ACTION: Final

DATE: 07/01/2021 1:29 PM

Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, 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

Rule Number(s): 4123-6-21.3

Date of Submission for CSI Review: 03/10/2021

Public Comment Period End Date: 03/31/2021

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Rescinded/____ rules (FYR?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 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. This proposed revision shall make the following changes in coverage:

MEDICATIONS TO BE DELETED FROM THE FORMULARY

- Albiglutide pen-injector 30 mg
- Albiglutide pen-injector 50 mg
- Alirocumab SubQ Prefilled Syringe 150 MG/ML
- Alirocumab SubQ Prefilled Syringe 75 MG/ML
- Aliskiren-Valsartan Tab 150-160 MG
- Aliskiren-Valsartan Tab 300-320 MG

- Aluminum & Magnesium Hydroxides Susp 500-500 MG/5ML
- Aminocaproic Acid Syrup 25%
- Amoxicillin (Trihydrate) Tab ER 24HR 775 MG
- Ampicillin Cap 250 MG
- Ampicillin For Susp 250 MG/5ML
- Antipyrine-Benzocaine Otic Soln 54-14 MG/ML (5.4-1.4%)
- Antipyrine-Benzocaine-Polycosanol Otic Sol 5.4-1.4-0.0097%
- Aspirin-APAP-Salicylamide-Caffeine Tab 500-250-150-32.5 MG
- Aspirin-Caffeine-Dihydrocodeine Cap 356.4-30-16 MG
- Azithromycin Extended Release For Oral Susp 2 GM
- Balsalazide Disodium Tab 1.1 GM
- Beclomethasone Diprop Inhal Aero Soln 40 MCG/ACT (50/Valve)
- Beclomethasone Diprop Inhal Aero Soln 80 MCG/ACT (100/Valve)
- Benzocaine Aerosol 10%
- Bromfenac Sodium Ophth Soln 0.09% (Base Equivalent)
- Butabarbital Sodium Tab 30 MG
- Ceftibuten Cap 400 MG
- Ceftibuten For Susp 180 MG/5ML
- Cefuroxime Axetil For Susp 250 MG/5ML
- Ciprofloxacin-Ciprofloxacin HCl Tab ER 24HR 1000 MG (Base Eq)
- Ciprofloxacin-Ciprofloxacin HCl Tab ER 24HR 500 MG (Base Eq)
- Clobazam Tab 5 MG
- Cresyl Acetate Otic Soln 25%
- Crotamiton Cream 10%
- Daclatasvir Dihydrochloride Tab 30 MG (Base Equivalent)
- Daclatasvir Dihydrochloride Tab 60 MG (Base Equivalent)
- Daclatasvir Dihydrochloride Tab 90 MG (Base Equivalent)
- Desloratadine & Pseudoephedrine Tab ER 24HR 5-240 MG
- Desvenlafaxine Fumarate Tab ER 24HR 100 MG (Base Equiv)
- Desvenlafaxine Fumarate Tab ER 24HR 50 MG (Base Equiv)
- Exenatide For Inj Extended Release Susp 2 MG
- Flunisolide HFA Inhal Aerosol 80 MCG/ACT
- Fluticasone Propionate Aer Pow BA 113 MCG/ACT
- Fluticasone Propionate Aer Pow BA 232 MCG/ACT
- Fluticasone Propionate Aer Pow BA 55 MCG/ACT
- Formoterol Fumarate Inhal Cap 12 MCG
- Gemifloxacin Mesylate Tab 320 MG (Base Equiv)
- Guaifenesin-Codeine Liquid 300-10 MG/5ML
- Hexachlorophene Liq 3%
- Homatropine HBr Ophth Soln 2%
- Hydrocodone-Ibuprofen Tab 2.5-200 MG
- Interferon Beta-1a For IM Inj Kit 30MCG (33MCG(6.6 MU)/Vial)
- Ipratropium-Albuterol Aerosol 18-103 MCG/ACT (20-120MCG/ACT)
- Levobunolol HCl Ophth Soln 0.25%
- Lindane Lotion 1%
- Meclizine HCl Tab 50 MG
- Meloxicam Susp 7.5 MG/5ML
- Meprobamate-Aspirin Tab 200-325 MG
- Mesalamine Tab Delayed Release 400 MG
- Metaproterenol Sulfate Tab 10 MG
- Metaproterenol Sulfate Tab 20 MG

