

Economic Impact Statement

LSA Document #14-343

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

In 2014, the Indiana General Assembly passed House Enrolled Act (HEA) 1218 (Public Law 131), which became effective July 1, 2014. HEA 1218 amended [IC 12-23-18-5](#) and [IC 12-23-18-7](#) requiring the DMHA to promulgate rules. HEA 1218 changes standards for operation rules concerning prior authorization for a take-home supply of opioid treatment medication from 14 days of medication to seven days of medication and only if certain conditions are met. HEA 1218 also requires the DMHA to establish certain standards and protocols for opioid treatment programs:

- To assess new opioid treatment program patients to determine the most effective opioid treatment medications to start the patient's opioid treatment;
- To ensure that each patient voluntarily chooses maintenance treatment and that the use of opioid treatment medications are clearly and adequately explained to the patient;
- To transition opioid treatment program patients who are receiving methadone to other approved opioid treatment medications; and
- To list other medications as alternatives to methadone that may be used by opioid treatment programs to treat opioid treatment program patients.

Impact on Small Business

The following section provides responses to the following questions outlined in [IC 4-22-2.1-5](#):

1. An 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 preceding 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.

The DMHA estimates that there are 13 opioid treatment programs (OTP) that meet the criteria of a small business.

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

This rule amendment will impose additional annual reporting, record keeping, or other administrative costs on small businesses in order to comply with the proposed rule. However, the costs are not thought to be substantive and are necessary to comply with state law. For example, training for this rule amendment will occur at each facility; however, entities will incorporate these trainings into their existing training requirements so the training costs may differ for each entity and cannot be estimated at this time.

3. An estimate of the total annual economic impact that compliance will have on small businesses subject to the rule.

Compliance will have minimal economic impact on small businesses subject to this proposed rule. The costs are not thought to be substantive and are necessary to comply with state law.

4. A statement justifying any requirement or cost that is imposed by the rule and not expressly required by law. The statement must reference any data, studies, or analyses relied upon by the agency in determining imposition of the requirement or cost is necessary.

This rule amendment promulgates changes in [440 IAC 10](#), Minimum Standards for the Provision of Services by Opioid Treatment Facilities and Programs, that are required by [IC 12-23-18-5](#) and [IC 12-23-18-7](#) as added by House Enrolled Act (HEA) 1218 (Public Law 131). It does not impose any requirements or costs that are not expressly required by law.

5. Any regulatory flexibility analysis that considers any less intrusive or less costly alternative methods of achieving the same purpose.

Other factors considered:

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

DMHA did not consider less stringent compliance or reporting requirements for small businesses. This rule amendment promulgates changes in [440 IAC 10](#) that are required by state law. Furthermore, this rule amendment has minimal impact on reporting requirements for small businesses.

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

See response 5.A., above.

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

This rule amendment will impose additional annual reporting requirements on small businesses.

However, these requirements are necessary to comply with state law.

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

DMHA did not consider performance standards in place of operational standards imposed on these regulated entities by this rule amendment. This rule amendment promulgates changes in [440 IAC 10](#) that are required by state law.

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

This rule amendment will not exempt small businesses from the requirements imposed by this rule.

If there are any programmatic or fiscal questions, please contact Mick Schoenrad at (317) 232-7913 or Mick.Schoenradt@fssa.in.gov. Questions regarding any other aspect of the proposed changes should be addressed to Kim Crawford at (317) 232-1244 or kim.crawford@fssa.in.gov.

Please contact Kim Crawford at (317) 232-1244 or kim.crawford@fssa.in.gov regarding OSBE's comments about this rule amendment. The public hearing will be scheduled after receipt of authorization from Legislative Services Agency. Ms. Crawford will then contact you to provide the date of the hearing for your convenience.

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