive, special treatment for an extended period.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45107 Definitions; M to R.**

Rule 107. As used in these rules:

(a) “Nursing care facility” means any of the following types of health facilities:

- (i) County medical care facility.
- (ii) Hospital long-term care unit.
- (iii) Nursing home.

(b) “Nursing home” means that term as defined in section 20109(1) of the code, MCL 333.20109.

(c) “Nurse practitioner” means a registered professional nurse who has been granted a specialty certification in the health profession specialty field of nurse practitioner under section 17210(1)(c) of the code, MCL 333.17210.

(d) “Ownership” means the ownership or control of 5% or more of the equity in the capital of, or stock in, or interest in the profits of a health facility or agency.

(e) “Patient” means that term as defined in section 21703(1) of the code, MCL 333.21703. In addition, “patient” means an individual who receives services from any type of health facility or agency.

(f) “Patient and family unit” means a hospice patient and his or her relatives or other individuals with significant personal ties to the patient, who are designated by the hospice patient and the relative or individual by agreement.

(g) “Patient room” means a room containing licensed patient beds. Patient room does not include rooms used for observation or preoperative or postoperative care.

(h) “Patient’s representative” means that term as defined in section 21703(2) of the code, MCL 333.21703.

(i) “Physician” means an individual licensed to engage in the practice of medicine or the practice of osteopathic medicine and surgery under part 170 or 175 of the code, MCL 333.17001 to 333.17084 and 333.17501 to 333.17556. For a freestanding surgical outpatient facility, an individual licensed to engage in the practice of dentistry or podiatric medicine and surgery under part 166 or 180 of the code, MCL 333.16601 to 333.16659 and 333.18001 to 333.18058, when acting within his or her scope of practice, may carry-out the duties and responsibilities assigned to a physician in these rules.

(j) “Physician’s assistant” means an individual licensed to engage in practice as a physician’s assistant under part 170 of the code, MCL 333.17001 to 333.17084.

(k) “Registered professional nurse” means an individual who is licensed to practice nursing pursuant to part 172 of the code, MCL 333.17201 to 333.17242.

(l) “Resident” means that term as defined in section 21703(4) of the code, MCL 333.21703. In addition, “resident” means an individual who resides in a residential health care facility.

(m) “Residential health care facility” means a category of facilities in which long term health services are provided, including but not limited to a nursing care facility or hospice residence.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45109 Definitions; S to Z.**

Rule 109. As used in these rules:

(a) “Supervision” means that term as defined in section 16109 of the code, MCL 333.16109.

(b) “Surgery” means the treatment of human beings by a physician in an operating room, procedure room, examination room, or other setting as determined by the physician to safely perform 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; the removal or repair of diseased or damaged tissue, organs, tumors, or foreign bodies; or a Caesarean section.

(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 terminating a pregnancy.

(vi) Human sterilization procedures.

(vii) Endoscopic procedures.

(c) “Transfer” means that term as defined in section 21703(5) of the code, MCL 333.21703. In addition, “transfer” means the movement of a patient from one health facility or agency to another health facility or agency.

History: 2020 MR 4, Eff. Feb. 21. 2020.

## **PART 2: LICENSING**

### **R 325.45111 Application; application review process; licensure.**

Rule 111. (1) As authorized in article 17, an application for initial licensure or licensure change, including change in ownership, bed capacity, bed designation, location, and business name, must be made on the most recent applicable form authorized and provided by the department.

(2) An application is not deemed complete by the department until all of the following are received:

(a) Completed application form and required attachments.

(b) Application or licensing fee as applicable.

(c) Applicable certificate of need approval.

(d) Applicable occupancy transmittal for the physical space.

(3) The department shall conduct a pre-licensure survey within 3 months of an application for initiation being deemed complete.

(4) Upon determination of compliance with article 17 and these rules, the department shall issue a license that identifies all of the following:

- (a) Name of the licensee person or entity.
- (b) Business name of the health facility or agency.
- (c) Physical address of the health facility or agency.
- (d) Type of health facility or agency.
- (e) Licensed bed capacity, if applicable.

(5) The licensee shall post the license in a conspicuous public area of the health facility or agency.

(6) Before a license may be transferred to a different owner through a change of ownership application, or transferred from one physical location to another physical location through an application to relocate the health facility or agency, the application must be approved by the department and the department shall issue a new license.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45113 License renewal process.**

Rule 113. (1) The renewal of a license must be completed through an electronic web-based system authorized and provided by the department.

(2) A license is renewed and valid only upon electronic payment of the applicable renewal fee.

(3) A license must be renewed before August 1 of each calendar year, unless otherwise specified on the license.

(4) The department may require changes or corrections to a license prior to renewal.

(5) If a license is not renewed within 30 days after the expiration date, the department may take any enforcement action authorized by section 20165 of the code, MCL 333.20165.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45115 Survey and evaluation process.**

Rule 115. (1) A pre-licensure survey must be scheduled and announced. All other licensure surveys and complaint investigations must be unannounced.

(2) A licensure survey or complaint investigation may be conducted by the department during any hours of operation of the licensed health facility or agency.

(3) An applicant or licensee shall provide access to the health facility or agency and relevant documents that are required to be maintained for the department to evaluate compliance with the code and these rules.

(4) A department employee shall obtain the verbal consent of the patient or the patient's representative before observing direct care and treatment of a patient.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45117 Waiver from licensure survey.**



Rule 117. (1) The department shall provide and make publicly available a procedure for when a licensee may be eligible for a waiver from licensure survey. The procedure will include maintaining a list of approved accrediting bodies for health facilities or agencies.

(2) On or before October 1 of each year, the department shall publish a list of health facilities and agencies to be visited for a state licensure survey in the next calendar year.

(3) Providers who maintain accreditation from an approved accrediting agency may request a waiver from state licensure survey. Eligible licensees may request a waiver on or before November 1 of each year. A waiver request must be submitted on a form authorized by the department.

(4) On or before January 1 of the survey year, the department will provide in writing an approval or denial of the waiver to the licensee.

(5) Denial of a waiver request is not subject to an appeal and will result in an unannounced onsite state licensure survey and evaluation during the survey year.

(6) An approved waiver does not prohibit the department from conducting an onsite state licensure survey and evaluation at any point in the future to protect the health, safety, and welfare of individuals receiving care and services in or from a health facility or agency.

History: 2020 MR 4, Eff. Feb. 21, 2020.

#### **Rule 325.45119 Licensed bed capacity.**

Rule 119 (1) A licensee shall maintain the approved physical space to support the number of beds listed on the license in compliance with article 17 and these rules.

(2) If a patient room is being utilized for another purpose, the department may reduce the licensee's bed capacity if the licensee cannot demonstrate compliance with subrule (1) of this rule within 48 hours, unless the licensee has an approved building program agreement with the department in accordance with section 20144 of the code, MCL 333.20144.

### **PART 3: ADMINISTRATION**

#### **SUBPART A: OWNERSHIP, GOVERNANCE, AND COMPLIANCE**

#### **R 325.45121 Ownership.**

Rule 121. Ownership, whether by the individual desiring to establish, conduct, or maintain a licensed health facility or agency, or by the authorized representative of an individual, co-partnership, corporation, or association desiring to establish, conduct, or maintain a health facility or agency, must be disclosed to the department upon initial licensure application.

History: 2020 MR 4, Eff. Feb. 21, 2020.

#### **R 325.45123 Governing body.**

Rule 123. (1) A licensee shall have an organized governing body that assumes responsibility for the management of the health facility or agency, the provision of all services, its fiscal operations, and continuous quality assessment and performance improvements.

(2) The governing body is responsible for ensuring the establishment of policies and procedures for the management, operation, and evaluation of the health facility or agency. The governing body shall ensure that these policies and procedures are reviewed at least every 3 years and revised as appropriate. Dates of reviews and revisions must be a matter of record in the health facility or agency.

(3) The governing body shall meet according to its bylaws, but at least once a year, to carry out its obligations and shall keep a written record of its actions.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45125 Compliance; local; state; federal; law; rule; regulation; standard.**

Rule 125. (1) The applicant or licensee shall comply with applicable local, state, and federal laws, rules, regulations, and standards.

(2) During review of an application or a licensure survey or complaint investigation, the department may request from the health facility or agency documentation of noncompliance from local, state, or federal authorities if such documentation exists.

(3) The department may only cite this rule if the local, state, or federal authority that has jurisdiction over the specific law, rule, regulation, or standard has found the applicant or licensee to be non-compliant, in writing, and there is a need to protect the health, safety, and welfare of individuals receiving care and services in or from the health facility or agency.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45127 Fiscal audit.**

Rule 127. (1) The department may request financial documents including all of the following:

- (a) Invoices.
- (b) Purchase orders.
- (c) Order confirmations.
- (d) Receipts.
- (e) Other non-proprietary financial documents maintained in the normal course of business and that demonstrate the provision of care and services.

(2) A request for financial documents in subrule (1) of this rule must be made only when the department requires these documents to evaluate the delivery of care and services in limited circumstances for state licensing purposes including bankruptcies or a state licensing survey that has clearly identified a lack of resources to support the care and services offered.

(3) The department shall notify an applicant or licensee of information relied upon in issuing a decision. If the department relies on information other than that submitted by the applicant or licensee, the department shall cite the information it relied upon in its decision.

(4) This rule does not limit the department's authority to consider other relevant financial information from other governmental entities. However, the department shall have a duty to maintain the confidentiality of this information.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## SUBPART B: POLICIES AND PROCEDURES

### **R 325.45129 Admission; policy; procedure.**

Rule 129. (1) A health facility or agency shall have a written admission policy and procedure that is provided to the patient or any other person or agency responsible for the patient upon request.

(2) An admitting diagnosis must be recorded promptly on each patient.

(3) At the time of admission of a patient, a physician must be designated to be responsible for the medical care of the patient. This designation may be transferred to another physician who accepts responsibility for the medical care of the patient in accordance with the health facility or agency's policy and procedures.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45131 Discharge; transfer; policy; procedure; planning.**

Rule 131. (1) A health facility or agency shall have a written discharge policy and procedure that is provided to the patient or any other person or agency responsible for the patient upon request.

(2) A health facility or agency shall have a written transfer policy and procedure that is provided to the patient or any other person or agency responsible for the patient upon request.

(3) In addition to subrule (2) of this rule, a nursing care facility shall have a written involuntary transfer policy and procedure in compliance with R 325.45385.

(4) Discharge or transfer planning must be provided for each patient in conjunction with patient care planning.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## SUBPART C: INFECTION PREVENTION AND CONTROL

### **R 325.45133 Infection prevention and control program.**

R 133. An applicant or licensee shall have an infection prevention and control program and allocate resources to provide all of the following:

(a) A qualified health care professional must be designated in writing to be responsible for the program. The designee shall have completed training in the principles and methods of infection control and maintain qualification through ongoing education and training. Ongoing education and training may be demonstrated by any one of the following:

(i) Certification in infection control (CIC).

(ii) Certification as an ambulatory infection preventionist (CAIP).

(iii) Completion of an infection control course.

(iv) Participation in meetings that include infection control and are organized by recognized professional societies or other associations applicable to the services offered by the health facility or agency.

(b) A designated, multi-disciplinary infection control team to collect, analyze, and report data.

- (c) Authority and procedures to conduct outbreak investigations.
- (d) Implementation of basic measures for infection prevention.
- (e) Prioritize infection control program needs and design infection control program initiatives accordingly.
- (f) Ongoing evaluation and revision of the infection prevention and control program.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45135 Infection prevention and control policies and procedures.**

Rule 135. (1) An applicant or licensee shall maintain written, evidence-based infection prevention and control policies and procedures that are appropriate for the services offered. These policies and procedures must be available in electronic or written format. These policies and procedures must represent the complexity of the healthcare provided and the characteristics of the patient population served.

(2) The policies and procedures for standard precautions must include, but are not limited to, all of the following:

- (a) Hand hygiene.
- (b) Use of personal protective equipment.
- (c) Respiratory hygiene and cough etiquette.
- (d) Safe injection practices.
- (e) Safe handling of potentially contaminated equipment or surfaces in the patient environment, which for hospice agencies includes a private residence.

(3) The policies and procedures for transmission-based precautions must include, but are not limited to, all of the following:

- (a) Contact precautions.
- (b) Droplet precautions.
- (c) Airborne precautions.
- (d) Multi-route transmission-based precautions.

