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)? **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, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.66**

5. Statute(s) the rule, as filed, amplifies or implements: **4121.12, 4121.121, 4121.44, 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 its

responsibility as listed in rule 4123-6-21.1 of the Administrative Code.

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 listed below 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 revisions shall:

1. Add reimbursement for the abuse deterrent sustained release formulation Embeda® (Morphine sulfate/naltrexone). Reimbursement will not be provided for concurrent use of more than one sustained release opioid.

2. Add reimbursement for the abuse deterrent sustained release formulation Hysingla ER® (Hydrocodone Bitartrate). Reimbursement for Hysingla ER® will be limited to a total quantity of one dose per day for all strengths of the medication. Reimbursement will not be provided for concurrent use of more than one sustained release opioid

3. Remove reimbursement for the sustained release formulation Zohydro ER® (Hydrocodone Bitartrate). This was replaced by the drug Hysingla ER® which has a higher rating for abuse deterrent technology by the FDA.

4. Add reimbursement for the drug Movantik® (Naloxegol). Reimbursement requires a prior authorization with documentation of confirmed opioid induced constipation. Reimbursement is limited of no more than 30 doses per month.

5. Add the same requirements as those on Movantik® to reimbursement for the currently covered injectable drug Relistor® (Methylnaltrexone Bromide)

6. Add reimbursement for the drug Harvoni® (Ledipasvir/Sofosbuvir). Reimbursement requires prior authorization and an allowed condition of Type 1 Hepatitis C.

7. Add reimbursement for the drug Noxafil® (Posaconazole). Reimbursement requires prior authorization and documentation of a drug resistant systemic fungal infection.

8. Add reimbursement for the drug Eliquis® (Apixaban). Reimbursement requires prior authorization and documentation of an allowed condition of atrial fibrillation, venous thrombosis or post operative venous thromboprophylaxis.

9. Add reimbursement for the drug Savaysa® (Edoxaban). Reimbursement requires prior authorization and documentation of atrial fibrillation or venous thrombosis.

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:

This rule is being revised due to an error discovered and now fixed to reflect the correct verbiage on Embeda & Morphine ER, in the appendix.

12. Five Year Review (FYR) Date: **2/1/2020**

(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 of medical necessity be provided to the bureau for short term reimbursement of new drugs or new dosage forms or strengths of existing drugs approved for use in the United Sates by the FDA on or after the effective date of this rule.