

State Budget Office
Office of Regulatory Reinvention
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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:	Department of Licensing and Regulatory Affairs		
Division/Bureau/Office:	Bureau of Professional Licensing		
Name, title, phone number, and e-mail of person completing this form:	Andria M. Ditschman 517-241-9255 DitschmanA@michigan.gov		
Name of Departmental Regulatory Affairs Officer reviewing this form:	Liz Arasim Department of Licensing and Regulatory Affairs		

2. Rule Set Information

ORR assigned rule set number:	2018-031 LR
Title of proposed rule set:	Board of Midwifery

PART 2: KEY SECTIONS OF THE APA

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.

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).

[**Note:** Additional questions have been added to these statutorily-required questions to satisfy the **cost-benefit analysis** requirements of Executive Order 2011-5].

MCL 24.245b Information to be posted on office of regulatory reinvention website.

Sec. 45b. (1) The office of regulatory reinvention shall post the following on its website within 2 business days after transmittal pursuant to section 45:

- (a) The regulatory impact statement required under section 45(3).
 - (b) Instructions on any existing administrative remedies or appeals available to the public.
 - (c) Instructions regarding the method of complying with the rules, if available.
 - (d) Any rules filed with the secretary of state and the effective date of those rules.
- (2) The office of regulatory reinvention shall facilitate linking the information posted under subsection (1) to the department or agency website.

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.

Each state establishes its own requirements with respect to licensed midwives so there are no federal rules or standards set by a national or state agency that the proposed rules can exceed.

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

The proposed rules are required by state law. Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123, effective April 4, 2017, established the formation of the Michigan Board of Midwifery and required the Board to enact rules within 24 months after the effective date of Part 171.

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.

The proposed rules do not exceed any federal standards.

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

Each state is responsible for implementing its own laws and rules pertaining to licensed midwives.

In Indiana, Minnesota, and Wisconsin midwives are licensed as independent licensed midwives instead of licensing them as nurse midwives/advanced practice registered nurses (APRN). In Illinois, Ohio, and Pennsylvania, midwives are licensed as APRNs, not as independent licensed midwives.

In order to be licensed as a midwife in Indiana, an applicant must submit: a Certified Professional Midwife (CPM) credential from the North American Registry of Midwives (NARM), proof of education, cardiopulmonary resuscitation (CPR) card, American Academy of Pediatrics certificate showing completion of a program in neonatal resuscitation, observation of birth forms, proof of passing an emergency skills training course, proof of liability insurance, a collaborative practice agreement, and a criminal background check. A licensed midwife must work pursuant to a collaborative agreement with a physician holding an unrestricted license to practice medicine in Indiana.

In Minnesota, an applicant must submit: proof of having graduated from an approved education program, a certificate as a CPM by NARM, certification by the American Heart Association (AHA) or the American Red Cross in CPR for adults and infants, a medical consultation plan, and the required practical experience.

In Wisconsin, an applicant is required to provide a certification from NARM or the American College of Nurse Midwives, submit certification in CPR, obtain certification for use of an automated external defibrillator, and background information. In Wisconsin the administrative rules include regulations regarding testing, care of clients, and screening.

Most states do not allow licensed midwives to have prescriptive authority, however, they are allowed to administer medications, order laboratory tests and use devices under certain circumstances. Most states that regulate midwives also address situations pertaining to the transfer of clients and informed consent. All states that issue licenses as an independent midwife require continuing education.

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

Similarly, to Indiana, Minnesota, and Wisconsin, the proposed rules will license midwives as independent midwives and not as APRNs. The proposed rules do not require an applicant to submit proof of liability insurance or a collaborative practice agreement to the Department like Indiana; or proof of use of an automated external defibrillator like Wisconsin. The proposed rules also offer a temporary license which allows an applicant with a CPM from NARM, who does not have a Midwifery Education and Accreditation Council (MEAC) approved educational program or pathway, to earn a midwifery bridge certificate from NARM, that will then allow an applicant to qualify for a full license.

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

There are no other laws, rules or other legal requirements that duplicate, overlap, or conflict with the proposed rules.

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.

There are no other laws, rules or other legal requirements that duplicate, overlap, or conflict with the proposed rules.

Purpose and Objectives of the Rule(s):

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

The purpose of the proposed rules is set forth below:

General Provisions

R 338.17101: This proposed rule lists the definitions of terms used in the proposed rules.

