CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title: Outpatient Medication Formulary Rule

Rule Number(s): 4123-6-21.3 **Date:** May 19, 2014

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- ☐ Rescinded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.

   BWC adopted Rule 4123-6-21.3 effective September 1, 2011 to establish an outpatient medication formulary. A formulary is a list of drugs approved for reimbursement when prescribed to treat conditions allowed in the claim. The formulary is maintained by BWC with input from the BWC Pharmacy and Therapeutics Committee.

Proposed Changes

The proposed changes to OAC 4123-6-21.3 listed below are contained in the Appendix to the rule, which is the formulary drug list. A copy of the Appendix with the proposed changes will be available on the BWC website for stakeholder review. In addition to several non-substantive compositional changes to the appendix, these proposed revisions shall:

1. Add reimbursement for the sustained release gabapentin agents Gabapentin (Gralise®) and Gabapentin Encarbil (Horizant®). Reimbursement for these agents will require a Prior Authorization that reflects a 30 day trial and clinical failure (as defined by O.A.C. 4123-6-21(J)(2) of the immediate release forms of gabapentin. Reimbursment shall be restricted to a single form of gabapentin at any one time.

2. Add reimbursement for ziconotide (Prialt®). Reimbursement requires previous approval of the use of an implanted pain pump. The combination of ziconitide with any other medication results in a compounded sterile parenteral product which will be approved and reimbursed as described in O.A.C. 4123-6-21 (E)(1)(a)(b.

3. Limit reimbursement for all testosterone products (oral, topical, injections) to only those claims that have medical allowances that involve the genitourinary or endocrine systems.

4. Allow reimbursement for treatment with transdermal forms of the drugs Fentanyl and Buprenorphine (Butrans®) as initial sustained release opiates in claims with clinical documentation of an inability to swallow or absorb oral medications. Reimbursement will also be allowed for either transdermal agent in claims with documentation of a therapeutic failure, demonstrated unacceptable side effects or systemic allergic reaction (as defined in OAC 4123-6-21 paragraphs (J) (1) and (J) (2) to any oral sustained release opiate. Reimbursement for all sustained release opiate medications is limited to use of a single sustained release agent at any one time.

5. Limit reimbursement for each strength of buprenorphine patch (Butrans®) to a prescription for 4 patches per 28 days. Reimbursement for (Butrans®) is further limited to claims requiring a daily morphine equivalent dose of 90mg or less per day. The maximum daily dose covered will be 20mcg/day.

6. Limit coverage for prescriptions of fentanyl patches to a maximum of 10 patches per 30 days. Reimbursement for all strengths of these products shall be restricted to not more than every 72 hours. Dosing at every 48 hours may be reimbursed with prior authorization upon submission of documentation that supports clinical failure, as defined in OAC 4123-6-21(J)(2), of a 72 hours dosing interval and evidence of an escalation of the dose before a reduction in frequency.

7. Limit coverage of all formulary products containing acetaminophen to only those products that contain 325mg or less of acetaminophen per dosage unit.

8. Revise the language that describes the coverage of the proton pump inhibitor drug class to clarify specifically what over the counter products and prescription products would be covered.
   The current language states:
   Proton Pump Inhibitor Class Specific Restrictions:
   Effective July 1, 2012, reimbursement is restricted to only the following drugs in this class: omeprazole, Prilosec OTC® ,Prevacid OTC®,Prevacid Solutab (lansoprazole) This coverage restriction shall apply effective August 31, 2012 for claims in which non-covered drugs in this class were reimbursed by BWC prior to July 1, 2012, and July 1, 2012 for all other claims. Reimbursement for covered drugs in this class is only permitted when they are prescribed as gastrointestinal protectants during non-steroidal anti-inflammatory drug therapy or to treat an allowed condition that involves a gastrointestinal disorder such as ulcer or GERD (gastrointestional esophageal reflux disease)
   The new language would state:

Proton Pump Inhibitor Class-Specific Restrictions:
Reimbursement for covered drugs in this class is only permitted when they are prescribed as gastrointestinal protectants during chronic oral steroid or non-steroidal anti-inflammatory drug therapy or to treat an allowed condition that involves a gastrointestinal disorder such as ulcer or GERD (gastrointestinal esophageal reflux disease). Effective with the date of this revision, reimbursement is limited to only the following drugs in this class:

Prescription Strength Delayed Release Product: Omeprazole(10mg, 20mg, 40mg) products
Prescription Strength Dispersible Tablet: Prevacid Solutab® (15mg, 30mg)
(Requires Prior Authorization to document inability to utilize the standard oral product)
Over-The-Counter (OTC) Product: Omeprazole OTC 20mg products only.

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.**

   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 purpose of Rule 4123-6-21.3 is to improve the efficiency of treatment for injured workers by providing prescribers with a concise list of medications that can be utilized for treatment of approved conditions related to the claim. The formulary also provides the prescriber with information regarding any restrictions or limitations to the use of an approved medication. Likewise, the prescriber will know that if a medication is not listed in the formulary, then it will not be reimbursed for treatment of any conditions in a claim. The use of a formulary enhances medication safety by allowing time for BWC's Pharmacy and Therapeutics Committee to conduct a thorough review of the clinical merits of new medications before they are approved for use. It also provides a process by which BWC may remove or limit the inappropriate utilization of medications in keeping with FDA recommendations as well as current clinical literature and best medical practices.

