Rule Summary and Fiscal Analysis
Part A - General Questions

Rule Number: 4123-6-21.3

Rule Type: Amendment

Rule Title/Tagline: Outpatient medication formulary.

Agency Name: Bureau of Workers' Compensation

Division:

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I. Rule Summary

1. **Is this a five year rule review?** No

    A. **What is the rule's five year review date?** 5/1/2025

2. **Is this rule the result of recent legislation?** No

3. **What statute is this rule being promulgated under?** 119.03

4. **What statute(s) grant rule writing authority?** 4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.66

5. **What statute(s) does the rule implement or amplify?** 4121.12, 4121.121, 4121.44, 4121.441, 4123.66

6. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** No

    A. **If so, what is the citation to the federal law or rule?** Not Applicable

7. **What are the reasons for proposing the rule?**

    BWC maintains and periodically updates the outpatient medication formulary in the appendix to this rule with input received from the BWC Pharmacy & Therapeutics Committee pursuant to its responsibilities as set forth in OAC 4123-6-21.2.

8. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

   This rule establishes the outpatient medication formulary list of drugs approved for reimbursement when prescribed to treat conditions allowed in a claim filed by an injured worker. The proposed changes include adding, removing, and changing coverage for certain medications detailed in the Business Impact Analysis, attached to this rule package.

9. **Does the rule incorporate material by reference?** No

10. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

    Not Applicable

11. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

    Not Applicable

II. Fiscal Analysis

12. **Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

    This will have no impact on revenues or expenditures.

    $0.00

    This will have no impact on revenues or expenditures.

13. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

    The prescriber and pharmacy business communities involved with prescribing and dispensing medication are affected by this rule. There should not be any 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. Any prescriptions that result from the changes in the drug regimen would continue to be processed by a pharmacy.

14. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B).** No

15. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C).** No

16. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

    Not Applicable.

III. Common Sense Initiative (CSI) Questions

17. **Was this rule filed with the Common Sense Initiative Office?** Yes

18. **Does this rule have an adverse impact on business?** Yes

    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 BWC for short term reimbursement of new drugs or new dosage forms or strengths of existing drugs approved for use in the United States by the FDA on or after the effective date of the rule.

    D. **Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies?** No

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. **Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95?** Yes

A. How many new regulatory restrictions do you propose adding to this rule? 0

B. How many existing regulatory restrictions do you propose removing from this rule? 8

Ketorolac Tromethamine Tab 10 MG
Quantity shall not exceed 20 units or a 5 day supply

Methadone HCL Products
All forms of methadone shall be considered to be sustained release opioids

Buprenorphine HCl Buccal Film Product
Reimbursement for this product shall not exceed 2 films per day

Fentanyl Citrate Buccal Tab Products Fentanyl Citrate Lozenge Products
Claim must be allowed for neoplasm or malignancy for reimbursement

Methadone HCL Products
Reimbursement for this product may not exceed a maximum dose of 90 mg per day.

All Benzodiazepine Products
Prior authorization is required for continued therapy past 30 days

Antipsychotics - ALL antipsychotic agents
Prior authorization is not required if the injured worker has an allowed condition of schizophrenia or bipolar disorder

Certolizumab Pegol and Golimumab Subcutaneous Soln Products
Prior authorization required

C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.

D. Please justify the adoption of the new regulatory restriction(s).

Not Applicable