**Michigan Office of Administrative Hearings and Rules**
611 W. Ottawa Street
Lansing, MI 48909
Phone: 517-335-8658  Fax: 517-335-9512

# AGENCY REPORT TO THE JOINT COMMITEE ON ADMNINISTRATIVE RULES (JCAR)

**1. AgencyInformation**

**Agency name:**
Licensing and Regulatory Affairs

**Division/Bureau/Office:**
Bureau of Community and Health Systems

**Name of person completing this form:**
Tammy Bagby

**Phone Number of person completing this form:**
517-335-4084

**E-mail of person completing this form:**
bagbyt@michigan.gov

**Name of Department Regulatory Affairs Officer reviewing this Form:**
Elizabeth Arasim

**2. Rule Set Information**

**ORR assigned rule set number:**
2017-101 LR

**Title of proposed rule set:**
Licensing Health Facilities or Agencies

**3. Purpose for the proposed rules and background:**

There are six rule sets for licensing health facilities and agencies. Although most of them have undergone periodic review and revision, it has been too long since a comprehensive review and revision was done to assure they comport with current practice standards, to harmonize them with current federal law and regulations, and to reflect the current organization of state licensing functions. Some of these rules are obsolete and there is a significant amount of duplication between rule sets. The purpose of promulgating a single new rule set for health facility licensing is to better protect the health, safety, and welfare of individuals receiving care and services in or from a health facility or agency, and to assure the medical accountability for reimbursed care provided by a certified health facility or agency participating in a federal or state health program. The new rule set will: Focus on core principles and standards of health facility licensing; fulfill statutory requirements; comport with current practice standards; harmonize with federal law and regulations; and be free of redundant, obsolete, or unnecessary language. The new rule set will replace the following six rule sets, which will be rescinded: 1.Minimum Standards for Hospitals – R 325.1001 to R 325.1101. 2. Complaints – R 325.1213 to R 325.1217. 3. Public Inspection of License Records – R 325.1281 to R325.1282. 4. Freestanding Surgical Outpatient Facilities – R 325.3801 to R 325.3877. 5. Hospice Licensure Rules – R 325.13101 to R 325.13541. 6. Nursing Homes and Nursing Care Facilities – R 325.20101 to R 325.22004.

**4. Summary of proposed rules:**

This new single set of administrative rules replaces six individual rules sets for the licensing health facilities and agencies. This new rule set has been updated to comport with current practice standards, to harmonize them with current federal law and regulations, and to reflect the current organization of state licensing functions. The purpose of promulgating a single new rule set for health facility or agency licensing is to better protect the health safety and welfare of individuals receiving care and services in or from a health facility or agency and to assure the medical accountability for reimbursed care provided by a certified health facility or agency participating in a federal or state health program.

**5. List names of newspapers in which the notice of public hearing was published and publication dates:**

Jackson Citizen Patriot- May 14, 2019
Grand Rapids Press- May 14, 2019
The Mining Journal- May 16, 2019

**6. Date of publication of rules and notice of public hearing in Michigan Register:**

6/7/2019

**7. Date, time, and location of public hearing:**

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**8. Provid the link the agency used to post the regulatory impact statment and cost-benefit analysis on its website:**

https://dtmb.state.mi.us/ARS_Public/Transaction/RFRTransaction?TransactionID=9

**9. List of the name and title of agency representative(s) attending public hearing:**

Tammy Bagby, Analyst Legislative Reporting, Rules, Training and FOIA Section; Larry Horvath, Bureau of Community and Health Systems Director; Heather Hosey, Health Facility Licensing, Permits and Support Division Director; Karen Krzanowski, Manager Legislative Reporting, Rules, Training and FOIA.

**10. Persons submitting comments of support:**

a. Margaret Chamberlain
b. Dan Holmes, NSF International
c. Andrew Ward, NSF International
d. Andrew Beck and Merissa Kovach, of the American Civil Liberties Union, on behalf of the Women's Center of Saginaw and Women's Center of Flint.
e. Shelly Miller, of Scotsdale Women's Center
f. Andrew Gwinnell, of Truvista Surgery Center
g. Cara Jansma, of Spectrum Health
h. Salli Pung, State Long Term Care Ombudsman
i. Karen Cafeo, Angela Hospice.

