CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Bureau of Workers' Compensation

Regulation/Package Title:
Payment for outpatient medications, Payment for outpatient medications by a self insured employer and Outpatient medication formulary rules

Rule Number(s): 4123-6-21, 4123-6-21.1, 4123-6-21.3

Date: September 22, 2016

Rule Type:

- New
- X Amended
- ☐ 5-Year Review
- ☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

BWC is proposing to amend rules OAC 4123-6-21, OAC 4123-6-21.1 and OAC 4123-6-21.3 effective January 1, 2017 for claims with a date of injury on or after January 1, 2017, to update the agency's prescription reimbursement model to better reflect pricing in the current marketplace, revise coverage and reimbursement of compounded prescriptions and implement coverage changes to various formulary medications.

Proposed Changes

OAC 4123-6-21 and 4123-6-21.1 Payment of outpatient medications, Payment of outpatient medications by a self insured employer

- Update the BWC prescription reimbursement model to better align the agency with current market standards by changing the prescription pricing methodology from average wholesale price (AWP) minus 9% to AWP minus 15%
- Revise reimbursement and coverage limitations of compounded prescriptions in the following areas:
    - Require that compound prescription ingredients have a National Drug Code (NDC) number for reimbursement
    - Require that prescriptions for compound drugs comply with Ohio State Pharmacy Board rules
    - Require a 30 day trial with a non-compounded commercially available topical product, reimbursed by BWC, with documented therapeutic failure prior to approval of a non-sterile topical compound prescription
    - Increase dispensing fees for non-sterile / sterile compound prescriptions from $12.50 / $25.00 to $18.75 / $37.50
    - Decrease the maximum allowable cost for non-sterile compound prescriptions from $600 to $400
- Add coverage by the BWC Managed Care Organizations of injectable drugs for opioid dependency
- Delete language relating to "accepting assignment" that is no longer applicable
- Delete language requiring OAARS registration for prescribers, as registration is now required by Ohio State Medical Board statute and rule
- Delete language relating to dispensing fee limitation for controlled substances, as BWC's proposed opiate rules encourage short-term prescriptions for opioids
- Clean-up references relating to use of acronyms
- Incorporate the following revisions into the outpatient medication rule for self insurers:
    - Revise the prescription pricing methodology from AWP minus 9% to AWP minus 15%,
    - Increase in dispensing fees for non-sterile / sterile compound prescriptions from $12.50 / $25.00 to $18.75 / $37.50.
    - Decrease in the maximum allowable cost for compound prescriptions from $600 to $400,
    - Delete language relating to "accepting assignment,
    - Delete the dispensing fee limitation for controlled substances

Proposed Changes

OAC 4123-6-21.3 Formulary medications

- Changes in coverage of immediate release opioid drug formulations:
  - Limit initial coverage of any opioid for use in a non-post operative condition to 7 days of coverage or 30 doses, whichever is less.
  - Eliminate coverage of concurrent use of more than one immediate release opioid agent without a Prior Authorization.
  - Implement a quantity limit of 180 doses (6 doses per day) for any immediate release opioid, will be implemented in all claims.
  - Eliminate coverage of methadone as an immediate release opioid
- Changes in coverage of sustained release opioid dosage formulations.
  - Concurrent use of any SR opioid, oral or transdermal, with any parenteral pain management medications (e.g. IM, SC, IV, IT analgesic medications) will not be covered.
  - Sustained release opioids will not be covered in post operative conditions unless the injured worker was being treated with the sustained release drug prior to surgery.
- Deletion of reimbursement for the following medications
  - All dosage forms of levorphanol
  - The auto-injector dosage form of naloxone
- Add reimbursement for the following medication
  - Nasal inhalation forms of naloxone

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**

   R.C. 4121.441, R.C. 4123.66

3. **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.**

   The rule does not implement a federal requirement.

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

   There are no federal requirements regarding reimbursement for opioid prescriptions dispensed to treat a work related injury or occupational disease, or for peer review or provider decertification procedures in the Ohio workers' compensation system.

5. **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 Rules 4123-6-21 and 41236-21.1 is to define the context, criteria, limitations and processes by which outpatient medications are covered by BWC and self insured employers. In addition to defining requirements for approved medications, the rules also define the types of providers who are eligible to write covered prescriptions as well as requirements for pharmacies that process the prescriptions. Payments for specific types of medications and the methodologies to be used to calculate those payments are defined in these rules.

