ACTION: Original

DATE: 10/24/2014 1:27 PM

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title: First Fill of Outpatient Medications Rule

Rule Number(s): 4123-6-21.6 **Date:** September 5, 2014

Rule Type:

X New

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☐ Rescinded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.

Chapter 4123-6 of the Administrative Code contains BWC rules implementing the Health Partnership Program (HPP), including reimbursement for outpatient medication by BWC in State Insurance Fund claims.

In response to recent legislative changes enacted by Substitute House Bill 493 (Sub.H.B. 493) effective September 17, 2014, BWC is proposing a new rule governing reimbursement for the first fill of prescription medications prior to the initial allowance of a claim.

Proposed Changes

BWC is proposing a new rule, OAC 4123-6-21.6, to implement new R.C. 4123.66(B). The proposed new rule would detail the circumstances under which BWC will reimburse for the first fill of prescription drugs, for medical conditions identified in an application for payment of workers' compensation or provision of other benefits, prior to the date BWC issues an initial claim determination order.

These circumstances include the following:

- The new rule includes an appendix which constitutes the complete list of medications, and the maximum quantity of such medications, that are approved for reimbursement for first fill prior to issuance of an initial claim determination order. However, in cases of medical necessity supported by clinical documentation and evidence of need BWC may, with prior authorization, reimburse for the first fill of medications that are listed in the appendix to BWC's formulary rule 4123-6-21.3 but are not listed in the appendix to the first fill rule.

- Approval for reimbursement of medications under the first fill program will be for a period of ten days or less, at the most commonly prescribed dosing schedule, and no refills will be approved.

- Approval for reimbursement of medications under the first fill program will be limited to one drug per therapeutic drug class listed in the appendix to the rule.

- Extemporaneous compounded prescriptions are not eligible for reimbursement under the first fill program.

- Pharmacy providers shall be reimbursed for dispensing the first fill of medications in the manner described in BWC's outpatient medication rule OAC 4123-6-21 if the prescriber, or their agent has written "Work Related Injury" on and signed the prescription blank. A pharmacist or pharmacy intern who receives a telephone prescription may also write and sign the phrase on the prescription.

- As provided in new R.C. 4123.66(B), if a claim in which the first fill of outpatient medication was reimbursed pursuant to the rule is ultimately disallowed in a final administrative or judicial order, and the employer is a state fund employer who pays assessments into the R.C. 4123.34 surplus fund account, the first fill payment shall be charged to the surplus fund account and not charged to the employer.

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

   R.C. 4121.441, R.C. 4123.66 (effective 9/17/14)

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 4123-6-21.6 is to permit BWC to provide reimbursement for medications during the period after an acute industrial injury and before the claim has been reviewed and allowed by BWC. Currently, during this period, which is typically less than 10 days, any medications required for the injury are the responsibility of the injured worker. Prior to the statutory change mentioned above, BWC was prohibited from paying for any treatments prior to allowance of a claim. This meant injured workers paid out of pocket for critical medications required in the immediate post injury period. This rule will allow the bureau to cover a limited number of drugs that are typically required during the acute phase following an injury. If the claim is later disallowed then it permits the cost of those drugs to be charged to the BWC surplus fund and will not be charged to the employer's premium.

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

   In order for an injured worker to obtain reimbursement for out of pocket medication expenses, they are required to complete and file a standard BWC form. In FY-14 these forms were filed in 1150 claims for reimbursements of $163,983 in out of pocket expenses. Based on the medications involved with these claims the bureau anticipates at least an 80% decrease in the number of these paper filings. Some filings will continue to be necessary, depending on the medication involved or other unique issues within a claim.

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.

   - 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?**

   BWC received no responses to the solicitation for input from the stakeholder group.

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?**

   This rule was developed by BWC as a response to an awareness of the limitations to timely treatment imposed by the current statute. It created a situation that many times caused financial burdens and in some cases delays in treatment for injured workers.

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?**

    Prior to the previously cited statutory change, BWC had no other option but to process claims in the manner dictated by law.

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 this situation.

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

    This only affects injured workers receiving prescription benefits from BWC. No other Ohio agency adopts regulations 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.

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;**
    This rule will impact the prescription coverage for every newly injured worker in Ohio. However, it will change nothing for employers as far as worker's compensation premium cost. If the claim is approved by BWC, then the employer's experience will be unchanged from what it would have been under the previous statute. If the claim is denied, then the cost of the medications will be charged to the state surplus fund and the employer's insurance rate will be unaffected. It will actually benefit pharmacies since payment for any prescriptions dispensed under this rule in the specified quantities is guaranteed.

    There will be a cost to the surplus fund for claims that are denied. Based on calendar year 2013 drug costs and the number of denied claims, it is estimated that the cost impact of this rule on the surplus fund would have been around $108 thousand dollars for that year.

    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
    No adverse impact identified.

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.

As indicated above, the only identified negative impact from the rule is a potential cost to the state surplus fund. Based on 2013 drug costs and denied claims, it was estimated that the cost would have been around $108,000 in that year. That cost would have represented less than 1% of the total 2013 BWC drug expenditures.

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

This rule offers BWC an opportunity to address a problem in the prompt provision of necessary medical care for injured workers. Making a change that will positively improve how the system helps over a thousand injured workers is clearly consistent with BWC's mission.

Regulatory Flexibility

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

Not applicable to this rule since BWC is required to provide prescription medications for any injured workers requiring them. Coverage of these medications is only available for prescriptions dispensed through licensed and BWC enrolled pharmacies.

16. **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 to this rule since there are no penalties involved in filling these prescriptions.

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

Prescribers may utilize the BWC website for a complete list of first fill medications and their associated quantity limits. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@ bwc.state.oh.us) that prescribers and pharmacies can use to ask questions about drug coverage.