ACTION: Refiled

DATE: 11/21/2013 2:59 PM

Rule Summary and Fiscal Analysis (Part A)

Bureau of Workers' Compensation

Agency Name

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Division

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4123-6-21.3 AMENDMENT

Rule Number TYPE of rule filing

Rule Title/Tag Line <u>Outpatient medication formulary.</u>

RULE SUMMARY

- 1. Is the rule being filed consistent with the requirements of the RC 119.032 review? **No**
- 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:

BWC initially adopted rule OAC 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 the claim. The formulary is maintained, and updated periodically, by BWC with input from the BWC Pharmacy & Therapeutics Committee (P&T Committee) pursuant to their responsibilities as listed in OAC 4123-6-21.1.

BWC now proposes to revise rule OAC 4123-6-21.3 by revising the coverage of

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one class of drugs listed in the formulary. The proposed changes are the result of recommendations from the P&T Committee and reflect BWC's dedication to providing for appropriate care while ensuring the safety of our injured workers. The committee's recommendations resulted from consideration of current literature, accepted treatment guidelines and best clinical practice as well as FDA and information published by the drug manufactures.

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 to OAC 4123-6-21.3 are contained in the Appendix to the rule, which is the formulary drug list. A copy of the Appendix with the proposed changes will be available on the BWC website for stakeholder review. These proposed changes shall, in addition to the current limitations on reimbursement that are based on the amount of acetaminophen contained in each dose of medication, limit the reimbursement of all butalbital containing medications to not more than twenty four (24) doses in any calendar month.

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.

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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:

The rule was revised to reflect the new effective date as January 1, 2014, and the appendix was replaced because of the initial filing of this rule had an outdated appendix and not the one approved by the BWC Board of Directors and the CSI office. The current filing has the correct appendix.

12. 119.032 Rule Review Date: 9/1/2016

(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:

The only impact on the prescriber community from the formulary additions will be the need to reassess the drug therapy being prescribed for an injured worker to see Page 4 Rule Number: **4123-6-21.3**

if the new drug may be a better therapeutic option.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? N_0

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? N_0
- 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? N_0
- 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 State by the FDA, on or after the effective date of this proposed rule.