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REGULATORY IMPACT STATEMENT and COST-BENEFIT ANALYSIS (RISCBA)

PART 1: INTRODUCTION

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate the rules must complete and submit this form electronically to the Office of Regulatory Reinvention (ORR) at **orr@michigan.gov** no less than 28 days before the public hearing.

1. Agency Information

Agency name:	Licensing and Regulatory Affairs
Division/Bureau/Office:	Bureau of Community and Health Systems
Name, title, phone number, and e-mail of person completing this form:	Karen Krzanowski, Manager, 517-284-8968, krzanowskik@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim, LARA

2. Rule Set Information

ORR assigned rule set number:	2017-101 LR
Title of proposed rule set:	Licensing Health Facilities or Agencies

PART 2: KEY SECTIONS OF THE APA

MCL 24.207a "Small business" defined.

Sec. 7a. "Small business" means a business concern incorporated or doing business in this state, including the affiliates of the business concern, which is independently owned and operated, and which employs fewer than 250 full-time employees or which has gross annual sales of less than $6,000,000.00.

MCL 24.232 (8) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than the applicable federally mandated standard unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(9) Except for an emergency rule promulgated under section 48, and subject to subsection (10), if the federal government has not mandated that this state promulgate rules, an agency shall not adopt or promulgate a rule more stringent than an applicable federal standard unless specifically authorized by a statute of this state or unless the director of the agency determines that there is a clear and convincing need to exceed the applicable federal standard.

(10) Subsections (8) and (9) do not apply to the amendment of the special education programs and services rules, R 340.1701 to R 340.1862 of the Michigan Administrative Code. However, subsections (8) and (9) do apply to the promulgation of new rules relating to special education with the rescission of R 340.1701 to R 340.1862 of the Michigan Administrative Code.

MCL 24.240 Reducing disproportionate economic impact of rule on small business; applicability of section and MCL 24.245(3).

Sec. 40. (1) When an agency proposes to adopt a rule that will apply to a small business and the rule will have a disproportionate impact on small businesses because of the size of those businesses, the agency shall consider exempting small businesses and, if not exempted, the agency proposing to adopt the rule shall reduce

the economic impact of the rule on small businesses by doing all of the following when it is lawful and feasible in meeting the objectives of the act authorizing the promulgation of the rule:

(a) Identify and estimate the number of small businesses affected by the proposed rule and its probable effect on small businesses.

(b) Establish differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

(c) Consolidate, simplify, or eliminate the compliance and reporting requirements for small businesses under the rule and identify the skills necessary to comply with the reporting requirements.

(d) Establish performance standards to replace design or operational standards required in the proposed rule.

(2) The factors described in subsection (1)(a) to (d) shall be specifically addressed in the small business impact statement required under section 45.

(3) In reducing the disproportionate economic impact on small business of a rule as provided in subsection (1), an agency shall use the following classifications of small business:

(a) 0-9 full-time employees.

(b) 10-49 full-time employees.

(c) 50-249 full-time employees.

(4) For purposes of subsection (3), an agency may include a small business with a greater number of full-time employees in a classification that applies to a business with fewer full-time employees.

(5) This section and section 45(3) do not apply to a rule that is required by federal law and that an agency promulgates without imposing standards more stringent than those required by the federal law.

MCL 24.245 (3) Except for a rule promulgated under sections 33, 44, and 48, the agency shall prepare and include with the notice of transmittal a **regulatory impact statement** which shall contain specific information (information requested on the following pages).

PART 3: AGENCY RESPONSE

Please provide the required information using complete sentences. **Do not answer any question with "N/A" or "none."**

Comparison of Rule(s) to Federal/State/Association Standards:

1. Compare the proposed rule(s) to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

There are no parallel federal rules or standards set by a state or national licensing agency. However, the proposed rules were compared to federal regulations for the certification of health facilities by the U.S. Center for Medicare and Medicaid Services (CMS). The proposed rules were also compared to accreditation standards of The Joint Commission. The proposed rules are consistent with the CMS regulations and Joint Commission standards without duplicating or exceeding them. They focus on licensing requirements as opposed to Medicare and Medicaid requirements or accreditation standards.