Prelicensure Licensed Midwifery Education

R 338.17111: Pursuant to section 16148 of the code, MCL 333.16148, this proposed rule requires an individual seeking licensure to complete a training in identifying victims of human trafficking.

R 338.17113: This proposed rule pertains to licensed midwifery accrediting organizations. In this proposed rule the Board approves the Midwifery Education Accreditation Council (MEAC) as an accrediting organization and states that other midwifery accrediting organizations equivalent to MEAC may be approved by the Board.

R 338.17115: This proposed rule pertains to licensed midwifery credentialing programs. In this proposed rule the Board, by petition, may approve a licensed midwifery credentialing program if it is equivalent to the credential of CPM from the NARM, meets the criteria of section 16148 of the code, MCL 333.16148, and is accredited by the National Commission for Certifying Agencies (NCCA) or another accrediting organization approved by the Board.

Licensure

R 338.17121: This proposed rule pertains to licensure for licensed midwives. The proposed rule adopts the examination developed and scored by NARM and allows the Board to accept other examinations. The proposed rule will also allow an applicant for licensure to petition the Board to approve an educational program or pathway, or a credential that is equivalent to the CPM from NARM.

R 338.17123: This proposed rule pertains to licensure by endorsement. The proposed rule will allow an applicant who is licensed as a midwife in another state, who has never been licensed as a midwife in Michigan, to apply for a license by submitting an application and meeting the requirements in section 16174 and 17119 of the code, MCL 333.16174 and 333.17119. The proposed rule will also allow an applicant to petition the Board to evaluate whether a credential is equivalent to the CPM from NARM and whether an examination meets the requirements of section 16178(1) of the code, MCL 333.16178(1).

R 338.17125: This proposed rule pertains to lapsed licenses of licensed midwives. The proposed rule will require applicants who have let their license to lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include an application and fee, good moral character, a background check, 30 hours of continuing education, an examination, proof of no disciplinary action from another state, and the CPM or equivalent credential. The proposed rule also addresses the requirements for applicants who have let their Michigan license lapse but who have a valid license in another state.

R 338.17127: This proposed rule requires an applicant for a license who attended a nonaccredited program, or a program outside of the United States, to demonstrate a working knowledge of the English language.

Practice, Conduct, and Classification of Conditions

R 338.17131: This proposed rule lists definitions of terms used in Part 4 of the rules.

R 338.17132: This proposed rule pertains to informed disclosure by the licensed midwife and consent

by the patient. The proposed rule specifies what is required for informed disclosure and informed consent and when they are required. Informed disclosure includes: a description of the licensed midwife's training, philosophy of practice, transfer of care plan, credentials and legal status, services to be provided, availability of a complaint process both with NARM and the state, and relevant Health Insurance Portability and Accountability Act (HIPAA) disclosures; access to the midwife's personal practice guidelines; whether the licensed midwife is permitted to administer drugs and medications pursuant to R 338.17137, and which medications the licensed midwife carries for potential use; access to the Michigan Board of Licensed Midwifery rules; whether the licensed midwife has malpractice liability insurance coverage, and if so, the policy limitations of the coverage. The informed consent process includes: explanation of the available treatments and procedures; explanation of both the risks and expected benefits of the available treatments and procedures; discussion of alternative procedures, including delaying or declining of testing or treatment, and the risks and benefits associated with each choice; documentation of any initial refusal by the patient of any action, procedure, test, or screening that is recommended by the licensed midwife; and obtaining the patient's signature acknowledging that the patient has been informed, verbally and in writing, of the disclosures.

R 338.17133: This proposed rule pertains to additional informed consent requirements. Additional informed consent is required when a patient presents to a licensed midwife under any of the following circumstances: previous cesarean birth, at the inception of care; fetus in a breech presentation, when it is likely in the midwife's judgment the fetus will present in breech presentation at the onset of labor; and twin or multiple gestation, at the time of discovery by the midwife. If additional informed consent is required the licensed midwife is required to: disclose to the patient his or her personal practice guidelines surrounding the management of the pregnancies with these additional circumstances, which includes the licensed midwife's level of experience, type of special training, care philosophy, and outcome history relative to such circumstances; disclose information regarding the licensed midwife's care team and style of management to be expected under such circumstances, including a description of conditions under which the licensed midwife shall recommend transfer or transport; practice within the limits of his or her personal practice guidelines; and provide the patient with an informed choice document, specific to the patient's situation, which includes the potential increased risks and benefits of these additional circumstances, a birth outside a hospital setting, medical care options, and the risks of cesarean section. The licensed midwife is exempt from the requirements in the proposed rule if the circumstances listed in the rule are discovered after the inception of active labor, in an emergent situation, or if the change in the condition of a patient requires immediate action on the part of the licensed midwife.

