ACTION: Revised

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Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Outpatient medication formulary.

Rule Number(s): 4123-6-21.3

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__1__ 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Rescinded/____ rules (FYR?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 the Appendix to OAC 4123-6-21.3, the formulary drug list:

   MEDICATIONS TO BE ADDED TO THE FORMULARY

   - Atogepant 10, 30, and 60 mg tablets
   - Baclofen 5mg tablets
   - Deutetrabenazine 6, 9, and 12 mg tablets
   - Menthol Gel 5.5%
   - Mometasone Furoate Inhal Aerosol Suspension 50 MCG/ACT
   - Phenylephrine-Mineral Oil-Petrolatum Oint 0.25-14-71.9%
   - Semaglutide Soln Pen-inj 1 MG/Dose (4 MG/3ML), 2 MG/Dose (8 MG/3ML), and 0.25 or 0.5 MG/DOSE (2 MG/3ML)
   - Tacrolimus (Topical) Soln 0.1%
   - Valbenazine 40, 60, 80, and 40-80 mg capsules

MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Aspirin-Al Hydro-Mg Hydro-Ca Carb 325 mg tablets
- Cromolyn Sodium Soln Nebu 20 MG/2ML
- Dipyridamole 25, 50, and 75 mg tablets

MEDICATIONS/CLASSES WITH CHANGES IN COVERAGE

- Albuterol Sulfate Aer Pow BA: May be reimbursed with prior authorization. Covered only after a minimum of a 14-day trial and documented therapeutic failure (as defined in O.A.C. 4123-6-21 (J)) of another agent in this class within the past 60 days.
- Antipsychotics: Except as noted for specific agents, the restrictions apply to all agents:
    - Prior authorization is not required if the injured worker has an allowed condition of schizophrenia or bipolar disorder.
    - May be considered for reimbursement for augmentation of antidepressant therapy upon submission of a prior authorization request that reflects:
        - a minimum of a 90-day trial and documented inadequate response to at least two antidepressants of different classes within the past 180 days, and
        - the injured worker has an allowed condition of major depressive disorder or dysthymic disorder.
    - Documentation of Abnormal Involuntary Movement Scale (AIMS) testing is required at initial antipsychotic prescribing and every 6 months thereafter for ongoing use of all antipsychotic medications.
    - Concurrent use of antipsychotics will not be approved.
- Antipsychotics: paliperidone, risperidone, haloperidol, asenapine, clozapine, quetiapine (immediate-release only), molindone, lurasidone, ziprasidone, chlorpromazine, fluphenazine, perphenazine, prochlorperazine, thioridazine, trifluoperazine, and thiothixene: Will not be considered for reimbursement for augmentation of antidepressant therapy for the treatment of major depressive disorder.
- Antipsychotics: olanzapine: Will only be considered for reimbursement for augmentation of antidepressant therapy for the treatment of major depressive disorder in combination with fluoxetine.
- Atogepant: Reimbursement will be 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. Limited to one (1) per day.
- Dabigatran: After 30 days of use, coverage may be considered for reimbursement upon submission of a prior authorization request that reflects use for an allowed condition in the claim.
- Fluticasone-Umeclidinium-Vilanterol AEPB: May be reimbursed with prior authorization showing documented allergic reaction to or clinical failure of, as

defined in OAC 4123-6-21(J)(1) and (J)(2), at least two (2) other medications in this class other than short-acting beta agonist products.

- Migraine Products – calcitonin gene-related peptide (CGRP) receptor antagonists: may be used with "triptan" migraine products.
- Movement disorder drug therapy: May be considered for reimbursement upon submission of a prior authorization request that reflects an allowed condition of tardive dyskinesia and baseline Abnormal Involuntary Movement Scale (AIMS). Approval is limited to no more than 12 weeks and AIMS is required for all subsequent renewals.
- Psychostimulants (ADHD): Will only be considered for approval for allowed conditions in the claim related to post-concussion syndrome or concussion, as defined in OAC 4123-6-34: "concussion" means a type of traumatic brain injury induced by external force, which might include a bump or blow to the head, or a jolt or hit to the body, which causes the brain to bounce around or twist in the skull, causing chemical changes in the brain and sometimes stretching and damaging brain cells.
- Respiratory – Antiasthmatic – Monoclonal Antibodies: add improvement in pulmonary function tests to subsequent approval criteria.
- Single-ingredient tiotropium products: May be reimbursed with prior authorization. Covered ONLY after a minimum of a 30-day trial and documented therapeutic failure (as defined in O.A.C. 4123-6-21 (J)) of another agent in this class within the past 120 days.
- Tiotropium Br-Olodaterol Inhal Aero Soln and Umeclidinium-Vilanterol Aero Powd BA: May be reimbursed with prior authorization showing documented allergic reaction to or clinical failure of, as defined in OAC 4123-6-21(J)(1) and (J)(2), at least one (1) other medication in this class other than short-acting beta agonist products.
- Zileuton: Reimbursement may be considered upon submission of a prior authorization request that reflects a minimum of a 60-day trial and documented therapeutic failure (as defined in O.A.C. 4123-6-21 (J)) of another agent in this class within the past 120 days.

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.**

   R.C4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.34, 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?**
   If yes, please briefly explain the source and substance of the federal requirement.

   No.

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

   Not Applicable.

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.

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

   No.

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 published for stakeholder comment on February 15, 2023 with a comment period open through March 1, 2023.

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?

Please see the stakeholder feedback grid.

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 rule 4123-6-21.3 was 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? ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

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

13. **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.

14. **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

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**

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.

    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
    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.

16. **Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

Yes, BWC has made technical changes to this to remove and reword verbiage pursuant to R.C. 121.95 and R.C. 121.951.

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

    Formulary revisions are routinely made based on opportunities to improve the clinical impact of the formulary, pricing, 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?**

    Not Applicable.

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.