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:** November 26, 2012

Rule Type:

- New
- X Amended
- ☐ 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- ☐ Rescinded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, initially 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.

   These proposed changes to rule 4123-6-21.3 shall:

   1. Add coverage of two sustained release forms of gabapentin in the Anticonvulsant Drug Class. Those two drugs are Horizant® (gabapentin encarbil) and Gralise® (gabapentin sustained release). These two drugs will be covered by the bureau after a trial of at least 30

days of the immediate release form of gabapentin has demonstrated unacceptable side effects or systemic allergic reaction (as defined in OAC 4123-6-21 paragraph (J) (1).

2. Add coverage of the drug Stendra® (avanafil) in the Erectile Dysfunction Drug class. The same quantity restrictions will apply to this drug that apply to similar drugs in the class (6 units per 30 days).

3. Add the drug Butrans® (buprenorphine topical patches) to the sustained release opiate coverage with the same guidelines for use as fentanyl patches (clinical documentation of an inability to swallow or absorb oral medications). Use of Butrans® in existing claims will not be impacted by this change.

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?**

   BWC measures the success of the revisions to the BWC formulary by comparing drug utilization data pre and post rule revision. The prescription benefit manager (PBM) captures prescription data electronically at the point of dispensing. BWC houses this data in the data warehouse of the Bureau. The BWC pharmacy program routinely monitors this data for trends to demonstrate the impact of the formulary revisions on cost and utilization by injured workers. This is how the bureau was able to report a 12% decrease in opiate utilization and a 54% decrease in utilization of skeletal muscle relaxant drugs in calendar year 2012 under the prior formulary.

   By selecting formulary products to treat allowed conditions, prescribers are assured that their prescriptions will be covered. This assurance reduces calls to BWC and delays in treatment.

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 30, 2012 with comments due back by December 14, 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?**

   Feedback is currently being collected.

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.**

    Ohio prescribers and pharmacies will be notified of the addition of the three drugs to the formulary by email, fax or direct mail. The change in coverage of the existing formulary drug will not be applied to any injured worker who is currently receiving the drug.

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;**
       Out of a total of nearly 14,000 prescribers who have prescribed medications for injured workers in 2012, there are over 7,400 individual Ohio prescribers who are currently impacted by the BWC formulary. Two of the three drugs being added to the BWC formulary are a direct result of formal requests from Ohio prescribers.

b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
The only impact on the prescriber community from formulary additions will be the need to reassess the drug therapy being prescribed for an injured worker to see if one of the new drugs may be a better therapeutic option. The change to coverage of the existing formulary product will require the prescriber to utilize this topical narcotic in the same manner as other topical narcotic formulary products.

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 4123-6-21.2 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.