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

Per Rule 4123-6-21.1, BWC's Pharmacy and Therapeutics Committee is charged with making recommendations to BWC regarding the creation and ongoing management of the BWC drug formulary. The committee fulfills this charge through routine monitoring of prescription data from our pharmacy benefit manager, reviews of current clinical literature and current best practice guidelines.

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 23, 2014 with comments due back by May 15, 2014:

- 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?

Feedback from the stakeholders listed in question 7 above was solicited and accepted beginning April 28, 2014 through May 15, 2014. Only the three comments listed below were received during this period.

Stakeholder	Feedback	BWC Response
Linda Kimble, MSN, RN,CNP Health Educator/Consultant East Canton, OH	Expressed concern that medications might not be available in hospital setting.	Clarified with Ms. Kimble that the Formulary applies only to outpatient settings, and the medications that she mentioned would be covered under

		BWC fee structure or physician office billing processes
Dorothy Gariety, CNP Wilson Memorial Hospital of Occupational Health Sidney, OH	As a CNP (Certified Nurse Practitioner), is gabapentin going to be limited for me to prescribe for patients?	No. This revision adds the two sustained release forms of gabapentin to the formulary. It also spells out the restrictions to coverage if a prescriber chooses to use one of those sustained release products.
Derek Scranton, Esq. Compliance Manager Corvel Ohio MCO Cincinnati, OH	Corvel has no comment on the proposed changes.	

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 aware of many published studies by health care institutions and private insurance firms that describe a drug formulary as a fundamental component of a well managed prescription benefit program.

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?**

    These revisions to coverage of specific drugs are the result of recommendations by the BWC Pharmacy and Therapeutics Committee following a review of utilization data, current clinical literature and federal regulatory changes.

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.**

    This process is not applicable to drug formulary management.

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

This revision to the formulary rule only affects injured workers receiving prescription benefits from BWC. No other Ohio regulations exist regarding what drugs are covered by BWC.

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.**

    Ohio prescribers and pharmacies caring for injured workers will be notified of this change in coverage by email, fax or direct mail. Injured workers currently receiving one of these drugs will be notified by first class mail and advised that they have six months to meet with their physician and initiate any necessary changes in therapy.

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;**

    Revisions 1 & 2 – no impact since these represent additions to drug coverage

    Revision 3 – In 2013 there were 129 injured workers who received testosterone prescriptions from 154 prescribers. In the first quarter of 2014 only 45 of those injured workers continued the treatment from the previous year with 28 prescribers. This would represent the number of injured workers using this drug on an ongoing basis. This would mean an estimated 28 prescribers would be impacted by this formulary revision.

    Revision 4 – no impact as this represents a decrease in the limitations placed on the two drugs

    Revisions 5 & 6 – In 2013 approximately 50 prescribers routinely prescribed these two topical products to be used more frequently than the FDA recommended dosing interval. Under the current formulary rule, BWC currently has no administrative mechanism to evaluate the clinical rationale for this non-approved use of the drugs or to intervene when the use is not in keeping with best clinical practices. This is the prescriber group that would be impacted by this revision.

    Revision 7 – No impact since this revision results from a product being removed from the market. Effective January 14, 2014, The FDA ordered a stop to the production and marketing of all acetaminophen combination drugs containing more than 325mg

of acetaminophen. The current formulary language indicates that BWC will cover combination products that contain 500mg of acetaminophen, products which are no longer on the market.

Revision 8 – No impact since this is simply a restatement of the current formulary language that has been in force since 2012.

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

Revision 3 - Based on the possibility of testosterone dependency in chronic use, prescribers will have sixty days to make any necessary changes in the dose level in order to wean the injured worker from the drug. This timeframe will also allow the injured worker to file for an additional allowance in their claim if the physician feels that continued therapy is warranted.

Revisons 5 & 6 - The impact on the prescriber community from this formulary revision will be the need to reassess the drug dose and schedule for those injured workers who are being prescribed doses or quantities that exceed the new limits for fentanyl or Butrans®. These prescribers may submit a prior authorization request to document the need for the dose schedule or they must adjust the dose schedule to the FDA recommended one.

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/estimate*d impact.

There should be no negative financial impact on the prescriber community as any necessary changes to the injured worker's drug regimen should be done in the context of routine office visits.

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

Rule 4123-6-21.1 charges the BWC Pharmacy and Therapeutics Committee to conduct regular reviews of the drug formulary and to make recommendations to the Administrator directed at improving overall efficiency and effectiveness of drug utilization. These changes to drug coverage result from that activity. Formulary revisions are routinely made based on

opportunities to improve the clinical impact of the formulary or changes in federal drug regulations.

Regulatory Flexibility

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

No. All prescribers are required to utilize formulary 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 since non-formulary drugs may still be prescribed for an injured worker, however they are not reimbursed by BWC.

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

Prescribers may utilize the BWC website for a complete list of formulary medications and any restrictions to those drugs. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@ bwc.state.oh.us) that prescribers can use to ask questions about drug coverage.