

**Business Impact Analysis**

**Agency Name:** Ohio Bureau of Workers' Compensation

**Regulation/Package Title:** Coordinated Services Program (also known as the "lock-in" pharmacy rule)

**Rule Number(s):** 4123-6-21.4

**Date:** February 8, 2012

**Rule Type:**

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> New | <input type="checkbox"/> 5-Year Review |
| <input type="checkbox"/> Amended        | <input type="checkbox"/> Rescinded     |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.*  

Under certain conditions, the BWC can restrict an injured worker to the use of a single pharmacy. An emergency exception is available to the injured worker.
- 2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**  

R.C. 4121.50; R.C. 4123.66; and 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)?**

The proposed rule, which would direct an injured worker who met specific drug utilization criteria to a single pharmacy, and in some cases a single physician, is intended to further the bureau's mission to provide for the health and safety of injured workers.

R.C. 4121.50, enacted by the 129<sup>th</sup> General Assembly as part of "pill mill bill" HB 93 to combat prescription drug abuse in Ohio, requires BWC to adopt rules implementing a coordinated services program substantially similar to that of Ohio Medicaid by not later than July 1, 2012.

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

Through monitoring prescriptions at our pharmacy benefit manager and bills submitted by prescribers.

### **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 December 12, 2011 with comments due back by January 3, 2012:

- 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?**

All comments were acknowledged by agency staff. Specific questions about the new rule were addressed directly with the stakeholders. No changes were introduced into the language as a result of stakeholder feedback.

BWC received 13 responses which expressed support for the rule and 8 responses which requested clarification of portions of the rule. BWC has provided the clarification. Just 3 respondents opposed the rule with a common theme of increased paperwork for pharmacies. We explained to those respondents that pharmacies participating in the coordinated services program would be reimbursed for their expenses.

**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 is mandated by R.C. 4121.50 to adopt a coordinated services program rule. However, we are aware that numerous studies exist documenting the problem of prescription drug abuse and its impact on injured workers and their families.

**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?**

Not applicable. R.C. 4121.50, enacted by the 129<sup>th</sup> General Assembly as part of "pill mill bill" HB 93 to combat prescription drug abuse in Ohio, requires BWC to adopt rules implementing a coordinated services program substantially similar to that of Ohio Medicaid by not later than July 1, 2012.

**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 met with representatives of ODJFS to maximize similarities between OAC 4123-6-21.3 and ODJFS' Ohio Medicaid coordinated services program rules, as mandated by R.C. 4121.50. The rules are not duplicative because BWC and ODJFS serve different patient populations.

**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.**

Retail pharmacies that agree to participate in the program will provide specific clinical and utilization monitoring of the prescriptions presented by injured workers. Injured workers will have the opportunity to select a pharmacy to provide their medications. Results of this clinical monitoring by the pharmacies will be routinely reported to BWC for review and evaluation. Injured workers will be enrolled in the program based on computerized analysis of specific criteria. Selection is based on patterns of using multiple physicians or multiple pharmacies to obtain prescription drugs. Violations of any drug law will be cause for an injured worker to be enrolled into the program.

**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 pharmacy is the business community impacted by this regulation. However, the rule is primarily directed toward injured workers who meet certain drug utilization criteria, and impacts retail pharmacies indirectly.

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

There is no adverse impact from this regulation. Participation by the pharmacies in BWC’s coordinated services program is strictly voluntary

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**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.*

Participating pharmacies that contract with BWC will be compensated for their work with injured workers who select that pharmacy to provide prescription services.

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

Not applicable. R.C. 4121.50, enacted by the 129<sup>th</sup> General Assembly as part of “pill mill bill” HB 93 to combat prescription drug abuse in Ohio, requires BWC to adopt rules

implementing a coordinated services program substantially similar to that of Ohio Medicaid by not later than July 1, 2012.

**Regulatory Flexibility**

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

Not applicable. R.C. 4121.50, enacted by the 129<sup>th</sup> General Assembly as part of “pill mill bill” HB 93 to combat prescription drug abuse in Ohio, requires BWC to adopt rules implementing a coordinated services program substantially similar to that of Ohio Medicaid by not later than July 1, 2012.

**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?**

Not applicable.