(4) The policies and procedures for a sanitary and functional environment must include, but are not limited to, all of the following:

- (a) Cleaning and disinfecting environmental surfaces, floors, and furniture.
- (b) Cleaning and disinfecting objects that are shared by patients, staff, and visitors.
- (c) Disposal of regulated and non-regulated medical and non-medical waste.
- (d) Screening for and management of patients infested with ectoparasites.
- (e) With the exception of a hospice patient's private residence, single use disposable hand towels must be used for hand hygiene. The use of a common-use hand towel is prohibited.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45137 Ongoing surveillance and prevention program; communicable disease reporting.**

Rule 137. The applicant or licensee shall provide and maintain an ongoing surveillance and prevention program that includes, but is not limited to, all of the following:

- (a) An active surveillance program for infection detection through ongoing data collection and analysis that includes patients and personnel who have access to or contact with active

patient care areas, and other individuals identified by the health facility or agency policies and procedures.

(b) Communicable disease reporting in compliance with section 5111 of the code, MCL 333.5111, and the communicable and related diseases rules, R 325.171 to R 325.199.

(c) An ongoing program to prevent, control, and investigate healthcare associated infections.

(d) Implementation of healthcare associated infections risk mitigation including, but not limited to, all of the following:

(i) Monitoring personnel hand hygiene.

(ii) Monitoring infections caused by organisms that are multidrug-resistant.

(iii) Monitoring device-associated infections.

(iv) Monitoring antibiotic use.

(v) Monitoring safe practices for injecting medication, saline, or other infusates.

(vi) Monitoring use of disinfectants and germicides in accordance with manufacturers' instructions.

(vii) Monitoring use of medical equipment, including air filtration equipment, ultra-violet lights, and other equipment used to control the spread of infectious agents in accordance with manufacturers' recommendations.

(viii) Monitoring sterilization and disinfection practices and reporting failures.

(ix) Monitoring cleaning procedures used in patient care areas.

(x) Monitoring surgical services in accordance with standards of care for all of the following:

(A) Appropriate use of antibiotic prophylaxis to prevent surgical site infection, such as protocol to assure that antibiotic prophylaxis to prevent surgical site infection for procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery.

(B) Aseptic technique practices are used in surgery, including sterilization or high-level disinfection of instruments, as appropriate.

(C) Skin antisepsis methods.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45139 Personnel; communicable disease screening; immunization; mitigation.**

Rule 139. (1) An applicant or licensee shall adopt written policies and procedures to ensure that all of the following communicable disease prevention measures are implemented:

(a) Evaluation of the immunization status of personnel for vaccine preventable diseases as designated in the "Healthcare Personnel Vaccination Recommendations," 2017 edition, published by the Immunization Action Coalition (IAC). These recommendations are adopted by reference and are available for inspection and distribution at cost at the Lansing office of the Department of Licensing and Regulatory Affairs. They are available free of charge at the Immunization Action Coalition, 2550 University Avenue West, Suite 415 North, Saint Paul, MN 55114 or <http://www.immunize.org/catg.d/p2017.pdf>.

(b) Identification of the authority and circumstances under which the licensee screens personnel for infections likely to cause spread of communicable disease or other risks to exposed patients and personnel.

(c) Identification of the authority and circumstances under which the licensee restricts personnel who are infectious from providing direct patient care or from entry into the health

facility or agency, as recommended by the Centers for Disease Prevention and Control (CDC) in its “Guideline for Infection Control in Health Care Personnel 1998,” published in the American Journal of Infection Control, v. 23, no. 3, p. 289-354. This guideline is adopted by reference and is available for inspection and distribution at cost at the Lansing office of the Department of Licensing and Regulatory Affairs. It is available free of charge at <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/index.html>.

(2) A licensee shall screen employees upon hire for communicable disease, including tuberculosis (TB).

(3) A licensee shall follow the “CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005,” published in MMWR 2005; 54 (No. RR-17); and, the 2019 update to these recommendations by Sosa LE, Njie GJ, Lobato MN, et al. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. MMWR Morb Mortal Wkly Rep 2019;68439-443. DOI: <http://dx.doi.org/10.15585/mmwr.mm681913>. These guidelines are adopted by reference. They are available for inspection at the Lansing office of the Department of Licensing and Regulatory Affairs. They are available free of charge at <https://www.cdc.gov/tb/education/professionaltools.htm>.

History: 2020 MR 4, Eff. Feb. 21. 2020.

#### **R 325.45141 Infection control education and training.**

Rule 141. (1) The licensee shall maintain an ongoing program of education and training on methods to prevent or reduce the transmission of infectious agents for all personnel upon hire and at ongoing intervals as applicable, including employees, onsite contract workers, medical providers, students, medical residents, and volunteers.

(2) The licensee shall document compliance with initial and ongoing training for personnel in methods of infection prevention and control.

(3) The licensee shall make available information to patients and visitors on methods to prevent or reduce the transmission of infectious agents within the health facility or agency.

History: 2020 MR 4, Eff. Feb. 21. 2020.

#### **R 325.45143 Infection prevention and control program; quality assurance and performance improvement.**

Rule 143. (1) The applicant or licensee shall document how its infection prevention and control program is integrated into its quality assurance and performance improvement program. Documentation must include, but is not limited to, both of the following:

(a) Actions taken in response to data analysis to improve infection control performance and patient outcomes.

(b) Infection prevention activities, including the measures selected for monitoring, data collection, analytical methods, actions taken, and outcomes.

(2) Infection prevention and control and quality assurance and performance improvement activities must be continuous and ongoing based on surveillance data results.

(3) Monitoring may include follow-up with patients after discharge to gather evidence of whether the patient has developed an infection associated with their stay with the licensee.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45145 Employee; health; communicable disease.**

Rule 145. (1) The licensee shall ensure that an employee is free from communicable disease. A health facility or agency shall maintain employee files containing baseline screening for communicable diseases or immunizations, and records of illness and accidents occurring on duty.

(2) Employees, contract personnel, students, volunteers, and other persons who have direct physical contact with patients or food while providing care or services in the facility may participate only when free of signs of infection.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**SUBPART D: EMERGENCY PREPAREDNESS**

**R 325.45147 Emergency preparedness program.**

Rule 147. The applicant or licensee shall have an all-hazard emergency preparedness program to meet the health and safety needs of its patient population and personnel. The emergency preparedness program must provide guidance on how to respond to emergency situations that could impact the operation of the health facility or agency, such as natural or man-made disasters. The emergency preparedness program must include all of the following components:

- (a) A risk assessment.
- (b) A written emergency response plan.
- (c) Written policies and procedures that support the successful execution of the emergency response plan.
- (d) A written communication plan.
- (e) A written training and testing plan.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45149 Risk assessment.**

Rule 149. (1) An applicant or licensee shall conduct a risk assessment or use a risk assessment conducted by its municipal or county emergency management agency. If an emergency management agency's risk assessment is used, the applicant or licensee shall maintain a copy of it and is required to work with the agency that developed it to ensure that the facility's emergency response plan is in alignment. The risk assessment must be used to assist the health facility or agency to address the needs of its patient population, identify essential services and vendors to provide support during an actual emergency, and identify alternate service providers and vendors to assure continuity of operations.

(2) The risk assessment must be available to the department upon request.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45151 Emergency response plan.**

Rule 151. (1) An applicant or licensee shall have a written emergency response plan. The plan must be based on the risk assessment.

(2) The emergency response plan must address capacities and capabilities critical for a response to and recovery from the types of emergencies likely to impact the health facility or agency that could result in 1 of the following:

- (a) Equipment and power failures.
  - (b) Interruptions in communications that could include cyber-attacks.
  - (c) Loss of all or a portion of a physical facility.
  - (d) Extraordinary staffing shortages where the health facility or agency continues to operate.
  - (e) Interruptions in the normal supply of essentials such as food and water, medications, or medical supplies including medical gases where the health facility or agency continues to operate.
- (3) The licensee shall review, update, and approve the emergency response plan annually.
- (4) The emergency response plan must be available to the department upon request.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45153 Policies and procedures for emergency preparedness.**

Rule 153. (1) An applicant or licensee shall have written policies and procedures for emergency preparedness and recovery that are based on the risk assessment.

(2) The policies and procedures must address, but are not limited to, all of the following subjects:

- (a) Subsistence needs of patients receiving inpatient or residential services.
  - (b) Evacuation.
  - (c) Shelter in place.
  - (d) Tracking patients and personnel.
  - (e) Patient transfers for continuity of care that may include transfer agreements or other arrangements based upon the services offered and needs of the patients.
  - (f) Preservation and transfer of patient records.
  - (g) Continuity of operations and recovery.
- (3) The policies and procedures must be available to the department upon request.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45155 Communication plan.**

Rule 155. (1) As part of its emergency preparedness program, an applicant or licensee shall have a written communication plan. The communication plan must include, but is not limited to, notification of the following as appropriate to the emergent event:

- (a) Local emergency response agencies.
- (b) Personnel.
- (c) Patients.



- (d) Patient's guardian, family, or other persons designated by the patient.
  - (e) Patient's physician.
  - (f) Utility maintenance and repair vendors.
  - (g) Information management support.
  - (h) Other essential suppliers and vendors.
  - (i) The department.
- (2) The communication plan must include a provision for the transfer of patients and their records to a receiving health facility or agency.
- (3) The communication plan must be available to the department upon request.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45157 Emergency preparedness training and testing program.**

Rule 157. (1) An applicant or licensee shall develop and implement an emergency preparedness training and testing program. The training and testing program must include initial emergency response training for new and existing personnel, as well as annual refresher trainings.

(2) Each year the licensee shall exercise its emergency response plan at least twice. This requirement may be fulfilled by participating in 1 or more community-based exercises, facility-based exercises, or by activating its emergency plan in response to one or more actual incidents. One of the two exercises may be a paper-based table-top exercise.

(3) The training and testing program plan, exercise manual, and after-action reports must be retained for a minimum of 4 years or according to the licensee's records retention schedule, whichever is longer; and they must be available to the department upon request.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## **SUBPART E: MEDICAL AUDIT AND UTILIZATION REVIEW**

### **R 325.45159 Medical audit; utilization review; document access.**

Rule 159. (1) A health facility or agency shall establish a process for medical audits of individual patient cases. Medical audits shall be conducted on a representative sample of patient cases. A medical audit is to ensure proper documentation of clinical information, continuity and coordination of patient care, and the quality and safety of medical and other health care services provided.

(2) A health facility or agency shall establish a process for utilization review of care and services on a systemic and aggregated basis. A utilization review is to ensure the provision and utilization of health care services provided in terms of cost, effectiveness, efficiency, and quality.

(3) Medical audit and utilization review documents may be accessed by the department during a survey or complaint investigation when necessary to determine compliance with the code and these rules. The department shall maintain and protect these documents in accordance with state and federal laws, including privacy laws.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## **SUBPART F: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM**

### **R 325.45161 Quality assessment and performance improvement program.**

Rule 161. The governing body shall ensure the health facility or agency has a quality assessment and performance improvement program that is defined, implemented, maintained, and includes all of the following:

- (a) Addresses identified priorities.
- (b) Evaluates improvements for effectiveness.
- (c) Specifies data collection methods, frequency, and detail.
- (d) Establishes an expectation for patient safety and quality health care services.
- (e) Allocates staff, time, information systems, and training to implement the quality assessment and performance improvement program.
- (f) Is evaluated and revised on a periodic basis in accordance with the applicable subject matter.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45163 Quality assessment and performance improvement program; monitor quality; ongoing program; measurable improvements.**

Rule 163. (1) The quality assessment and performance improvement program must monitor quality in all areas of operations that may adversely affect patient care or core services, demonstrate measurable improvements in patient health or palliative outcomes, and improve patient safety.

