ACTION: Revised

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Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Pharmacy rules.

Rule Number(s): 4123-6-21.3, 4123-6-21.6, 4123-6-21.7, & 4123-6-21.8

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

- ✓ New/ 2 rules
- ✓ Amended/ 2 rules (FYR? Yes)
- ☐ No Change/____ rules (FYR? ___)
- ☐ Rescinded/ 1 rules (FYR? Yes)

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) for state fund employers. BWC enacted the bulk of the Chapter 4123-6 HPP operational rules (Ohio Administrative Code 4123-6-01 to 4123-6-19) rules in February 1996 and the Chapter 4123-6 HPP medical rules (Ohio Administrative Code 4123-6-20 to 4123-6-46) in January and February 1997. The rules have been periodically updated as needed.

   In accordance with Ohio Revised Code 119.04 and 106.03, BWC makes the proposals listed below as to Chapter 6 rules scheduled for 5-year review.

   Amending:

   4123-6-21.3 Outpatient medication formulary.

   4123-6-21.6 First fill of outpatient medications.

   Enacting:

   4123-6-21.7 Reimbursement of opioids in the treatment of pain for a work related injury or

occupational disease.

4123-6-21.8 Reimbursement for services to assist in the discontinuation of medications.

Rescinding:

4123-6-21.7 Utilization of opioids in the subacute or chronic phases of pain treatment for a work-related injury or occupational disease.

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.**

   R.C. 4121.441(A), 4123.66(A) and (B)

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.

   N/A

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

   N/A

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 revisions to BWC formulary rule 4123-6-21.3 expand medications that are available to injured workers. This includes cancer medications to treat an allowed cancer condition, medication to prevent migraine when other preventative treatments have failed, anti-inflammatory patches for pain, and a topical spray for painful conditions. The revisions also remove a tiering requirement for pregabalin, which was recently made widely available as a generic drug.

   Revisions to BWC "first fill" rule 4123-6-21.6 include changes to allow the recommended therapy for injured workers that require HIV post-exposure prophylaxis and for injuries that require treatment with more than one antibiotic. Requirements for writing a first fill prescription were revised to simply the program for our providers.

   The purpose of rule 4123-6-21.7 is to provide enhanced safety in the use of opioid medications prescribed to treat injured workers by asking prescribers to follow best medical practices outlined by the State Medical Board of Ohio. If the prescriber does not follow these best practices, BWC will not reimburse for opioid medication.

The purpose of rule 4123-6-21.8 is to allow reimbursement for necessary and appropriate treatment to asssist injured workers in the discontinuation of medications that may increase the risk of dependency, misuse, and substance use disorder.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**
   The BWC Pharmacy Department monitors claims utilizing opioids over a 50 morphine equivalent daily dose or beyond six weeks from the date of injury for compliance with OAC 4123-6-21.7. If a prescriber is non-compliant, BWC reaches out to the prescriber to request missing documentation. If the presciber refuses after multiple attempts by BWC to gather this documentation, BWC will no longer reimburse for opioids from that prescriber in that claim. BWC will continue to review monthly reports to review opioid prescribing trends. BWC will monitor requests for treatment related to the discontinuation of medication, and the utilization of the medications to be added to the OAC 4123-6-21.3 formulary.

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.
   N/A

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.

   The proposed rules were published for stakeholder comment on Friday December 11, 2019 with a comment period open through December 27, 2019, and notice was e-mailed to the following lists of stakeholders:

   - 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
     - Council of Smaller Enterprises (COSE)
     - 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.

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

Stakeholder responses received by BWC are summarized on the Stakeholder Feedback Summary Spreadsheet.

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?

BWC relied on recommendations from the State Medical Board of Ohio and regulations outlined in OAC Chapter 4731-11 regarding the appropriate prescribing of opioid medications. BWC also considered guidelines and recommendations published by the US Center for Disease Control and the Washington State Agency Medical Directors.

Revisions to rules 4123-6-21.3 and 4123-6-21.6 were based on recommendations accepted by the BWC Pharmacy & Therapeutics Committee. The committee reviews data from clinical trials, published studies, and relevant guidelines regarding medications prior to making recommendations.

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?

These rules apply specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility.

13. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the proce7ss the regulated stakeholders must use to achieve compliance.***

In many ways rule 4123-6-21.7 is a performance based regulation in that the specific testing, assessment and treatment planning processes to be used by the prescriber of opioids are not dictated − but the prescriber must document the actions being accomplished.

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

This rule only affects injured workers receiving prescription benefits from BWC. No other state agency has adopted regulations regarding what drugs are reimbursed by BWC.