R 338.17134: This proposed rule pertains to the circumstances in the antepartum, intrapartum, and postpartum phases of labor and in regard to an infant, where the licensed midwife must consult with or refer a patient to an appropriate health professional. The proposed rule allows the licensed midwife to remain in communication with the appropriate health professional until resolution of the concern. The proposed rule also provides that the licensed midwife may maintain care of the patient if possible, or in circumstances where the patient elects to not accept the referral or the appropriate health professional's advice, and the refusal is documented in writing.

R 338.17135: This proposed rule pertains to emergent circumstances involving the mother or infant where the licensed midwife must transfer care of a patient to an appropriate health professional. The licensed midwife is required to: initiate immediate transport according to the licensed midwife's emergency care plan; provide necessary emergency stabilization until emergency medical services arrive or transfer is completed; provide pertinent information to the appropriate health professional; and is encouraged to fill out a patient transfer form provided by the department. The proposed rule allows for transport by private vehicle if it is the most expedient method for accessing medical services. A licensed midwife may continue to provide care to a patient if: no appropriate health professional or other equivalent medical services are available; delivery occurs during transport; the patient refuses to be

transported to the hospital; or the transfer or transport entails futility, or extraordinary and unnecessary human suffering. If authorized by the patient, a licensed midwife may be able to be present during the labor and childbirth, and care may return to the midwife upon discharge.

R 338.17136: This proposed rule lists the conduct by a licensed midwife that is prohibited.

R 338.17137: This proposed rule pertains to the administration of prescription drugs and medications by a licensed midwife. The proposed rule allows a licensed midwife who has appropriate pharmacology training, as defined in the rules, and holds a standing prescription from an appropriate health professional with prescriptive authority, to administer specific listed drugs and medications. Administration of the drugs or medication must be in accordance with Table 1.

R 338.17138: This proposed rule requires a licensed midwife to report a patient’s data to the statistics registry maintained by Midwives Alliance of North America’s (MANA) Division of Research (DOR), pursuant to MANA’s policies and procedures, or a similar registry maintained by a successor organization approved by the Board unless the patient refuses. A licensee shall register with MANA’s DOR, and must annually, by the date determined by MANA, submit patient data on all completed courses of care in the licensee’s practice during the previous 12 months, plus during the first year of licensure, a licensee must submit data from the date of licensure to the date determined by MANA.

License Renewal and Continuing Education

R 338.17141: This proposed rule establishes the requirements for renewal of a license. The proposed rule requires the applicant to: hold the credential of CPM from NARM, or an equivalent credential approved by the Board; accumulate 30 hours of continuing education that is met by obtaining and maintaining, the credential of CPM from NARM, or an equivalent credential approved by the Board; accumulate one hour of continuing education in pain and symptom management; and accumulate two hours of continuing education on cultural awareness that include examination of disparate maternal infant mortality and morbidity experienced by the African American and indigenous populations. The proposed rule states that submission of an application for renewal constitutes the applicant’s certification of compliance with the requirements of the rule. The proposed rule will allow the Board to require an applicant for license renewal to submit evidence to demonstrate compliance with the continuing education requirements. Further, the proposed rule will require a licensee who seeks a waiver of continuing education to submit the request prior to the expiration date of the license. A CPM credential from NARM, or equivalent credential approved by the Board, may not be waived.

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

The proposed rules are required by Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123. All of the proposed rules are new; therefore, midwives were not previously licensed nor were they subject to continuing education or any of the other limitations in the proposed rules. The proposed rules will license midwives, require minimum education and certification, require an examination, require informed disclosure and consent, require consultation and transfer of a client in certain circumstances, limit the drugs and medications used by a midwife, and specify the requirements for a lapsed license or renewal of a license. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function and it is consistent with the law and the proposed rules.

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

The proposed rules are required by Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123. All of the proposed rules are new therefore midwives were not previously licensed

nor were they subject to continuing education or any of the other limitations in the proposed rules. The proposed rules will license midwives, require minimum education and certification, require an examination, require informed disclosure and consent, require consultation and transfer of a client in certain circumstances, limit the drugs and medications used by a midwife, and specify the requirements for a lapsed license or renewal of a license. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function and it is consistent with the law and the proposed rules.