**11. Persons submitting comments of opposition:**

None.

**12. Identify any changes made to the proposed rules based on comments received during the public comment period:**

| | Name & Organization | Comments made at public hearing | Written Comments | Agency Rationale for change | Rule number & citation changed |
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| 1 | Cara L. Jansma Deputy General Counsel Spectrum Health | | See email message from Ms. Jansma on June 7, 2019, regarding the definition of "governing body." She expressed concern that the proposed definition could be problematic for health systems that have multiple health facilities. She requested a revision to make the definition consistent with the definition of "governing body" that is used by the federal Centers for Medicare and Medicaid Services (CMS). | Clarified the definition of "governing body" to mean "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." This definition is consistent with the definition used by the Centers for Medicare and Medicaid Services (CMS). | R 325.45105 (a) |

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| 2 | Andrew Gwinnell, MHSA, CASC Executive Director Truvista surgery Center He was representing the Michigan Ambulatory Surgical Association (MASA) | | See email message from Mr. Gwinnell on June 7, 2019 concerning the definition of "physician." He pointed-out that, in freestanding surgical outpatient facilities, the term "physician" is not only used in reference to an allopathic physician and an osteopathic physician, but could also mean a doctor of dentistry or a doctor of podiatry. CMS recognizes all four types of physicians as performing surgery in ambulatory surgical facilities. | The definition of "physician" was expanded to mean "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." This is consistent with the CMS definition. | R 325.45107 (i) |

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| 3 | Margaret Chamberlain | Consider adding language in Part 10, Subpart A, which pertains to freestanding surgical outpatient facilities, that the location of the surgical procedure is decided by the physician based on the procedure and the medical condition of the patient. | | Revised the definition of "surgery" to mean "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: . . . . " | R 325.45109 (b) |

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| 4 | Andrew Gwinnell, MHSA, CASC Executive Director Truvista surgery Center He was representing the Michigan Ambulatory Surgical Association (MASA) | | See email message from Mr. Gwinnell on June 7, 2019 concerning an active surveillance program for infection detection through ongoing data collection an analysis that includes patients, personnel, including contract workers who have access to or contact with active patient care areas. MASA is concerned that gathering this type of data on contract workers who have very little exposure to active patient care areas would be overly burdensome. | This requirement was revised as follows: "(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." | R 325.45137 (a) |

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| 5 | Karen Cafeo, BSN, RN, CHPN, CPHQ Director of Quality Angela Hospice Ms. Cafeo was representing the Michigan HomeCare and Hospice Association (MHHA). | | See email message from Ms. Cafeo, June 6, 2019, regarding recommendations from the Centers for Disease Prevention and Control (CDC) for Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel. She pointed-out that, since the proposed rules were submitted for public comment, the CDC updated its recommendations. | The proposed rule was revised to reference the current CDC recommendations. | R 325.45139 (3) |
| 6 | Cara L. Jansma Deputy General Counsel Spectrum Health | | See email message from Ms. Jansma, June 7, 2019, regarding the requirement for the governing body to appoint an administrator. For hospitals, she requested to have the term "administrator" replaced with "chief executive officer," which is consistent with CMS regulations. | This rule was revised to be consistent with the CMS regulation. | R 325.45171 |
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| 7 | Cara L. Jansma<br>Deputy General Counsel<br>Spectrum Health | | See email message from Ms. Jansma, June 7, 2019, regarding Medical Director. She pointed-out that the proposed language in this rule doesn't fit well with hospitals because they have elected medical staffs who are responsible for oversight of the medical care provided in hospitals. | This proposed rule was revised to ensure that it fits well for all types of health facilities and agencies; and, to make it consistent with CMS regulations. The revised rules reads: "Rule 173. (1) The governing body must 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." | R 325.45173 |

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| 8 | Andrew Gwinnell, MHSA, CASC Executive Director Truvista surgery Center He was representing the Michigan Ambulatory Surgical Association (MASA) | | See email message from Mr. Gwinnell, June 7, 2019, regarding employee records. He asked for clarification on what communicable diseases will employees need to be screened for and have a record maintained. He also asked for clarification on when an employee is considered to be a former employee. | The proposed rule was revised to provide these clarifications. It now reads: "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. | R 325.45183 |