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.

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

   The impact of the proposed revisions to the rules will be readily apparent in the monthly operational reports submitted to BWC by the Prescription Benefit Manager (PBM). The report was developed specifically to monitor critical operational points, both fiscal as well as clinical. Outcomes from the monitoring are reported by the pharmacy management staff to both BWC Administration as well as to the BWC Pharmacy & Therapeutics Committee.

Development of the Regulation

7. **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 revisions to the rules were e-mailed to the following lists of stakeholders on August 15, 2016 with comments due back by September 9, 2016:

- BWC's Managed Care Organizations and the MCO League representative
- 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 Manufacturer's 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

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

Feedback from the stakeholders listed in question 7 above was solicited and accepted beginning August 15, 2016 through September 9, 2016. An additional late comment that was submitted on September 14, 2016 was also accepted. Comments were received from three stakeholders. The comments and responses are shown below:

Stakeholder	Feedback	BWC Response
Mr. Clay Galbavi Workers' Compensation Supervisor for Maine and Ohio Claims Management Inc. PO Box 14731 Lexington, KY 40512	Request for information regarding how the decision was made and what data was utilized for the recommended changes to the reimbursement methodologies.	BWC thanked Mr. Galbavi for his comments and responded that the recommendations were made based on current market reimbursement data as provided by our prescription pricing consultant (Healthplan Data Solutions) and our Prescription Benefits Manager (OptumRx)

Stakeholder	Feedback	BWC Response
Mr. Ray Roshek, Director of Risk Management & Employee Benefits Lancaster Colony Corporation 37 West Broad Street, Columbus, OH	Submitted positive comments for the direction that the rules were taking for Self-Insured Employers. Recommended that BWC utilize clinical teams to make drug coverage decisions.	BWC thanked Mr. Roshek for his comments and responded with a description of the BWC Pharmacy & Therapeutics committee structure and responsibilities in making recommendations for coverage of medications. We reasserted our willingness to assist self insured employers with any pharmacy benefit related issues.
Ms Sandra Kay Guckian, VP State Government Affairs National Assn of Chain Drug Stores	-Observed that this would result in lower prescription reimbursement for workers compensation prescriptions than in some other states. -Indicated that there were higher labor costs involved in processing prescriptions for workers' compensation patients -Claimed that pharmacies incurred a greater financial risk for covering workers compensation prescriptions	BWC thanked Ms Guckian for her comments. -The proposed revision to the pricing methodology was made based on recommendations from an independent prescription pricing consultant as well as input from the pharmacist members of two agency committees. -The fact that the new pricing formula is lower than other states is not really relevant since over 95% of BWC prescriptions are processed in Ohio by Ohio pharmacies. The plan was also reviewed by retail pharmacists who agreed that the methodology would result in reasonable payments based on today's market. -BWC disagrees with the position that entering the necessary information for coverage of an injured worker is any more labor intensive than entering the data required for a commercial insurer or Medicaid recipient. The number of data elements is nearly identical and are shown on the claim card issued to each injured worker.

Stakeholder	Feedback	BWC Response
		–Regarding an inherent financial risk in processing workers' compensation prescriptions, with the introduction of the First Fill coverage rule in 2015 pharmacies that process prescriptions are guaranteed reimbursement even if the claim is denied. Electronic edits are in place at the point of sale that prevent unauthorized prescriptions from being processed as workers compensation medications.

9. 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?

BWC relied on recommendations from a national pharmaceutical cost containment firm (Healthplan Data Solutions) as well as data supplied by our Prescription Benefit Manger (OptumRx) to develop the proposed revisions to our reimbursement methodology. Material from both sources demonstrated that our reimbursement was not consistent with current levels of prescription reimbursement in either the workers compensation or commercial insurance markets.

For the proposed revisions to the outpatient formulary BWC relied on the recommendations from the clinicians on the agency Pharmacy & Therapeutics Committee as well as those contained in the opioid prescribing guidelines published by the US Center for Disease Control, Washington State Agency Medical Directors, and the Ohio Governor's Cabinet Opiate Action Taskforce. Both the federal CDC as well as Washington State guidelines contain data that link adherence to best prescribing practices with reduced opiate prescribing.

10. **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. There is currently no other rule in the Ohio Administrative Code that specifically addresses reimbursement for outpatient medications in workers' compensation.

