Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

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

Rule Contact Name and Contact Information: Eva Dixon (614) 644-8346

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

Pharmacy and therapeutics committee, Outpatient medication formulary, and First fill of outpatient medications

Rule Number(s): 4123-6-21.2, 4123-6-21.3, and 4123-6-21.6

Date of Submission for CSI Review: April 17, 2024

Public Comment Period End Date: May 3, 2024

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/_3__ 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Rescinded/____ rules (FYR?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 OAC 4123-6-21.2 effective January 10, 2011 to establish the BWC Pharmacy and Therapeutics Committee (P&T Committee), which was created to advise BWC with regard to issues involving medication therapy for injured workers, including development and review of a formulary of approved medications.

   The proposed changes to OAC 4123-6-21.2 include:

   - P&T committee members may resign or be removed by the administrator at any time.
   - The pharmacy program director may designate an alternate to serve in the director's absence.
   - The P&T committee will hold at least two meetings annually.

   In addition to the above, the proposed changes also eliminate, where appropriate, regulatory restrictions "shall," "must," "require," "shall not," "may not," and "prohibit" from the rule, in accordance with the regulatory restriction reduction mandate found in R.C. 121.95 and R.C. 121.951.

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, are:

MEDICATIONS WITH CHANGES IN COVERAGE

- Antipsychotic class restriction: May be reimbursed in claims with an allowed condition of schizophrenia, bipolar disorder, or psychosis.
- Benzodiazepines class restriction: For all oral benzodiazepines, excluding clobazam, after 30 days of use, may be considered for reimbursement upon submission of a prior authorization request that reflects a minimum of a 90-day trial and documented inadequate response to at least two SSRIs and/or SNRIs within the past 180 days. Reimbursement for all oral benzodiazepines is limited to one (1) product per month.
- Modify quantity limits for benzodiazepines:
    - Chlordiazepoxide: Maximum dose 100 milligrams per day
    - Oxazepam: Maximum dose 120 milligrams per day
- Migraine Products – calcitonin gene-related peptide (CGRP) receptor antagonists:
    - CGRP products for acute treatment: Reimbursement will be considered for individuals who have not received an adequate response from use of at least two triptan medications, or if the injured worker has a contraindication for triptans.
    - CGRP products for prophylaxis: Reimbursement will be considered for individuals who have a minimum of a 90-day trial and documented inadequate response to at least three (3) agents from different classes within the past 180 days: 1) Topiramate, sodium valproate, divalproex sodium, 2) amitriptyline, nortriptyline, 3) venlafaxine, duloxetine, 4) atenolol, metoprolol, nadolol, propranolol, timolol. The initial reimbursement may be for up to 3 months. Subsequent approvals may be granted if there is a documented positive response to therapy demonstrated by a reduction in migraines AND there is documented improvement in function.
- Muscle Relaxant Class Restriction: After 90 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. This limitation does not apply to baclofen or dantrolene. Prior authorization may be submitted to request reimbursement of more than one muscle relaxant.
- Add quantity limits to selected muscle relaxant agents:

- Baclofen: 80 MG per day; prior authorization may be submitted to request up to 120 MG per day
- Chlorzoxazone: 2000 MG per day
- Cyclobenzaprine: 30 MG per day
- Dantrolene: 200 MG per day
- Metaxalone: 3200 MG per day
- Methocarbamol: 6000 MG per day
- Orphenadrine: 200 MG per day
- Tizanidine: 24 MG per day

MEDICATIONS TO BE ADDED TO THE FORMULARY

- Bexagliflozin Tab 20 MG
- Semaglutide Tab 3MG, 7MG, 14MG
- Tirzepatide Soln Pen-injector 2.5MG/0.5ML, 5MG/0.5ML, 7.5MG/0.5ML, 10MG/0.5ML, 12.5MG/0.5ML, 15MG/0.5ML

MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Dexamethasone Sodium Phosphate Inj 4 MG/ML
- Dexamethasone Sodium Phosphate Inj 10 MG/ML
- Dexamethasone Sod Phosphate Preservative Free Inj 10 MG/ML
- Dexamethasone Sodium Phosphate Inj 20 MG/5ML
- Dexamethasone Sodium Phosphate Inj 120 MG/30ML
- Dexamethasone Sodium Phosphate Inj 100 MG/10ML
- Insulin Detemir Inj 100 Unit/ML
- Insulin Detemir Soln Pen-injector 100 Unit/ML
- Insulin Lispro Subcutaneous Soln 100 Unit/ML
- Lixisenatide soln pen-injector 20 MCG/0.2ML (100 MCG/ML)
- Lixisenatide pen-inj starter kit 10 MCG/0.2ML & 20 MCG/0.2ML
- Methylprednisolone Acetate Inj Susp 40 MG/ML
- Methylprednisolone Acetate Inj Susp 80 MG/ML
- Methylprednisolone Sod Succ For Inj 125 MG (Base Equiv)
- Methylprednisolone Sod Succ For Inj PF 125 MG (Base Equiv)
- Rosiglitazone Tab 2 MG
- Rosiglitazone Tab 4 MG
- Triamcinolone Acetonide Inj Susp 40 MG/ML

