

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title:

Opioid Prescribing, Peer Review, and Provider Decertification Rules

Rule Number(s): 4123-6-21.7, 4123-6-02.7, 4123-6-21.2, 4123-6-22

Date: May 13, 2016

Rule Type:

☒ New

☐ 5-Year Review

☒ Amended

☐ Rescinded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 adopt new opioid prescribing rule OAC 4123-6-21.7, effective October 1, 2016 for claims with a date of injury on or after September 1, 2016 and for all claims on or after January 1, 2017 and to amend rules OAC 4123-6-02.7, 4123-6-21.2, and 4123-6-22 to:

- Encourage the incorporation of best current clinical practices in the utilization of opioids in the treatment of injured workers;
- Establish provisions and criteria for the treatment of opioid dependence that arose secondary to treatment with opioid medications covered by BWC; and

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- Provide and strengthen BWC peer review processes for opioid prescribing that can be implemented to address serious non-compliance with these best practices.

Proposed Changes

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

Proposed new opioid prescribing rule OAC 4123-6-21.7 provides standards and criteria governing BWC's reimbursement of opioid prescriptions used to treat a work related injury or occupational disease in the subacute phase of pain treatment, at high doses, or in the chronic phase of pain treatment, and for discontinuing opioids in the chronic phase of pain treatment.

Upon proposed rule OAC 4123-6-21.7 taking effect, BWC reimbursement for opioid prescriptions used to treat a work related injury or occupational disease shall be limited to claims in which current best medical practices as implemented by Ohio State Medical Board rule OAC 4731-21-02 and proposed BWC rule OAC 4123-6-21.7 are followed. BWC shall not reimburse for any further prescriptions for opioids, and prescribers should discontinue prescribing opioids, if the applicable criteria of the rules are not met.

Furthermore, a prescriber's failure to comply with the requirements of OAC 4731-21-02 and OAC 4123-6-21.7 may constitute endangerment to the health and safety of injured workers, and claims involving opioid prescribing not in compliance with these rules may be subject to peer review by the BWC Pharmacy and Therapeutics (P&T) Committee, the BWC Health Care Quality Assurance Advisory Committee (HCQAAC), or such other peer review committee established by BWC.

- **OAC 4123-6-21.2 Pharmacy and therapeutics committee**
- **OAC 4123-6-22 Stakeholders' health care quality assurance advisory committee**

The proposed changes to OAC 4123-6-21.2 and 4123-6-22 provide that any decertification or sanction of a provider by BWC pursuant to peer review recommendation of the HCQAAC or the P&T committee shall be conducted in accordance with the Chapter 119 hearing procedures set forth in BWC rule OAC 4123-6-17 of the Administrative Code.

- **4123-6-02.7 Provider access to the HPP - provider decertification procedures**

The proposed changes to OAC 4123-6-02.7 provide that the progressive compliance procedures of that rule do not apply to, and the BWC Administrator may proceed directly to enrollment termination and/or decertification of a provider upon, peer review recommendation of the HCQAAC, the P&T committee, or other peer review committee established by BWC.

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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 opioid prescriptions dispensed to treat a work related injury or occupational disease, or for peer review or provider decertification procedures in the Ohio workers' compensation system.

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 4123-6-21.7 is to provide enhanced safety and efficacy in the use of opioid medications prescribed to treat injured workers. This will be done through the expanded utilization of best medical practices as described in national and state prescribing guidelines. There is an undisputed link between the current opioid crisis affecting Ohio's citizens and the inappropriate utilization of prescription opioid medications. By prompting prescribers to utilize nationally recognized best practices in their prescribing of these drugs, BWC will be helping to change the general attitude toward appropriate utilization of opioids. The agency will be directly improving the overall safety of the care being rendered to Ohio's injured workers.

The revisions to rules OAC 4123-6-02.7, 4123-6-21.2, and 4123-6-22 provide and strengthen BWC peer review processes for opioid prescribing that can be implemented to address serious provider non-compliance with these best practices.

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

BWC currently extracts a monthly report that shows all opioid utilization by injured workers. Under Rule 4123-6-21.7 this report will be used to conduct a monthly review of the documentation submitted in claims that meet the criteria of the rule. The outcomes from that review will be used to generate follow up contacts with prescribers who have not provided appropriate documentation of compliance. The number of such contacts will be monitored and reported to the BWC Pharmacy & Therapeutics Committee.

Additionally, success will be measure by the providers' compliance with all Ohio rules and regulations, timely provision of services to injured workers, and the maintenance of costs within the annual fee schedule projections for the relevant services.