- (2) A quality assessment and performance improvement program must:
  - (a) Be data driven.
  - (b) Identify problems.
  - (c) Reduce medical errors.
  - (d) Improve patient safety.
  - (e) Evaluate systems and processes.
  - (f) Be ongoing.
- (3) The selection and prioritization of quality assessment and performance improvement program activities must be based on the complexity and scope of services provided and focus on high risk, high volume, problem-prone areas, and new services provided.
- (4) Data collected must be used to:
  - (a) Monitor effectiveness and safety of services.
  - (b) Monitor quality of care.
  - (c) Act to make improvements.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45165 Performance improvement initiatives; indicators.**

Rule 165. The quality assessment and performance improvement program must establish performance improvement initiatives that focus on high risk, high volume, and problem-prone areas. If no performance improvement projects are conducted in a calendar year, justification explaining why no performance improvement projects were conducted must be documented.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45167 Documentation; evidence; program activities; data usage.**

Rule 167. A health facility or agency shall maintain documentation and demonstrate evidence of an ongoing quality assessment and performance improvement program that includes both of the following:

- (a) Methods and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events.
- (b) Documentation demonstrating the development, implementation, and evaluation of corrective actions resulting from quality assessment and performance improvement activities.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**SUBPART G: CLOSURE**

**R 325.45169 Proposed closure of a health facility or agency; notification; closure plan; patient referral package.**

Rule 169. (1) At least 30 days prior to the proposed closure date, a licensee shall notify the department in writing and identify all of the following:

- (a) The name and address of the health facility or agency.
- (b) The proposed closure date.
- (c) The patient census at the time of notification.
- (d) The name, title, telephone number, and email address of the individual who is designated by the governing body to serve as the contact person for the closure process.

(2) The department may modify, at its discretion, requirements and timeframes set forth in this rule upon a showing of good cause and solely for the purposes of an involuntary or emergency closure. The department shall not modify any provision that will affect the safety and welfare of patients.

(3) A licensee shall submit a closure plan to the department. The licensee shall not initiate any closure activity until the department reviews and approves the closure plan. If the department disapproves a closure plan, the licensee will have the opportunity to correct and resubmit the plan for additional review.

- (4) The closure plan must include all the following as applicable to the services offered:
  - (a) A timeline and system to discontinue admissions.
  - (b) A method to ensure adequate staffing throughout the closure process.
  - (c) Provisions for the maintenance, storage, and safekeeping of patient records and, if applicable, by including the name of the organization, the address, and the contact information where patient records will be stored, pursuant to sections 20175 and 20175a of the code, MCL 333.20175 and 333.20175a.

(d) Provisions for notifying all affected state, federal, and local governmental authorities of the proposed closure.

(e) The voluntary surrendering of any license and federal certification, including any de-licensure or transfer of licensed beds.

(f) The disposition of onsite drugs, biologicals, chemicals, and radioactive materials.

(g) Appropriate methods for labeling, safekeeping, and transferring patients' belongings during relocation.

(h) A method to identify a new health facility or agency or other appropriate location for each patient that includes all of the following:

(i) Assessment of patient needs.

(ii) Determination regarding availability of bed space in local health facilities or agencies.

(iii) Provision of information to patients and families about other health facilities or agencies.

(iv) Evaluation of patient and family needs concerning geographic location, public transportation, and type of health facility or agency.

(5) At the time of discharge or transfer of a patient, the licensee shall prepare and deliver a referral package, in a secure manner, to each patient and individuals designated by the patient, and to a receiving facility, if applicable. The referral package must include, but is not limited to, all of the following:

(a) A current patient assessment, medical evaluation, and care plan.

(b) Medication and treatment records.

(c) Discharge summary, if the patient is being discharged.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## **PART 4: HUMAN RESOURCES**

### **R 325.45171 Administrator.**

Rule 171. (1) The governing body shall appoint one individual who is responsible for managing the health facility or agency, including but not limited to the following duties:

(a) Directing all day-to-day activities.

(b) Ensuring the implementation of all policies and procedures.

(c) Ensuring regulatory compliance.

(2) For a hospital, this individual shall be the Chief Executive Officer.

(3) For a nursing home, this individual shall be a Nursing Home Administrator licensed pursuant to part 173 of the code, MCL 333.17301 to 333.17319.

(4) This role may be delegated, in writing, to another qualified individual as needed to assure continuity of operations and in accordance with the health facility or agency's policy.

(5) If a licensed nursing home administrator is also licensed as a registered professional nurse, and the nursing home has less than 50 licensed nursing home or long-term care beds, then the nursing home administrator may also serve as the director of nursing.

(6) As used in this rule, "nursing home" does not include a hospital long-term care unit or an extended care services program, commonly known as a swing bed program.

History: 2020 MR 4, Eff. Feb. 21, 2020.

Editor's Note: An obvious error in R 325.45171 was corrected at the request of the promulgating agency, pursuant to Section 56 of 1969 PA 306, as amended by 2000 PA 262, MCL 24.256. The rule containing the error was published in *Michigan Register*, 2020 MR 4. The memorandum requesting the correction was published in *Michigan Register*, 2020 MR 4.

### **R 325.45173 Medical Staff.**

Rule 173. (1) The governing body shall ensure that medical staff requirements are met and that the medical staff is accountable to the governing body.

(2) A physician must be designated as the leader of the medical staff and be assigned the responsibility for the organization and conduct of the medical staff.

(3) The leader of the medical staff may delegate this role in writing to another qualified physician as needed to ensure continuous medical direction and in accordance with the health facility or agency's policy.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45175 Director of nursing.**

Rule 175. (1) A health facility or agency shall designate a registered professional nurse to serve as the director of nursing.

(2) The director of nursing shall direct all nursing services.

(3) A health facility or agency may assign a different title to this position.

(4) The director of nursing may delegate this role in writing to another qualified registered professional nurse as needed to ensure continuous nursing services and in accordance with the health facility or agency's policy.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45177 Nursing personnel.**

Rule 177. At all times during each shift, a health facility or agency shall meet the minimum staffing requirements specified in the code. For the purposes of determining compliance with nursing personnel-to-patient ratios specified in the code, a member of the nursing staff who works less than 2 continuous hours may be counted as part of full-time equivalent personnel only if such member was scheduled to work more than 2 continuous hours.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45179 Independently licensed health professional.**

Rule 179. A health facility or agency may employ, contract, or grant privileges to a qualified individual who is independently licensed to practice a health profession pursuant to article 15 of the code.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45181 Ancillary personnel.**

Rule 181. A health facility or agency may employ or contract ancillary personnel to assist in patient care within the areas of their competence if the individual is adequately trained and working under appropriate supervision.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45183 Employee records.**

Rule 183. A health facility or agency shall maintain a record for each employee that includes all of the following:

- (a) Relevant professional license or registration number.
- (b) Relevant credentialing and education.
- (c) Beginning date of employment and position for which employed.
- (d) Results of baseline screening for communicable disease as set forth in R 325.45139.
- (e) For former employees, the date employment is severed.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45185 Credentialing; clinical privileges; policy; procedure; record.**

Rule 185. A health facility or agency shall maintain policies and procedures for the credentialing and granting of clinical privileges to medical and allied health professionals. Records must be maintained and include the individual's education, training, and experience.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**PART 5: PATIENT AND ADMINISTRATIVE RECORDS**

**R 325.45191 Patient record; required information.**

Rule 191. (1) A health facility or agency shall keep and maintain a record for each patient in compliance with sections 20175 and 20175a of the code, MCL 333.20175 and 333.20175a.

(2) The patient record must include, as a minimum, all of the following:

- (a) Patient identification, including name, address, and birthdate.
- (b) Admission date or date services are initiated.
- (c) Information submitted by a referral source, if any.
- (d) Admitting diagnosis.
- (e) Medical history and physical examination.
- (f) Clinical diagnostic tests and findings.
- (g) Physician and other health professional orders.
- (h) Health professional progress notes.
- (i) Medication and treatment records.
- (j) Notes and observations by other personnel providing care.
- (k) Final diagnosis, including pathological findings if any.
- (l) Record of discharge, transfer, or death.

(m) Patient designated representative for care, if applicable, and emergency contact information.

(n) Consent forms as required and appropriate.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45193 Surgical patient record; required information; informed consent.**

Rule 193. (1) In addition to R 325.45191, a freestanding surgical outpatient facility and a hospital shall keep and maintain in the surgical patient record all of the following:

- (a) Name of the surgeon.
- (b) Name of the anesthesiologist or anesthetist, if other than the surgeon, if applicable.
- (c) Preoperative study and diagnosis details if medically necessary.
- (d) Provider notes including preoperative and postoperative vital signs and other relevant observations to document the patient's stabilized condition at the time of discharge.

(e) Product name and dosage of any sedative and anesthetic used.

(f) Method of anesthesia and any pertinent information concerning results or reactions.

(g) Operation and treatment notes and consultations.

(h) The postoperative diagnosis, including pathological findings.

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

(j) Surgeon's operative note including all of the following:

(i) Name of each procedure performed.

(ii) Duration of procedure and any unusual problems or occurrences encountered.

(iii) Surgeon's description of gross appearance of any tissues removed.

(k) Summary of instructions given for follow-up observation and care.

(2) The facility shall obtain informed consent from a patient, or the responsible relative or guardian in the case of an unemancipated minor, before the performance of a surgical procedure and maintain the signed written consent form(s) in the patient's record.

(3) A facility that performs pregnancy terminations shall require that informed consent be obtained in compliance with sections 17015 and 17015a of the code, MCL 333.17015 and 333.17015a. In the case of an unemancipated minor, informed consent must also be obtained in compliance with the parental rights restoration act, 1990 PA 211, MCL 722.901 to 722.908.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45195 Hospice patient record; additional requirement.**

Rule 195. In addition to R 325.45191, a hospice agency or residence shall keep and maintain in the patient record the individual's terminal prognosis in compliance with section 21417 of the code, MCL 333.21417.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45197 Nursing care facility patient record; additional requirements.**

Rule 197. In addition to R 325.45191, a nursing care facility shall document in the patient record that a clinical history and physical examination was performed by a physician within 5

days before or on admission, including a physician's treatment plan. The patient's record must be completed within 30 days following discharge.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45199 Standing order; written order; verbal order; telephone order.**

Rule 199. (1) Treatment rendered to a patient must be in accordance with the specific standing, written, verbal, or telephone order of a physician or other licensed health professional ordering within their scope of practice and clinical privileges.

(2) Standing and written orders must be recorded in the patient record and be signed by the licensed health professional who issued the order in accordance with the policy of the health facility or agency.

(3) When verbal or telephone orders are used, they must only be accepted by persons who are authorized to do so by the health facility or agency's policy and procedures consistent with federal and state law. Orders must be recorded in the patient record, restated back to the ordering licensed health professional, and then signed by the person who recorded the order. The licensed health professional who issued the order shall subsequently sign the order in accordance with the health facility or agency's policy and procedures.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45201 Administrative record.**

Rule 201. (1) A health facility or agency shall maintain administrative records that include all of the following:

- (a) Daily census records.
- (b) Staffing records.
- (c) Incident and accident reports.
- (d) Transfer of patient to hospital records.

(2) The retention of administrative records is 1 year or in accordance with the health facility or agency's record retention schedule, whichever is longer.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45203 Patient and administrative records; storage.**

Rule 203. (1) Patient and administrative records must be preserved and readily available to assure necessary access by appropriate health care professionals and staff to deliver needed care.

(2) Records must be secured to assure confidentiality and protect them from access by unauthorized persons and maintained in accordance with section 20175 of the code, MCL 333.20175.

History: 2020 MR 4, Eff. Feb. 21. 2020.



**R 325.45205 Patient and administrative records; survey and review by department; confidentiality.**

Rule 205. (1) Relevant patient and administrative records must be available for survey and complaint investigation by an employee assigned by the department as a surveyor.

(2) Records must 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 of the patient or the patient's designated representative.

(3) Notwithstanding subrule (2) of this rule, a health care facility or agency shall maintain the confidentiality of all non-essential information and documents.

(4) The department shall maintain records received as confidential to the extent permitted by law.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45207 Data collection; informal advisory group.**

Rule 207. (1) In addition to the collection of information and documents necessary to determine compliance during a licensure survey or complaint investigation, the department may also collect non-personally identifiable patient information and aggregated data from licensees including, but not limited to, all of the following:

(a) Availability of services.

(b) Hours of operation.

(c) Demographic data.

(d) Morbidity and mortality data.

(e) Volume of care provided to patients.

(2) Prior to any data collection under this rule, the department shall establish an informal advisory group, with representation from providers, to determine the data elements to be collected.

(3) The licensee shall provide the required data on an individual basis for each licensed site in a format and media designated by the department.

