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 proposes to revise the formulary appendix to this rule by amending coverage to the opioid drug class and 50 drug products listed in the formulary. These recommended changes are the result of recommendations from the Bureau's Pharmacy & Therapeutics Committee (P&T) Committee as well as a general clean up of the formulary appendix. These revisions reflect the Bureau'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:

These proposed changes will:

* Limit initial coverage of any opioid for use in a non-post operative condition to 7 days of coverage or 30 doses, whichever is less.

* Eliminate coverage of concurrent use of more than one immediate release opioid agent without a Prior Authorization.

* Implement a quantity limit of 180 doses (6 doses per day) for any immediate release opioid in all claims.

* Eliminate coverage of methadone as an immediate release opioid.

* Coverage will not be permitted for concurrent treatment of multiple sustained release (SR) Opioids

(Including methadone).

* Concurrent use of any SR opioid, oral or transdermal, with any parenteral pain management medications (e.g. IM, SC, IV, IT analgesic medications) will not be covered.

* SR opioids will not be covered in post operative conditions unless the injured worker was being treated with the sustained release drug prior to surgery.

* Delete reimbursement for the all dosage forms of Levodromoran, coverage for claims currently receiving Levodromoran will continue, auto-injector dosage forms of naloxone.

* Add reimbursement for the nasal inhalation forms of naloxone, and

* Delete reimbursement for several medications and dosage forms that are no longer on the market.

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:

The Bureau did not make any changes to the rule itself. However, we are revising and refiling the Appendix to the rule, removing the word "draft" from the footer to the Appendix and making minor changes for purposes of clarification to language regarding coverage restrictions or limitations for certain drugs. We also removed a column regarding prior authorization from the Appendix, as it is not part of the current Appendix to the rule, and BWC has determined it is unnecessary.BWC did not make any changes to the rule itself. However, we are revising and refiling the Appendix to the rule, removing the word "draft" from the footer to the Appendix and making minor changes for purposes of clarification to language regarding coverage restrictions or limitations for certain drugs. We also removed a column regarding prior authorization from the Appendix, as it is not part of the current Appendix to the rule, and BWC has determined it is unnecessary.

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 medicalnecessity 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.