Rule Summary and Fiscal Analysis (Part A)

Bureau of Workers' Compensation
Agency Name

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4123-6-21.3 **AMENDMENT**
Rule Number TYPE of rule filing

Rule Title/Tag Line **Outpatient medication formulary.**

RULE SUMMARY

1. Is the rule being filed for five year review (FYR)? **Yes**

2. Are you proposing this rule as a result of recent legislation? **No**

3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**

4. Statute(s) authorizing agency to adopt the rule: **4121.12, 4121.121**

5. Statute(s) the rule, as filed, amplifies or implements: **4121.441, 4123.66**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

The Bureau adopted rule 4123-6-21.3 effective September 1, 2011 to establish an outpatient medication formulary. A formulary is a list of drugs approved for reimbursement when prescribed to treat conditions allowed in a claim. This rule is maintained and updated periodically by the Bureau with input from the Bureau Pharmacy & Therapeutics Committee (P&T Committee) pursuant to their responsibility as listed in rule 4123-6-21.1 of the Administrative Code. The Bureau now proposes to revise the coverage to two drug classes and five drug products listed in the attachment to this rule.

This filing also serves as a review required by chapter 119. of the Revised Code; five year rule review.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

The proposed changes are contained in the appendix to this rule, which is the formulary drug list. The Bureau new proposes to revise the coverage to two drug classes and five drug products listed in the attachment. The changes are a result of careful consideration of current literature, accepted treatment guidelines and best clinical practice as well as FDA and information published by the drug manufactures.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

This response left blank because filer specified online that the rule does not incorporate a text or other material by reference.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

Not Applicable.

12. Five Year Review (FYR) Date: **2/9/2015**

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

0.00

n/a

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

n/a

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

There should be no negative financial impact on the prescriber community as any necessary changes to the injured worker's drug regimen should be done in the context of routine office visits.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component

dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

A.) Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? **No**

B.) Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? **No**

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **Yes**

> The proposed rule, requires that clinical documentation and evidence to be provided, in cases of medical necessity to the bureau for reimbursement approved for use in the United Sates by the FDA, on or after the effective date of this rule.