ACTION: Original

DATE: 11/12/2021 1:49 PM

Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Sean McCullough, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Bureau of Workers' Compensation

Rule Contact Name and Contact Information: Aniko Nagy (614) 466-3293

Regulation/Package Title (a general description of the rules' substantive content):

Outpatient medication formulary and First fill of outpatient medications

Rule Number(s): 4123-6-21.3 and 4123-6-21.6

Date of Submission for CSI Review: October 6, 2021

Public Comment Period End Date: October 25, 2021

Rule Type/Number of Rules:

New/___rules

No Change/____ rules (FYR? ___)

Amended/__2__ rules (FYR? _No__)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **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.

   The proposed changes to OAC 4123-6-21.3:

   - Add language to provide for the reimbursement of antiretroviral drugs prescribed for an allowed condition of human immunodeficiency virus (HIV); an exposure to HIV in an allowed claim ; or pursuant to R.C. 4123.06, which provides for payment of post-exposure medical diagnostic services consistent with the standards of medical care existing at the time of the exposure for a peace officer, firefighter, emergency medical worker, or detention facility employee exposed to blood or other body fluid.

   The proposed changes to the Appendix to OAC 4123-6-21.3, the formulary drug list:

   Medications to be deleted from the formulary

- Tolmetin Sodium cap. 400 MG and tab. 200 and 600 MG
- Ketoprofen cap. 50, 75, and ER 24 HR 200 MG
- Fenoprofen Calcium cap. 200, 400, and tab. 600 MG
- Meclofenamate Sodium cap. 50 and 100 MG

Medications and drug class to be added to the formulary

- Brivaracetam 10, 25, 50 and 75 MG, with prior authorization. Reimbursement limited to claims with an allowed condition of seizure disorder and the injured worker has tried and failed at least one anticonvulsant.
- Fluticasone-umeclidinium-vilanterol AEPB 200-62.5-25 MCG/INH
- Glycopyrrolate oral solution 1 MG/5ML
- Isavuconazonium 186 MG, with prior authorization. Reimbursement considered for individuals who are being treated for a fungal infection related to an allowed condition in the claim who have tried and failed at least one antifungal.
- Lanthanum carbonate 500mg chewable tab
- Lasmiditan 50 and 100 MG, with prior authorization. Reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans. Reimbursement limited to claims in which migraine headaches are related to an allowed condition in the claim. Reimbursement will not be approved for duplicate therapy with a triptan or CGRP antagonist. Maximum reimbursement of 4 tablets per 30 days.
- Migraine Products – calcitonin gene-related peptide (CGRP) receptor antagonists –All drugs within this class may be reimbursed with prior authorization. Reimbursement limited to claims in which migraine headaches are related to an allowed condition in the claim. Reimbursement will not be approved for duplicate therapy with a triptan or other CGRP antagonists.
    - Rimegepant 75 MG ODT, in addition to the restrictions for this drug class:
      When the request is for treatment of migraine: reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans.
      When the request is for prevention of migraine: reimbursement considered for individuals who have not received an adequate response from use of at least three of the following: topiramate, valproic acid, divalproex, amitriptyline, venlafaxine, atenolol, metoprolol, nadolol, propranolol, and timolol.
      Maximum reimbursement of 18 tablets per 30 days.
    - Ubrogepant 50 and 100 MG, in addition to the restriction for this drug class, reimbursement considered for individuals who have not received an adequate response from use of at least one triptan medication, or if the injured worker has a contraindication for triptans.
      Maximum reimbursement of 16 tablets per 30 days.

Drug class with changes in coverage:

- Anticoagulants - Direct Factor Xa Inhibitors: after 30 days of use, prior authorization is required if treatment is not directly for an allowed condition in the claim
- Hypnotics - Non-Barbiturate: reimbursement for eszopiclone, zaleplon, zolpidem, zolpidem ER within this drug class is restricted to a total of a 30 day supply without prior authorization. Prior authorization is required beyond 30 days. Reimbursement for these drugs considered for acute care only and not in combination with opioids or stimulants.

BWC adopted rule OAC 4123-6-21.6 effective February 1, 2015 governing reimbursement for the first fill of prescription medications prior to the initial determination order of a claim.

The proposed changes to OAC 4123-6-21.6:

- Revise the language to clarify that medications eligible for reimbursement under OAC 4123-6-21.3 (not just the appendix to OAC 4123-6-21.3) may be reimbursed as a first fill medication when medically necessary.
- Add "antiretrovirals" to those medications under the first fill program that are not limited to one drug per therapeutic drug class.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Authorize: 4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.34, 4123.66

   Amplify: 4121.12, 4121.121, 4121.44, 4121.441, 4123.66

4. **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?**
   No
   If yes, please briefly explain the source and substance of the federal requirement.

