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 4123-6-21.5; OAC 4123-6-21.1

Date: October 25, 2013

Rule Type:

X 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☐ Rescinded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 new rule OAC 4123-6-21.5 that would:

   1. Adopt standard dose tapering or weaning schedules to be employed when payments are denied for drug classes listed in the appendix to the rule. The initial drug classes impacted by this rule are opioid analgesics, such as Oxycontin® and morphine and

benzodiazepine (anti-anxiety) drugs such as Valium® and Xanax®. Both of these drug classes commonly cause dependence and patients routinely experience withdrawal symptoms upon abrupt discontinuance of therapy.

2. Provide for assurances that drug dependent injured workers of both state fund as well as self insured employers will not experience symptoms of drug withdrawal due to an abrupt termination of coverage for the medication.

BWC is proposing a revision to OAC 4123-6-21.1 that would:

1. Require self insured employers to utilize the weaning tables listed in the appendix to OAC 4123-6-21.5. This will ensure that a standard process is used for weaning these kinds of drugs is in place and is applied to all injured workers, whether their employer participates in the state insurance fund or is self insured.

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)?

It was brought to the attention of BWC by Industrial Commission Hearing Officers that they were frequently facing situations such as this:

A worker from a state fund employer had drugs denied in their claim and the denial order specified a period of time for the injured worker to be weaned from the drug. Then in the next claim they heard it was the same situation, only from a self insured employer. In the self insured employer claim the denial order took effect immediately with no weaning period. This disparity in how the two claims were being handled caused the Hearing Officers to be concerned that their orders could possibly be causing harm to the injured worker. BWC fully agreed with their position and brought these rules forward as a result.

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

The BWC pharmacy program has been using the standard opiate weaning table in state insurance fund claims for over a year and the benzodiazepine weaning table for over 6 months. An evaluation of the need for weaning is a standard consideration that goes into the preparation of any drug denial order issued by the BWC pharmacy staff. The rule will not change any work processes for BWC.

A joint BWC/IC coordinating committee meets regularly to discuss inter-agency operational and policy issues. Monitoring the application of this rule by self insured employers will be done through this committee.

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 will be e-mailed to the following lists of stakeholders on July 11, 2013 with comments due back by August 1, 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?

BWC received three substantive comments from stakeholders. Two were supportive of the proposed rules. One commenter recommended that patients on even a lower dose will need weaning, and also suggested the weaning schedule be modified for a slower weaning at the lower end of the MED range.

While these suggestions have merit, they must be addressed by the prescriber. BWC is constrained from dictating specifics of care to a treating physician. The thrust of the proposed rules is to ensure consistent weaning in both state insurance fund and self insured claims.

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?**

   Withdrawal from opioid and anti-anxiety drugs is a widely understood consequence of abrupt discontinuance of the drugs. A common threshold for the induction of physical dependence to opioids is the consumption of 60mg of Morphine Equivalent Dose of an opioid for 60 days.

   BWC currently has over 6,000 injured workers who meet or dramatically exceed this criteria for drug dependence. If the opiate medications of these injured workers were abruptly stopped after a drug review and denial order being issued, they would experience withdrawal symptoms. There is no reason to believe that a similar number of injured workers of self insured employers are any less likely to be physically dependent on opiates.

   A review of clinical literature makes it quite clear that withdrawal from anti-anxiety medications is a much more challenging medical situation to manage than withdrawal from opiates. BWC has over 3,000 injured workers who consume these medications on a regular and ongoing basis. As was stated above, there is no reason to believe that fewer workers of self insured employers would be using these drugs in the same manner.

   The opiate weaning table developed by BWC was adapted from the published work of the Washington State Agency Medical Directors Group and the federal Centers for Disease Control. The weaning table for benzodiazepines was adapted from the Clinical Handbook of Psychotropic Drugs, 19th Revised Edition.

   The BWC Pharmacy and Therapeutics Committee reviewed both weaning tables and recommended BWC adopt them.

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. The potential for harm to injured workers by allowing this disparity between state fund and self insured employers to continue requires the imposition of a standard process.

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.**

    The self insured employers' professional associations will be notified via email of the pending rule change. The Self Insured Employer section of BWC will ensure communication with the SI employers. The Industrial Commission hearing and adjudication process will provide evidence of compliance with the rule.

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;**
    There are 3,300 self insured employers (SI) in Ohio who employ approximately 49% of Ohio workers, with state insurance fund employers (SIF) accounting for 51% of all workers. However, there is no centralized reporting of prescription or claims data from the SI employers as there is on the SIF side. As was stated previously in this report, there is no reason to believe that workers of SI employers or the physicians who prescribe to them approach medications any differently than do workers of SIF employers.

    Using that assumption as a basis for comparison, in 2012 narcotics were used by 42,943 out of 60,395 injured workers from SIF employers. BWC performed drug reviews on 3,718 of those claims with narcotics. A weaning provision was included as part of any denial order that resulted from these reviews. Thus it seems reasonable to project that this rule would result in SI employers having to utilize a weaning schedule in a maximum of 3,700 claims, assuming that every review done by SI employers results in a denial order. Given that 15% of SIF injured workers use anti-anxiety medications, compared with the 71% who use narcotics, a reasonable estimate would be that SI employers could possibly have an additional 700 claims impacted by this rule.

Using this methodology yields a maximum impact of 4,400 claims out of an estimated 58,000 total claims that could require a weaning order. For context, in 2012 BWC performed a total of 4,187 drug utilization reviews on a population of 60,391 SIF injured workers receiving opiates or anti-anxiety medications.

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

The adverse impact on the SI employers would be that they would continue to pay for denied opiate and benzodiazepine prescriptions during any required weaning period. This is the current situation for SIF employers when one of these drugs is denied in their claims.

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.

In 2012, the average BWC cost of an opiate prescription was $86.00 and the average for an anti-anxiety prescription was $14.78. The most frequent weaning period for SIF workers on these medications was 60 days. Based on these averages, every opiate prescription denied and weaned could cost the SI employer an additional 2 months of prescriptions at $172.00 and 2 months of anti-anxiety medications at $30 or a total of $202.00 for the average weaning period if both drugs are involved.

Again assuming that every SI drug utilization review ended in a denial that was upheld by the Industrial Commission, the 3,700 opiate claims for two additional months could cost the SI employers overall an additional $747,000, plus an additional $21,000 for the 700 anti-anxiety prescriptions. The maximum estimated cost of this rule to self insured employers overall would be $789,000 per year. A most likely scenario based on BWC's experience with reviews and IC hearings is that 44% of the denials were upheld on appeal, so a much more likely overall cost would be in the neighborhood of $347,000.

This estimated cost must be balanced against the adverse medical impact on those 4,400 injured workers who would otherwise be denied coverage for their medications on the day the order is written.

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

The fact that Industrial Commission Hearing Officers have documented such a disparity in treatment of injured workers requires a response by BWC. This situation goes well beyond simple process equity and enters the realm of patient safety for those injured workers of SI employers whose opiates and anti-anxiety medications are currently being abruptly terminated. Once discovered, it must be addressed.

Regulatory Flexibility

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

    Generally not applicable. In general, a small business cannot be a self insured employer since the statute requires that the employer have at least 500 employees to qualify for that designation, unless waived by the Administrator.

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 BWC Self Insured Employer department will be available to support the legal and human resource staff of their SI employers. The BWC pharmacy department will provide education and training for SI employers in how to incorporate the weaning schedules into denial orders.