A. Are these rule(s) required by state law or federal mandate?

These rules are required by state mandate pursuant to sections 20115, 20171, 21419, 21521, 21523, 21561, 21562, 21563, 21615, and 21741 of the Public Health Code, MCL 333.20115, 333.20171, 222.21419, 333.21521, 333.21523, 333.21562, 333.21563, and 333.21741. In addition, these rules are permitted pursuant to sections 333.21561 and 333.21615.

B. If these rule(s) exceed a federal standard, identify the federal standard or citation, describe why it is necessary that the proposed rule(s) exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

These rules do not exceed a federal standard.

2. Compare the proposed rule(s) to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

The proposed rules were developed by the department in collaboration with a broad array of stakeholders representing each type of health facility or agency. More than 50 organizations and individuals contributed to the development of these rules. Six work groups were formed to develop rules on the following subjects: Complaints and investigations, environment of care, freestanding surgical outpatient facilities, hospice, hospital, and nursing homes. Each work group studied the existing rules applicable to their subject; they identified obsolete rules, rules that need to be retained or revised, and gaps that need to be addressed with new rules. In the course of their deliberations they reviewed parallel rules in other states that were identified as good models. For example, the State of Indiana's rules for licensing hospitals were reviewed, and the State of Ohio's rules for licensing health care facilities were also reviewed. In general, Michigan's proposed rules are fairly similar.

A. If the rule(s) exceed standards in those states, explain why and specify the costs and benefits arising out of the deviation.

The proposed rules do not exceed standards in other, similarly situated states.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rule(s).

To the best of our knowledge, the proposed rules do not duplicate, overlap, or conflict with any other laws, rules or other legal requirements. Actually, by rescinding the six existing rule sets for licensing different types of health facilities or agencies, and consolidating their licensing rules in a single rule set, we were able to eliminate many duplicative rules. In total, 191 rules would be eliminated.

A. Explain how the rule has been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

The department undertook this project to review and update the licensing rules for health facilities and agencies because the existing rules are outdated and do not comport with current standards of practice. One of the objectives of this project is to eliminate any duplication or conflict with other federal or state requirements. In addition, the existing rules for freestanding surgical outpatient facilities, hospice, hospitals, and nursing homes include many rules that are duplicated across these facility types. By rescinding the six rule sets that apply to these facilities, and replacing them with a single rule set, these duplicate rules will be eliminated (191 rules would be eliminated).

4. If MCL 24.232(8) applies and the proposed rule(s) is more stringent than the applicable federally mandated standard, **a statement of specific facts that establish the clear and convincing need to adopt the more stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard** is required below:

MCL 24.232(8) does not apply to the proposed rules because there are no applicable federally mandated standards for licensing health facilities or agencies.

5. If MCL 24.232(9) applies and the proposed rule(s) is more stringent than the applicable federal standard, **either the statute that specifically authorizes the more stringent rule(s) or a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rule(s) and an explanation of the exceptional circumstances that necessitate the more stringent standard** is required below:

MCL 24.232(9) does not apply to the proposed rules because there are no applicable federal standards for licensing health facilities or agencies.

Purpose and Objectives of the Rule(s):

6. Identify the behavior and frequency of behavior that the proposed rule(s) are designed to alter.

Article 17 of the Public Health Code, MCL 333.20101 to 333.22260, regulates health facilities and agencies. Section 20131 of the code, MCL 333.20131, requires the department to establish a comprehensive system of licensure and certification for health facilities or agencies in accordance with Article 17 to:

a. Protect the health, safety, and welfare of individuals receiving care and services in or from a health facility or agency.
b. Ensure the medical accountability for reimbursed care provided by a certified health facility or agency participating in a federal or state health program.

