

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4123-6-21

Rule Type: Amendment

Rule Title/Tagline: Payment for outpatient medication.

Agency Name: Bureau of Workers' Compensation

Division:

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I. Rule Summary

1. **Is this a five year rule review?** Yes
 - A. **What is the rule's five year review date?** 1/5/2021
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. **What are the reasons for proposing the rule?**

Pursuant to R.C. 119.032, state agencies are required to review all agency rules every five years to determine whether to amend the rules, rescind the rules, or continue the rules without change. Due to such review, the Bureau is proposing to amend this rule for the purposes explained below.

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

This rule governs reimbursement for outpatient medication by BWC in State Insurance Fund claims. The proposed changes to this rule are to:

Add language that BWC may require prior authorization of certain drugs or therapeutic classes of drugs, drugs above a certain cost threshold, drugs submitted outside a certain timeframe from the date of injury or the last prescription submitted. or drugs being prescribed for a condition or in a manner not approved by the FDA.

Simplify language regarding compounded prescriptions.

Remove the language requiring a signature log verifying receipt of medications as redundant to Ohio Board of Pharmacy requirements.

Add language to prohibit the pharmacy provider from providing anything of value to "any other person, firm, or corporation" as an inducement for their business.

Remove language requiring claimant requests for reimbursement to comply with BWC's Provider Billing and Reimbursement Manual.

Remove language regarding protocols formulated by BWC for medications.

8. **Does the rule incorporate material by reference?** Yes
9. **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.**

FDA publication: "Approved Drug Products With Therapeutic Equivalence Evaluations" in effect on the billed date(s) of service.

BWC Provider Billing and Reimbursement Manual, in effect on the billed date(s) of service.

10. **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

11. **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.

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

All medical and pharmacy services providers are directly affected by this rule and the estimated cost of compliance is the time for reviewing or receiving education on the changes, as well as applying any modifications to relevant systems.

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

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

15. 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

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

17. 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? Yes

Medication may only be prescribed by a treating provider that is authorized by law to prescribe medication.

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 pharmacy provider must include prescriber information with the bills submitted electronically for payment, including the prescriber's NPI and DEA number, the pharmacy provider must submit for billing the national drug code of the stock bottle from which the dispensed medication is obtained.

- 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 Restrictions (This section only applies to agencies indicated in R.C. 121.95 (A))

18. 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? 0

B. How many existing regulatory restrictions do you propose removing? 7

4123-6-21(D) Removes "...shall publish a list..." and replaces it with "The bureau will publish a list..."

4123-6-21(E)(1)(b) Removed language that all compounded drugs must be dispensed in compliance with United States Pharmacopeia.

4123-6-21(I) Removed the sentence stating what the cost of a drug shall be.

4123-6-21(M) Removed language stating claimant's request for reimbursement shall be in accordance with rule.

4123-6-21(M) Removed language stating claimant's request shall comply with billing instructions.

4123-6-21(N) Removed language providing that compliance with protocols shall be monitored.

4123-6-21(N) Removed language providing that refusal to comply with protocols shall result in refusal of...