

Economic Impact Statement

LSA Document #18-416

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

Description of the Rule

The Perinatal Levels of Care rules create a system for certification of level of facilities offering birthing services, meaning an obstetric unit intended to care for pregnant women or a neonatal unit intended to care for newborns. Each facility will be certified at a level to ensure that pregnant women and infants are treated at facilities capable of meeting their needs.

Economic Impact on Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

There are five birth centers in Indiana that under this rule would be subject to these rules as well as up to ten delivering hospitals.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

These rules do not require additional reporting or record keeping for the facilities subject to the rule. The Indiana State Department of Health (ISDH) may request information from the facilities for evaluation of this program, but facilities are not being required to collect any particular information or create additional documentation.

ISDH believes that the administrative cost for hospitals, if any, would be minimal.

Birth centers will be required to submit verification of accreditation within twenty-four (24) months after the effective date of this rule which does impose some cost. However, three of the five birth centers already meet this standard and one more is already in the process of accreditation. Based on that information, there is only one facility that will need to meet this additional cost.

If a birthing center has existed for one year or has had 100 births, the center will apply for accreditation and then seek reaccreditation every three years. The initial expense for registering for accreditation is \$4,000 followed by a monthly expense of \$250.

There are grants available from the American Association of Birth Centers (AABC) Foundation to support accreditation expenses.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Based on the gap analysis conducted with all Indiana delivering hospitals, we believe they are all prepared to meet the qualifications for at least a minimum level of designation. Facilities are generally aware of what level of certification they currently meet and what it will take for them to meet the standard they are seeking. There may be some additional costs to meet those standards, but those choices are made by each facility based on what is best for them. The unaccredited birth center will have an annual cost of \$3,000, but this may be mitigated by the grants available from AABC.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

The rules governing birth centers, including the rule requiring birth center accreditation, is quoted from the *Guidelines for Perinatal Care* 8th edition published by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG). The implementing legislation for this certification program requires the rules to be based on AAP and ACOG standards, so this requirement is in accordance with legislative requirements.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The legislation directing the establishment of perinatal levels of care requires compliance with the *Guidelines for Perinatal Care* 8th edition published by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG). The ISDH does not have the option to draft rules that are less stringent than these document standards.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements

for small businesses.

The rules will only require delivering facilities to provide the ISDH with outcomes data they already have access to which will not make it onerous to produce in the timeframes outlined in the rules.

ISDH has been working with facilities for several years on this issue so we believe they will have enough time to comply with any compliance requirements.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The rules are based on national standards, as required by legislation, and so the rule is as simplified as can be based on those standards. As for reporting requirements, the rules will only require delivering facilities to provide the ISDH with outcomes data they already have access to which will not have an economic impact.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The legislation directing the establishment of perinatal levels of care requires compliance with the *Guidelines for Perinatal Care* 8th edition published by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG). The ISDH does not have the option to draft rules that are less stringent than these document standards.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The perinatal levels of care designation process is intended to ensure Indiana mothers and babies receive care at facilities that are appropriate for their clinical needs. Therefore, exempting any delivering facility from this process could result in poor health outcomes.

Conclusion

The ISDH does not believe based on the information available at the time of this statement that delivering facilities will have a significant economic impact towards meeting the minimal requirements for perinatal levels of care designation.

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