Section 20171 of the Public Health Code, MCL 333.20171, requires the department to promulgate and enforce rules to implement Article 17 of the Code, including rules necessary to enable a health facility or agency to qualify for and receive federal funds available for patient care or for projects involving new construction, additions, modernizations, or conversions. In addition, section 20171 requires that rules applicable to health facilities or agencies shall be uniform insofar as is reasonable. Finally, section 20171 stipulates that the rules shall establish standards relating to:

a. Ownership.
b. Reasonable disclosure of ownership interests in proprietary corporations and partnerships.
c. Organization and function of the health facility or agency, owner, operator, and governing body.
d. Administration.
e. Professional and nonprofessional staff, services, and equipment appropriate to implement section 20141(3) of the code, MCL 333.20141(3), which requires a health facility or agency to have the physician, professional nursing, health professional, technical and supportive personnel, and the technical, diagnostic, and treatment services and equipment necessary to assure the safe performance of the health care undertaken by or in the facility or agency.
f. Policies and procedures.
g. Fiscal and medical audit.
h. Utilization and quality control review.
i. Physical plant including planning, construction, functional design, sanitation, maintenance, housekeeping, and fire safety.
j. Arrangements for the continuing evaluation of the quality of health care provided.
k. Other pertinent organizational, operational, and procedural requirement for each type of health facility or agency.

The rules are designed to ensure that health facilities or agencies will continuously meet all of these standards.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rule(s).

The proposed rules won't change the frequency of the targeted behavior expected because the department already has a comprehensive system of licensure and certification for health facilities or agencies in accordance with Article 17. The proposed rules would replace six existing, outdated rule sets for this purpose.

B. Describe the difference between current behavior/practice and desired behavior/practice.

The proposed rules replace outdated rules. They require health facilities or agencies to comply with current standards of practice.

C. What is the desired outcome?

The desired outcome is an improved comprehensive system of licensure and certification of health facilities or agencies that leads to improved patient care, safety, and more effective and efficient use of resources.

7. Identify the harm resulting from the behavior that the proposed rule(s) are designed to alter and the likelihood that the harm will occur in the absence of the rule.

Rules for licensing health facilities and agencies are essential for protecting public health and safety. They are also required in order for health facilities or agencies to qualify for Medicare and Medicaid funding. Without them public health and safety would be jeopardized.

A. What is the rationale for changing the rule(s) instead of leaving them as currently written?

Currently, there are six separate rule sets for licensing health facilities and agencies. Although these rule sets have undergone periodic review and revision, it's been too long since they have undergone a comprehensive review and revision to comport with today's practice standards, to harmonize them with current federal law and regulations, and to reflect the current organization of state licensing functions. Quite a few of the current rules are obsolete. For example, the Minimum Standards for Hospitals include rules that apply to "maternity hospitals," which no longer exist and are no longer licensed separately; and, the Nursing Homes and Nursing Care Facilities rules contain obsolete references, such as "Nursing Facilities for Care of Mentally Retarded Patients" and "Child Care Homes and Units." Furthermore, there is a lot of duplication between rules sets. For example, most of these rule sets include provisions for patient rights and responsibilities, a complaint process, and requirements for buildings; but they are not consistent across facility types.

8. Describe how the proposed rule(s) protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The proposed rule set was developed by the department through a collaborative project that included representatives from all types of licensed health facilities and agencies, including freestanding surgical outpatient facilities, hospice agencies and residences, hospitals, and long-term care facilities. The purpose of the project was to identify the core principles and standards of health facility licensing; conduct a comprehensive review of the exiting rule sets for licensing health facilities or agencies; update all health facility licensing rules; and consolidate them into a single, streamlined rule set. The proposed rule set meets the project objectives to:

- Fulfill statutory requirements for rule-making.
- Be uniform insofar as is reasonable.
- Enable the department and health facilities and agencies to focus on a core set of principles and standards for health facility licensing and regulation.
- Be free of unnecessary repetition of federal and state statutory and regulatory language.
- Be free of obsolete and unnecessary rules.
- Be consistent across different types of health facilities and agencies, unless differences are necessary to fulfill statutory, medical or structural requirements.
- Result in at least 25 percent fewer rules.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

Six rules sets will be rescinded and replaced with one new rule set. The number of rules to be rescinded is 315. The proposed new rule set has 124 rules. The number of rules that would be eliminated is 191. This is a 60% decline in the number of rules for licensing health facilities and agencies.

