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:** August 13, 2013

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- ☐ Rescinded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 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.

   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 changes shall:

1. Limit reimbursement for sedative hypnotic agents to the following medications: zolpidem IR & CR tablets (Ambien®), Eszopiclone (Lunesta®), Temazepam (Restoril®), Zaleplon (Sonata®).

2. Remove the following sleep aid agents from the formulary: Chloral Hydrate, Halcion®, Dalmane®, Prosom® Doral®, Rozerem®, Edular®, Silenor®, Zolpimist®. These changes will not apply to injured workers who are currently receiving regular prescriptions for any of the medications removed from the formulary.

3. Limit the maximum daily dose to be reimbursed for anti-anxiety drugs in the benzodiazepine class to the equivalent of 40mg of diazepine (Valium®). This change will not apply to injured workers who are currently receiving regular prescriptions for anti-anxiety medications above the maximum daily dose limit.

4. Limit reimbursement for the drug Metaxalone (Skelaxin®) to only those cases in which the injured worker has tried one other formulary skeletal muscle relaxant for at least 14 days and has experienced a therapeutic failure, demonstrated unacceptable side effects or systemic allergic reaction (as defined in OAC 4123-6-21 paragraphs (J) (1) and (J)(2). The skeletal muscle relaxant drug class formulary restriction of 90 days of coverage plus one additional 30 days of coverage with prior authorization still applies to Metaxalone.

5. Allow reimbursement for transdermal forms of the drugs Fentanyl and Buprenorphine (Butrans®) as first tier sustained release opiates in claims with clinical documentation of an inability to swallow or absorb oral medications. Reimbursement will also be allowed for either transdermal agent in claims with documentation of a therapeutic failure, demonstrated unacceptable side effects or systemic allergic reaction (as defined in OAC 4123-6-21 paragraphs (J) (1) and (J)(2) to an oral sustained release opiate. Reimbursement for Butrans® is limited to claims requiring a daily morphine equivalent dose of 90mg or less per day. Reimbursement for all sustained release opiate medications is limited to use of a single sustained release agent at any one time.

6. Add the drug Vilazodone (Viibryd®) to the serotonin reuptake inhibitor class of anti-depressants.

7. Approved forms of sustained release gabapentin and gabapentin encarbil will be eligible for reimbursement following a 30 day trial of immediate or sustained release gabapentin that results in a documented clinical failure, as defined in OAC 4123-6-21(J)(2). Reimbursment shall be restricted to a single form of gabapentin at any one time.

8. Limit the number of doses of all butalbital containing formulary products to 24 doses per calendar month. This revision is based on a review of current medical literature, FDA drug approval information and best medical practice. There is universal agreement in clinical

literature that drug combinations containing butalbital should not be used in treatment of chronic pain and are not appropriate for long term routine use in any condition.

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 formulary rule changes (except the limitation on butalbital) were e-mailed to the following lists of stakeholders on April 18, 2013 with comments due back by May 6, 2013; the proposed formulary rule change involving butalbital was emailed to the same list of stakeholders on July 11, 2013 with comments due back by August 1, 2013:

   - 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?**

   Most feedback from stakeholders are in support of the new regulations proposed in this rule. Some suggestion were including possible surveillance and restricting all physician-prescribed narcotic medications, and, for the Bureau, to do more to prevent physicians from prescribing highly addictive narcotics to injured workers because it is not only ending up with drug-addicted employees, but also the costs to insurance companies and employers are higher without regulating the prescriptions of these medications.

   BWC's response is that the Bureau is preparing a rule that will accomplish the monitoring and limiting of prescribing highly addictive narcotics to injured workers.

   One stakeholder expressed concerns by stating: "I find a major problem with the proposed changes in that the justification for the changes is not explained in the e-mail. I do not think it is appropriate to ask for stakeholders to approve policies when the basis for those policies are not explained. I would encourage the pharmacy program to reissue the feedback request with an explanation on why it intends to limit the medications it is seeking to limit. That is the

only way to ensure that meaningful feedback can be offered. Without such justification, I do not think it is appropriate to further limit medications."

The Bureau, in its response, explained the history of the P&T committee, which meets in a public forum, and that discussion on these particular drugs began in June 2012.The response further explained dosing recommendations and dose equivalents and the newer and safer alternatives to some of the older drugs still on the market, noting our particular concern for our older injured workers. Before implementation of the proposed rule, current prescribers will be notified and asked to modify their prescribing to be in compliance with our formulary.

Other concerns the Bureau addressed relating to allowing non-addicting "and very popular choice among psychiatrists" sleeping pills and anxiety disorder doses may need higher dosing in certain situations. The Bureau explained that: 1) Regular generic trazadone is a formulary product and is allowed for sleep. However, branded forms of low dose trazadone that are specifically marketed for sleep such as Silenor® are being removed from Formulary coverage at this time. 2) The 2012 BWC prescribing data that was used by the Pharmacy & Therapeutics Committee in evaluating the proposal, demonstrated that in nearly all claims where doses of alprazolam or diazepam exceeded the new maximum daily dose, the drugs were not being prescribed by psychiatrists or for claims that had general anxiety disorder as an allowed condition. As with any formulary action, the injured worker always has the right to file a motion with the industrial commission requesting to obtain the drugs at a higher dose. Also, this change will not apply to injured workers currently taking benzodiazepines at doses above the new maximum daily limit.

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 r*egulations 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 this change in coverage by email, fax or direct mail. Injured workers currently receiving this drug will be notified by first class mail and advised that they have six months to meet with their physician 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;**

       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.

       Between January 1 and May 31 2013 there were 584 injured workers who received monthly prescriptions for butalbital containing products. Of that number 108 were being prescribed daily doses above the maximum daily dose listed in the FDA package insert, in some cases as much as twice the recommended daily dose. There were 134 injured workers receiving the drug at the level proposed by the rule revision. There were 331 prescribers associated with these 584 injured workers.

    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 the formulary additions will be the need to reassess the drug therapy being prescribed for an injured worker to see if the new drug may be a better therapeutic option. The change to coverage of the existing formulary products: (1) will permit prescribers to utilize the two topical narcotics Fentanyl and Buprenorphine (Butrans®) in more clinical situations (2) requires prescribers to limit maximum daily doses of anti-anxiety medications in the benzodiazepine class to those that are considered safe in recognized clinical references (3) limits the selection of sedative hypnotic medications to those deemed most safe and effective by the BWC Pharmacy & Therapeutics Committee (4) establishes additional clinical requirements for coverage of the specific skeletal muscle relaxant Metaxalone (Skelaxin®) in keeping with similar criteria that was applied to certain opiates (5)

The prescriber community will need to reassess the drug therapy being prescribed for those injured workers who are being prescribed quantities of butalbital that exceed the new limit. Based on the addictive nature of the drug butalbital, they will have six months to make any changes in the dose level or to wean the injured worker off of the drug.

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.

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.