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: 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: _____

Public Comment Period End Date: _____

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Rescinded/____ rules (FYR?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

   MEDICATIONS TO BE ADDED TO THE FORMULARY

   - Dulaglutide Soln Pen-injector 4.5 MG/0.5ML
   - Dextromethorphan-Doxylamine-APAP Liquid 10-6.25-325 MG/15ML
   - Lubiprostone Cap 8 MCG
   - Sodium Chloride Irrigation Soln 0.9%
   - Cyanocobalamin Inj 1000 MCG/ML
   - Water For Irrigation, Sterile Irrigation Soln
   - Water For Injection (for use in pain pumps)

- Water For IV Injection (for use in pain pumps)
- MG Plus Tab Protein
- Sodium Chloride Tab 1 GM
- Sodium Chloride Inj 0.9%
- Brimonidine Tartrate Ophth Soln 0.025%
- Dextran 70-Hypromellose (PF) Ophth Soln 0.1-0.3%
- Betaxolol HCl Ophth Soln 0.5%
- Travoprost Ophth Soln 0.004%
- Hydrocortisone Acetate w/ Pramoxine Perianal Cream 1-1%
- Hydrocortisone Acetate w/ Pramoxine Perianal Cream 2.5-1%
- Oxymetazoline HCl Nasal Gel 0.05%
- Benzoyl Peroxide Liquid 5%
- Benzoyl Peroxide Liquid 10%
- Benzoyl Peroxide Gel 5%
- Benzoyl Peroxide Gel 10%
- Cholecalciferol Tab 5,000 Unit
- Cholecalciferol Tab 50,000 Unit

MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Tobramycin nebulizer solution 300 mg/4 mL
- Minocycline tab 100 mg
- Minocycline tab ER 90 mg
- Omega-3 fatty acids cap DR 500 mg
- Omega-3 fatty acids chew tab 240 mg
- L-Methylfolate w/ Vit B6 Vit B12 tab 3-43.75-2.72
- Ferrous Fumarate tab CR 50 mg (Fe Equivalent)
- Peginterferon alfa 2b for inj kit 80 mcg/0.5 mL
- Temazepam cap 7.5 mg
- Temazepam cap 22.5 mg
- Calcium carbonate-vitamin D tab 500 mg-400 unit
- Calcium citrate tab 200 mg
- Magnesium oxide tab 400 mg (241.3 mg elemental mg)
- Artificial tear opth ointment
- Carboxymethylcellulose-sodium (PF) ophth soln 1%
- Glycerin (ophth lubricant) soln 0.25% (PF)
- Hypromellose ophth soln 0.4%
- Polyvinyl alcohol-povidone ophth soln 1.4-0.6%

- Bimatoprost ophth soln 0.03%
- Sulfacetamide sodium w/ sulfur emulsion 10-5%
- Methenamine-Hyosc-Meth Blue-Sod Phos-Phen Sal Cap 118 MG
- Methenamine-Hyos-Meth Blue-Sod Phos-Phen Sal Tab 81.6 MG
- Multiple Vitamins w/ Calcium Chew Tab
- Multiple Vitamins w/ Minerals & FA Cap 0.5mg
- Niacinamide w/ Zn-Cu-Methylfolate tab 750-25-1.5-0.5 mg
- Ascorbic acid chew tab 1000 mg

