ACTION: Revised

DATE: 10/27/2016 10:32 AM

Rule Summary and Fiscal Analysis (Part A)

Bureau of Workers' Compensation

Agency Name

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4123-6-21 AMENDMENT

Rule Number TYPE of rule filing

Rule Title/Tag Line Payment for outpatient medication.

RULE SUMMARY

- 1. Is the rule being filed for five year review (FYR)? N_0
- 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:

BWC is proposing to amend this rule to update the agency's prescription reimbursement model to better reflect pricing in the current marketplace, revise coverage and reimbursement of compounded prescriptions and implement coverage changes to various formulary medications.

Page 2 Rule Number: 4123-6-21

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 Bureau is proposing revisions to:

* Change the Bureau's overall prescription pricing methodology from average wholesale price (AWP)

minus 9% to AWP minus 15%.

- * With regard to compounded prescriptions,
- o Distinguish between parenteral & non-parenteral sterile compound prescriptions,
- o Require that compound prescription ingredients must have an National Drug Code (NDC)number or reimbursement,
- o Require that prescriptions for compound drugs comply with Ohio State Pharmacy Board rules.
- o Require a 30 day trial with a non-compounded commercially available topical product, reimbursed by BWC, with documented failure prior to approval of a non-sterile compound prescription,
- o Increase dispensing fees for non-sterile / sterile compound prescriptions from \$12.50 /\$25.00 to \$18.75 / \$37.50,
- o Decrease the maximum allowable cost for compound prescriptions from \$600 to \$400.
- * Add MCO coverage of injectable drugs for opioid dependency,
- * Delete language relating to "accepting assignment" that is no longer applicable,
- * Delete language requiring OAARS registration for prescribers, as registration is now required by

Ohio State Medical Board statute and rule,

* Delete language relating to dispensing fee limitation for controlled substances, as the Bureau's

proposed opiate rules encourage short-term prescriptions for opioids,

* Clean-up references relating to use of acronyms

Page 3 Rule Number: 4123-6-21

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:

FDA Publication "Approved Drug Products with Therapeutic Equivalence Evaluations" in effect on the filled date of service.

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:

The FDA publication is readily available online.

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:

There were no changes to this rule.

12. Five Year Review (FYR) Date: 8/25/2020

(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 /

Page 4 Rule Number: 4123-6-21

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:

The proposed revisions to the pricing methodology will only impact brand name and single source generic medications. The impact on individual pharmacies will depend on their patient and prescription volumes and medication mix. The adverse impact of incorporating best practices for opioid prescribing into daily office processes can only be determined by the level of office automation, staff efficiency and commitment of the prescriber and their staff. The impact on pharmacies of changes in prescribing patterns as a result of the new formulary limitations will be highly varied due to the number of factors involved. For pharmacies that are doing a high volume of business with prescribers who are not following best practices in opioid prescribing, the impact may be significant. Other than pharmacies with this business profile, the impact of these formulary changes will be minimal.

- 16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? N_0
- 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:

Page 5 Rule Number: 4123-6-21

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? N_0
- 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.