

Economic Impact Statement

LSA Document #22-287

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

IC 4-22-2.1-5(a) provides that an agency that intends to adopt a rule under IC 4-22-2 that will impose requirements or costs on small businesses must prepare a statement that describes the annual economic impact of the rule on small businesses after the rule is fully implemented as described in IC 4-22-2.1-5(b). That statement must be submitted to the Indiana Economic Development Corporation (IEDC). The IEDC is required to review the rule and submit written comments to the agency not later than seven days before the public hearing.

In 2020, P.L. 68-2020, which requires the Indiana Department of Insurance (IDOI) to regulate pharmacy benefit managers (PBMs) was enacted. PBMs are companies that function as intermediaries between insurance providers and pharmaceutical manufacturers. To meet the definition of a PBM set forth in IC 27-1-24.5-12, the entity must be performing functions on behalf of a health plan, state agency, insurer, managed care organization, or other third party payor. The entity further meets the definition of PBM if it: contracts directly or indirectly with pharmacies to provide prescription drugs to individuals; administers a prescription drug benefit; processes or pays pharmacy claims; creates or updates prescription drug formularies; makes or assists in making prior authorization determinations on prescription drugs; administers rebates on prescription drugs; or establishes a pharmacy network.

IC 27-1-24.5-20 requires the IDOI to adopt rules to establish PBM licensing requirements, licensing fees, a license application, financial standards for PBMs, annual reporting requirements, the timeline for resolution of an appeal concerning maximum allowable cost pricing, and procedures for auditing submitted claims by a contracted pharmacy. The IDOI is permitted to adopt rules to implement IC 27-1-24.5-20 and to specify requirements for prohibited market conduct practices; data reporting in connection with violations of state law; maximum allowable cost list compliance and enforcement requirements; prohibitions and limits on PBM practices that require licensure under IC 25-22.5; PBM affiliate information sharing; and lists of health plans administered by a PBM in Indiana.

The proposed rule adds 760 IAC 5 regarding licensure requirements for PBMs, application and renewal fees, pharmacy claims audits, maximum allowable cost pricing, annual reporting, and fines.

Estimated Number of Small Businesses Affected:

The proposed rule will impact PBMs. As of July 29, 2022, there are 45 PBMs operating in Indiana. IDOI estimates that three of these PBMs may qualify as small businesses.

Estimated Administrative Costs Imposed on Small Businesses:

IC 27-1-24.5-18 and the proposed rule require PBMs to apply to obtain a license from the commissioner of the IDOI before operating as a PBM. The application must be accompanied by an application fee of \$500. In addition, the PBM must provide various information and documentation, including a copy of its articles of incorporation, biographical affidavits of certain individuals associated with the management or ownership of the PBM, and a detailed explanation of certain adverse regulatory actions taken against the PBM. IDOI estimates the cost of preparing an application will be \$1,000 for each PBM.

The application must also include the PBM's current audited annual financial statement prepared by an independent certified public accountant in accordance with generally accepted accounting principles reflecting a positive net worth. The estimated cost of an annual financial audit is ten thousand dollars \$10,000.

The proposed rule permits a PBM to cause an onsite or remote audit of pharmacy claims to occur at a particular pharmacy location not more than one time per calendar year. The proposed rule sets forth requirements for the conduct of an audit, written audit reports, and an internal appeals process under which a pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report. If the audit requires the use of clinical or professional judgment, the audit must be conducted by or in consultation with an individual licensed as a pharmacist under IC 25-26. For the three PBMs which may be small businesses, IDOI estimates the cost of retaining a licensed pharmacist will be \$70,000 per year.

IC 27-1-24.5-22 and the proposed rule require PBMs to identify to contracted pharmacy services administrative organizations, or pharmacies if the PBM contracts directly with pharmacies, the sources used by the PBM to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health plan administered by the PBM. PBMs must update and make available to pharmacies the PBM's maximum allowable cost list at least every seven days. A PBM must maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with pricing changes in the marketplace. IC 27-1-24.5-22 and the proposed rule require a PBM to establish an appeal process for contracted pharmacies, pharmacy services administrative organizations, or group purchasing organizations to appeal and resolve disputes concerning the maximum allowable cost pricing. IDOI estimates the cost to comply

with these provisions of the proposed rule to be \$2,000.

Finally, [IC 27-1-24.5-21](#) and the proposed rule require PBMs to file an annual report with the IDOI, which must contain information set forth in [IC 27-1-24.5-21\(a\)](#). IDOI estimates the cost of preparing the annual report will be \$100 for each PBM.

Estimated Total Annual Economic Impact on Small Businesses:

The annual economic impact to each small business is \$83,600 per PBM, per year. The estimated total annual economic impact on small businesses is \$250,800.

Justification of Requirements or Costs:

[IC 27-1-24.5-20](#) allows the commissioner to charge a license application fee in an amount not to exceed \$500. [IC 27-1-24.5-18](#) requires a PBM to obtain a license from the IDOI, and [IC 27-1-24.5-20\(a\)\(1\)](#) requires the commissioner to prescribe an application. A PBM must file an annual report under [IC 27-1-24.5-21\(a\)](#). [IC 27-1-24.5-20\(a\)\(2\)\(D\)](#) requires the IDOI to adopt rules to establish financial standards for PBMs. The IDOI requires an audited financial statement to appropriately assess the financial condition of PBMs. IDOI requires similar statements to be filed with respect to other regulated entities. The greatest cost the proposed rule imposes on small businesses is the requirement to retain the services of a licensed pharmacist, if applicable. This requirement is not imposed by the statute but is necessary to ensure the pharmacy claims audit is performed accurately. This requirement is in line with the pharmacy audit requirements of [IC 25-26-22-5\(4\)](#) and is consistent with the requirements of several other states.

Regulatory Flexibility Analysis:

The IDOI determined that adoption of the proposed rule would be most beneficial for the marketplace. There are no less intrusive or less costly alternative methods for achieving the purposes of the proposed rule. Costs and requirements imposed by [IC 27-1-24.5](#) and the proposed rule are necessary for the regulation of the PBM industry and must apply equally to all PBMs, including those qualifying as small businesses.

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