C. What is the desired outcome?

The proposed rules will license midwives, clarify their scope of practice and subject licensees to discipline which will hopefully create a licensure system in Michigan that encourages insurance companies to begin covering services provided by licensed midwives, further lowering the costs for users of midwifery services, and increasing the number of users of such services. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function and it is consistent with the law and the proposed rules.

5. 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.

Without the proposed rules midwives would not be licensed. In addition, although Public Act 417 of 2016 does not require insurance companies to offer coverage for midwifery services, it was the hope of supporters of the Act that by creating a licensure system in Michigan that insurance companies would begin covering services provided by a licensed midwife and the out of pocket costs of midwifery services would be reduced.

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

The proposed rules are required by state law. Public Act 417 of 2016, which took effect April 4, 2017, established Part 171 in the Public Health Code, MCL 333.17101 to MCL 333.17123. Part 171 provides for the creation of the Board of Midwifery and requires the Board to enact rules within 24 months after the effective date of the Act and Part 171.

6. 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 rules will license midwives, require minimum education and certification, require an examination, require informed disclosure and consent, require consultation and transfer of a client in certain circumstances, limit the drugs and medications used by a midwife, and specify the requirements for a lapsed license or renewal of a license. The proposed rules will protect the welfare of Michigan citizens by: subjecting licensure and relicensure applicants to a screening process and discipline to ensure they are qualified to serve the public and safely treating their clients, and by creating a licensure system in Michigan that encourages insurance companies to begin covering services provided by licensed midwives which lowers the costs for users of midwifery services and increases the number of users of such services. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function and it is consistent with the law and the proposed rules.

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

There are no rules being rescinded.

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.

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

As the result of Public Act 417 of 2016, the Department has estimated the implementation of the licensure program, including technology costs to be approximately \$20,000, with ongoing costs to implement, administer and enforce the program to be approximately \$6,281 per year. The Department has estimated that approximately 45 individuals would apply for licensure initially, which would generate \$20,250 in the first year, and approximately \$9,000 each year thereafter.

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

The licensing and regulation of the profession, including the promulgation and implementation of rules, is funded by the collection of licensing fees, as provided under Public Act 417 of 2016. Those fees would be \$450 for an application processing and \$200 for an annual license. Once total application processing fee revenue exceeds \$23,000, Public Act 417 provides that the \$450 application fee would be reduced to \$75. As a result, there was no reason to make an agency appropriation or provide a funding source.

10. 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.

Licensing: The proposed rules will implement the system of licensure for midwives that Public Act 417 of 2016 required and has been established in Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123, which requires an applicant to: complete and pay for an educational program or pathway; complete and pay for the credential of CPM from NARM or a credential approved by the Board; pass and pay for an examination approved by the Board; pay a licensing processing fee of \$450 or \$75, depending on when the fee is paid; and pay an annual licensing fee of \$200. The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated and safe to practice.

Relicensure and Continuing Education: The proposed rules will require applicants who have let their license lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include an application and fee, good moral character, a background check, 30 hours of continuing education which can be met by maintaining the CPM credential from NARM, an examination, and proof of no disciplinary action from another state. The applicant will pay a licensing fee, fees for attendance at continuing education (one hour of pain and symptom management and two hours of cultural awareness), an examination fee, if applicable, and the fee to maintain their CPM from NARM. All of the relicensure requirements are the minimum necessary to ensure that licensees are educated and safe to practice.

Practice, Conduct, and Classification of Conditions: The proposed rules specify what is required for informed disclosure and informed consent and when they are required as well as when a licensed midwife must consult with, refer, or transfer a patient to an appropriate health professional. The proposed rules also list prohibited conduct, specify the type and when drugs and medications may be administered, and require a licensee to report a patient's data to the statistics registry maintained by MANA DOR. The burdens of providing informed disclosure and obtaining informed consent, and reporting data are minimally burdensome on licensees and will protect the public health, safety, and welfare.

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

Licensing: The proposed rules will implement the system of licensure for midwives that Public Act 417 of 2016 required and has been established in Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123, which requires an applicant to: complete and pay for an educational program or pathway; complete and pay for the credential of CPM from NARM or a credential approved by the Board; pass and pay for an examination approved by the Board; pay a licensing processing fee of \$450 or \$75, depending on when the fee is paid; and pay an annual licensing fee of \$200. The proposed rules are necessary, suitable, and the least burdensome requirements on licensees to ensure that licensees are educated and safe to practice.