(4) The department may elect to verify the data through onsite review of appropriate records.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**PART 6: ANCILLARY CARE AND SERVICES**

**R 325.45211 Laboratory services.**

Rule 211. Where medically necessary, a health facility or agency shall provide, directly or through contract, laboratory services. These laboratory services must be in compliance with the Clinical Laboratory Improvement Amendments (CLIA) regulations, 42 CFR part 493 (2017).

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45213 Radiological and imaging services.**

Rule 213. (1) Where medically necessary, a health facility or agency shall provide, directly or through contract, radiological and imaging services.

(2) These services must be offered on a regular schedule based on the health facility's or agency's hours of operation.

(3) The staff responsible shall be trained, qualified, and competent for the services being offered. The health facility or agency shall maintain documentation demonstrating the staff's training, qualifications, and competencies.

(4) A health facility or agency shall have written policies and procedures for the maintenance of equipment related to this service that consider applicable manufacturers' guidelines.

(5) The health facility or agency shall immediately document any adverse testing or machine error that may cause an adverse patient reaction. Investigation and corrective action must be initiated promptly. Any investigation and corrective action taken in response to an adverse patient reaction must be reported to the appropriate licensed health care professional and recorded in the patient's record.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45215 Pharmacy services.**

Rule 215. (1) Medical supplies and appliances, durable medical equipment, drugs and biologicals related to patient care and treatment, as identified in the patient's plan of care, must be provided by the health facility or agency while the patient is under its care.

(2) Where medically necessary, a health facility or agency shall provide, directly or through contract, pharmacy services.

(3) Pharmacy services offered directly within a health facility or agency must be licensed. A health facility or agency contracting pharmacy services shall ensure these services are licensed.

(4) These services must be offered on a regular schedule based on the health facility's or agency's hours of operation.

(5) The staff responsible must be trained, qualified, and competent for the services being offered. A health facility or agency shall maintain documentation demonstrating the staff's training, qualifications, and competencies.

(6) A health facility or agency shall have written policies and procedures for both of the following:

(a) Drug control.

(b) Maintenance of equipment related to this service that consider applicable manufacturers' guidelines.

(7) Pharmacy services offered must be appropriate to the patient needs and treatment and recorded in the patient's record. Medication and other pharmaceutical services must be provided on the order of a licensed health professional authorized to do so under article 15.

(8) All medications and other pharmaceutical products must be properly labeled and identified with pertinent information such as use, storage, expiration, and other necessary information.

(9) A health facility or agency shall comply with the Clinical Laboratory Improvement Amendments (CLIA) regulations, 42 CFR part 493 (2017), as related to pharmacy services and as applicable.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45217 Dietary services.**

Rule 217. A health facility or agency that offers dietary services shall do all of the following:

- (a) Meet all the dietary and nutritional needs of the patient in accordance with the patient assessment and treatment plan.
- (b) Obtain a diet order for each patient upon admission, written by a physician or other qualified health professional, based on patient condition, diagnosis, food restrictions, preferences, and nutritional assessment. After the diet order is obtained, information must be provided to the patient regarding their diet order and how the patient can make food choices from the offerings on the facility menu.
- (c) Offer nutrition counseling and interventions to patients regarding appropriate nutritional intake in accordance with their condition and treatment plan. Nutrition counseling must be provided by a qualified individual.
- (d) Develop and adopt policies and procedures including a diet manual that outlines facility diet orders.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45219 Communication services.**

Rule 219. A health facility or agency shall assure the availability of appropriate methods and tools to communicate with patients who are non-English speaking or have communication impairments. While a patient is receiving services, a health facility or agency shall safeguard any patient sensory items such as eye glasses, dentures, and hearing aids.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45221 Transportation services.**

Rule 221. (1) A health facility offering inpatient or residential services shall arrange and provide for appropriate transportation services if diagnostic, medical, or other services are necessary and not available onsite.

(2) Excluding a hospital with an emergency department, a health facility or agency shall have protocols for obtaining emergency transportation services for patients requiring emergency medical treatment. When indicated, a qualified health professional from the health facility or agency shall accompany a patient requiring transfer to a facility for emergency medical treatment.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**PART 7: PATIENT RIGHTS AND RESPONSIBILITIES**

**R 325.45231 Patient rights and responsibilities; policies and procedures.**

Rule 231. (1) A health facility or agency shall develop, adopt, implement, post, and distribute written policies and procedures to protect the rights and responsibilities of patients as provided in sections 20201, 20202, and 20203 of the code, MCL 333.20201, 333.20202, and 333.20203.

(2) Before a patient's admission, and if requested after admission, policies and procedures related to rights and responsibilities must be made available to all of the following:

- (a) The patient.
- (b) The patient's guardian.
- (c) The patient's representative.

(3) Information transmitted to a patient, or to the person legally responsible for the patient, must be in a manner that he or she can reasonably be expected to understand.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**PART 8: COMPLAINTS, INVESTIGATIONS, AND HEARINGS**

**SUBPART A: COMPLAINTS AND INVESTIGATIONS**

**R 325.45241 Complaint filed with health facility or agency; procedure.**

Rule 241. (1) A health facility or agency shall adopt written policies and procedures for the initiation, investigation, and resolution of complaints filed by a patient, or the patient's legal guardian or designated representative when that person has standing. The procedure to file a complaint must be made available to the patient at the time of admission and upon request. The procedure must contain, at a minimum, all of the following:

(a) A notice that an individual may file a complaint, orally or in writing, with the health facility or agency, the department, or both.

(b) The name, title, and contact information of the health facility or agency staff member who is responsible for receiving complaints.

(c) The contact information necessary to file a complaint with the department.

(d) Resources to assist the individual with writing a complaint if needed.

(2) If a complaint does not allege serious injury, harm, impairment, or death and is resolved to the individual's satisfaction prior to the completion of the investigation, the investigation may be discontinued.

(3) If a standard complaint form is used, a copy of the form must be provided to each patient or the patient's legal guardian or designated representative upon request.

(4) Investigation of a complaint that alleges serious injury, harm, impairment, or death must start within 3 business days of receipt of the complaint.

(5) Investigation of a complaint that does not allege serious injury, harm, impairment, or death must start within 7 business days of receipt of the complaint.

(6) A complaint investigation must be completed within 15 business days of initiation of the investigation. If the investigation is not completed within 15 business days, the health facility or agency shall document the reason for the delay and notify the complainant of the anticipated completion date.

(7) A health facility or agency shall deliver to the individual the written results within 10 business days of completion of the investigation. This subrule does not apply when a complaint is filed anonymously.

(8) A comment on a patient satisfaction survey or other method used by a health facility or agency to gather feedback does not constitute a complaint.

(9) The individual's allegation must be of a nature that describes a possible violation of state law or rule. The individual does not need to cite the specific state law or rule.

(10) A health facility or agency shall maintain for 3 years any complaints filed under its complaint procedure, all complaint investigation reports, and correspondence delivered to each individual that filed a complaint.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45243 Complaint filed with department; procedure.**

Rule 243. (1) When a complainant files a complaint with the department pursuant to section 20176 or 21799a of the code, MCL 333.20176 or 333.21799a, it must be filed within 12 months of the alleged violation. If it is not filed within 12 months of the alleged violation, the department may investigate the complaint if the complainant shows good cause for the delay in filing the complaint.

(2) A complaint must be submitted using the department's hotline or in writing using the US Postal Service, e-mail, online form, fax, or other method provided for on the department's website, [www.michigan.gov/lara](http://www.michigan.gov/lara).

(3) The complaint must be limited to matters involving an alleged violation of an applicable law or rule affecting the complainant or, in the case of a public interest group, affecting the public or a portion thereof.

(4) A complainant shall provide enough information to identify the specific health facility or agency where the alleged violation took place. Such information includes but is not limited to the name and address of the health facility or agency.

(5) A complaint may be filed anonymously.

(6) The department shall receive, evaluate, and, if warranted, investigate a filed complaint. The department shall not investigate a complaint that, as alleged, does not violate a law or rule regulated by the department. The department shall send a letter of acknowledgement to each complainant upon evaluation of the complaint, except when a complaint is submitted anonymously.

(7) The department shall notify the health facility or agency of the nature of the complaint no earlier than the initial visit to the health facility or agency to investigate the complaint.

(8) The department shall provide the complainant with the written findings of the complaint investigation, or instructions for how to obtain the written findings, no later than 30 days after the conclusion of the complaint investigation process. This subrule does not apply when a complaint is filed anonymously.

(9) The department shall inform the complainant of the department's actions if the health facility or agency does not correct areas of noncompliance, when applicable. This subrule does not apply when a complaint is filed anonymously.

(10) A complaint filed with the department about a federally certified health facility or agency will be triaged and the subsequent survey or investigation will be conducted pursuant to the state

agreement with the United States Secretary of Health and Human Services under section 1864 of the Social Security Act, 42 USC 1395aa.

(11) A complaint filed with the department about a state licensed-only health facility or agency will be triaged and the subsequent survey or investigation will be conducted pursuant to article 17 and these rules.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45245 Investigation by department.**

Rule 245. (1) The department shall assign a qualified employee to investigate a health facility or agency for a complaint that alleges violation of state law or rule.

(2) An investigation may include, but is not limited to, all of the following:

(a) Inspection of the health facility or agency, observation of its operations, and interviews with the complainant, staff, and relevant patients with their consent.

(b) Inspection of relevant administrative records, patient records, and other documents and media maintained by the health facility or agency.

(3) The department employee may copy relevant records, documents, or media, and where applicable, allow the health facility or agency an opportunity to redact non-relevant information. The department shall maintain and protect these materials in accordance with state and federal laws, including privacy laws. All such records, documents, or media must be disposed of after the completion of the final investigation and appeal process.

(4) The department shall provide the health facility or agency with its written findings no later than 30 days after the conclusion of the investigation.

History: 2020 MR 4, Eff. Feb. 21. 2020.

## **SUBPART B: HEARINGS**

### **R 325.45247 Applicability.**

Rule 247. (1) The procedures set forth in this subpart apply to the hearings and penalties related to violations under sections 20165, 20166, 20168, 21799b(2), and 21799c of the code, MCL 333.20165, 333.20166, 333.20168, 333.21799b, and 333.21799c.

(2) Unless otherwise provided by article 17 or these rules, the procedures for a hearing must comply with sections 71 to 92 of the administrative procedures act, 1969 PA 306, MCL 24.271 to 24.292, and part 1 of the Michigan administrative hearing system administrative hearing rules, R 792.10101 to R 792.10137.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45249 Correction notice; opportunity to show compliance.**

Rule 249. (1) Before commencing hearing proceedings for denial, limitation, suspension, or revocation of a license pursuant to section 20165 and 20166 of the code, MCL 333.20165 and 333.20166, the department shall give notice to the applicant or licensee, by certified mail or

personal service, of the facts or conduct that warrant the intended action and provide the applicant or licensee with an opportunity to show compliance at a compliance conference. The notice of a compliance conference must state the date, time, and location of the conference. If the licensee is unable to demonstrate, to the satisfaction of the department at the compliance conference, compliance with all lawful requirements for a license, the department may proceed with a hearing. This subrule does not apply to notices issued under sections 20162, 20168, 21799a(9), 21799b(2), or 21799c of the code, MCL 333.20162, 333.20168, 333.21799a, 333.21799b, or 333.21799c, or section 63 of the administrative procedures act of 1969, 1969 PA 306, MCL 24.263.

(2) When the department issues a correction notice to a nursing home under the provisions of section 21799b of the code, MCL 333.21799b, the correction notice must conform to the requirements of that section. The department will have a hearing officer present to conduct a hearing, within 72 hours after the licensee receives the notice, at the time and place specified in the correction notice. The licensee may waive the opportunity for the hearing. Failure to raise objections to the correction notice on or before the scheduled hearing, or failure to appear at the hearing, will be deemed an admission of the matters asserted in the correction notice. If the respondent fails to make an appearance or to timely contest the notice, the correction notice is final. The licensee may notify the department that it believes it has complied with the correction notice and may request verification of compliance from the department in accordance with section 21799b(3) of the code, MCL 333.21799b.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45251 Discovery and depositions.**

Rule 251. (1) The same rights to discovery and depositions provided in the Michigan court rules for civil procedure apply to hearings commenced and conducted under section 20165 and 20166 of the code, MCL 333.20165 and 333.20166. The presiding officer shall rule on all motions relative to depositions and discovery.

