Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Bureau of Workers' Compensation

Rule Contact Name and Contact Information: Eva Dixon (614) 644-8346

Regulation/Package Title (a general description of the rules' substantive content):

Payment for outpatient medication; Payment of outpatient medication by self-insuring employer

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

Date of Submission for CSI Review: September 3, 2024

Public Comment Period End Date: September 17, 2024

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/_2__ rules (FYR? _No_)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **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). OAC 4123-6-21 governs reimbursement for outpatient medication by BWC in State Insurance Fund claims. OAC 4123-6-21.1 governs reimbursement of outpatient medication by self-insuring employers.

   BWC is proposing revisions to OAC 4123-6-21 that would:

   - Update references to Ohio state board of pharmacy rules.
   - In the lesser of logic of payment for medications, including compounds, to pharmacy providers, change cost component to average wholesale price (AWP) minus a percentage determined by BWC.
   - Change dispensing fee component for medications, including compounds, to a flat rate determined by BWC, subject to annual review.
   - The change in pricing logic for ingredient cost also applies to injured workers who request a brand name drug when a generic equivalent exists.

   Since self-insuring employers are required to pay benefits equal to or greater than BWC, where applicable BWC is proposing to make changes parallel to those proposed in OAC 4123-6-21 in the Chapter 4123-6 self-insuring employer outpatient medication rule, OAC 4123-6-21.1.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Authorize: 4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.35, 4123.66

   Amplify: 4121.12, 4121.121, 4121.44, 4121.441, 4123.66

4. **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?**
   No.

   If yes, please briefly explain the source and substance of the federal requirement.

   Not Applicable.

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

   Not Applicable.

6. **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-insuring 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.

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

   Success will be measured by the providers' and self-insuring employers' compliance with the modifications to the rule, and by routine monitoring of prescription data from our pharmacy benefit manager.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

   No.

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Not Applicable.

Development of the Regulation

9. 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 proposed revisions to rules OAC 4123-6-21 and 4123-6-21.1 were e-mailed to the following lists of stakeholders on August 7, 2024 with comments due back by August 21, 2024:

- BWC's Managed Care Organizations
- BWC's Medical Services Division's medical provider stakeholder list
- BWC's Healthcare Quality Assurance Advisory Committee
- Ohio Association for Justice
- Employer Organizations
    - o Council of Smaller Enterprises (COSE)
    - o Ohio Manufacturers' Association (OMA)
    - o National Federation of Independent Business (NFIB)
    - o 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.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Any stakeholder responses received by BWC are summarized on the Stakeholder Feedback Summary Spreadsheet. No changes were made based on the stakeholder feedback.

11. 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 medication payment rules. The proposed changes reflect language updates necessary for contemporary agency operations.

12. **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?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    Not applicable. These rules apply specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility. There are currently no other rules in the Ohio Administrative Code that specifically address reimbursement for outpatient medications in workers' compensation.

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

    These rules only affect prescription drug benefits provided by BWC or self-insuring employers in allowed Ohio workers' compensation claims. No other state agency has adopted regulations regarding reimbursement of outpatient medications in the Ohio workers' compensation system.

14. **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.**

    Once the rules are approved and through the JCARR process, BWC staff impacted by the rule and BWC's contracted pharmacy benefits manager will be informed of the effective date. Providers caring for injured workers will be notified of the key points contained in the rules by email, fax, or direct mail. They will also be provided with a link to find a complete copy of the rule.

    BWC's Medical Services Division will ensure that relevant sections of the MCO Policy Reference Guide and the Provider Billing and Reimbursement Manual are updated to reflect appropriate rule modifications.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community:**
    The prescriber and pharmacy business communities are involved with the prescribing and dispensing of medications. The impacted segments of those communities are the BWC enrolled or certified providers who prescribe and dispense medication to injured workers.
    and

b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
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.
The potential impact on each individual pharmacy may increase or decrease depending on the number of workers' compensation patients, prescription volume, the mix of dispensed brand and generic medications, and the maximum allowable cost list of BWC's contracted pharmacy benefits manager under OAC 4123-6-21(I).

16. **Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

    No.

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

    BWC is obligated to apply sound fiscal principles in overseeing expenditures from the state insurance fund. Ensuring that our prescription reimbursement methodology is consistent with the current market standards is part of that obligation.

Regulatory Flexibility

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

    No. Prescription reimbursement methodology is defined in rule and is applied to all pharmacies.

19. **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.

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

Prescribers may utilize the BWC website for an overview of the revised rules. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@bwc.ohio.gov) that prescribers can use to ask questions about drug coverage.