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?** 2/1/2020

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?**

   The Bureau proposes to revise the formulary appendix to this rule by amending coverage to the drug products listed in the formulary. These proposed changes are the result of recommendations from the Bureau's Pharmacy & Therapeutics Committiee (P&T). These revisions reflect the Bureau's dedication to providing for appropriate care while ensuring the safety of our injured workers. The committiee'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 manufacturers.

7. **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 to the formulary listed in the Appendix of the rule are additions and deletion of medications approved for reimbursement when prescribed to treat conditions allowed in a claim for the following purposes:
   1) Addition of Xtampza ER capsules to the formulary. This is a sustained release form of oxycodone, like OxyContin. This would be added as a tier two, sustained-release, abuse-deterrent, opioid. This medication utilizes a unique abuse deterrent technology that makes it difficult to manipulate for aberrant use, such as crushing, snorting, or injecting.
   2) Removal of OxyContin (oxycodone sustained release) tablets and generic oxycodone sustained release tablets from the formulary. This change was made possible by the new abuse-deterrent technology now available in Xtampza, which is equally effective in its pain-relieving properties. Although the removal of OxyContin from the formulary will occur when the rule goes into effect, from and administrative standpoint, the drug will be phased out over time.
   3) Applying tiering methodology to gabapentin and Lyrica. These are very similar non-addictive, non-opioid pain medications, and both are similarly effective for neuropathic pain. Gabapentin is generic, Lyrica is still under patent. Lyrica is the number 1 medication by spend in our system ($11 million over the last 3 quarters) and the number 4 drug by utilization with over 20,000 prescriptions over the last 3 quarters.

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

9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.**

   Not Applicable

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. **As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.**

    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?**

    The prescriber and pharmacy business communities are the only two business communities involved 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.

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

III. Common Sense Initiative (CSI) Questions

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

16. **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 Sates by the FDA on or after the effective date of the rule.