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| 9 | Cara L. Jansma<br>Deputy General Counsel<br>Spectrum Health | | See email message from Ms. Jansma, June 7, 2019, regarding orders. Subrule (3) of the proposed rule required a licensed health professional to record a verbal or telephone order. Ms. Jansma pointed-out that CMS and the Joint Commission allow hospitals to specify who is qualified to record a verbal order. | Subrule (3) of the proposed rule was revised to read: "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." | R 325.45199 (3) |
| 10 | Cara L. Jansma<br>Deputy General Counsel<br>Spectrum Health | | See email message from Ms. Jansma, June 7, 2019, regarding radiological services. Rule 213, subrule (5), required a health facility or agency | The department sought advice from T.R. Wentworth II, Supervisor, Radioactive Materials Unit, Materials Management Division, | R 325.45213 (5) |

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| | | | | to immediately report any adverse testing or machine error or adverse patient reaction to the appropriate licensed health care professional as soon as possible and record this information in the patient's record. Any corrective action must be initiated promptly and recorded in the patient's record. Ms. Jansma points-out that standard of care should dictate documentation that goes in the patient record. She states: "Adverse testing, machine error, or adverse patient reaction all could be inconsequential, and this level of response may not be necessary. If it is material, any investigation and corrective action is not appropriate for documentation in the patient's record. Instead, a requirement for | Michigan Department of Environment, Great Lakes, and Energy. Rule 213, subrule (5) was revised to read: "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." | |

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| | | | facility investigation and corrective action alone should be sufficient. Facilities should be able to demonstrate to surveyors our process for investigation and corrective action." | | |
| 11 | Andrew Gwinnell, MHSA, CASC Executive Director Truvista surgery Center He was representing the Michigan Ambulatory Surgical Association (MASA) | | See email from Mr. Gwinnell, June 7, 2019, regarding scrub sinks. The proposed rule stipulates that 2 scrub positions with gooseneck outlets must be provided near the entrance to each operating room. Mr. Gwinnell asked if it is necessary to have 2 scrub sinks for each OR, or could that number be reduced? | The department revised this rule to be consistent with the FGI Guidelines for Design and Construction of Hospitals. The rule was revised to read: "(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." | R 325.45277 (d)(ii) |

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| 12 | Andrew Gwinnell, MHSA, CASC Executive Director Truvista surgery Center He was representing the Michigan Ambulatory Surgical Association (MASA) | | See email message from Mr. Gwinnell, June 7, 2019, regarding individual dressing rooms. He stated that "Some surgery centers are one room ORs with a one room dressing area. Can that serve both female and male without the need to build a second dressing room?" | Rule 295, subrule (3) was revised to read: "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." | R 325.45295 (3) |
| 13 | Margaret Chamberlain, representing herself. | In the general provisions for surgery, consider acknowledging past physical plant waivers and allowing those waivers to remain in effect. This pertains to R 325.45343 Waiver of modification provisions. | | Rule 343 was revised to add subrule (4), which reads: "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. | R 325.45343 |

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| 14 | Salli Pung, Long Term Care Ombudsman | | See her written comment, attached, which pertains to R 325.45385. | Since the proposed rules were submitted for public comment, the name of the Michigan Administrative Hearing System was changed to the Michigan Office of Administrative Hearings and Rules (MOAHR). Subrule (2) was revised to use the current name. | R 325.45385 (2) |
| 15 | LARA-BCHS | | Technical correction by adding the legal citation. | Rule 367, subrule (1) as revised to read: "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. | R 325.45367 (1) |
| 16 | LARA-BCHS | | None. | Technical correction to delete "department of environmental quality" and replace it with "department of environment, great lakes and energy (DEGLE). | R 325.45303 (3) |
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| 17 | LARA-BCHS | | None. | Corrected a reference to other rules within this rule set. Subrule (1) was revised as follows: "In addition to the human resources requirements in part 4 of these rules, R 325.45171 to R 325.45185, . . . ." | R 325.45355 (1) |

**13.Date Report Completed:**

10/15/2019