

Economic Impact Statement

LSA Document #07-547

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

This proposed rule amendment removes the federal maximum allowable cost (MAC) limiter from the determination of payment for legend drugs in the Medicaid program.

The federal MAC rates are calculated by CMS only for select multiple source (generic) drugs, and CMS does not calculate MAC rates for single source brand drugs. Effective January 30, 2008, CMS will implement MAC rates for multiple source drugs using average manufacturer price (AMP) data. CMS periodically collects AMP data from pharmacy manufacturers and will publish MAC rates using this data. Extensive analysis of this AMP data by OMPP clearly indicates this data is unreliable and a poor predictor of the average actual acquisition costs that pharmacies pay to acquire multiple source drugs. The majority of AMP-based rates published by CMS are either substantially more or less than the average actual cost of drugs acquired by Indiana pharmacies.

Impact on Small Business

1. An estimate of the number of small businesses, classified by industry section, that will be subject to the proposed rule.

Of the approximately 1,200 Medicaid participating pharmacies, less than half are believed to be small businesses as that term is defined in [IC 4-22-2.1-4](#).

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

None.

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

None.

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 imposes no cost or requirements on small businesses.

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

Since no small businesses are impacted by this rule, completing a regulatory flexibility analysis is not necessary.

Conclusion:

The agency has determined that this rule will not have an impact on small businesses, as defined in [IC 4-22-2.1-4](#). By amending the rule so that the new federal MAC rates are not applied as a rate limiter, Medicaid reimbursement to pharmacies for multiple source drugs will continue to be sufficient to allow reasonable access by providers to drugs at or below the Medicaid reimbursement rate.

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