(2) The presiding officer shall not allow discovery depositions and motions for discovery if they are likely to interfere with the efficient and timely conduct of the hearing, unless substantial prejudice would result.

(3) The presiding officer may administer oaths and issue subpoenas upon request of a party or the party's representative.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## **PART 9: ENVIRONMENT OF CARE FOR HEALTH FACILITIES**

### **SUBPART A: PHYSICAL PLANT**

### **R 325.45261 Health facility; construction; hazards.**

Rule 261. A health facility must be of safe construction and free from hazards to patients, visitors, and staff.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45263 Construction permit review; guidelines; adoption by reference.**

Rule 263. (1) In performing a construction permit review for a health facility, the department shall apply the following guidelines, which are adopted by reference, unless a different standard is otherwise specified in these rules:

(a) The following 3 guidelines from the Facility Guidelines Institute (FGI):

(i) “Guidelines for Design and Construction of Hospitals,” 2018 edition.

(ii) “Guidelines for Design and Construction of Residential Health, Care, and Support Facilities,” 2018 edition.

(iii) “Guidelines for Design and Construction of Outpatient Facilities,” 2018 edition.

(b) “American Society for Heating Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 170 – 2017, Ventilation of Health Care Facilities.”

(2) All of the guidelines listed in subrule (1) of this rule are available for inspection at the Lansing office of the Department of Licensing and Regulatory Affairs, Bureau of Community and Health Systems. All these documents can be purchased at the MADCAD cloud-based reference library at [www.madcad.com](http://www.madcad.com). Each of the FGI guidelines cost \$200. The ASHRAE standard costs \$60.57.

(3) Where the requirements of these rules are more stringent than the FGI Guidelines, these rules take precedence.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45265 Submission of plans and specifications for a construction permit.**

Rule 265. (1) To assure compliance with the code and these rules, a health facility shall submit to the department for review and approval or disapproval complete plans and specifications for all the following projects:

(a) New buildings.

(b) Additions.

(c) Building change.

(d) Conversion of existing structures for use as a health facility.

(2) A health facility shall not begin construction or renovation until the plans and specifications have been approved by the department and a permit for construction has been issued.

(3) Architectural and engineering plans and specifications that are submitted to the department must be prepared and sealed by architects and professional engineers licensed to practice in Michigan.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45267 Existing licensed health facility; exception.**

Rule 267. An existing licensed health facility that is not in compliance with the provisions of these rules may be permitted to continue in use so long as the facility is sufficient to protect patient health and safety and provide services, unless the department determines that such use constitutes a hazard.



History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45269 Health facility floor plan.**

Rule 269. A health facility shall keep onsite a floor plan of the facility with a description of rooms showing size, use, door locations, window area, number of beds, and fixed equipment.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45271 Exterior; ramps; steps; handrail, light; entrance; access.**

Rule 271. Exterior ramps and steps must have a handrail on both sides. Sufficient light for an exterior ramp or steps must be provided for the safety of persons using the facility. At least 1 entrance to the health facility must provide easy access for persons with mobility limitations.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45273 Interior; illumination; standards.**

Rule 273. (1) The applicant or licensee shall comply with the interior illumination standards in Table 1.

(2) In addition to the interior illumination standards in Table 1, a health facility shall provide both of the following:

(a) Night lighting in a toilet room and in a patient room that is sufficient to illuminate a footpath from the bed to the toilet room with a minimum of 1 foot-candle at floor level.

(b) Light fixtures that are equipped with lenses or shields for protection of the lamps or lamps that will not shatter.

Table 1: Illumination of Health Care Facilities

The following table is intended to be representative, not inclusive, of all clinical facilities. These measured minimum foot-candle (fc) values must be provided at 36 inches above the floor or at task locations as applicable and must account for bulb and fixture depreciation.

One-half of the lighting levels must be maintained in operating rooms, delivery rooms, trauma rooms and emergency department exam rooms, nursing stations, intensive care rooms, special care nurseries, full term nurseries, angiography labs, interventional radiology rooms, cardiac catheterization labs, resuscitation areas, post anesthesia care units, patient holding areas, medication preparation and dispensing areas, and work areas within the laboratory, when on emergency power. These levels are not required during the transfer to emergency power (10 seconds max).

Operating, Delivery, Trauma Rooms <sup>1</sup>	150 fc
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These illumination levels must be provided within a six-foot perimeter of the table or stretcher with the remainder of the room provided with a minimum of 75 foot-candle (fc).

Critical Task Areas	75 fc
<ul style="list-style-type: none"> <li>Cardiac catheterization labs<sup>1</sup></li> <li>Angiography<sup>1</sup></li> <li>Interventional radiology<sup>1</sup></li> <li>Scrub sinks</li> <li>Central sterile task locations</li> <li>Patient exam or treatment locations</li> <li>Decontamination task locations</li> <li>Pharmacy and laboratory hoods</li> <li>Intensive care bed and bassinet locations<sup>1</sup></li> <li>Labor, delivery, recovery, postpartum bed locations<sup>1</sup></li> <li>Post anesthesia care unit or cardiovascular recovery unit<sup>1</sup></li> <li>Procedure rooms</li> <li>Autopsy<sup>1</sup></li> </ul>	

The 75 fc is the minimum for patient examination, resuscitation, or a procedure in the patient vicinity. The patient vicinity is defined as three feet around the sides and head of the patient bed or table. The remainder of these rooms must be a minimum of 15 fc.

The 75 fc level is required in some areas for patient emergencies and resuscitation events. It is not intended to require this lighting level during normal procedures, such as cardiac catheterizations.

<sup>1</sup> Fixed task lighting must be on emergency power.

Specialized Task Areas	50 fc
<ul style="list-style-type: none"> <li>Food service work counter</li> <li>Medication preparation and dispensing locations</li> <li>Nurse, physician, and clinician charting locations</li> <li>Laboratories</li> <li>Triage areas</li> <li>Hot lab task locations</li> <li>Dialysis patient locations</li> </ul>	

Task Areas	30 fc
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Patient care bed, stretcher, table, and chair locations (non-examination areas)	
Resident bed locations	
Handwashing, water closets, tub and shower	
Staff work counter	
Patient and resident day and dining rooms	
Patient and resident reading locations	
Patient preparation and holding areas	
General radiology rooms, MRI, PET, CT, and Lithotripsy	
Morgue	
General Areas	15 fc
Corridors	
General patient and resident room locations	
Clean and soiled utility rooms	
Clinical storage and holding	
Locker rooms	
Janitor closets	
Stairways, elevators, waiting rooms	

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45275 Patient room.**

Rule 275. (1) A room used for patient living or sleeping purposes must have a minimum total window glass area on the outside walls equal to 10% of the required floor area, and a clear unobstructed window view for a minimum distance of 20 feet from the face of the window measured perpendicular to the window. One additional foot must be added to the minimum distance of 20 feet for each 2-foot rise above the first story, up to a maximum of 40 feet of required unobstructed space. Forty-five percent of this window glass area must be openable, unless the room is artificially ventilated.

(2) A 1-bed patient room must provide a minimum of 120 square feet of clear floor area. A 2-bed room must provide a minimum of 100 square feet of clear floor area per bed. A room used for bassinets must provide a minimum area of 40 square feet per bassinet.

(3) A patient room must have not less than a 3-foot clearance available on both sides and at the foot of each bed. A 2-bed room must have a minimum of 4 feet of clearance available at the foot of each bed.

(4) A patient room must be provided with a toilet room opening into the room. A water closet or bathing facility must have grab bars that are anchored to sustain a concentrated load of 250 pounds.

(5) Handwashing facilities must be provided in each patient room and in each connecting toilet room.

(6) Usable floor space must not include a toilet room, closet, or vestibule.

(7) A wardrobe or closet must be provided for the storage of personal clothing. A patient room in a residential facility must provide a minimum of 5 square feet of floor space per bed for this wardrobe and closet, in addition to other requirements for usable floor space per bed.

(8) A 2-bed room must provide visual privacy from other patients and visitors. The design for privacy must not restrict patient access to the entrance, lavatory, toilet room, window view or wardrobe.

(9) A basement or cellar must not be used for sleeping or living quarters. A patient room must have the floor surface at or above grade level along exterior walls with windows.

(10) A patient room must permit the functional placement of furniture and equipment essential to the patients' comfort and safety.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45277 Surgical service; examination room; operating or procedure room.**

Rule 277. A facility that provides surgical services shall meet all the following requirements:

(a) The facility must have enough examination rooms to meet the volume of work to be accomplished. Each single-patient examination room must have a minimum clear floor area of 120 square feet and must provide a minimum 3-foot clearance at each side and the foot of the examination table. In freestanding surgical outpatient facilities, the room size may be reduced to 100 square feet and must provide a minimum 3-foot clearance at each side and at the foot of the examination table.

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

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

(d) The facility must have enough operating or procedure rooms to meet the volume of work to be accomplished and they must comply with both of the following:

(i) Each operating room must have a minimum clear floor area of 400 square feet, with a minimum clear dimension of 20 feet, exclusive of fixed or wall mounted cabinets and built-in shelves. In freestanding surgical outpatient facilities, where the surgical procedures are restricted to eye, endoscopy, and other similar minor procedures, the room size may be reduced to 270 square feet.

(ii) One scrub sink with a gooseneck outlet must be provided near the entrance to each operating room. A scrub sink with two positions may be shared between two adjacent operating rooms, provided that it is located near the entrances to both rooms.

(e) Each procedure room must have a minimum clear floor area of 160 square feet with a minimum dimension of 12 feet, exclusive of fixed or wall mounted cabinets and built-in shelves.

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

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

(h) The operating or procedure room must contain suitable equipment necessary for the types of procedures to be performed.

(i) Operating rooms and procedure rooms must be cleaned and disinfected between cases and terminally cleaned daily in accordance with the facility's policy and procedure.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45279 Surgical patient observation and recovery areas.**

Rule 279. (1) A facility that provides surgical services must have patient observation and recovery areas 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 must be comfortably furnished and adequately equipped for the patient's safe postoperative observation and recovery.

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

(3) Single patient rooms must have a minimum of 100 square feet of usable floor space.

(4) Multiple patient rooms must have a minimum of 80 square feet of floor space per bed or stretcher.

(5) A recovery room must be designed to provide a minimum of 3 feet between beds or stretchers and the adjacent wall, 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 who do not need bed or stretcher accommodations. Each congregate-type room must provide a minimum of 50 square feet of usable floor space for each patient to be accommodated.

(7) A toilet and lavatory must be provided for each 8 recovery patients at a minimum.

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

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45281 Airborne infection isolation patient room.**

Rule 281. (1) A health facility that accepts patients who require airborne infection isolation must provide 1-bed airborne infection isolation (AII) patient rooms with attached lavatory, water closet, and bathing facility, reserved for the use of the occupant of that room only.

(2) The number of 1-bed AII patient rooms must be determined by an infection control risk assessment. An AII patient room must have an area located directly outside or immediately inside the entry door for staff hand washing and gowning and for storage of clean and soiled materials.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45283 Nursing care facility; long-term acute care hospital; hospice residence; dayroom; dining; activity; space.**

Rule 283. (1) A nursing care facility shall provide a minimum of 30 square feet of floor space per bed for dayroom, dining, and activity space. This space must always be accessible to patients.

(2) A hospice residence or a long-term acute care hospital shall provide a minimum of 15 square feet of floor space per bed for dayroom, dining, and activity space. This space must always be accessible to patients.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45285 Residential health care facilities; special requirements.**

Rule 285. Residential health care facilities shall meet all the following requirements:

(a) A patient room must open to a corridor, lobby, or dayroom. Traffic to and from any room must not be through a sleeping room, kitchen, bathroom, utility room, toilet room, or service room, except where a utility room, toilet room, or bathroom opens directly off the room or rooms that it serves.

(b) Patient bathing facilities must be provided at the rate of one bathing fixture for every 20 patients not otherwise served by bathing facilities in patient rooms.

(c) Nursing stations must be located within 120 feet of each patient room door.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45287 Doors.**

Rule 287. (1) The minimum clear width for door openings in the means of egress from sleeping rooms, diagnostic and treatment rooms, and nursery rooms must be 41.5 inches.

