

Economic Impact Statement

LSA Document #12-619

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**I. Estimate of Number of Small Businesses That Will Be Subject to this Rule**

As required by IC 4-22-2.1-5(a)(1), the number of small businesses, classified by industry sector, that will be subject to the proposed rule:

Approximately 200 to 1,400

The proposed rule is voluntary. Small businesses may be impacted by this rule, but only if they choose to engage in the new practices allowed under this rule or change their business models to take advantage of these opportunities. The definition of small business, as defined by IC 4-22-2.1-4 and IC 5-28-2-6, relies on the number of employees working in Indiana during the previous year. Chain pharmacy companies and major hospital systems, which account for the majority of pharmacies in Indiana, typically employ more than 150 people, thus excluding them from the definition of small business. However, if each individually licensed facility is considered an entity independent of its corporate parent, then approximately 1,400 licenses could be impacted as each individual pharmacy location typically does not employ more than 150 individuals in any given year. If chains and major hospital systems are excluded, this reduces the number of licensees to less than 200. If the definition includes an examination of the revenue produced in a given year, the number is even smaller. Most small, independently owned and run pharmacies, still produce gross revenue in excess of 5-10 million dollars a year. Because the changes advanced in this proposed rule are voluntary, these small businesses will only be impacted if they decide the changes fit their business model.

As required by IC 4-22-2.1-5(a)(2), the estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule:

None.

The proposed rule is voluntary. As such, no mandatory costs will be imposed on small businesses. Entities that may choose to invest in the technologies authorized by this proposed rule are already subject to state and federal reporting, record keeping, and administrative requirements, and will incur no new state-mandated costs.

As required by IC 4-22-2.1-5(a)(3), the estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule:

None.

The proposed rule is voluntary. As such, no mandatory costs will be imposed on small businesses.

II. Justification Statement

As required by IC 4-22-2.1-5(4) [*sic*, IC 4-22-2.1-5(a)(4)], the following statement justifies 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 statement required by this subdivision must include a reference to any data, studies, or analyses relied upon by the agency in determining that the imposition of the requirement or cost is necessary.

The Indiana Board of Pharmacy has determined that this proposed rule will not impose new or additional costs or requirements on small businesses operating under the current regulations that exist today. The proposed rule updates and expands various pharmacy regulations to allow all licensed pharmacies to utilize new and advanced technologies and/or processes to deliver pharmaceutical care or other provider services to Indiana patients or consumers. The additions and changes in the proposed rules do not require the use of new technology but merely allow companies seeking to make the investment and utilize web-based, mobile, automated, or telecommunications based technology in their business model to more safely and cost effectively serve consumers. The changes also ensure that when a business chooses to utilize new technologies and/or processes made permissible under this rule by advances in modern technology, that they do so in accordance with standards that adequately protect public health and safety and safeguard patient privacy. These changes are a result of multiple large and small business entities (including major pharmacy chains, hospital systems, and pharmacy benefit managers) approaching the Board and expressing their concerns about the obsolete nature of several Indiana pharmacy regulations that impede their ability to do business in Indiana. The changes reflect the desired flexible language that will enable businesses in Indiana to utilize and invest in advanced technologies that improve delivery and quality of care.

III. Regulatory Flexibility Analysis

As required by IC 4-22-2.1-5(5) [*sic*, IC 4-22-2.1-5(a)(5)], this regulatory flexibility analysis considers any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule. The analysis under this subdivision considers the following methods of minimizing the economic impact of the proposed rule on small businesses.

- (A) The establishment of less stringent compliance or reporting requirements for small businesses.
The proposed rule does not impose new compliance or reporting requirements on small businesses. The proposed rule allows businesses the flexibility to invest in and utilize technology solutions that may result in increases in efficiency and positive patient outcomes.
- (B) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.
There are no less stringent schedules or deadlines for compliance or reporting requirements. Under the proposed rule, entities that choose to implement the technologies being authorized will be subject to the same compliance requirements as an entity utilizing traditional methods.
- (C) The consolidation or simplification of compliance or reporting requirements for small businesses.
The proposed rule does not impose any new compliance or reporting requirements. As such, consolidation or simplification of those requirements is not necessary.
- (D) The establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.
Performance standards are not appropriate for this proposed rule, as it simply allows for the utilization of new technologies and does not impose any new standards.
- (E) The exemption of small businesses from part or all of the requirements or costs imposed by the rule.
The proposed rule is voluntary. Small businesses are not required to utilize the technologies being authorized by the proposed rule.

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