

Economic Impact Statement

LSA Document #20-603

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

The Indiana State Department of Health (ISDH) is proposing to expand Long Term Care (LTC) facilities' options for disposing of medications within the facility. The proposed rule amendment allows facilities to use a secured, protective box provided by a disposal company to store medications so that they can be sent to the company to be disposed of properly. The proposed rule amendment is supported by federal regulations and was requested by the industry. In addition, the proposed rule amendment strikes the existing provision that medication must be disposed of in the facility within seven (7) days, and instead requires the medication to be disposed of within three (3) days.

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 5-28-2-6](#) 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.

Every LTC facility in Indiana will be subject to this rule. ISDH estimates that out of the 536 SNF/NF facilities in Indiana and 352 licensed residential facilities, 100 facilities in Indiana are considered small businesses under the above definition.

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

The proposed rule amendment imposes no additional reporting, record keeping, or other administrative costs because the proposed rule amendment introduces an additional, optional method of medication disposal. Should the small business choose to utilize the additional method of medication disposal, the business will keep the same records regarding medication disposal and will be subject to the same annual reporting requirements. The small businesses choosing to utilize this method will incur additional administrative costs in acquiring the approved disposal receptacle and for subsequent removal; however, this is an optional cost as the disposal receptacle is not required.

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

Compliance with the proposed rule amendment will have no economic impact, as the rule is not eliminating current options for compliance. The small businesses may choose to incur the additional cost to improve efficiency and safety in their facilities by improving their method of medication disposal. However, this improvement is not required and, therefore, the economic impact would be voluntary.

The amendment to three (3) day disposal from disposal within seven (7) days will not have economic impact on the facilities, as it does not change the method of disposal, only the timeframe. However, the change to three (3) day disposal will presumably have the effect of reducing the facility's risk of theft and drug diversion.

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 requirement of three (3) day disposal of medication if not using the disposal receptacle is justified by safety of the facility residents, decreased drug diversion, and decreased opportunity for theft. Three (3) day disposal is in line with federal regulations and other states. Introducing the opportunity to dispose of medication through the on-site disposal receptacle increases flexibility and allows facilities to dispose of medication safely and in an environmentally friendly way.

5. Regulatory Flexibility Analysis

Other factors considered:

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

The proposed rule amendment will not impose any new reporting requirements. The same reporting is required regardless of how the medication is rendered unretrievable. By striking the seven (7) day destruction window and changing the language to three (3) day destruction, the compliance requirement is

more stringent if the facility chooses not to use a disposal receptacle. However, this change is in line with federal regulation and is safer for the facility and residents, as they are less exposed to drug diversion and theft.

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

As noted above, the timeline for rendering medication unretrievable is now three (3) days, rather than within seven (7) days. However, the proposed rule amendment adds the option for facilities to use disposal receptacles. The additional option will increase efficiency and safety in disposing of medications in the facility.

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

Rather than having to go through the process of rendering medication unretrievable on-site through means of chemical alteration, which is difficult, or flushing, which is environmentally dangerous, the facility is now able to easily place medications into the medication receptacle and send the medication out for disposal. This is a simplification of the disposal process.

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

Though the operational standards imposed have been lessened by the introduction of the disposal receptacle, the operational standards cannot be removed or changed to performance standards due to a required adherence to federal regulations.

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

Due to federal regulations, all LTC facilities, regardless of size, must adhere to requirements of medication disposal.

Conclusion

The proposed rule amendment allows LTC facilities more flexibility in how they dispose of medications in their facilities. Following the amendment, facilities will be able to use medication disposal containers to safely store unused medication until it can be sent to a company to be properly destroyed. Previously, facilities have not been allowed to use this type of receptacle, and have been required to destroy medication on site. Medication disposal is difficult for most facilities to accomplish on their own—most do not have incinerators, which leaves them with flushing medication as their only option. Allowing facilities to use medication disposal receptacles will improve their ability to comply with federal law, remove the burden of requiring facilities to directly dispose of medication, and protect the environment by avoiding flushing large amounts of medication into the sewer system.

In addition, the proposed rule amendment will decrease the timeframe facilities have to dispose of medication, reducing it from seven (7) days to three (3) days. While this is a stricter guideline, it is more closely aligned to federal regulations. Moreover, by allowing the use of disposal containers, the facility does not have to destroy the medication on site, which removes any burden incurred by the decreased timeframe.

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