(2) Door openings to patient toilet rooms and other rooms needing access for wheelchairs must provide a minimum clear opening of 32 inches.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45289 Ceiling height.**

Rule 289. The minimum ceiling height of rooms and corridors must be 7 feet 10 inches, with the following exceptions:

(a) Ceilings in storage rooms and toilet rooms must be not less than 7 feet 6 inches in height.

(b) Ceiling heights in small, normally unoccupied spaces may be reduced below 7 feet 6 inches if approved by the department.

(c) Suspended tracks, rails, and pipes located in the traffic path for patients in beds or on stretchers, including those in inpatient service areas, must be not less than 7 feet above the floor. Clearances in other areas may be 6 feet 8 inches and applies to the lowest fixed point of ceiling mounted surgical lights, overhead rails/cables in diagnostic and therapeutic radiology rooms, and ceiling/wall mounted televisions under potential footpaths.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45291 Handrails.**

Rule 291. A handrail with ends returned to the wall must be provided on both sides of a corridor, ramp, or stairway used by patients.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45293 Lobby; waiting area; public toilet rooms; public drinking water.**

Rule 293. (1) A lobby or waiting area for visitors must be functionally separate from patient care units.

(2) Except as provided in subrule (3) of this rule, a health facility shall provide one or more public toilet rooms, equipped with a lavatory and water closet, located near waiting and reception areas.

(3) Facilities with a licensed bed capacity of 8 or less may share staff and public toilet facilities.

(4) In new construction or renovations, a source of public drinking water must be provided.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45295 Personnel areas.**

Rule 295. (1) A health facility shall provide space for reception, waiting, interviewing, administrative, and business office functions.

(2) A health facility shall provide space for admission, interviewing, and consultation functions so located as to provide reasonable privacy. This must include office space with audible privacy and furnishings for a social worker if one is employed and for counselors and outside agency workers, when indicated, to interview and advise patients.

(3) A health facility shall provide locker room space or other security resources for the personal effects of employees. Individual dressing rooms must be provided for employees when surgical attire is required. A lavatory and water closet must be located convenient to the break or locker room space.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45297 Heating, ventilation, and air conditioning.**

Rule 297. (1) Heating, ventilation, and air conditioning systems must be designed, installed, operated and maintained to meet the requirements of the American Society for Heating Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 170 - 2017 Ventilation of Health Care Facilities. This standard is available as described in R 325.45263.

(2) Exhaust ventilation shall be designed as central systems with the fan at the building exterior and at least 10 feet from all doors, operable windows, and domestic outside air intakes.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45299 Electrical equipment; outlets; receptacles.**

Rule 299. (1) Electrical equipment must be maintained in good repair and be properly grounded.

(2) Duplex electrical outlets with a 3-wire system must be provided in sufficient number and convenient locations to meet the needs of the areas served. A health facility shall provide at least 2 duplex outlets located at the head of each bed.

(3) A patient room must have at least 1 grounded duplex electrical receptacle located on each side of the head of each bed and 1 duplex receptacle on each other wall.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45301 Emergency electrical service.**

Rule 301. (1) A health facility shall have emergency electrical service permanently installed in the facility to provide all the following:

- (a) Lighting in corridors, exits, operating rooms, procedure rooms, recovery rooms, congregate rooms, and nurse stations.
- (b) Telephone switchboard.
- (c) Heating plant.
- (d) Other critical mechanical equipment essential to the safety and welfare of patients, personnel, and visitors.

(2) Emergency electrical service must be capable of providing a minimum of 72 hours of service and more than 72 hours if required by the facility's emergency preparedness plan. A freestanding surgical outpatient facility may reduce this requirement in accordance with its emergency preparedness plan to evacuate the facility.

(3) In new construction or renovation, an emergency generator that has an automatic transfer switch or an alternative source of immediate electrical power acceptable to the department must be provided for lighting and operation of equipment essential to the safety and welfare of patients, personnel, and visitors.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45303 Water supply system.**

Rule 303. (1) A health 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 must comply with the safe drinking water act, 1976 PA 399, MCL 325.1001 to 325.1023.

(3) The location and construction of a well and the operation of the system must comply with standards approved for public water supplies by a health facility's or agency's local health department and the Michigan department of environment, great lakes and energy.

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

(5) The plumbing system must supply an adequate amount of hot water at all times to meet the needs of each patient and the functional needs of the various service areas. Hot water temperatures at fixture outlets must be regulated to provide tempered water in the range of 105 to 120 degrees Fahrenheit.

(6) There must be no cross-connections between water systems that are safe for human consumption and those that are or may become unsafe for human consumption. The entire



plumbing system and all plumbing fixtures must be so designed and maintained that the possibility of back-flow or back-siphonage is eliminated.

(7) A health facility must implement a water management program that follows the “American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 188-2018 – Legionellosis: Risk Management for Building Water Systems.” This standard is available for inspection at the Lansing office of the Department of Licensing and Regulatory Affairs, Bureau of Community and Health Systems. It can be purchased for \$88.00 from the ASHRAE Store, <https://www.ashrae.org/technical-resources/bookstore/ansi-ashrae-standard-188-2018-legionellosis-risk-management-for-building-water-systems>.

(8) A health facility must utilize the Centers for Disease Control and Prevention (CDC) best practice guidance on water management, including the “CDC Toolkit: Developing a Water Management Program to Reduce Legionella Growth and Spread in Buildings.” This toolkit is adopted by reference. It is available for inspection at the Lansing office of the Department of Licensing and Regulatory Affairs, Bureau of Community and Health Systems. It is available without charge at <https://www.cdc.gov/legionella/wmp/toolkit/>.

(9) The water management program must include a facility risk assessment, control measures, and ongoing verification of the program.

(10) If secondary treatment of the public water system is incorporated as part of the water management program, the health facility must comply with the Michigan safe drinking water act, 1976 PA 399, MCL 325.1001 to 325.1023, and the administrative rules, R 325.10101 to 325.12820.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45305 Elevator.**

Rule 305. An elevator must be provided where patient care is provided at different floor levels. The cab size of the elevator must be sufficient to accommodate a stretcher and attendant. An elevator must have a minimum cab size of 5 feet 8 inches wide by 9 feet deep for acute care facilities and a cab size of 5 feet 0 inches wide by 7 feet 6 inches deep for residential facilities.

History: 2020 MR 4, Eff. Feb. 21. 2020.

## **SUBPART B: MAINTENANCE, SANITATION, AND HOUSEKEEPING**

### **R 325.45307 Medical waste; biohazard; solid waste; sanitary sewage.**

Rule 307. (1) A health facility shall comply with the requirements of the medical waste regulatory act, part 138 of the code, MCL 333. 13801 to 333.13832.

(2) A health facility shall have a written policy to govern the storage, transportation, and disposal of surgical specimens and other biohazards.

(3) The collection, storage, and disposal of solid wastes, including garbage, refuse, and dressings, must be accomplished in a manner that will minimize the danger of disease transmission and avoid creating a public nuisance or a breeding place for insects and rodents.

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

(5) Sanitary sewage must be discharged into a public sanitary sewage system when a system is available. When a public sanitary sewage system is not available, and a private sanitary sewage disposal system is used, the type, size, construction and alteration of, or major repairs to the system, must be approved by the authority having jurisdiction and the department. The sewage disposal system must be maintained in a sanitary manner.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45309 Laundry; linen; ventilation; lavatory; equipment; storage.**

Rule 309. (1) A health facility that processes its own linen shall have all of the following:

(a) A well-ventilated laundry room of sufficient size to allow functional separation of soiled linen holding, laundry processing, and clean linen folding.

(b) The laundry must be ventilated to provide directional airflow from clean to soiled areas.

(c) A lavatory for hand washing must be provided in the laundry processing area.

(d) Laundry equipment must be rated commercial and be of sufficient capacity to meet the needs of the facility.

(2) The collection, storage, segregation, and transfer of clean and soiled linen must be accomplished in a manner that will minimize the risk of disease transmission.

(3) A separate clean linen storage room must be provided.

(4) A separate soiled linen storage room must be provided. When justified by the operational characteristics and special needs of the health care facility, a properly sized and located soiled workroom may serve as a soiled linen holding room.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45311 Storage.**

Rule 311. (1) Space must be provided sufficient to meet the need for storage of medical equipment, medical supplies, and furniture.

(2) Space must be provided sufficient to meet the need for segregation of cleaned and used equipment.

(3) A patient toilet room or bathroom must not be used for storage or housekeeping functions.

(4) A central general storage room must be provided with space necessary to meet storage needs of the facility. In residential health care facilities, at least 10 square feet per bed of general storage space must be provided in the facility.

(5) Space must be provided for the storage of clean linen. Soiled linen holding must be separate from storage of clean linen.

(6) Corridors, hallways, passageways, and doorways must always be kept free from obstruction. A corridor may not be used for storage to accommodate insufficient space for storage of medical equipment.

(7) A workroom must be provided for holding trash, medical waste, and soiled linens. The room must be separate from clean storage.

(8) Dedicated clean storage space must be provided.

(9) A patient care unit must have a dedicated area for medication storage, preparation, and documentation. The space must be well lighted and equipped with a lavatory for hand washing, a refrigerator, and locked storage for medication.

(10) A room must be provided on the premises for equipment and furniture maintenance and repair and storage of maintenance equipment and supplies.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45313 Kitchen; dietary.**

Rule 313. A health facility shall be in compliance with the food law, 2000 PA 92, MCL 289.1101 to 289.8111.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45315 Integrated pest management.**

Rule 315. A health facility shall be kept free from insects and vermin utilizing active integrated pest management processes. Insect and vermin control procedures involving the use of insecticides or pesticides must be carried out in a manner consistent with manufacturers' indications for use and in a manner that protects the health and safety of patients, personnel, and visitors.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45317 General maintenance; cleaning.**

Rule 317. (1) The premises of a health facility must be maintained in a safe and sanitary condition and in a manner consistent with the public's health and welfare.

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

(3) A storage area for housekeeping items and a janitor's closet must be provided for the building. A separate dedicated janitor's closet must be provided with convenient access for the kitchen and dietary areas.

(4) Routine cleaning and disinfection must be conducted at specified intervals and between uses by different patients.

(5) Routine cleaning and disinfection must be conducted according to the environmental disinfectant's indication for use.

(6) Patient care equipment and supplies must be single use disposable or must be disinfected between patients.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45319 Sterilization; high-level disinfection.**

Rule 319. (1) A health facility that provides sterilization and high-level disinfection shall have sufficient space for both of the following:

(a) The volume of sterilization and high-level disinfection processing to allow orderly work flow for instrument decontamination, instrument cleaning, assembly and packaging, and the number of sterilization units.

(b) Unimpeded staff movement to avoid environmental contamination of supplies.

(2) A health facility shall restrict access to sterile processing and high-level disinfection spaces.

(3) Sterilization and high-level disinfection spaces must contain a work table, counter, handwashing fixture, sterilizer carts, and dedicated space for drying and storage.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### SUBPART C: COMMUNICATION AND SECURITY

R 325.45321 Nurse call system; equipment; telephone.

Rule 321. (1) A nurse call system must be provided in each facility. This system must provide call devices of the designated types shown at the locations identified in Table 2.

(2) A health facility shall provide a telephone service that is available on patient care units.