15. 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, the BWC staff impacted by the

rules will be informed of the effective date. Providers caring for injured workers will be notified of the key points contained in this rule 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 PolicyGuide and the Provider Billing and Reimbursement manuals are updated to reflectappropriate rule modifications.

Nurses in the BWC pharmacy department will review all claims exceeding a 50 morphine equivalent daily dose or with opioid prescribing beyond 6 weeks from the date of injury for compliance with rule 4123-6-21.7. Prescribers who are not compliant will be notified and given an opportunity to provide the required documentation before the reimbursement of opioids is impacted.

Adverse Impact to Business

16. 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; and

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.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

For prescribers whose opioid prescribing practices currently incorporate the treatment and monitoring steps identified as best practices there will be no impact. Pharmacies filling opioid prescriptions written by these practitioners will see no change in their volume of prescriptions due to this rule. Prescribers who are not currently following best practice guideline for opioid prescribing will have to adopt the steps described in the guidelines or BWC will not reimburse the cost of opioid prescriptions written by those prescribers. Pharmacies filling opioid prescriptions from these prescribers will receive electronic messaging at the time the prescription is entered into the prescription benefit manager computer system that the prescription will not be paid for by BWC.

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.

The adverse impact of incorporating best practices for opioid prescribing into daily office processes can only be determined by the level of office automation, staff

efficiency and commitment of the prescriber and their staff.

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

    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 the safety and efficacy of treatment should be taken. In both the clinical as well as the general media, inappropriate opioid prescribing is consistently identified as a principle causal factor in the opioid epidemic currently afflicting our state. The new rules
    are focused on addressing that factor.

Regulatory Flexibility

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

    No. All prescribers of opioid medications will be required to incorporate best practices for prescribing those medications if BWC is to reimburse for those prescriptions.

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?**

    N/A

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

    The managed care organizzations (MCOs) and the BWC Medical Services Division will provide support and direction to impacted businesses regardless of size with respect to meeting regulations in these rules.

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Stakeholder Feedback 5-Year Rule Review for Health Partnership Program
OAC 4123-6-21.3, 4123-6-21.6, 4123-6-21.7, 4123-6-21.8

Line	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
1	OAC 4123-6-21.8 (A) (3)	Ohio Physical Therapy Association (OPTA)	We would request that physical therapists be able to initiate a dependency assessment under paragraph (A)(3).	The OPTA would like to see more specific language that promotes the utilization of physical therapy. Many times, it is a PT who may notice a patient is not seeing the results that would be expected and that could be because of an underlying addition.	The rule's language reflects BWC's current approach to expectations of a Physician of Record (POR). Various BWC rules reflects the expectations that PORs handle injured workers treatment needs and appropriately request services as needed. This approach ensures effective and consistent adherence to the intent of the service rules and in this instance assessment services when needed to aid in an injured worker's discontinuation of medication. It should be noted that nothing in the rule prevents appropriate collaboration of any attending physician with a POR to facilitate a request by the POR of an assessment if the service is appropriate.	No Change
2	OAC 4123-6-21.8 (C)	Ohio Physical Therapy Association (OPTA)	Request more specific clarification be specified in paragraph (C) that allowable/reimbursable treatment include PT services.	The OPTA indicated that it is not clear under the current language that PT services are included.	After review of the language BWC determined the language as written is appropriate. The language in the paragraph is speaking specifically to the amount of time for which BWC will provide reimbursement for services. Given this is applicable to all non - pharmacologic treatment alternatives,	No Change

Line	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
					to list one particular type of therapy would require a listing of all types of non-pharmacologic treatments, which would be unwieldy and confusing. Additional clarification, on specifics services or therapies, will be provided in a companion policy as determined to be necessary and appropriate to the effective implementation of the rule.	
3	OAC 4123-6-21.8	Thomas Andreshak MD, Consulting Orthopaedic Associates, Inc	Request a statement of reconsideration for additional coverage greater than the 42 days or 18 months for reimbursement which could be granted by the administrator under extenuating circumstances.	If an injured worker has an additional need due to aggravation of the current condition or needs additional surgery and is now needing treatment of a new dependency.	These timeframes were developed and reviewed by our clinical committees. BWC will monitor requests and if it is identified that 42 days of inpatient treatment or 18 months of outpatient treatment is insufficient these limits may be reconsidered.	No Change
4	OAC 4123-6-21.7 OAC 4123-6-21.3 OAC 4123-6-21.6	James Anthony, Mercy Health	No suggestions	Overall very well done. Rule 7: Agree with the development of consistency between the Ohio law regarding this and the HPP rules. That makes perfect sense. Rule 3 and 6: I appreciate the entire formulary and the specific formulary for the "First Fill" rule being clearly specified. That brings all the pharmacy rules together with clarity.	No response needed.	No Change

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