Fiscal Impact on the Agency:

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, higher contract costs, programming costs, changes in reimbursement rates, etc. over and above what is currently expended for that function. It does not include more intangible costs or benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

10. Describe the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings).

The proposed new rule set is budget neutral. They would not change the agency's cost or revenue.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rule(s).

No appropriations have been made or funding source provided for any expenditures associated with the proposed rules because they are budget neutral.

12. Describe how the proposed rule(s) is necessary and suitable to accomplish its purpose, in relationship to the burden(s) it places on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

No new burdens (fiscal, administrative, or duplicative) would be placed on individuals.

A. Despite the identified burden(s), identify how the requirements in the rule(s) are still needed and reasonable compared to the burdens.

No new burdens would be placed on any individuals.

Impact on Other State or Local Governmental Units:

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for such other state or local governmental units as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There would be no increase or decrease in revenues to other state or local governmental units as a result of the new rule set.

A. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

The new rule set would not increase or decrease the cost for other state or local governmental units.

14. Discuss any program, service, duty or responsibility imposed upon any city, county, town, village, or school district by the rule(s).

No program, service, duty or responsibility would be imposed upon any city, county, town, village, or school district by the proposed rule set.

A. Describe any actions that governmental units must take to be in compliance with the rule(s). This section should include items such as record keeping and reporting requirements or changing operational practices.

There are no actions that governmental units must take to be in compliance with the new rule set.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rule(s).

No additional expenditures are associated with the new rule set, so no appropriation to state or local governmental units will be required.

Rural Impact:

16. In general, what impact will the rule(s) have on rural areas?

The new rule set does not have any impact on rural areas.

A. Describe the types of public or private interests in rural areas that will be affected by the rule(s).

Licensed health facilities or agencies, public and private, in rural areas are currently affected by the existing rules for licensing health facilities or agencies. They would continue to be affected by the proposed new rule set, just like those in non-rural areas. That is, they will be subject to fewer rules.

Environmental Impact:

17. Do the proposed rule(s) have any impact on the environment? If yes, please explain.

They would have a small positive impact on the environment. For example, the rule on water supply systems (R 325.45303) includes updated requirements. Under the proposed rules, a health facility would be required to 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." In addition, a health facility would be required to 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." The rule for managing medical waste, biohazards, solid waste, and sanitary sewage was updated to reflect current best practices. Furthermore, health facilities would be required to utilize active integrated pest management processes.

Small Business Impact Statement:

18. Describe whether and how the agency considered exempting small businesses from the proposed rule(s).

For the most part, the types of health facilities and agencies that are required to be licensed and, therefore, are subject to the new rule set, are not small businesses. Those that are small businesses were considered, and the rules include provisions to ensure they would be able to comply with no more costs than they have now under the existing rules.

19. If small businesses are not exempt, describe (a) how the agency reduced the economic impact of the proposed rule(s) on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rule(s) upon small businesses as described below, per MCL 24.240(1)(a)-(d), or (b) the reasons such a reduction was not lawful or feasible.

The new rule set would not have a disproportionate impact on small businesses. On the contrary, small businesses, just like larger ones, would be subject to fewer rules.

A. Identify and estimate the number of small businesses affected by the proposed rule(s) and the probable effect on small business.

Some freestanding outpatient surgical facilities and hospices are small businesses. These businesses will not be negatively impacted by the new rule set.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

No differences in compliance or reporting requirements or timetables for small businesses are needed. Currently, under the existing rule sets, all licensed health facilities and agencies have the same requirements. That would not change under the proposed new rule set.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

The department consolidated and simplified compliance and reporting requirements for all licensed health facilities or agencies, including small businesses, because outdated and duplicative rules would be eliminated.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rule(s).