TABLE 2  
Location of Nurse Call Devices

Key: ● Required  
□ Optional, but must be justified

Area Designation	Patient Station	Patient Bath Station	Emergency Signal Station	Code Call Station	Nurse Master Station	Duty Station	Notes
Nursing Units							
Inpatient Bed Location	●		●	□			
Patient Water Closets, Showers, and Baths		●					
Nurse Control Station					●		
Clean Workroom						●	
Clean Supply Room						□	
Soiled Workroom						●	
Soiled Holding Room						□	
Medication Preparation Room						●	
Examination or Treatment Room	□		●			●	
Nurse Lounge						●	
Clean Linen Storage						□	

Nourishment Station						<input type="checkbox"/>	
Equipment Storage Room						<input type="checkbox"/>	
Multi-Purpose Room						<input type="checkbox"/>	
Other Clinical Areas							
Operating or Delivery Rooms			•	<input type="checkbox"/>			
Procedure Rooms			•	<input type="checkbox"/>			
Labor, Delivery, Recovery, Post-Partum Rooms	•		•	•			
Recovery Phase 1	<input type="checkbox"/>		•	•	<input type="checkbox"/>		
Recovery Phase 2	•		•	<input type="checkbox"/>	<input type="checkbox"/>		
Emergency Exam, Treatment and Triage Areas	•		•	•	<input type="checkbox"/>		1,2,4
Patient Preparation and Holding Areas	•		•	<input type="checkbox"/>	<input type="checkbox"/>		1,2
Critical Care Bed Locations, including NICU	•		•	•	<input type="checkbox"/>		1,2,3,4
Newborn and Special Care Nurseries			•		<input type="checkbox"/>		
Cardiac Catheterization, Interventional and Radiological Areas Angiography	<input type="checkbox"/>		•	•	<input type="checkbox"/>		
MRI, CT, Stress Testing Areas	<input type="checkbox"/>		•	•			2,4
Outpatient Examination Areas	<input type="checkbox"/>			<input type="checkbox"/>			
Outpatient Waiting and Changing Areas	<input type="checkbox"/>						2
Psychiatric Seclusion, Ante, and Exam Rooms			•		<input type="checkbox"/>		
Outpatient Toilet Rooms, Showers, Baths		<input type="checkbox"/>					2

Psychiatric Patient Room	<input type="checkbox"/>						2
Notes:							
1. One device may accommodate both patient station and emergency staff assistance station functionality.							
2. Must activate a visible signal in the corridor at the patient's door, at the nurse control station, and all duty stations.							
3. Provide 2-way voice communication with nurse control station.							
4. One device may accommodate both emergency staff assistance and code call station functionality.							
5. Patient station not required in NICU.							

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45323 Security system.**

Rule 323. A security system must be provided that meets all of the following objectives:

- (a) To meet the needs of the population served and the services provided.
- (b) To provide safe ingress and egress to the health facility.
- (c) To restrict access to specific areas including, but not limited to, all of the following:
  - (i) Surgical suites.
  - (ii) Central sterile supply.
  - (iii) Obstetric unit.
  - (iv) Pediatric unit.
  - (v) Medication storage areas.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**PART 10: SPECIAL REQUIREMENTS**

**SUBPART A: FREESTANDING SURGICAL OUTPATIENT FACILITY**

**R 325.45331 Anesthesia.**

Rule 331. A qualified anesthesiologist or anesthetist shall be present where medically necessary to evaluate and select the most appropriate anesthetic agent to be used and to supervise or administer the anesthetic.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45333 Surgical procedures.**

Rule 333. (1) Surgical procedures must be performed by licensed and credentialed health professionals.

(2) A physician or registered professional nurse shall be onsite until all surgical patients have been discharged and leave the health facility.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45335 Surgical hand-scrub hygiene procedures.**

Rule 335. A facility shall have a written policy and procedure, adopted by the medical staff, to provide for adequate surgical hand-scrub throughout the surgical operative and postoperative procedure.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45337 Surgical equipment, instruments, supplies, and reprocessing.**

Rule 337. (1) Surgical equipment, instruments, and supplies must be maintained in sufficient quantities, stored in a sanitary environment, and maintained in accordance with the applicable manufacturer guidelines and nationally recognized infection prevention and control guidelines published by any of the following organizations:

- (a) Centers for Disease Control and Prevention (CDC).
- (b) Association for Professionals in Infection Control and Epidemiology (APIC).
- (c) Society for Healthcare Epidemiology of America (SHEA).
- (d) Association of Perioperative Registered Nurses (AORN).

(2) Policies and protocols must be established for onsite or offsite reprocessing of surgical instruments and equipment to include sterilization, high level disinfection, immediate-use steam sterilization, and indicators to capture sterilization or disinfection failures.

(3) Reprocessing must be performed by trained personnel.

(4) Documentation of reprocessing personnel competency evaluations is to be regularly performed. Certification, competency assessment, and training records are to be kept on each employee.

(5) Records of use, processing, and maintenance are to be kept on each piece of equipment to trace utilization and repair.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45339 Food and beverage.**

Rule 339. If food and beverage are provided to patients, the facility shall store and serve them in a safe and sanitary manner.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45341 Counseling; referral.**

Rule 341. (1) A freestanding surgical outpatient facility that performs 120 or more surgical abortions per year and publicly advertises outpatient abortion services shall make available and offer non-directive, non-coercive counseling and referral for subsequent indicated care. These counseling and referral services may be provided by a physician, physician's assistant, nurse, social worker, counselor, or other licensed health professional under article 15.

(2) The facility shall maintain liaisons 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.

(3) The individual who provides the counseling shall consult with the physician concerning results of counseling and the initiation of any referrals that seem necessary.

(4) An appropriate method for providing information to and receiving information from legitimate referral sources must be established.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45343 Waiver or modification provisions.**

Rule 343. (1) In accordance with section 20115(4) of the code, MCL 333.20115, for a freestanding surgical outpatient facility that performs 120 or more surgical abortions per year and publicly advertises outpatient abortion services, the department may modify or waive 1 or more of the rules contained in part 9 of these rules.

(2) The licensee may submit to the department a written request for variance.

(3) The variance may be granted and remain in effect for as long as the facility continues to comply with the conditions of the variance, or the variance may be granted for a set period of time as designated in the variance approval.

(4) A variance that was granted pursuant to licensure before the effective date of these rules remains in effect for as long as the facility continues to comply with the conditions of the variance.

History: 2020 MR 4, Eff. Feb. 21. 2020.

## **SUBPART B: HOSPICE AND HOSPICE RESIDENCE**

### **R 325.45345 General services.**

Rule 345. (1) As the needs of the hospice or hospice residence and its patient and family units dictate, the services of qualified personnel, who need not be an employee, must be made available in all the following disciplines:

- (a) Physician services.
- (b) Nursing services.
- (c) Social work services.
- (d) Counseling services, including spiritual, dietary, and bereavement counseling.
- (e) Hospice aide services.
- (f) Volunteer services.
- (g) Therapy services, including physical, occupational, and speech therapy.
- (h) Short term inpatient care.



- (i) Pharmaceuticals, medical supplies, and durable medical equipment services.
- (2) A hospice residence shall provide overnight accommodations for family members.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45347 Policies and procedures for home or inpatient care and services.**

Rule 347. (1) In addition to the policies and procedures required in part 3 of these rules, the hospice administrator shall ensure the development of written policies and procedures for all the following services:

- (a) Bereavement services.
- (b) Social work services.
- (c) Counseling services.
- (d) Volunteer services.

(2) The hospice administrator shall review these policies and procedures at least once every 24 months and update them as necessary.

History: 2020 MR 4, Eff. Feb. 21, 2020.

**R 325.45349 Contractual services.**

Rule 349. (1) A hospice shall routinely provide all nursing, social work, and counseling services directly by hospice employees, except as provided in subrule (2) of this rule.

(2) A hospice may contract with other health care providers or appropriate parties for nursing, social work, and counseling services to supplement hospice employees to meet the needs of patients under extraordinary or other non-routine circumstances.

(3) A hospice may contract with other health care providers or appropriate parties for the provision of physician services and general services other than nursing, social work, and counseling services when the hospice does not have sufficient qualified staff or available adequate equipment to render such services directly.

(4) The department may provide an exception to subrules (1), (2) and (3) of this rule for a hospice that meets all of the following:

- (a) The hospice requests an exception to contract for nursing services due to a shortage of nurses in the geographic area served by the hospice.
- (b) The hospice is in a non-urbanized area.
- (c) The hospice provides evidence to the department that it has made a good faith effort to hire a sufficient number of nurses to provide services.

(5) Contracts for shared services must be written and delineate the authority and responsibility of the contracting parties. Contracts with providers must maintain the responsibility of the hospice for coordinating and administering the hospice program.

(6) The hospice administrator shall maintain responsibility for coordinating and administering the contracted services of the hospice.

(7) Any and all personnel provided to the hospice under the terms of contracted services must be licensed or credentialed as required by law.

(8) All contracts must include financial arrangements and charges, including donated services.

(9) All contracts must state the availability of service.

(10) A contracted service must not absolve the hospice from responsibility for the quality, availability, documentation, or overall coordination of patient and family unit care or responsibility for compliance with any federal, state, or local law or rules and regulations.

(11) All contracts must be reviewed and revised if necessary.

(12) All contracts must be signed and dated by the hospice administrator or designee and the authorized official of the agency providing the contractual service.

(13) All contracts must state that the contractor will provide services to the patient in accordance with the patient care plan developed by the hospice.

(14) Employees of an agency providing a contractual service shall not seek or accept reimbursement in addition to that due the agency for the actual service delivered.

(15) All contracts must prohibit the sharing of fees between a referring agency or individual and the hospice.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45351 Physician services.**

Rule 351. (1) A patient shall be under the care of a physician who is responsible for providing or arranging for medical care that emphasizes prevention and control of pain and other distressing symptoms. This physician may be the attending physician.

(2) The physician providing the medical care to a patient shall be responsible for the direction and quality of medical care rendered to that patient.

(3) The physician shall review the patient's medical history and initial assessment no greater than 15 days prior to or 2 days following admission to hospice services. This review may be of a preadmission assessment or an intake physical assessment, and may be reviewed in person, electronically, or by phone consultation.

(4) The physician shall do both of the following:

(a) Validate the prognosis and life expectancy of the patient, pursuant to section 21417 of the code, MCL 333.21417.

(b) Assist in developing the care plan of the patient.

(5) The hospice shall arrange for the availability of physician services 24 hours a day, 7 days a week.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45353 Nursing services.**

Rule 353. (1) A hospice shall assure that a registered professional nurse completes an initial assessment of the patient's condition within 48 hours after the election of hospice care, unless sooner as requested by the physician, patient, or patient representative.

(2) A comprehensive assessment of the patient must be completed by the hospice interdisciplinary care team no later than 5 calendar days after the election of hospice care. The comprehensive assessment must identify the patient's immediate physical, psychosocial, emotional, and spiritual needs related to the terminal illness.

(3) The patient care plan must be established by the hospice interdisciplinary care team. The patient care plan must include problems, interventions, and goals specific to the patient and family unit and all medications, medical equipment, and other pertinent items used by the

patient. The patient care plan must be revised or updated every 15 days or as the needs of the patient/family unit change.

(4) A staff member, as designated in the patient's record, is responsible for the coordination, implementation, and ongoing review of each plan. The plan must be recorded and maintained as part of the patient and family unit record.

(5) The patient care plan must give direction to the care given in meeting the physical, psychosocial, and spiritual needs of the patient and family unit. The plan must be personalized to meet the individual's needs and treatment decisions.

(6) Resource materials relating to the administration and untoward effects of medications and treatments used in pain and symptom control must be readily available to hospice personnel.

(7) The hospice shall arrange for the availability of nursing services 24 hours a day, 7 days a week.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45355 Hospice residence; additional staffing requirements.**

Rule 355. (1) In addition to the human resources requirements in part 4 of these rules, R 325.45171 to R 325.45185, a hospice residence shall also comply with all of the following staffing requirements:

(a) Provide 24-hour nursing services for each patient pursuant to the patient's hospice care plan.

(b) Direct and staff nursing services to assure that the nursing needs of patients are met.

(c) Specify patient care responsibilities of nursing and other hospice personnel.

(d) Provide services in accordance with recognized standards of practice.

(2) A hospice residence shall maintain a nursing staff sufficient to provide at least 1 registered professional nurse to each 8 patients on the morning shift; 1 to each 12 patients on the afternoon shift; and 1 to each 15 patients on the nighttime shift. Additional nursing personnel must be added based upon patient or family needs.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45357 Bereavement services.**

Rule 357. The hospice shall offer a program to provide bereavement services to the family for no less than one year after the death of the patient. The program must be designed to meet the needs of individuals in their adjustment to experiences associated with death, both before and following the patient's death. A professional educated or otherwise qualified in providing grief or loss services shall supervise the bereavement program.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45359 Spiritual services.**

Rule 359. The hospice shall offer spiritual services to the patient and family. Services will be provided, if accepted, based upon an assessment of spiritual needs in accordance with beliefs and choices, and will be delivered as directed within the plan of care developed by the

interdisciplinary care team, which includes a pastoral or other counselor. When identified as beneficial to the patient or family, local clergy and others may be sought to assist with meeting the patient and family needs.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45361 Volunteer services.**

Rule 361. (1) The hospice shall utilize lay or professional volunteer services to promote the availability of care, meet the broadest range of patient and family unit needs, and affect financial economy in the operation of the hospice.