Relicensure and Continuing Education: The proposed rules will require applicants who have let their license lapse to meet specific requirements depending on the length of time they have been unlicensed. The requirements include an application and fee, good moral character, a background check, 30 hours of continuing education which can be met by maintaining the CPM credential from NARM, an examination, and proof of no disciplinary action from another state. The applicant will pay a licensing fee, fees for attendance at continuing education (one hour of pain and symptom management and two hours of cultural awareness), an examination fee, if applicable, and the fee to maintain their CPM from NARM. All of the relicensure requirements are the minimum necessary to ensure that licensees are educated and safe to practice.

Practice, Conduct, and Classification of Conditions: The proposed rules specify what is required for informed disclosure and informed consent and when they are required as well as when a licensed midwife must consult with, refer, or transfer a patient to an appropriate health professional. The proposed rules also list prohibited conduct, specify the type and when drugs and medications may be administered, and require a licensee to report a patient's data to the statistics registry maintained by MANA DOR. The burdens of providing informed disclosure and obtaining informed consent, and reporting data are minimally burdensome on licensees and will protect the public health, safety, and welfare.

Impact on Other State or Local Governmental Units:

11. 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 are no anticipated increases or decreases in revenues to other state or local government units as a result of the proposed rules.

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.

There are no anticipated increases or decreases in costs to other state or local government units as a result of the proposed rules.

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

There are no anticipated or intended programs, services, duties, or responsibilities imposed on any city, county, town, village, or school district as a result of these proposed rules.

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 these proposed rules.

13. 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 appropriations have been made to any governmental units as a result of these rules. No additional expenditures are anticipated or intended with the proposed rules.

Rural Impact:

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

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensure of midwives, regardless of their location.

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

The proposed rules are not expected to impact rural areas. The proposed rules apply to licensure of midwives, regardless of their location.

Environmental Impact:

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

No, the rules will not have an impact on the environment.

Small Business Impact Statement:

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

The proposed rules impose requirements on individual licensees rather than small businesses. Even if a licensee's practice qualifies as a small business, the Department could not exempt his or her business because it would create a disparity in the regulation of licensed midwives.

17. 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 proposed rules cannot exempt small businesses because the rules do not directly regulate small businesses, but individual licensees.

While licensees may practice independently or as part of a small business, the law does not allow the rules to exempt these individuals from the requirements of the rules. However, the impact on licensees who practice as part of a small business is minimized in the proposed rules, as the rules are written broadly. The proposed rule changes will have a minimal impact on licensees. As a result, a licensee, whether in small business or not, should not be significantly impacted by the changes.

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

The department does not collect or have access to information that would allow it to identify and estimate the number of small businesses that may be affected. No matter what type of business environment a licensee works in, he or she will have to take the necessary steps in order to comply with the proposed rules. The rules do not affect small businesses differently.

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.

The agency did not establish separate compliance or reporting requirements for small businesses.

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 agency did not consolidate or simplify compliance and reporting requirements with the proposed rules.

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

The agency did not establish performance standards to replace design or operation standards required by these rules.

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

The proposed rules affect individual licensees, rather than small businesses. Therefore, there is no disproportionate effect on small businesses because of their size or geographic location.

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

There is no separate cost for report preparation to small businesses.

20. 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.

There are no expected increased costs for small businesses concerning the costs of equipment, supplies, labor, or administrative costs.

21. 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).

There are no expected increased costs for small businesses concerning legal, consulting, or accounting services.

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

There are no expected costs to small businesses that will cause economic harm to a small business or the marketplace as a result of the proposed rules.

23. 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.

The proposed rules impose requirements on licensees. Even if a licensee's employer qualifies as a small business, the department could not exempt his or her business because it would create disparity in the regulation of licensed midwives. Therefore, exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

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

The proposed rules impose requirements on licensees. Even if a licensee's employer qualifies as a small business, the department could not exempt his or her business because it would create disparity in

the regulation of licensed midwives. Therefore, exempting or setting lesser standards of compliance for small businesses is not in the best interest of the public.

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

The Department worked with the Michigan Board of Midwifery in the development of the proposed rules. The Board is composed of licensed health professionals, midwives, and public members. Concerns were received from various associations.