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 April 15, 2016 with comments due back by May 9, 2016:

- 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

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 April 15, 2016 through May 9, 2016. Comments were received from five stakeholders. The comments and responses are shown below:

Stakeholder	Feedback	BWC Response
Julie L. Ehemann, R.Ph Commissioner, Shelby County	Commended BWC on the effort to rein in overuse of opioids and to support weaning of patients who are receiving them, in order for the patient to return to work. Asked about mandates that would require physicians to communicate any changes in drug regimen to the patient. Also asked why there was no monetary penalty being assessed against prescribers who did not follow the rule.	Thanked Commissioner Ehemann for her support. Explained that BWC had no authority to levy a monetary penalty against prescribers who do not comply with the rule. Also explained that BWC cannot mandate specific communications between a prescriber and their patient.
John Van Doorn Ohio Association for Justice	The Ohio Association for Justice consulted with a pain management physician to provide comments on the rule. The physician agreed with much of the rule but recommended a requirement for an earlier referral to a pain management specialist. He recommended a referral trigger based on both a shorter time frame as well as a lower daily opioid dose.	Thanked Mr. Van Doorn as well as the physician reviewer for their comments regarding the proposed rule. Explained that our referral triggers were taken from published national and Ohio guidelines. BWC felt that such verifiable public sources provided the best foundation for our rule.

Stakeholder	Feedback	BWC Response
Ernest Boyd, R.Ph., MBA Executive Director Ohio Pharmacists Association	The Ohio Pharmacists Association did not have any problems with the rule a proposed but did have questions regarding implementation. Specifically whether the rule would apply to only new injured workers. What would the role of the Prescription Benefit Manager (PBM) be in applying the rule? Would a Prior Authorization (PA) request be needed in order for a prescriber to go beyond the stated daily opioid loads.	Thanked Mr. Boyd for his comments and questions. Responded that the rule would apply to all injured workers, but noted that paragraph G gives the Administrator the ability to exclude claims based on specific clinical situations. Explained that the PBM would only block payment of prescriptions in the claim after an extensive communication process between BWC, the injured worker and the prescriber. Additionally if reimbursement for a prescription were blocked under this rule, the pharmacist would receive an electronic message explaining why. Further explained that the PA process was not involved with application of this rule.
Stephen Northrup Rampy Northrup LLC Washington DC and Srinivas G. Rao MD, PhD Chief Medical Officer Depomed, Inc	Dr. Rao's letter indicates that Depomed supports the efforts of BWC to to incorporate best clinical practices into the treatment of injured workers. However, he indicates that Depomed takes exception to the use of Morphine Equivalent Dose (MED) as a measure of daily opioid load. The company feels that use of this metric could result in an under dosing of their tapentadol product.	Thanked both Mr. Northrup and Dr. Rao for their support. Explained that national opioid prescribing guidelines, clinical literature as well as FDA package inserts clearly state that a patient's daily opioid load as measured by an aggregate MED is not an appropriate metric for conversion between different opioids. The specific pharmacological attributes of each medication and dosage form must always direct the clinical decision making process. Our rule references the MED metric purely from the intent to trigger a review and evaluation of the patient's drug regimen by the clinician, certainly not to direct selection of one medication over another.
Matthew S. Whitehead Director of Legislative Affairs Governmental Policy Group, Inc Columbus, OH	Mr. Whitehead indicated that their client Pfizer, Inc had no issues with the proposed opiate prescribing rule.	Thanked Mr. Whitehead for his comment.

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 relied on the recommendations contained in the opioid prescribing guidelines published by the US Center for Disease Control, Washington State Agency Medical Directors, and the Ohio Governor's Cabinet Opiate Action Taskforce. Both the federal CDC as well as Washington state guidelines contain data that links adherence to best prescribing practices with reduced opiate prescribing.

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 opioid prescriptions in workers' compensation.

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.

In many ways these rule are performance based regulations in that the specific testing, assessment and treatment planning processes to be used by the prescriber of opioids are not dictated – only that there must be documentation of the actions being accomplished. If a provider does not comply with Ohio laws and regulations, recommendations from a Peer group could provided the basis for a decertification process including a hearing on the matter leading to the recommendation.

12. 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 Ohio regulations exist regarding what drugs are covered by BWC.

Also, BWC is the only state agency responsible for regulating HPP related medical services for Ohio's workers' compensation programs, including the sanctioning of providers under the workers' compensation system for violating workers' compensation laws, rules and policies.

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.

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Once the rules are approved and through the JCARR process, the BWC staff impacted by the rules will be informed of the effective date.

Ohio prescribers and pharmacies 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 Policy Guide and the Provider Billing and Reimbursement manuals are updated to reflect appropriate rule modifications.

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 the prescribing and dispensing of opioid medications. The impacted segments of those communities are the BWC enrolled or certified providers who prescribe opioids for and those network pharmacies enrolled with the bureau that dispense the medications to injured workers covered by BWC.

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

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.

15. 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 rule and changes to the existing rules are focused on addressing that factor.

Regulatory Flexibility

16. 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.

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.

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

The MCOs have a responsibility in the contract they sign with BWC to provide training and support to all providers that they utilize in managing the medical care of their injured workers. Additionally, by contract the MCOs are responsible for providing education and support to injured workers and employers on all workers’ compensation services and programs including medical services. The various units of the Medical Services Division, along with the Provider Relations business unit within the Medical Operations Division of BWC will also provide support and direction to impacted businesses regardless of size with respect to meeting Bureau regulations.

Additionally, prescribers may utilize the BWC website for an overview of the new rule. They will also be provided with a toolkit of various methods to ensure compliance with best current opioid prescribing practices. The website will also contain links to the standards used to develop the opioid prescribing rule as well as the full text of the rule. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@bwc.state.oh.us) that prescribers can use to ask specific questions about the rule.