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CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title: Outpatient Medication Formulary Rule

Rule Number(s): 4123-6-21.3 **Date:** December 19, 2014

Rule Type:

- New
- X Amended
- X 5-Year Review
- ☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   BWC adopted Rule 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 by BWC with input from the BWC Pharmacy and Therapeutics Committee.

Proposed Changes
The proposed changes to OAC 4123-6-21.3 listed below are contained in the Appendix to the rule, which is the formulary drug list. A copy of the Appendix with the proposed changes will be available on the BWC website for stakeholder review. These proposed revisions shall:

1. Add reimbursement for naloxone injection (Evzio®). This is a prefilled syringe form of injectable naloxone that can be administered by the patient or a caregiver to treat an opioid overdose. This is the same type of device marketed as the Epi-pen® for emergency treatment of severe allergic reactions. Reimbursement for this agent will require a Prior Authorization and documentation that BWC is currently providing reimbursement for opioids.

2. Add reimbursement for sustained release hydrocodone tablets (Zohydro ER®). Reimbursement will require a Prior Authorization, documentation of allergies to acetaminophen, morphine sulfate, and oxycodone and will be limited to 60 dosage units per month. Reimbursement will not be provided for concurrent use of more than one sustained release opioid

3. Limit reimbursement for all butalbital containing products (e.g. Fioricet®) to only those claims that have medical allowances that are generally known to cause headaches or to claims that have a specific type of headache listed as a medical allowance.

4. Limit reimbursement for all forms of diclofenac topical liquid (e.g. Pennsaid 1.5%®) to only those products with a concentration of 1.5% and only in new claims that have osteoarthritis as an allowed medical condition.

5. Limit reimbursement of sustained release forms of cyclobenzaprine (Amrix®) in new claims to only those claims where a 30 day trial of immediate release cyclobenzaprine tablets has been prescribed and the injured worker has experienced extreme drowsiness as a side effect.

6. Limit reimbursement for prescriptions of all anti-anxiety or anticonvulsant drugs in the benzodiazepine drug class (e.g. Xanax® or Valium®) in new claims to sixty (60) days from the date of injury in any claim that does not have an allowance for a psychological condition.

7. Remove the sustained release naproxen product Naprelan® and liquid filled capsule diclofenac product Zipsor® from the BWC drug formulary and stop reimbursement for these two products.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

R.C. 4121.441, R.C. 4123.66

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.

No.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   The purpose of Rule 4123-6-21.3 is to improve the efficiency of treatment for injured workers by providing prescribers with a concise list of medications that can be utilized for treatment of approved conditions related to the claim. The formulary also provides the prescriber with information regarding any restrictions or limitations to the use of an approved medication. Likewise, the prescriber will know that if a medication is not listed in the formulary, then it will not be reimbursed for treatment of any conditions in a claim. The use of a formulary enhances medication safety by allowing time for BWC's Pharmacy and Therapeutics Committee to conduct a thorough review of the clinical merits of new medications before they are approved for use. It also provides a process by which BWC may remove or limit the inappropriate utilization of medications in keeping with FDA recommendations as well as current clinical literature and best medical practices.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Per Rule 4123-6-21.1, BWC's Pharmacy and Therapeutics Committee is charged with making recommendations to BWC regarding the creation and ongoing management of the BWC drug formulary. The committee fulfills this charge through routine monitoring of prescription data from our pharmacy benefit manager, reviews of current clinical literature and current best practice guidelines.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The proposed rule was e-mailed to the following lists of stakeholders on November 14, 2014 with comments due back by December 5, 2014:

   - BWC's Managed Care Organizations and the MCO League representative
   - BWC's internal medical provider stakeholder list - 68 persons representing 56 medical provider associations/groups
   - BWC's Healthcare Quality Assurance Advisory Committee
   - Ohio Association for Justice

- Employer Organizations
    - Council of Smaller Enterprises (COSE)
    - Ohio Manufacturer's Association (OMA)
    - National Federation of Independent Business (NFIB)
    - Ohio Chamber of Commerce
- BWC's Self-Insured Division's employer distribution list
- BWC's Employer Services Division's Third Party Administrator (TPA) distribution list

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   Feedback from the stakeholders listed in question 7 above was solicited and accepted beginning November 14, 2014 through December 5, 2014. Only the one comment listed below was received during this period.

Stakeholder		
Ernest Boyd, Pharm. Director, MBA, Ohio Pharmacists Assn.	OPA has no objection to latest rule changes. Thanks.	Thanks for your feedback. So noted.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   BWC is aware of many published studies by health care institutions and private insurance firms that describe a drug formulary as a fundamental component of a well managed prescription benefit program.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    These revisions to coverage of specific drugs are the result of recommendations by the BWC Pharmacy and Therapeutics Committee following a review of utilization data, current clinical literature and federal regulatory changes.

11. **Did the Agency specifically consider a performance-based regulation? Please explain. Performance-*based regulations define the required outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.**

    This process is not applicable to drug formulary management.

12. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    This revision to the formulary rule only affects injured workers receiving prescription benefits from BWC. No other Ohio regulations exist regarding what drugs are covered by BWC.

13. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    Ohio prescribers and pharmacies caring for injured workers will be notified of this change in coverage by email, fax or direct mail. Injured workers currently receiving one of these drugs will be notified by first class mail and advised that they have sixty days to meet with their prescriber and initiate any necessary changes in therapy.

Adverse Impact to Business

14. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    a. **Identify the scope of the impacted business community;**
       The prescriber and pharmacy business communities are the only two business communities involved with medication prescribing and dispensing. The impacted segments of those communities are the BWC providers who prescribe and those network pharmacies enrolled with the bureau that dispense the prescriptions.

    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
       There will not be an adverse impact on either of the two business communities identified in that both prescribers and pharmacies currently prescribe and dispense prescriptions based on the BWC formulary. These revisions do not change the process of prescribing or the dispensing nor do they make any changes to reimbursement for those activities.

c. **Quantify the expected adverse impact from the regulation.**
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a *"representative business." Please include the source for your information/estimated* impact.

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. And any prescriptions that result from the changes in the drug regimen would continue to be processed by a pharmacy.

15. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

Rule 4123-6-21.1 charges the BWC Pharmacy and Therapeutics Committee to conduct regular reviews of the drug formulary and to make recommendations to the Administrator directed at improving overall efficiency and effectiveness of drug utilization. These changes to drug coverage result from that activity. Formulary revisions are routinely made based on opportunities to improve the clinical impact of the formulary or changes in federal drug regulations.

Regulatory Flexibility

16. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No. All prescribers are required to utilize formulary medications if BWC is to reimburse for those prescriptions.

17. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

Not Applicable since non-formulary drugs may still be prescribed for an injured worker, however they are not reimbursed by BWC.

18. **What resources are available to assist small businesses with compliance of the regulation?**

Prescribers may utilize the BWC website for a complete list of formulary medications and any restrictions to those drugs. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@ bwc.state.oh.us) that prescribers can use to ask questions about drug coverage.