CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Bureau of Workers' Compensation

Regulation/Package Title: Payment for outpatient medication; Payment for outpatient medication by self-insuring employer

Rule Number(s): OAC 4123-6-21; OAC 4123-6-21.1

Date: August 13, 2013

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- ☐ Rescinded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.

   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:

   1. Restrict reimbursement by BWC of controlled substance prescriptions written by Ohio prescribers for purposes of chronic care to only those prescribers who are currently enrolled in the Ohio Automated Rx Reporting System (OARRS). The OARRS data base is maintained by the Ohio Board of Pharmacy and contains

information on every controlled substance dispensed by every Ohio pharmacy. The database is updated each week. House Bill 93 as well as current Medical Board rules require Ohio prescribers who are using controlled substances to treat chronic conditions to be registered with and to utilize the OARRS database in monitoring the controlled substance use of their patients. This revision to our rule is in keeping with the goal of the bureau to provide appropriate medications to our injured workers in a safe and efficacious manner.

2. Restrict reimbursement by BWC for topical compounded prescriptions to those preparations that meet the following criteria: contains not less than one nor more than three FDA approved medications; contains only one FDA approved drug from any specific therapeutic class of drugs; requires submission of a prior authorization request that contains a copy of the signed prescription listing all ingredients and indicates the usual and customary cost of the prescription; requires clinical documentation of improvement in pain and function for continued use past 90 days;

3. Limit reimbursement by BWC for the product cost component of topical compounded prescriptions to the lesser of AWP minus nine percent for each ingredient or two dollars and fifty cents per gram or milliliter of finished product.

4. Allow BWC to (within affected geographical areas) lift any restrictions on timing of prescription refills during a state of emergency declared by the governor of Ohio or the president of the United States.

BWC is also recommending that the limitation on reimbursement for compounded topical prescriptions to the lesser of AWP minus nine percent for each ingredient or two dollars and fifty cents per gram or milliliter of finished product and the ability to lift restrictions on timing of prescription refills during a state of emergency be incorporated into self-insuring employer outpatient medication rule OAC 4123-6-21.1.

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

R.C. 4123.66; R.C. 4121.441

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)?

Revision One:

This revision will permit BWC to stop reimbursement for controlled substance prescriptions written by Ohio prescribers who are not in compliance with the Ohio State Medical Board requirement that any prescriber who writes prescriptions for controlled substances must be enrolled in the OARRS system. If a prescriber is not enrolled in the system they are unable to comply with current best medical practice, which is to utilize prescription monitoring program tools like OARRS to ensure appropriate prescribing of controlled substances.

In response to feedback from stakeholders and the CSI office, BWC has modified this proposed revision to clarify that it applies only to providers writing prescriptions for the purpose of providing chronic care. The revision defines "for the purpose of providing chronic care" as the provider has written three or more prescriptions for controlled substances for the same injured worker in a twelve week period. This modification was approved by the BWC Board of Directors at its May 30, 2013 meeting.

Revision Two:

Compounded topical preparations of prescription drugs are currently being directly marketed to Ohio prescribers by pharmacies located both in Ohio as well as out of state. These products are not FDA approved nor are they being prepared in FDA regulated facilities. There is no clinical literature to support the topical use of most of these products. Injured workers are being subjected to treatment with preparations containing as many as 8 drugs, where there is no evidence of safety or efficacy. This revision will permit BWC to limit reimbursement for topical compounded products to only those where there is evidence in the clinical literature of some limited benefit.

Revision Three:

This revision will allow BWC and self-insuring employers to limit reimbursement of these products to a standard fee schedule. Presently these products are priced at up to $3,000 per 8 ounce container. In some cases, these products have been shipped to injured workers by out of state pharmacies before BWC was contacted to determine coverage. If the coverage was denied, the injured worker faced paying out of pocket for the product. Most physicians are unaware of the excessive amounts being charged for these creams.

Revision Four:

Rules 4123-6-21 and 4123-6-21.1 contain a requirement that prevents an injured from refilling a prescription before 75% of the original quantity has been used. This revision to the rule will permit BWC and self-insuring employers to allow injured workers to obtain early

refills of prescriptions during or in anticipation of a state of emergency declared by the governor or president.