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

The Department worked with the Michigan Board of Midwifery in the development of the proposed rules. The Board is composed of licensed health professionals, midwives, and public members. Concerns were received from various associations.

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

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

The Department does not expect any statewide compliance costs of the proposed rules on businesses or groups.

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

The Department does not expect any businesses or groups to be directly affected by, bear the cost of, or directly benefit from the proposed rules.

- 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.

The Department does not expect the proposed rules to result in any additional costs such as new equipment, supplies, labor, accounting, or recordkeeping on businesses or other groups.

27. 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.

The proposed rules will implement the system of licensure of midwives that Public Act 417 of 2016 required and that has been established in Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123. Regulated individuals will pay: \$1 to \$25 for training on human trafficking; the costs for an educational program; \$1000 to \$2200 for the credential of CPM from NARM and an examination approved by the Board; \$75 to \$450 for an application processing fee; and \$200 for an annual license. Applicants who have let their license lapse may incur fees to meet specific requirements depending on the length of time they have been unlicensed, as specified in these rules. The fees could include a \$450 application processing fee, a \$200 annual license fee, a criminal history background check fee, the fees to maintain a CPM from NARM, fees for attendance at continuing education (one hour of pain and symptom management and two hours of cultural awareness), and an examination fee, if applicable. Once total application fee revenue exceeded \$23,000, Public Act 417 provides that the \$450 application fee would be reduced to \$75.

The Department does not expect the proposed rules to result in new equipment, supplies, labor, accounting, or record keeping fees on the public.

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

Unlicensed midwives will be affected by the rules as they will now be required to apply for a license. In Michigan there are currently approximately 47 midwives with CPMs, 6 in the process of getting their CPMs, and 12 who are practicing but do not have CPMs. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function and it is consistent with the law and the proposed rules.

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

All of the proposed rules are new. Regulated individuals will not incur additional fees solely due to the proposed rules regarding licensure, however they will incur fees due to Public Act 417 of 2016, which added Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123, that specifies the requirements for licensure and the required fees. Regulated individuals will pay approximately: \$1 to \$25 for training on human trafficking; for an educational program; \$1000 to \$2200 for the credential of CPM from NARM and an examination approved by the Board; \$75 to \$450 for an application processing fee; and \$200 for an annual license. Applicants who have let their license lapse may incur fees to meet specific requirements depending on the length of time they have been unlicensed, as specified in these rules. The fees could include a \$450 application processing fee, a \$200 annual license fee, a criminal history background check fee, the fees to maintain a CPM from NARM, fees for attendance at continuing education (one hour of pain and symptom management and two hours of cultural awareness), and an examination fee, if applicable. Once total application fee revenue exceeded \$23,000, Public Act 417 provides that the \$450 application fee would be reduced to \$75.

Once total application fee revenue exceeded \$23,000, Public Act 417 provides that the \$450 application fee would be reduced to \$75.

The Department does not expect the proposed rules to result in any new equipment, supplies, labor, accounting, or record keeping fees on the public.

It is expected that there will be a positive impact on the profession's reputation, goodwill, and customer confidence after licensure.

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

There are no expected reductions in costs to businesses, individuals, groups of individuals or governmental units as a result of the proposed rules.

29. 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 proposed rules will license midwives, require minimum education and certification, require an examination, require informed disclosure and consent, require consultation and transfer of a client in certain circumstances, limit the drugs and medications used by a midwife, and specify the requirements for a lapsed license or renewal of a license. The proposed rules will protect the welfare of Michigan citizens by: subjecting licensure and relicensure applicants to a screening process and discipline to ensure they are qualified to serve the public and safely treating their clients; and creating a licensure system in Michigan that encourages insurance companies to begin covering services provided by licensed midwives, further lowering the costs for users of midwifery services, and increasing the number of users of such services. The system of licensure will prohibit an unlicensed individual from performing an act, task, or function within the practice of midwifery unless trained to perform that act, task, or function, and it is consistent with the law and the proposed rules.

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

The rules are not expected to have an impact on business growth, job creation, or job elimination.

31. 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.

There is not expected to be a disproportionate effect due to industrial sector, segment of the public, business size, or geographic location.

32. 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).