OBSOLETE MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Allergy Tray Kit 1 ML 27 x 3/8"
- Amoxicillin Cap-Clarithro Tab-Lansopraz Cap DR Therapy Pack
- Bacitracin-Polymyxin-Neomycin HC Oint 1%
- Calcium Gluconate Cap 500 MG
- Calcium-Vitamin D Tab 500 MG-3.125 MCG (125 Unit)
- Didanosine For Soln 4 GM
- Diltiazem HCl Coated Beads Tab ER 24HR 240 MG
- Diltiazem HCl Coated Beads Tab ER 24HR 360 MG
- Encorafenib Cap 50 MG
- Ferrous Sulfate Elixir 220 MG/5ML
- Ferrous Sulfate Liq 300 MG/5ML
- Ferrous Sulfate Liquid 220 MG/5ML
- Ferrous Sulfate Syrup 300 MG/5ML
- Hyaluronate Sodium (Emollient) Gel 0.2%
- Insulin Lispro Inj 100 Unit/ML
- Insulin Syringe/Needle U-100 0.3 ML 29 G
- Insulin Syringe/Needle U-100 0.3 ML 30 G
- Insulin Syringe/Needle U-100 1 ML 30 G
- Insulin Syringe/Needle U-100 1/2 ML 29 G
- Insulin Syringe/Needle U-100 1/2 ML 30 G
- Loratadine Syrup 5 MG/5ML
- Magnesium Chloride-Calcium Tab DR 64-106 MG (Base Equiv)
- Neomycin-Polymyxin-HC Crm 3.5 MG/GM-10000 UNT/GM-0.5%
- Omega-3 Fatty Acids Cap 900 MG
- Oxybutynin Chloride Syrup 5 MG/5ML
- Peginterferon alfa-2a Soln Auto-Injector 135 MCG/0.5ML
- Saline Nasal Soln
- Sod Chloride INJ 0.9%
- Sodium Phosphates - Enema (Pediatric)
- Testosterone Cyp IM or Subcutaneous Inj in Oil 50 MG/ML
- Testosterone Cyp IM or Subcutaneous Inj in Oil 100 MG/ML
- Testosterone Cyp IM or Subcutaneous Inj in Oil 150 MG/ML
- Testosterone Enanth IM or Subcutaneous Inj in Oil 200 MG/ML

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 the Appendix to OAC 4123-6-21.6, the first fill formulary drug list, are:

MEDICATIONS TO BE ADDED TO THE FIRST FILL FORMULARY

- Baclofen Tab 5 MG, quantity limit 42
- Baclofen Tab 10 MG quantity limit 42
- Emtricitabine Cap 200 MG, quantity limit 30
- Etravirine Tab 200 MG, quantity limit 60
- Methocarbamol Tab 750 MG, quantity limit 42
- Rilpivirine Tab 25 MG, quantity limit 30

MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Indinavir Sulfate Cap 400 MG
- Nelfinavir Mesylate Tab 625 MG

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.

   Not Applicable.

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 OAC 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, created by OAC 4123-6-21.2, 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 allows the BWC Administrator to 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.

   Not Applicable.

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 4123-6-21.2, 4123-6-21.3, and 4123-6-21.6 were e-mailed to stakeholders on February 27, 2024, with comments due back by March 12, 2024.

Notice was e-mailed to the following list of stakeholders:

- BWC's Managed Care Organizations
- BWC's internal medical provider stakeholder list
- BWC's Health Care 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 State 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 feedback was received from the Industrial Commission Medical Director. In response, BWC adopted the following clarification to the proposed formulary restriction for several antipsychotic medications:

- 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 or intolerance to at least two antidepressants of different classes within the past ~~180~~240 days.

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 and 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. Performance-based regulations are not applicable to drug formulary management.

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:**
    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. **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 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.

    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 <u>reduce</u> 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).

No.

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, 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.ohio.gov) that prescribers can use to ask questions about drug coverage.