Common Sense Initiative

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

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):

Payment for outpatient medication; Payment of outpatient medication by self-insuring employer

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

Date of Submission for CSI Review: September 3, 2024

Public Comment Period End Date: September 17, 2024

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Rescinded/____ rules (FYR?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.

   Chapter 4123-6 of the Administrative Code contains BWC rules implementing the Health Partnership Program (HPP). OAC 4123-6-21 governs reimbursement for outpatient medication by BWC in State Insurance Fund claims. OAC 4123-6-21.1 governs reimbursement of outpatient medication by self-insuring employers.

   BWC is proposing revisions to OAC 4123-6-21 that would:

   - Update references to Ohio state board of pharmacy rules.
   - In the lesser of logic of payment for medications, including compounds, to pharmacy providers, change cost component to average wholesale price (AWP) minus a percentage determined by BWC.
   - Change dispensing fee component for medications, including compounds, to a flat rate determined by BWC, subject to annual review.
   - The change in pricing logic for ingredient cost also applies to injured workers who request a brand name drug when a generic equivalent exists.

   Since self-insuring employers are required to pay benefits equal to or greater than BWC, where applicable BWC is proposing to make changes parallel to those proposed in OAC 4123-6-21 in the Chapter 4123-6 self-insuring employer outpatient medication rule, OAC 4123-6-21.1.

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, 4123.35, 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 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-insuring 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.

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

   Success will be measured by the providers' and self-insuring employers' compliance with the modifications to the rule, and by routine monitoring of prescription data from our pharmacy benefit manager.

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 revisions to rules OAC 4123-6-21 and 4123-6-21.1 were e-mailed to the following lists of stakeholders on August 7, 2024 with comments due back by August 21, 2024:

- 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
    - o Council of Smaller Enterprises (COSE)
    - o Ohio Manufacturers' Association (OMA)
    - o National Federation of Independent Business (NFIB)
    - o 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.

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

Any stakeholder responses received by BWC are summarized on the Stakeholder Feedback Summary Spreadsheet. No changes were made based on the stakeholder feedback.

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?

Scientific data is not applicable to the language revisions being proposed for the outpatient medication payment rules. The proposed changes reflect language updates necessary for contemporary agency operations.

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.***

    Not applicable. These rules apply specifically to prescription coverage for Ohio injured workers. BWC is the only state agency charged with this statutory responsibility. There are currently no other rules in the Ohio Administrative Code that specifically address reimbursement for outpatient medications in workers' compensation.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    These rules only affect prescription drug benefits provided by BWC or self-insuring employers in allowed Ohio workers' compensation claims. No other state agency has adopted regulations regarding reimbursement of outpatient medications in the Ohio workers' compensation system.

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 and BWC's contracted pharmacy benefits manager 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.
The potential impact on each individual pharmacy may increase or decrease depending on the number of workers' compensation patients, prescription volume, the mix of dispensed brand and generic medications, and the maximum allowable cost list of BWC's contracted pharmacy benefits manager under OAC 4123-6-21(I).

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).***

No.

17. 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.

Regulatory Flexibility

18. 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.

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 utilize the BWC website for an overview of the revised rules. The BWC Pharmacy Department also maintains an email address (pharmacy.benefits@bwc.ohio.gov) that prescribers can use to ask questions about drug coverage.

Stakeholder Feedback
Ohio Administrative Code 4123-6-21 and 4123-6-21.1

Line #	**Rule #/ Subject Matter**	**Stakeholder**	**Draft Rule Suggestions**	**Stakeholder Rationale**	**BWC Response**	**Resolution**
1	4123-6-21 & 4123-6-21.1	Kelly Roush, DC CCSP ATC (Holzer)	None	"I have reviewed and agree with these rule revisions"	N/A	N/A
2						
3						
4						
5						

4123-6-21 Payment for outpatient medication.

(A) Except as otherwise provided in rule 4123-6-21.6 of the Administrative Code, medication must be for the treatment of a work related injury or occupational disease in a claim either allowed by an order of the bureau or the industrial commission, or recognized by a self-insuring employer. The bureau may deny a drug or therapeutic class of drugs as not being reasonably related to or medically necessary for treatment of the allowed conditions in a claim.

(B) Medication may be prescribed by any treating provider authorized by law to prescribe such medication; however, reimbursement for medication shall be denied under the following circumstances:

(1) Reimbursement for prescriptions written by providers who are not enrolled with the bureau and who refuse to become enrolled shall be denied.