- Methyl Salicylate Liniment 10%
- Metronidazole Tab ER 24HR 750 MG
- Moexipril-Hydrochlorothiazide Tab 15-25 MG
- Niacin-Lovastatin Tab ER 24HR 1000-20 MG
- Niacin-Simvastatin Tab ER 24HR 1000-20 MG
- Niacin-Simvastatin Tab ER 24HR 1000-40 MG
- Niacin-Simvastatin Tab ER 24HR 500-20 MG
- Niacin-Simvastatin Tab ER 24HR 500-40 MG
- Norfloxacin Tab 400 MG
- Oxycodone w/ Acetaminophen Soln 5-325 MG/5ML
- Oxycodone-Ibuprofen Tab 5-400 MG
- Pancrelipase (Lip-Prot-Amyl) DR Cap 13800-27600-27600 Unit
- Pancrelipase (Lip-Prot-Amyl) DR Cap 20700-41400-41400 Unit
- Pancrelipase (Lip-Prot-Amyl) DR Cap 23000-46000-46000 Unit
- Paregoric Tincture 2 MG/5ML
- PB-Hyoscy-Atrop-Scopol Tab ER 48.6-0.3111-0.0582-0.0195 MG
- Phenylephrine-Chlorphen-DM Liquid 10-2-15 MG/5ML
- Phenylephrine-Chlorphen-DM Liquid 6-2-15 MG/5ML
- Phenylephrine-Chlorphen-DM Syrup 10-4-20 MG/5ML
- Phenylephrine-Pyrilamine w/ Codeine Syrup 5-8.33-9 MG/5ML
- Phenylephrine-Pyrilamine-DM Syrup 5-8.33-10 MG/5ML
- Pirbuterol Acetate Breath Activated Inhal Aerosol 200MCG/INH
- Potassium Aminobenzoate Tab 500 MG
- Pseudoephedrine w/ DM-GG Tab 30-30-400 MG
- Psyllium Powder 70%
- Psyllium Powder Packet 49%
- Psyllium Powder Packet 70%
- Rimexolone Ophth Susp 1%
- Rosiglitazone Maleate Tab 8 MG (Base Equiv)
- Scopolamine HBr Ophth Soln 0.25%
- Senna Tab
- Sumatriptan Succinate Solution Jet-injector 6 MG/0.5ML
- Telithromycin Tab 400 MG
- Tramadol HCl Orally Disintegrating Tab 50 MG
- Travoprost Ophth Soln 0.004%
- Trazodone HCl Tab ER 24HR 150 MG
- Trazodone HCl Tab ER 24HR 300 MG
- Trypsin w/ Castor Oil & Peruvian Balsam Gel
- Trypsin w/ Castor Oil & Peruvian Balsam Oint
- Tyloxapol Ophth Soln 0.25%
- Urea-Hyaluronate Sodium Susp 40-0.3%
- Vilazodone HCl Tab Starter Kit 10 (7) & 20 (7) & 40 (16) MG
- Zinc Oxide Cream 30.6%

MEDICATIONS TO BE ADDED TO THE FORMULARY

Restrictions for the following proposed formulary additions are outlined in the proposed Appendix to OAC 4123-6-21.3:

- Certolizumab (Cimzia®)
- Golimumab (Simponi®)

- Tofacitinib (Xeljanz®)
- Upadacitinib (Rinvoq®)
- Baricitinib (Olumiant®)
- Abatacept (Orencia®)
- Dupilumab (Dupixent®)
- Lansoprazole 15 mg and 30 mg capsules
- Pantoprazole 20 mg and 40 mg tablets
- Esomeprazole 20 mg tablets
- Buprenorphine-Naloxone sublingual tablets
- Naltrexone (Vivitrol®) long-acting injection
- Ticagrelor (Brilinta®)
- Liquid glycerin suppository
- Mycophenolate mofetil oral suspension
- Cyanocobalamin sublingual tablet

MEDICATIONS WITH CHANGES IN COVERAGE

Coverage changes for the following drugs and drug classes are outlined in the proposed Appendix to OAC 4123-6-21.3:

- Non-Barbiturate Hypnotics
- Ondansetron 4 mg and 8 mg orally disintegrating tablets
- Ulcer Drugs- Proton Pump Inhibitors
- Topical Corticosteroids
- Buprenorphine-Naloxone Buccal Film

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.C. 4121.441(A), 4123.66(A)

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 revisions to BWC formulary rule 4123-6-21.3 will remove 100 drugs that have been discontinued from manufacturing. The revisions will also add several drugs to the formulary list and modify coverage for certain drugs already listed in the formulary. Specific restrictions and prior authorization requirements are listed in the Appendix to OAC 4123-6-21.3.

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

   Per Rule 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.

   The proposed rules were published for stakeholder comment on February 5, 2021 with a comment period open through February 15, 2021, and notice was e-mailed to the following lists of stakeholders:

- BWC's Managed Care Organizations
- BWC's Medical Services Division's medical provider stakeholder list
- 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 stakeholder feedback was received on the proposed changes.

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 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?

This rule applies 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?

This rule only affects 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 rule is 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 rule 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 the 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 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.

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

Governor **Mike DeWine**
Interim Administrator/CEO **John Logue**
www.bwc.ohio.gov
1-800-644-6292

Stakeholder Feedback Health Partnership Program
OAC 4123-6-21.3 - Outpatient medication formulary
Appendix to Rule 4123-6-21.3 Formulary List of Medications Covered by the Ohio Bureau of Workers' Compensation

Line	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
1	4123-6-21.3					