   N/A

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   N/A

6. **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.

The purpose of OAC 4123-6-21.6 to implement R.C. 4123.66(B), which provides that the BWC Administrator may adopt rules specifying the circumstances under which BWC will reimburse for the first fill of prescription drugs for medical conditions identified in an application for workers' compensation or benefits prior to the date BWC issues an initial claim determination order.

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

   Per rule OAC 4123-6-21.2, 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.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

   No

   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   N/A

Development of the Regulation

9. **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.

BWC's proposed rules OAC 4123-6-21.3 and 4123-6-21.6 were initially published for stakeholder comment on August 6, 2021 with a comment period open through August 16, 2021. Additional changes to proposed rule OAC 4123-6-21.3 were subsequently published for stakeholder comment on September 8, 2021 with a comment period open through September 20, 2021.

In both instances, notice was e-mailed to the following list of stakeholders:

- 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 Manufacturers 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
- Ohio Medical and Pharmacy Boards

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Stakeholder responses received by BWC are summarized on the Stakeholder Feedback Summary Spreadsheet.

11. 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?

The proposed revisions to rules 4123-6-21.3 and 4123-6-21.6 were based on recommendations accepted by the BWC Pharmacy & Therapeutics Committee. The committee reviews data from clinical trials, published studies, and relevant guidelines regarding medications prior to making recommendations.

12. 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?

The rules apply specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility.

13. 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.

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

These rules only affect injured workers receiving prescription benefits from BWC. No other state agency has adopted regulations regarding what drugs are reimbursed by BWC.

15. 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.

Once the rules are approved and through the JCARR process, BWC staff impacted by the rule will be informed of the effective date. Providers caring for injured workers will be notified of the key points contained in the rules 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 Reference Guide and the Provider Billing and Reimbursement Manual are updated to reflect appropriate rule modifications.

Adverse Impact to Business

16. 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 involved with the prescribing and dispensing of medications. The impacted segments of those communities are the BWC enrolled or certified providers who prescribe and dispense medication to injured workers.

and

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

There will not be an adverse impact on either of the two business communities identified in that both prescribers and pharmacies currently prescribe and dispense prescriptions based on the BWC formulary. These revisions do not change the process of prescribing or dispensing, nor do they make any changes to reimbursement for those activities.

and

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.

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. Any prescriptions that result from the changes in the drug regimen would continue to be processed by a pharmacy.

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

Rule 4123-6-21.2 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, address abusive pricing practices by manufacturers or incorporate changes in federal drug regulations.

Regulatory Flexibility

18. 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.

19. 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?

N/A

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

Prescribers may access 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.

Ohio | Bureau of Workers' Compensation
30 W. Spring St.
Columbus, OH 43215-2256

Governor **Mike DeWine**
Administrator/CEO **Stephanie McCloud**
www.bwc.ohio.gov
1-800-644-6292

Stakeholder Feedback Health Partnership Program
Ohio Administrative Code 4123-6-21.3 Outpatient medication formulary
Ohio Administrative Code 4123-6-21.6 First fill of outpatient medications

Stakeholder feedback comment period August 6 – 16, 2021 and September 8 – 20, 2021

Line	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
1	4123-6-21.3 4123-6-21.6	No stakeholder comments or feedback were received between August 6 – 16, 2021. The comments below were received between September 8 – 15, 2021. Any additional comments received between September 16 – 20, 2021 will be provided verbally during the September Medical Services & Safety committee meeting. An updated stakeholder feedback grid with all comments/feedback will be emailed to all board and committee members prior to the September meeting, provided at the September Medical Services & Safety committee meeting, and included in the October board materials.				
2	4123-6-21.3 4123-6-21.6	Dr. Timothy Nice, Sheakley Unicomp	This is very helpful. Thank you			No Change
3	4123-6-21.3 4123-6-21.6	James M. Anthony, MD, FAAFP BSMH System Medical Director of Occupational Health Medical Director Harness Health Partners Occupational Health - Lorain Chair of the Board – Mercy Health Select	I have no concerns about the formulary changes noted in yellow or green. They seem reasonable to me.			No Change
4	4123-6-21.3 4123-6-21.6	Doug Yunker MD, Anesthesia	Reviewed. Appropriate			No Change