(2) A volunteer services director shall develop and implement a program that meets the operational needs of the hospice, coordinate orientation and education of volunteers, define the role and responsibilities of volunteers, recruit volunteers, and coordinate the utilization of volunteers with other program directors.

(3) The hospice shall provide each volunteer with the information the volunteer needs to know to protect the patient's and the volunteer's health and safety.

(4) Services provided by volunteers must be in accordance with the written plan of care.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45363 Social work services.**

Rule 363. (1) The hospice shall provide social work services to the patient and family.

(2) Social work services must be available 7 days a week when reasonable and necessary to meet the needs of the patient and family.

(3) Social work services must provide support to enable an individual to adjust to experiences associated with death.

(4) Social work services must be delivered consistent with the patient care plan.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45365 Hospice aide services.**

Rule 365. (1) Hospice aide services must be available directly, or by written agreement, and must be under the supervision of a registered professional nurse.

(2) The hospice shall have policies and procedures for hospice aide services, approved by the director of nursing, to maintain standards of care.

(3) A registered professional nurse shall make an annual onsite visit to a location where a patient is receiving care to observe and assess each aide while he or she is performing care. This visit must be documented in the hospice aide's personnel file.

History: 2020 MR 4, Eff. Feb. 21. 2020.

**R 325.45367 Pharmaceuticals, medical supplies, and durable medical equipment.**

Rule 367. (1) The hospice shall have written policies and procedures for the management and disposal of drugs and biologicals in a patient's home, pursuant to section 21418 of the code, MCL 333.21418.

(2) The interdisciplinary care team, as part of the review of the plan of care, shall determine the eligibility of a patient or the patient's in-home caregiver to safely administer drugs and biologicals to the patient in the home.

(3) The hospice shall ensure a patient and in-home caregivers receive instruction in the safe use of drugs and biologicals, medical supplies, appliances, and durable medical equipment. A patient and in-home caregivers must be able to demonstrate the appropriate use of drugs and biologicals, medical supplies, appliances, and durable medical equipment to the satisfaction of the hospice staff.

History: 2020 MR 4, Eff. Feb. 21. 2020.

## **SUBPART C: HOSPITAL**

### **R 325.45369. Anesthesia.**

Rule 369. A qualified anesthesiologist or certified registered nurse anesthetist shall be present, when medically indicated, to evaluate and select the most appropriate anesthetic agent to be used and to supervise or administer the anesthetic.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45371. Surgical procedures.**

Rule 371. Surgical procedures must be performed by a licensed health professional under article 15 who is credentialed to do so by the hospital.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45373 Surgical hand-scrub hygiene procedures.**

Rule 373. The hospital shall have a written policy and procedure, adopted by the medical staff, to provide for adequate surgical hand-scrub throughout the surgical operative and postoperative procedure and in accordance with evidence-based standards.

History: 2020 MR 4, Eff. Feb. 21. 2020.

### **R 325.45375 Surgical equipment, instruments, supplies and reprocessing.**

Rule 375. (1) Surgical equipment, instruments, and supplies must be maintained in sufficient quantities, stored in a sanitary environment, and maintained in accordance with applicable manufacturers' guidelines.

(2) Policies and protocols must be established for onsite or offsite reprocessing of surgical instruments and equipment to include sterilization, high level disinfections, immediate-use steam sterilization, and indicators to capture sterilization or disinfection failures.

(3) The hospital shall have adequate dedicated space and the necessary equipment necessary to accommodate the surgical workload and to reprocess surgical instruments and equipment.

(4) Reprocessing must be performed by trained personnel.

History: 2020 MR 4, Eff. Feb. 21, 2020.

## **SUBPART D: NURSING CARE FACILITY**

### **R 325.45377 Admission and medical examination.**

Rule 377. (1) A patient shall only be admitted to a nursing care facility on the order of a physician. The order for admission and immediate care may be accomplished through a hospital transfer summary signed by a physician, paperwork signed by the patient's physician, or other written form signed by a physician.

(2) An initial medical examination of a patient by a physician must be completed within 30 days of the admission date.

(3) Routine medical examinations of a patient are required at least every 60 days after the date of the initial medical examination.

(4) Subsequent routine medical examinations may alternate between being completed by the attending physician and a physician assistant or a nurse practitioner at the direction of the attending physician.

(5) The frequency of additional medical examinations of the patient, beyond the initial and routine medical examinations, must be determined by the attending physician.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45379 Nursing care services.**

Rule 379. (1) Nursing care services must be based on assessment of the patient through a person-centered approach. Nursing care services must include, but are not limited to, personal care, restorative services, and patient treatments.

(2) Personal care must be provided in accordance with the patient's preferred schedule and meet all of the following patient needs:

(a) Hygiene through washing, bathing, oral care, and application of hygiene products.

(b) Grooming through haircare, shaving, and application of cosmetic products.

(c) Mobility through walking and propelling, including transfer assistance and use of ambulation devices, if needed.

(d) Incontinence and perineal care.

(e) Clothing that is clean and appropriate for the season, temperature, and activity, including undergarments and proper footwear.

(f) Nourishment provided through meals and supplementary fluids with the proper consistency and texture.

(3) Restorative services must focus on maintaining a patient's optimum level in the activities of daily living by providing all of the following:

- (a) Range of motion exercises.
- (b) Positioning and body alignment.
- (c) Preventative skin care.
- (d) Transfer and ambulation training.
- (e) Bowel and bladder training.
- (f) Training in activities of daily living, including eating, dressing, personal hygiene, and toilet activities.

(4) Patient treatments must be modified in accordance with the response or request of the patient consistent with physician orders and in consultation with the nursing staff.

(5) The nursing care facility shall have an inventory system for patient clothing and personal items addressing all of the following:

- (a) Marking and labeling clothing and personal items in a dignified and private manner.
- (b) Laundering and ironing of clothing.
- (c) Mending clothing, as necessary.
- (d) Separately storing each patient's clothing.
- (e) A method to add or remove items from the patient's clothing and personal items inventory.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45381 Activity program.**

Rule 381. A nursing care facility shall operate an activities program that meets all of the following requirements:

- (a) Activities are available based on patient assessments and preferences.
- (b) Individual and group activities that encourage mental and cognitive stimulation, physical movements, and social engagement.
- (c) Activities are overseen by qualified staff.
- (d) Activities are offered 7 days per week.
- (e) Necessary equipment and supplies for scheduled activities are provided.
- (f) When community-based activities are offered, transportation must be provided.
- (g) A patient's individual care plan may address participation, but participation by a patient is not required.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45383 Trust fund and surety bond.**

Rule 383. (1) A nursing care facility shall have a policy and procedures regarding how it will hold funds or property in trust for patients as a fiduciary when the facility receives money or property belonging or due a patient in accordance with section 21767 of the code, MCL 333.21767. The policy and procedure must describe the process for the safeguarding, holding, and management of patients' funds.

(2) The nursing care facility shall provide a summary of the policy and procedures to each individual patient and the patient's designated representative or guardian at the time of admission.

(3) The trust fund policy and procedure must include all of the following:

(a) A statement that a patient is not required to participate in the trust fund.

(b) Assurances that the nursing care facility has no financial interest in the trust fund and that no facility funds will be comingled with patient funds.

(c) A provision that written consent to participate in the trust fund is to be obtained prior to the acceptance of any money from a patient.

(d) Provisions for management of the funds belonging to a patient who is incapable of managing his or her own funds.

(e) A process for assisting the patient or the patient's legal representative in identifying a representative payee, if the patient can participate in the decision, or designating a representative payee for a patient who is not capable of participating in that decision and does not have a legal representative.

(f) Identification of the financial institution where the trust fund will be held.

(g) A requirement to provide a statement, at least quarterly, to each patient participating in the trust fund or upon request of the patient. The statement must include both of the following:

(i) A beginning and ending balance.

(ii) An accounting of all deposits, withdrawals, interest accrued, and fees assessed during the statement period.

(h) The fees charged in total to all patients may not exceed the amount of the fees charged by the bank for the maintenance of the account.

(i) Reasonable access for the patient to conduct transactions, including on weekends and holidays.

(j) Criteria to return within 7 business days all or any part of the personal funds of a patient held in the trust fund upon request or upon the patient's transfer, discharge, or death.

(4) Trust fund records must be kept in accordance with generally accepted accounting principles.

(5) A nursing care facility may keep up to \$200.00 of a patient's money in a non-interest-bearing account or a petty cash fund. If the patient provides more than \$200.00 within 15 days, the nursing care facility shall either return the money in excess of \$200.00 to the patient or deposit it in an interest-bearing account. The account may be individual to the patient or pooled with other patients, in accordance with the trust fund policy identified in subrule (3) of this rule.

(6) For a patient's personal funds that are received and deposited in an account outside the nursing care facility, upon request or upon the transfer or discharge of the patient, the facility shall return all or any part of those funds to the patient, legal guardian, or designated representative within 10 business days.

(7) A nursing care facility shall provide the executor or administrator of a patient's estate with a written accounting of the patient's personal belongings and funds within 10 business days of death. If a deceased patient's estate has no executor or administrator, the nursing care facility shall provide the accounting to the patient's next of kin, the patient's representative, or clerk of the probate court of the county in which the patient died.

(8) Upon the sale or other transfer of ownership of a nursing care facility, the facility shall provide the new owner with a written accounting of all patients' funds being transferred and obtain a written receipt for those funds from the new owner. The facility shall also provide each



patient, or the patient's representative, a written accounting of any personal funds held by the nursing care facility before any transfer of ownership occurs.

(9) A nursing care facility shall purchase a surety bond for the minimum amount of \$2,000.00 and develop a system to ensure the amount of the bond maintained to protect patients' financial assets is equal to or greater than 1.25% of the average trust fund balance as calculated by the average balance of the trust fund for the preceding 12 months. Proof of the current surety bond must be made available at the time of an initial and subsequent state licensing surveys, compliant investigations, or upon request of the department to meet the requirements of section 21721(2) of the code, MCL 333.21721.

History: 2020 MR 4, Eff. Feb. 21, 2020.

### **R 325.45385 Involuntary transfer or discharge.**

Rule 385. (1) When a nursing care facility provides a patient or the patient's legal guardian with a notice of involuntary transfer or discharge, the facility shall provide a copy of the notice to the department and the state long-term care ombudsman at the time the notice is issued to the patient or the patient's legal guardian and pursuant to the submission procedures established by the department.

(2) A patient or the patient's legal guardian or designated representative may submit a completed hearing request form, as required by section 21773 of the code, MCL 333.21773, and provided by the department on its website, or any written communication that clearly states a hearing is requested. The hearing request must be timely filed as described in section 21774(1) of the code, MCL 333.21774. Upon receipt of a timely filed hearing request, the department shall make arrangements for the scheduling of a hearing under section 21774 of the code, MCL 333.21774, through the Michigan Office of Administrative Hearings and Rules (MOAHR).

(3) After a hearing is concluded under R 325.45247, R 325.45249, and R 325.45251, and only if there was a finding in the hearing decision or order that a permitted basis for transfer or discharge exists under section 21773 of the code, MCL 333.21773, or if no appeal request is received from the patient and the 10 day appeal period has expired, the nursing care facility shall submit to the department a proposed transfer or discharge plan, which must include all of the following:

(a) Identification of the patient or other person, as identified by the patient, that participated in the selection of the new facility or setting.

(b) A statement by the patient's attending physician outlining how the new facility or setting meets the patient's medical and psychosocial needs.

(c) Identification of equipment or services that are needed for continued care of the patient in the new facility or setting and confirmation that those items have been prearranged by the transferring nursing care facility.

(d) Verification that the floor plans, brochures, pictures, and other documents to familiarize the patient with the new facility or setting have been provided to the patient, unless the patient is returning to a setting that the patient is familiar with. The patient may also request to visit the new facility or setting. Verification of how the transferring nursing care facility accommodated this request must be included.

(e) Identification of how the patient's clothing and personal items are being moved to the new facility or setting.

(4) The nursing care facility shall not transfer or discharge the patient without department approval in writing of the proposed transfer or discharge plan.

History: 2020 MR 4, Eff. Feb. 21, 2020.