The department did not establish performance standards to replace design or operation standards. However, design and operation standards are updated and made uniform to the extent possible. For example, for construction permit reviews, the new rules adopt three facility guidelines from the Facility Guidelines Institute (FGI), which comprise a nationally recognized model code.

20. Identify any disproportionate impact the proposed rule(s) may have on small businesses because of their size or geographic location.

The proposed rules would not have any disproportionate impact on small businesses due to their size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rule(s).

No new reports are required.

22. Analyze the costs of compliance for all small businesses affected by the proposed rule(s), including costs of equipment, supplies, labor, and increased administrative costs.

The proposed rules would not impose any new costs on small businesses.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rule(s).

Small businesses would not incur any new costs for legal, consulting, or accounting services to comply with the proposed rules.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

Licensed health facilities and agencies that are small businesses are subject to licensing rules now. The proposed rules would not impose any new costs that would affect competition in the marketplace.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

If the rules for licensing health facilities and agencies were not uniform (i.e., different standards were established for small businesses) the department would incur additional costs to administer a bifurcated licensing process.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

If lesser standards of compliance were established for licensed health facilities or agencies that are small businesses, public health and safety could be jeopardized. Consumers should be protected by the same health and safety standards regardless of the size of the licensed health facility or agency.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rule(s).

The department's project to develop the new rule set involved stakeholders from the very beginning. All of the licensed health facilities and agencies that are impacted by the rule set were invited to participate. Many associations, whose memberships include large and small businesses, sent representatives to participate, including but not limited to:

- Michigan Health and Hospital Association (MHA)
- Health Care Association of Michigan (HCAM)
- LeadingAge
- Michigan Ambulatory Surgery Association (MASA)
- Michigan County Medical Care Facilities Council
- Michigan HomeCare & Hospice Association (MHHA)
- Michigan Society for Healthcare Engineering (MiSHE)
- Long-Term Care Ombudsman.

A. If small businesses were involved in the development of the rule(s), please identify the business(es).

Since small businesses were represented by their respective Associations, it's not possible to name them. Several businesses did send personnel to represent them, but these businesses were not necessarily small, for example: Lakes Surgery Center, TruVista Surgery Center, Holland Home, Burcham Hills, Canterbury-on-the-Lake, Spectrum Health.

Cost-Benefit Analysis of Rules (independent of statutory impact):

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

Statewide compliance costs of the proposed new rule set on businesses or groups will not be substantially different than their current costs to comply with the existing rules. There could be some cost savings as a result of having fewer rules.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rule(s).

Licensed health facilities and agencies, including: Freestanding outpatient surgery centers (136), hospice agencies and residences (159), hospitals (167), long-term care facilities (460).

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

No additional costs will be imposed on businesses and other groups as a result of the proposed new rule set.

29. Estimate the actual statewide compliance costs of the proposed rule(s) on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

No new compliance costs would be imposed. The proposed new rule set simply replaces six existing rule sets and reduces the total number of rules for licensing health facilities or agencies.

A. How many and what category of individuals will be affected by the rules?

Individuals who use the services of freestanding outpatient surgery centers, hospice agencies and residences, hospitals, and long-term facilities will be affected by the rules.

B. What qualitative and quantitative impact does the proposed change in rule(s) have on these individuals?

The proposed new rule set would ensure that licensed health facilities and agencies meet minimum standards of quality that reflect current best practices to assure public health and safety.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rule(s).

No direct cost reductions to any of these entities are likely to occur as a direct result of the proposed rules.

31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rule(s). Provide both quantitative and qualitative information, as well as your assumptions.

