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 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 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.**

    BWC is revise filing this rule package to reflect the correct effective date in the footer of the Appendix, only.

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

    Not Applicable.

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 are the only two business communitiesinvolved with medication prescribing and dispensing and affected by this rule. 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. 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 orstrengths of existing drugs approved for use in the United Sates 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?** 1

    4123-6-21.3 Appendix - Opioid Combinations - "Acetaminophen content may not exceed 4 grams per day."

    B. **How many existing regulatory restrictions do you propose removing from this rule?** 33

    4123-6-21.3 Appendix - Analgesic Combinations - "...shall not exceed..."

    4123-6-21.3 Appendix - G.I. Agent - Gastrointestinal Chloride Channel Activators - "...Patient must have..."

    4123-6-21.3 Appendix - G.I. Agent - Gastrointestinal Chloride Channel Activators - "...office notes must document..."

    4123-6-21.3 Appendix - G.I. Agent - Peripheral Opioid Receptor Antagonists - "...Patient must have..."

    4123-6-21.3 Appendix - G.I. Agent - Peripheral Opioid Receptor Antagonists - "...office notes must document..."

    4123-6-21.3 Appendix - Hypnotics - Non-Barbiturate - "Prior authorization is required..."

    4123-6-21.3 Appendix - Opioid Agonists - Immediate Release - "Reimbursement shall be restricted..."

    4123-6-21.3 Appendix - Opioid Agonists - Immediate Release - "Reimbursement shall not exceed..."

    4123-6-21.3 Appendix - Opioid Agonists - Immediate Release - "Reimbursement shall not exceed..."

    4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Coverage of this product is limited to only those claims with a daily Morphine Equivalent Dose (MED) requirement of 90 mg or less..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "PA is required to show documented allergic reaction..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "...shall not exceed..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "...shall not exceed..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Prior authorization is required..."

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4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Initial coverage of oral methadone requires documentation of..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Ongoing coverage of oral methadone requires the documentation of..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Reimbursement shall be restricted..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Reimbursement for all strengths of this product shall not exceed..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Reimbursement shall not exceed..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Prior authorization is required..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Reimbursement shall not exceed..."

4123-6-21.3 Appendix - Opioid Agonists - Sustained Release - "Reimbursement for this product shall not exceed..."

4123-6-21.3 Appendix - Opioid Combinations - "Reimbursement shall not exceed..."

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4123-6-21.3 Appendix - Postherpetic Neuralgia (PHN) Agents - "Coverage of Gabapentin Sustained Release products requires..."

4123-6-21.3 Appendix - Restless Leg Syndrome (RLS) Agents - "Coverage of Gabapentin Sustained Release products requires..."

4123-6-21.3 Appendix - Restless Leg Syndrome (RLS) Agents - "...gabepentin will be a tier 1 medication requiring titration..."

4123-6-21.3 Appendix - Topical - Local Anesthetics - "Prior Authorization will be required..."

4123-6-21.3 Appendix - Topical - Local Anesthetics - "...a lidocaine 4% topical product will be 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).
The medically recommended maximum daily dose of acetaminophen is 4,000 mg (4 g) per day.