[http://www.legislature.mi.gov/\(S\(eh4exh2i4pz4oylqyklzrjdo\)\)/mileg.aspx?page=getObject&objectName=2015-HB-4598](http://www.legislature.mi.gov/(S(eh4exh2i4pz4oylqyklzrjdo))/mileg.aspx?page=getObject&objectName=2015-HB-4598)

Care of the Obstetrical Patient Experiencing Complications Related to Planned Birth at Home or in a Birth Center, by Spectrum Health

Perspectives on risk: Assessment of risk profiles and outcomes among women planning community birth in the United States, Bovbjerg, 2017

Mapping integration of midwives across the United States: Impact on access, equity, and outcomes, <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0192523>

<http://meacschools.org/>

<http://www.midwife.org/Accreditation>

<http://internationalmidwives.org/>

<http://narm.org/>

<http://www.homebirthsummit.org/>

Illinois:

<https://www.idfpr.com/profs/Nursing.asp>

<http://illinois.midwife.org/>

<http://www.illinoismidwifery.org/>

<http://illinoismidwives.org/>

<http://www.birthlink.com/directory/midwives.html>

Indiana:

<https://www.in.gov/pla/4021.htm>

<https://www.in.gov/pla/4023.htm>

http://www.in.gov/legislative/iac/iac_title?iact=844

Minnesota:

<https://mn.gov/boards/nursing/>

<https://mn.gov/boards/nursing/laws-and-rules/nurse-practice-act/>

<https://www.revisor.mn.gov/statutes/cite/147D>

<https://mn.gov/elicense/a-z/?id=1083-230815#/list/appId//filterType//filterValue//page/1/sort//order/>

Ohio:

<http://midwivesofohio.org/>

<https://www.alliedhealthworld.com/becoming-midwife-in-ohio.html>

<https://learn.org/articles/What-Are-the-Education-Requirements-to-Become-a-Midwife.html>

Pennsylvania:

<http://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Medicine/Pages/default.aspx#.VWy6nEJ9TGs>

<https://www.pacode.com/secure/data/049/chapter18/chap18toc.html>

Wisconsin:

<https://dsps.wi.gov/Pages/Professions/MidwivesLicensed/Default.aspx>

<http://docs.legis.wisconsin.gov/statutes/statutes/440/XIII/981/1>

https://docs.legis.wisconsin.gov/code/admin_code/sps/professional_services/180/182/03/4/a

Licensing Systems in Alaska, Arizona, Arkansas, California, Colorado, Florida, Montana, New Mexico, Oregon, South Carolina, Texas, and Washington.

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).

No estimates or assumptions were made.

Alternatives to Regulation:

33. 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.

The proposed rules are required by state law. Public Act 417 of 2016, which took effect April 4, 2017, established Part 171 of the Public Health Code, MCL 333.17101 to MCL 333.17123. Part 171 provided for the creation of the Michigan Board of Midwifery and required the Board to enact rules within 24 months after the effective date of the Act and Part 171. There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

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

The proposed rules are required by state law. Public Act 417 of 2016, which took effect April 4, 2017, established Part 171 in the Public Health Code, MCL 333.17101 to MCL 333.17123. Part 171 provided for the creation of the Michigan Board of Midwifery and required the Board to enact rules within 24 months after the effective date of the Act and Part 171. There is no other reasonable alternative to the proposed rules that would achieve the same or similar goal.

34. 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.

Since the rules are authorized by statute, private market-based systems cannot serve as an alternative. Each state is responsible for implementing its own laws and rules pertaining to licensing midwives. Private market-based systems are not used for regulating licensees. The licensing and regulation of licensed midwives are state functions, so a regulatory program independent of state intervention cannot be established.

35. 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.

Since the rules are required by statute, there are no alternatives to the proposed rules that the agency could consider. They are necessary for the administration and enforcement of the licensing process.

Additional Information:

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

Licensing: The rules will explicitly inform licensees of the license requirements.

Relicensure/Continuing Education: The rules will explicitly inform licensees of the relicensure and continuing education requirements.

Practice, Conduct, and Classification of Conditions: The rules will explicitly inform licensees of: the requirements for informed disclosure and informed consent and when they are required; when a licensed midwife must consult with, refer, or transfer a patient to an appropriate health professional; the type and when drugs and medications may be administered; and the requirements for reporting a patient’s data to the statistics registry maintained by MANA DOR.

 ↓ To be completed by the ORR ↓

PART 4: REVIEW BY THE ORR

Date RISCBA received:	9-20-2018
Date RISCBA approved:	9/27/18
Date of disapproval:	
Explanation:	