CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title:
Payment for outpatient medications, Payment for outpatient medications by a self insured employer and Pharmacy and Therapeutics Committee rules

Rule Number(s): 4123-6-21, 4123-6-21.1, 4123-6-21.2

Date: March 9, 2017 (Revised)

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- ☐ Rescinded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 is proposing to amend rules OAC 4123-6-21, OAC 4123-6-21.1 and OAC 4123-6-21.2 effective June 1, 2017 to remove language that refers to a proprietary drug classification system that is no longer in use, remove language that limits situations when dispensing fees will not be paid to pharmacists and to add the Industrial Commission Medical Director as a member of the P&T Committee

Proposed Changes

OAC 4123-6-21 and 4123-6-21.1 Payment of outpatient medications, Payment of outpatient medications by a self insured employer

- Remove language that specifically references the First Data Bank proprietary drug classification system "Generic Code Number (GCN) in the context of limiting payment of dispensing fees.
- Remove language that describes the time frame for prescription refills that could result in the dispensing fee being withheld from a pharmacist.

Proposed Changes

OAC 4123-6-21.2 Pharmacy and Therapeutics Committee

- Add language to provide that the Industrial Commission Chief Medical Officer may be a non-voting member of the P&T 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.**

   The rule does not implement a federal requirement.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   There are no federal requirements regarding reimbursement for prescriptions dispensed to treat a work related injury or occupational disease, or the establishment of a committee to advise the BWC administrator and the chief medical officer with regard to issues involving medication therapy for injured workers.

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 Rules 4123-6-21 and 41236-21.1 is to define the context, criteria, limitations and processes by which outpatient medications are covered by BWC and self insured employers. In addition to defining requirements for approved medications, the rules also define the types of providers who are eligible to write covered prescriptions as well as requirements for pharmacies that process the prescriptions. Payments for specific types of medications and the methodologies to be used to calculate those payments are defined in these rules.

What is the public purpose for this (Continued)

The purpose of Rule 4123-6-21.2 is to define the membership composition and responsibilities of the Pharmacy and Therapeutics (P&T) committee. The committee was created to advise the administrator and the chief medical officer with regard to issues involving medication therapy for injured workers. One of the committee's responsibilities is the maintenance of the BWC formulary.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
   There will be no stakeholder impact from the removal of the references to a drug coding system that is no longer in use by BWC. The removal of restrictive language on payment of dispensing fees eliminates possible unnecessary reductions in pharmacy reimbursement. The addition of the Industrial Commission Medical Director to the BWC P&T Committee will enhance the communications between the two agencies.

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 revisions to the rules were e-mailed to the following lists of stakeholders on January 18, 2017 with comments due back by February 10, 2017:

   - BWC's Managed Care Organizations
   - 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
   - Ohio Medical Board
   - Ohio Board of Pharmacy

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 January 18, 2017 through February 10, 2017. Only one comment was received from a stakeholder. The comment and response are shown below:

Stakeholder	Feedback	BWC Response
Paul T Scheatzle DO, Member, BWC HCQAAC Committee	Expressed his agreement with the revisions as proposed	BWC Thanked Dr. Scheatzle for his support.

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?**

   Scientific data is not applicable to the language revisions being proposed for the Outpatient Prescription Payment Rules or the Pharmacy and Therapeutics Committee rule. The proposed changes reflect language updates necessary for contemporary agency operations.

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 rule applies specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility. There is currently no other rule in the Ohio Administrative Code that specifically addresses reimbursement for outpatient medications in workers' compensation or the membership of the BWC Pharmacy and Therapeutics Committee.

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.**

    Not applicable . As previously stated, the revisions to the outpatient prescription payment are directed at incorporating language that reflects contemporary agency practices at BWC. The P&T Committee membership is being addressed to enhance communications between the Industrial Commission and BWC.

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

    These rules only affect internal operations at BWC. No other Ohio regulations exist regarding how drug classes are coded by BWC or what medical service committees exist in the agency.

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.**

    As indicated above, these revisions only impact internal BWC operations.

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;**
       Since these revisions are directed at internal administrative BWC operations, there will be no impact on the greater business community.
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);**
       See previous response.

    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.

       See previous response

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

    BWC is statutorily obligated to apply sound fiscal principles in overseeing expenditures from the state insurance fund. Ensuring that the language and application of our rules reflect current market standards is part of that obligation.

    Likewise, BWC is committed to ensuring the safest and most effective treatment for Ohio's injured workers. To that end we believe that any steps that can be taken to improve performance of the P&T Committee should be taken.

Regulatory Flexibility

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

Not Applicable. The proposed language revisions do not impact any small businesses

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. The proposed language revisions do not impact any prescribers or small businesses.

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

Not Applicable. The proposed language revisions do not impact any small businesses