The primary benefits of the proposed rules are:

- Replace six rule sets that include obsolete requirements.
- Ensure that licensed health facilities and agencies meet current standards for quality patient care and safety.
- Make the rules for licensing health facilities and agencies uniform insofar as is reasonable pursuant to section 20171 of the Public Health Code, MCL 333.20171.
- Help achieve the objectives of section 1111 of the Public Health Code, MCL 333.1111, and ensure consistency with applicable federal and state law.

32. Explain how the proposed rule(s) will impact business growth and job creation (or elimination) in Michigan.

Since the proposed rules replace existing rules, rather than establishing new requirements, they would have little if any impact on business growth and job creation (or elimination) in Michigan. By modernizing the regulation of health facilities or agencies in this way, some improvements in quality of care and some improvements in efficiency could be realized.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

No individuals or businesses would be disproportionately affected by the proposed rules.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of a proposed rule(s) and a cost-benefit analysis of the proposed rule(s).

The project to develop the proposed rules was initiated by the department in March 2017. A project charter was established. A steering committee was appointed. Subject matter experts were identified and invited to serve on the steering committee. Key stakeholders were identified. More than 50 organizations and individuals were invited to participate. A kick-off meeting was held in May 2017. Four work groups were established to focus on specific types of health facilities or agencies, including: freestanding surgical outpatient facilities, hospice agencies and residences, hospitals, and long-term care facilities. Work groups were also established to focus on major cross-cutting elements, including: complaints, investigations and hearings, emergency preparedness, infection prevention and control, and environment of care. The work groups spent about six months researching and writing their parts. This involved reviewing the existing rules, reviewing similar rules in other states, comparing rules to federal regulations for Medicare and Medicaid certification, comparing rules to Joint Commission accreditation standards, deciding which rules are obsolete and could be eliminated, deciding which rules should be retained, updating regulatory language, and addressing new issues.

The department hosted six meetings with key stakeholders:

- Project Kick-Off Meeting – May 22, 2017
- November 6, 2017
- March 5, 2018
- April 13, 2018
- May 14, 2018

- June 20, 2018.

Five drafts of the proposed rule set were distributed to stakeholders for review and comment. Each version incorporated recommendations from stakeholders and refined the language. To the greatest degree possible, the proposed rules represent a consensus between the department and these stakeholders.

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rule(s).

The need for the proposed rules has been long established. The problem is the existing rules are out-of-date. They don't properly address the essential health care systems and processes that need to be in place to assure public health and safety. The proposed new rules were developed with input from subject matter experts within LARA, the Department of Health and Human Services, the federal Center for Medicare and Medicaid Services, and representatives of trade associations for health facilities or agencies. In addition, the proposed rules were informed by various individuals with expertise in medicine, nursing, law, building construction, engineering, fire safety, environmental health, emergency management, and infection control.

Alternatives to Regulation:

35. Identify any reasonable alternatives to the proposed rule(s) that would achieve the same or similar goals. Include any statutory amendments that may be necessary to achieve such alternatives.

There are no reasonable alternatives to the proposed rules that would achieve the same or similar goals.

A. In enumerating your alternatives, include any statutory amendments that may be necessary to achieve such alternatives.

No statutory amendments are necessary to implement the proposed rule set.

36. Discuss the feasibility of establishing a regulatory program similar to that in the proposed rule(s) that would operate through private market-based mechanisms. Include a discussion of private market-based systems utilized by other states.

No states use a private market-based system to regulate health facilities or agencies.

37. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rule(s). This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

The bureau incorporated as many recommendations from stakeholders as possible, as long as they met statutory requirements and serve to protect public health and safety. To the extent possible, the proposed rules represent a consensus among associations representing the various licensed health facilities or agencies, consumers, and subject matter experts who participated in the project.

Additional Information:

38. As required by MCL 24.245b(1)(c), describe any instructions on complying with the rule(s), if applicable.

None

↓ To be completed by the ORR ↓

PART 4: REVIEW BY THE ORR

Date RISCBA received:	4-24-2019

Date RISCBA approved:	5/1/19

Date of disapproval:	
Explanation:	