MEDICATIONS WITH CHANGES IN COVERAGE

- All covered butalbital-containing products: restricted to claims in which headache is related to an allowed condition
- Gabapentin immediate release: Reimbursement limited to 3,600 MG/day
- Dulaglutide Pen-injector: Reimbursement limited to 2 ML per 28 days
- Nintedanib: Reimbursement will be considered for individuals who are being treated for interstitial lung disease related to an allowed condition in the claim. PA has to include documentation of fibrosis greater than or equal to ten percent within the past year and a Forced Vital Capacity (FVC) greater than or equal to forty percent of predicted.
- Gastrointestinal Chloride Channel Activators and Peripheral Opioid Receptor Antagonists: removed Morphine Equivalent Dose (MED) requirement
- Non-barbiturate hypnotics, temazepam is now subject to the class restriction
- Timolol Maleate Ophth Soln 0.5% (Once-Daily): May be reimbursed with prior authorization. Reimbursement is limited to claims in which the injured worker is unable to use non-once daily formulation.
- Timolol Maleate Preservative Free Ophth Soln 0.25%, 0.5%: May be reimbursed with prior authorization. Reimbursement is limited to claims in which the injured worker is unable to use non-preservative free.
- Brimonidine Tartrate Ophth Soln 0.1% and 0.15%; Betaxolol HCl Ophth Susp 0.25%; Timolol Ophth Soln 0.25% and 0.5%; Bimatoprost Opth Soln 0.01%: 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 30 days.
- Travoprost Ophth Soln 0.004% (Benzalkonium Free) (BAK Free): May be reimbursed with prior authorization. Reimbursement is limited to claims in which the injured worker is unable to use non-BAK Free.
- Butorphanol Tartrate Nasal Soln 10 MG/ML and Pentazocine w/ Naloxone Tab 50-0.5 MG: PA has to show documented allergic reaction to or clinical failure of, as defined in OAC 4213-6-21(J)(1) and (J)(2), nonopioid analgesics and opioid combination products.

- Opioids:
    - Each Tier requires trial and failure of two (2) products in the previous tier
    - Buprenorphine Buccal films: changed to Tier 2
    - Buprenorphine TD Patch weekly: changed to Tier 2
    - Oxycodone Cap ER 12hr Abuse-Deterrent changed to Tier 4
    - Tapentadol tab ER 12hr: changed to Tier 2
    - Methadone: prior authorization no longer requires documentation of electrocardiogram
- Naltrexone HCl Tab 50 MG: Restricted to use in claims with an allowed condition of opioid use disorder or as part of approved treatment under OAC 4123-6-21.8.
- Gabapentin (Once-Daily) tab: minimum 90-day trials of immediate release. Restricted to 1,800 mg/day
- Gabapentin enacarbil tab: minimum 90-day trials of immediate release. Restricted to 1,200 mg/day
- Lidocaine 5% ointment: 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 a lidocaine 4% topical product within the past 30 days. Claims in which lidocaine 5% ointment was covered in the 60 days prior to 10/1/2017 are not subject to the 14-day trial and failure of a lidocaine 4% topical product.
- Lidocaine 5% patch: 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 lidocaine patch 4% within the past 30 days. Authorization will be limited to one (1) patch per day.

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:

<u>MEDICATIONS TO BE ADDED TO THE FORMULARY</u>

- Doxycycline monohydrate cap 100 mg
- Doxycycline monohydrate tab 100 mg
- Doxycycline hyclate tab 100 mg
- Dolutegravir sodium tab 50 mg
- Diphenhydramine cap 25 mg
- Promethazine tab 12.5 mg
- Meclizine tab 12.5 mg
- Meclizine tab 25 mg
- Meclizine chew tab 25 mg

- Sennosides tab 8.6 mg
- Docusate sodium cap 100 mg
- Polyethylene glycol 3350
- Sennosides-docusate sodium tab 8.6-50 mg
- Aspirin tab 325 mg
- Aspirin chew tab 81 mg
- Aspirin tab delayed release 81 mg
- Aspirin tab delayed release 325 mg
- Acetaminophen tab 325 mg
- Acetaminophen tab 500 mg
- Celecoxib cap 100 mg
- Celecoxib cap 200 mg
- Diclofenac sodium tab delayed release 50 mg
- Diclofenac sodium tab delayed release 75 mg
- Indomethacin cap 50 mg
- Gabapentin cap 100 mg
- Gabapentin cap 300 mg
- Apixaban tab 2.5 mg
- Apixaban tab 5 mg
- Lidocaine patch 4%

MEDICATIONS TO BE REMOVED FROM THE FORMULARY

- Ofloxacin tab 400 mg
- Linezolid tab 600 mg
- Prednisolone tab 5 mg
- Prednisolone tab 5 mg dose pack
- Diclofenac potassium cap 25 mg
- Lidocaine cream 3%

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 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.

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 published for stakeholder comment on August 16, 2022 with a comment period open through August 30, 2022.

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?

No feedback was received from stakeholders.

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, 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?

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.