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:** February 23, 2012

Rule Type:

- X **Amended**
- **New**
- ☐ **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- ☐ **Rescinded**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.

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 February 14, 2012 with comments due back by February 28, 2012:

   - 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?**

   Response will be dictated by feedback received. This section will be completed at the second reading.

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?**

    This revision to specific drug coverage was recommended by the BWC Pharmacy and Therapeutics Committee following a review of utilization data and clinical literature.

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.**

    These changes in drug coverage will be implemented after notification to each injured worker who is receiving one of the drugs in question. The injured workers will be given 60 days to meet with their prescriber and discuss a revision to their plan of treatment. Prescribers will be notified in May of the impending change through mailings and internet based processes.

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;**
    Over 14,000 individual Ohio prescribers are currently impacted by the BWC formulary. Any number of them may have written a prescription for one of the drugs affected by this change. Some of these prescribers will have to adjust therapy for some injured workers. This is the reason for the 60 day notice period to injured workers, to enable any necessary changes to be accomplished during the course of routine scheduled office visits. These visits are reimbursed by BWC so there should be no additional cost incurred by prescribers.

    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
    The only adverse impact on the prescriber community from this formulary revision will be the need to reassess the drug therapy being prescribed for an injured worker and if therapy is to be continued, then a new prescription for a covered drug will need

to be written. Any therapy change for any reason requires ongoing assessment for effectiveness; this is an anticipated component of drug treatment.

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.

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 review of and make recommendations to BWC regarding ongoing maintenance of the drug formulary directed at improving overall efficiency and effectiveness of drug utilization. These changes to drug coverage result from that activity. Changes are routinely made when opportunities to improve the clinical and fiscal impact of the formulary are presented.

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. They may also receive the BWC formulary from a free web hosting service called Epocrates. 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.