

Economic Impact Statement

LSA Document #15-152

[IC 4-22-2.1-5](#) Statement Concerning Rules Affecting Small Businesses**Description of the Rule**

[410 IAC 35](#) establishes requirements for the disposition of aborted remains. The rule is mandated by SEA 329 of the 2015 session of the Indiana General Assembly.

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.**

[IC 4-22-2.1-4](#) defines a small business as a business entity that satisfies the following requirements:

- (1) On at least fifty percent (50%) of the working days of the business entity occurring during the proceeding calendar year, the business entity employed not more than one hundred fifty (150) employees.
- (2) The majority of the employees of the business entity work in Indiana.

There are approximately 131 licensed outpatient ambulatory surgical centers (ASCS) and approximately seven licensed abortion clinics subject to the rule. Acute care hospitals, while subject to the rule, are excluded herein due to employment size. All ASCS currently have policies and procedures in place that will be compliant with the proposed rule. This is also true for several of the licensed abortion clinics.

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

For ambulatory surgical centers and some abortion clinics, there will be no additional costs. These facilities will continue with current, pre-rule, procedures. For clinics that will need to come into compliance:

Compliance will be determined during licensure survey.

Based upon volume of the clinics that will be required to come into compliance, the costs will be in a range from \$6,000 to \$21,000 annually.

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

Several providers already meet the requirements of the proposed rule and therefore will not see any change in the cost of conducting business. For the small number that will be impacted (approximately three), the total impact will be less than \$100,000 in the aggregate.

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 rule sets forth proper disposition options for aborted remains.

5. Regulatory Flexibility Analysis

Other factors considered:

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

The production of compliance documentation at the time of licensure survey is the least stringent method demonstrating compliance. The licensee is not required to report through any other means or in any other time frame.

The least stringent and legal method of compliance in final disposition of the materials post terminated pregnancy is to render all material noninfectious and place the materials into a sanitary sewer. However, this concept has strong opposition. Therefore, the next least stringent method is to require other legal methods of disposition. Of the five methods of disposition allowed under Indiana law (interment/burial, cremation, entombment, burial at sea, and donation), the most appropriate and least stringent methods are interment/burial or cremation/incineration.

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

SEA 329 established the compliance deadline by statute. Likewise, reporting is required at the time of licensure survey and is the least stringent option.

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

N/A

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

Performance standards rather than design standards. The expected performance standard (disposal of aborted remains) was being met without imposition of a design standard. However, there exists varying opinions on the appropriateness of some of the performance standards employed. Therefore, a design standard has been implemented to resolve the issues.

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

SEA 329 does not provide the agency authority to exempt covered entities.

Conclusion

The proposed rule has a minimal economic impact on entities subject to the rule.

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