

**Economic Impact Statement**

LSA Document #12-414

**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:

150 independent pharmacies.

Participation in the program being authorized by this rule is voluntary. Entities that may participate include all facilities that are licensed by the Indiana Board of Pharmacy that are active and in good standing. The majority of these facilities that may participate in the program being authorized by the rule are not small businesses as defined by IC 5-28-2-6. Of the approximately 1,400 pharmacies licensed under IC 25-26, only approximately 150 are independent pharmacies that may constitute a small business under IC 5-28-2-6.

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 volunteer to participate in the program are already subject to state and federal reporting, record keeping, and administrative requirements. Costs that may be associated with voluntarily implementing a program authorized by this rule may be related to record keeping, security, and destruction. These costs would be de minimis given mandatory compliance with regulations already in place. The Board estimates that it may cost between \$300-\$500 in initial costs such as training and equipment, and approximately \$100-\$200 for return and destruction of collected medications. The frequency of the return and destruction costs depend on the amount of medications collected and are not expected to be more than \$100-\$200 per month. Pharmacies that stock controlled substances must comply with record keeping laws under 856 IAC 2-4-1. Furthermore, in order to assist participating entities the Board of Pharmacy will have model record keeping logs available as guidance.

Pharmacies are required to be secure under IC 25-26-13-18(a)(5). Pharmacies in compliance with IC 25-26-13-18(a)(5) would see no additional costs. The costs associated with destruction would also be de minimis given that most pharmacies already contract with reverse distributors in order to return unused medications under IC 25-26-23. Any costs would likely be offset by the increased foot traffic associated with participation in the program.

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), 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.

There are no additional costs imposed on small businesses. The program being authorized by the proposed rule is voluntary. The costs of implementing a program authorized by the proposed rule would mostly be de minimis given that eligible entities are already required to comply with substantially similar laws and regulations as part of their everyday business. The rule was designed to use a market-based approach that will allow small businesses to determine whether or not they want to participate.

**III. Regulatory Flexibility Analysis**

As required by IC 4-22-2.1-5(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 was designed to minimize compliance and reporting requirements while still protecting the public by ensuring safeguards against diversion, misuse, and/or improper disposal. For example, the proposed rule does not require an inventory of returned medications.

(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, participating entities need only to make their records available for review to the Board of

Pharmacy, and there are no reporting deadlines. Under the proposed rule, participating entities must maintain their records for a period of two years. This two year record retention schedule is the industry standard in Indiana pharmacies, as required by various state and federal laws. As such, there are no less stringent schedules.

(C) The consolidation or simplification of compliance or reporting requirements for small businesses.

The proposed rule was designed to minimize compliance and reporting requirements while still protecting the public by ensuring safeguards against diversion, misuse, and/or improper disposal. There are no areas where the requirements of the proposed rule can be consolidated or simplified without endangering the public and/or environment.

(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 voluntary program. The operational standards laid out in this proposed rule are designed to protect the public by ensuring safeguards against diversion, misuse, and/or improper disposal.

(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 participate in the program being authorized by the proposed rule.

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