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

   Revision One:

   In one report BWC identified 3900 prescribers who are currently prescribing drugs for injured workers but who are not registered in OARRS. Following implementation of this revision BWC will run monthly reports to determine the status of these prescribers and to identify any additional non-registered prescribers.

   Revision Two

   Success of this revision will be measured by the elimination of prior authorization requests for products that do not meet the compounding criteria established in the rule.

   Revision Three – No measurement of success necessary since pricing is automated.

   Revision Four:

   By monitoring application of the override during declared periods of emergency.

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 February 12, 2013 with comments due back by March 8, 2013:

   - 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?

Physicians providing feedback agreed with the changes to this rule.

However, Ernest Boyd, R.Ph., MBA, Executive Director of the Ohio Pharmacists Association (OPA) provided extensive feedback including both questions and suggestions. The OPA questioned how payment would be withheld from the prescriber rather than the pharmacist and expressed concern injured workers will not receive needed medication. BWC assured OPA we will send letters to both the prescriber and the injured worker at least two months before any action is taken to stop the prescription process.

Several suggestions from the OPA were recommendations to add and/or delete verbiage in the rule for more clarity. BWC generally incorporated the changes suggested by OPA to improve clarity.

OPA also request of expansion in the number of active pharmaceutical ingredients allowed in a compound medication from the three as proposed by BWC to five. BWC explained to OPA that the limit of three active ingredients was set based on research that supports up to three active ingredients. BWC's research found nothing that supports using more than three active ingredients in a compound medication.

Another concern shared by OPA was to change the dispensing fee to reflect the pharmacist's "level of effort," BWC will continue to investigate the best market practices, but will stay with the original proposal at this time.

Lora L. Miller, Director of Governmental Affairs & Public Relations of the Ohio Council of Retail Merchants (OCRM), indicated the OCRM shares OPA's concerns with the rule, specifically regarding OARRS registration and the extra burden it places on pharmacists. The OCRM believes the regulation should be on the prescriber. BWC assured the OCRM we will send letters to both the prescriber and the injured worker at least two months before any action is taken to stop the prescription process.

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?

An extensive literature search was conducted to find any examples of controlled studies of the efficacy and safety of multi-drug topical compounded products. Very few journal articles were found and those that were found spoke to specific single or at the most two drug combinations being used for specific indications.

A review of the Official Disability Guidelines revealed a universally negative position regarding multi-drug compounded preparations. This standard workers compensation medical reference endorsed a very limited number of drugs for this purpose and those only in single product compounds.

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?

None. Both the registration in OARRS as well as the irrational topical compound issues involve best practice and safety/efficacy concerns, and BWC considers the proposed revisions to be appropriate and justified.

However, in response to feedback from stakeholders and the CSI office, BWC is also exploring its options under OAC 4123-6-02.7, and possibly other legal authorities, including possibly pursuing a new, more comprehensive rule regarding opiate prescribing, to more directly address the issue of physicians failing to register in OARRS, not as an alternative, but rather as complementary to, these proposed revisions.

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.

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

BWC is the only provider for prescription benefits under the Ohio state fund workers compensation program. OAC 4123-6-21 is the only rule that speaks to payment of outpatient medication in the state fund workers compensation environment.

BWC is the only state agency responsible for regulating self-insuring employer workers' compensation programs. OAC 4123-6-21.1 is the only rule that speaks to payment of outpatient medication in the self-insuring employer workers compensation environment.

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.

Fax notices regarding the OARRS and compound prescription revisions will be sent to all Ohio pharmacies as soon as the effective date for the revisions have been determined. Out of state pharmacies will be notified when prior authorization requests are received. Prescribers will be individually lettered regarding the requirement for OARRS registration. They will be given 30 days to comply before a second letter is sent to both the prescriber and their injured worker patients notifying both parties that coverage for controlled substance prescriptions from the prescriber in question will be terminated in 60 days. If the prescriber has not registered in OARRS at the end of that 60 day period, their controlled substance prescriptions will be blocked in the BWC prescription payment system.

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;

Retail pharmacies engaging in compounding of topical products will be impacted by Revision Two. They will have to curtail their marketing of multi-drug products and limit their charges to the standard fee schedule.