11. **Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the r*equired outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.**

    In many ways this rule is a performance based regulation in that the specific testing, assessment and treatment planning processes to be used by the prescriber of opioids are not dictated – only that there must be documentation of the actions being accomplished.

12. **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 Ohio regulations exist regarding what drugs are covered by BWC.

13. **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.**

    Ohio prescribers and pharmacies caring for injured workers will be notified of the key points contained in this rule by email, fax or direct mail. They will also be provided with a link to find a complete copy of the rule.

Adverse Impact to Business

14. 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 the only two business communities involved with the prescribing and dispensing of medications. The impacted segments of those communities are the BWC enrolled or certified providers who prescribe opioids for and those network pharmacies enrolled with the bureau that dispense the medications to injured workers covered by BWC.

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

The changes in the formulary rule (O.A.C. 4123-6-21.3) are being made to better align opioid coverage with the Opioid Prescribing Rule (O.A.C. 4123-6-21.7) For prescribers whose opioid prescribing practices currently incorporate the treatment and monitoring steps identified as best practices there will be little or no impact. Prescribers who are not currently following best practice guidelines for opioid prescribing will have to comply with the new formulary restrictions or BWC will not reimburse the cost of the prescriptions.

As prescribers incorporate the new quantity and drug limitations on opioid prescriptions, pharmacies will see a decrease in the number of doses of opioids per prescription. Depending on their total opioid prescription volume and number of workers' compensation patients pharmacies could also see a small change in their volume of opioid prescriptions.

The proposed reduction to the AWP discount in the prescription pricing methodology will mean a reduction in total reimbursement paid by BWC to all pharmacies. The impact on each individual pharmacy will depend on the number of workers' compensation patients, prescription volume and the mix of brand vs generic medications. The impact of the proposed reduction in maximum payment for non-sterile compound prescriptions will primarily impact out of state compounding pharmacies that are using direct marketing to Ohio prescribers. These pharmacies typically submit charges at or slightly below the current maximum. The proposed maximum is based on the 2015 average reimbursement costs for all compounded prescriptions. This change will not impact pharmacies preparing sterile compounded products.

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.

The proposed revisions to the pricing methodology will only impact brand name and single source generic medications. In 2015 these products represented 52% of the cost of prescriptions covered by BWC. The other 47% of prescription volume is comprised of multi-source generic products that are reimbursed based on the Maximum Allowed Cost pricing list created by the Prescription Benefit Manger. The 2016 projected BWC drug cost is $87 million dollars. The estimated impact of the proposed pricing revision based on projected 2016 drug cost is a $2.7M reduction in pharmacy reimbursement. This will be spread over the 3000 pharmacies that currently process prescriptions for injured workers. The impact on individual pharmacies will depend on their patient and prescription volumes and medication mix.

The adverse impact of incorporating best practices for opioid prescribing into daily office processes can only be determined by the level of office automation, staff efficiency and commitment of the prescriber and their staff. The impact on pharmacies of changes in prescribing patterns as a result of the new formulary limitations will be highly varied due to the number of factors involved. For pharmacies that are doing a high volume of business with prescribers who are not following best practices in opioid prescribing, the impact may be significant. Other than pharmacies with this business profile, the impact of these formulary changes will be minimal.

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

BWC is obligated to apply sound fiscal principles in overseeing expenditures from the state insurance fund. Ensuring that our prescription reimbursement methodology is consistent with the current market standards is part of that obligation.

Likewise, BWC is committed to ensuring the safest and most effective treatment for Ohio's injured workers. To that end we believe that any steps that can be taken to improve the safety and efficacy of treatment should be taken. In both the clinical as well as the general media, inappropriate opioid prescribing is consistently identified as a principal, causal factor in the opioid epidemic currently afflicting our state. We believe that the proposed formulary changes are consistent with that commitment.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. Prescription reimbursement methodology is defined in rule and is applied to all pharmacies. The formulary applies to all prescribers. Prescribers of opioid medications are required to incorporate best practices for prescribing those medications if BWC is to reimburse for those prescriptions.

17. 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.

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

Prescribers may utilize the BWC website for an overview of the revised rules. The BWC Pharmacy Department also maintains an email address that prescribers can use to ask specific questions about any rule:
(pharmacy.benefits@ bwc.state.oh.us)

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