ACTION: Final

DATE: 11/20/2015 8:00 AM

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:** July 10, 2015

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- ☐ Rescinded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.

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 the abuse deterrent sustained release formulation Embeda® (Morphine sulfate/naltrexone). Reimbursement will not be provided for concurrent use of more than one sustained release opioid.

2. Add reimbursement for the abuse deterrent sustained release formulation Hysingla ER® (Hydrocodone Bitartrate). Reimbursement for Hysingla ER® will be limited to a total quantity of one dose per day for all strengths of the medication. Reimbursement will not be provided for concurrent use of more than one sustained release opioid

3. Remove reimbursement for the sustained release formulation Zohydro ER® (Hydrocodone Bitartrate). This was replaced by the drug Hysingla ER® which has a higher rating for abuse deterrent technology by the FDA.

4. Add reimbursement for the drug Movantik® (Naloxegol). Reimbursement requires a prior authorization with documentation of confirmed opioid induced constipation. Reimbursement is limited of no more than 30 doses per month.

5. Add the same requirements as those on Movantik® to reimbursement for the currently covered injectable drug Relistor® (Methylnaltrexone Bromide)

6. Add reimbursement for the drug Harvoni® (Ledipasvir/Sofosbuvir). Reimbursement requires prior authorization and an allowed condition of Type 1 Hepatitis C.

7. Add reimbursement for the drug Noxafil® (Posaconazole). Reimbursement requires prior authorization and documentation of a drug resistant systemic fungal infection.

8. Add reimbursement for the drug Eliquis® (Apixaban). Reimbursement requires prior authorization and documentation of an allowed condition of atrial fibrillation, venous thrombosis or post operative venous thromboprophylaxis.

9. Add reimbursement for the drug Savaysa® (Edoxaban). Reimbursement requires prior authorization and documentation of atrial fibrillation or venous thrombosis.

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 June 17, 2015 with comments due back by July 2, 2015:

- 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 June 17, 2015 through July 2, 2015. No comments were received from stakeholders during this period.

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 y*our 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.

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