Retail pharmacies processing controlled substance prescriptions that have been written for chronic care by Ohio prescribers who are not registered with OARRS could see those prescriptions denied. However, this would only occur if the prescriber elects to ignore both of the letters that were sent by BWC in the previous 90 days. Those letters would have informed the prescriber of the issue and also informed the prescriber that the medical board was notified of the rule violation. The injured worker presenting the prescription would also have received a copy of the second notification to the prescriber. It would seem that the bureau's denial of reimbursement is reasonable for prescriptions from a prescriber exhibiting such a level of recalcitrance toward delivering current best medical practice as well as toward following a medical board rule.

Self-insuring employers will have to comply with the new provisions added to OAC 4123-6-21.1

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

The adverse impact on pharmacies from the revision on coverage of compound prescriptions will be a loss of excessive charges. Prescription charge will be capped at a maximum of $600.00 per eight ounces. The advantage for the pharmacies is that if the prescriptions meet the proposed preparation criteria, they will be approved for payment.

Pharmacies processing prescriptions from non-OARRS registered prescribers could see a loss of revenue from denied prescriptions as well as the time required to explain the situation to the injured worker presenting the prescription. Given that these prescribers will have been previously notified twice within 60 days and both the injured worker and medical board will have received a copy of the second notification, it seems likely that this will occur in a very small number of cases. The impact on the pharmacy will be no different from the impact of the bureau's current

prior authorization and formulary restrictions that have been in place for nearly two years. It must be stressed that the slight negative impact of this proposed rule revision is far outweighed by the positive push that it exerts on prescribers and pharmacists to utilize all available tools to combat drug diversion and opiate misuse in Ohio.

Self-insuring employers should not experience any adverse impact. In fact, their expenditures on reimbursement for compounded topical prescriptions may decrease under Revision Three.

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.

Revision One: Based on the most recent analysis of 2012 prescribing by non-OARRS registered prescribers it appears that there are 1008 who appear to be prescribing opiates in chronic treatment situations for nearly 22 thousand injured workers. The opiate prescriptions written by these individuals accounted for a total of $7.8 million dollars. This is out of the bureau's total 2012 expenditure of $122 million dollars. In 2012 the automated prior authorization and formulary edits that are applied at the pharmacy level stopped over 155,000 prescriptions from being processed on their first presentation at the pharmacy. Of these rejections fewer than 1% resulted in contact with the bureau regarding an inability of the injured to obtain the medication, either by cash payment or other insurance coverage.

It would seem reasonable to assume that a similar percentage of failures to obtain other coverage for prescriptions would be present for prescriptions from Non-OARRS registered prescribers. This would equate to a maximum loss of $78,000 annually across all Ohio pharmacies, assuming that all of the current identified non-OARRS registered prescribers chose to ignore the notifications sent to them.

Revisions Two and Three: In 2012, BWC reimbursed for 363 compounded prescriptions at a cost of $162,000. Many of these prescriptions will not meet the proposed criteria and will not be covered in the future. BWC estimates that at least ½ of the prescriptions covered in 2012 will not meet the new criteria. Thus, a revenue impact of $81,000 annually could be anticipated among all Ohio and out of state compounding pharmacies.

Revision Four: No expected adverse impact.

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

The recent fungal meningitis outbreak caused by a compounding pharmacy in Massachusetts gives clear evidence of the potential problems with unregulated distribution of untested drugs. That injured workers are essentially being subjected to chemistry experiments with creams that contain 6 to 8 active drugs which have never been tested for safety or efficacy in topical use is a reasonable justification for taking action to stop this practice.

The use of the OARRS by a prescriber who is contemplating the use of controlled substances for a chronic condition is considered a best medical practice. It is a requirement in the Ohio medical board controlled substance prescribing guidelines. The BWC requirement that registration be a component of our reimbursement for these drugs is in keeping with our mission to ensure the best care is provided to our injured workers. As stated above, the small number of negative events incurred by retail pharmacies as a result of this rule revision are far surpassed by the positive impact that it will have in causing improvements in the prescribing of controlled substances in Ohio.

Regulatory Flexibility

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

Not applicable.

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?

To assist them in complying with the new rule, the BWC will send letters with instructions for registration in the OARRS to Ohio prescribers who are identified as needing to register with the system. BWC will also provide all Ohio pharmacies with fax notification of the specific criteria that are required for topical product prescriptions to be reimbursed. The BWC Pharmacy Program has routinely held conference calls for pharmacy providers to discuss specific issues with bureau rules or billing processes. These calls will be used to focus on compliance with these new rules.