(2) Reimbursement for prescriptions written by providers who are enrolled but non-certified shall be denied, except in the following situations:

(a) The prescription is written by a non-bureau certified provider during initial or emergency treatment of the injured worker if the injured worker's claim and treated conditions are subsequently allowed.

(b) The prescription is written by a non-bureau certified provider who is outside the state or within the state where no or an inadequate number of bureau certified providers exist and the MCO has determined that the treatment to be provided by the non-bureau certified provider is not reasonably available through a like bureau certified provider and has authorized the non-bureau certified provider to continue to provide the treatment.

(c) The prescription is written by a non-bureau certified provider for an injured worker with a date of injury prior to October 20, 1993, the provider was the injured worker's physician of record prior to October 20, 1993, and the injured worker has continued treatment with that non-bureau-certified provider.

(C) Drugs covered are limited to those that are approved for human use in the United States by the food and drug administration (FDA) and that are dispensed by a registered pharmacist from an enrolled pharmacy provider.

(D) The bureau may require prior authorization of certain drugs or therapeutic classes of drugs, drugs above a certain cost threshold, drugs submitted outside a certain time frame from the date of injury or the last prescription submitted, or drugs being prescribed for a condition or in a manner not approved by the FDA. The bureau will publish a list of all such drugs or therapeutic classes of drugs, cost thresholds, or time frames for which prior authorization is required.

(E) Prescriptions for compounded drug products:

(1) Prior authorization may be required for compounded sterile drug products.

(2) Compounded non-sterile prescriptions.

(a) Reimbursement for non-sterile compounded prescriptions will be denied, except when a commercially available formulary product becomes unavailable (listed on the "Food & Drug Administration Drug Shortages List," or "American Society of Health-System Pharmacists Drug Shortages List").

(b) Reimbursement for non-sterile compounded prescriptions shall only be considered upon the submission of both:

(i) A prior authorization request, and

(ii) A copy of the signed prescription that lists all active pharmaceutical ingredients. The prescription must comply with the Ohio state board of pharmacy requirements for a valid prescription set forth in rules ~~4729-5-13~~ 4729:5-5-05 and ~~4729-5-30~~ 4729:5-5-15 of the Administrative Code.

(c) Approval for reimbursement of non-sterile compounded prescriptions will be for an initial period of thirty days with subsequent approvals contingent upon commercial product availability. Not more than one prescription for a non-sterile compounded prescription will be approved for reimbursement in any thirty day period.

(F) Drugs which fall into one of the following categories may be approved and reimbursed by an MCO as part of a comprehensive treatment plan submitted by the physician of record or treating physician:

(1) Drugs for the treatment of obesity;

(2) Drugs for the treatment of infertility;

(3) Non-compounded parenteral drugs not intended for self-administration;

(4) Drugs used to aid in smoking cessation;

(5) Drugs dispensed to a injured worker while the injured worker is admitted to a hospital during an approved inpatient admission or during the course of an outpatient visit in a hospital.

(G) Payment for medications to pharmacy providers shall include both a product cost component and a dispensing fee component.

(1) Except as provided in this paragraph, the product cost component shall be the lesser of the following: maximum allowable cost, if applicable, or the average wholesale price (AWP) of the commonly stocked package size minus ~~fifteen per cent~~ a percentage determined by the bureau, subject to annual review.

(a) For repackaged brand name medications, the product cost component shall be calculated using the AWP of the original labeler.

(b) For compounded prescriptions, the product cost component shall be limited to the lesser of the maximum allowable cost, if applicable, for each ingredient, or the AWP of the commonly stocked package size minus ~~fifteen per cent~~ the percentage determined by the bureau for each ingredient pursuant to paragraph (G)(1) of this rule.

(c) The maximum reimbursement for any one non-sterile compounded prescription will be one hundred dollars.

(2) The dispensing fee ~~component~~ components for non-compounded prescriptions, non-sterile compounded prescriptions, and sterile compounded prescriptions shall be ~~three dollars and fifty cents~~ flat rate fees determined by the bureau, subject to annual review. Only pharmacy providers are eligible to receive a dispensing fee.

~~(3) The dispensing fee component for non-sterile compounded prescriptions shall be eighteen dollars and seventy five cents.~~

~~(4) The dispensing fee component for sterile compounded prescriptions shall be thirty seven dollars and fifty cents.~~

(H) The pharmacy provider is required to bill medication at their usual and customary charge. The amount paid to the provider will be the lesser of the provider's usual and customary charge or the reimbursement allowed as determined by the bureau under paragraph (G) of this rule. The bureau shall not reimburse any third-party pharmacy biller that submits pharmacy bills on behalf of a pharmacy provider or that has purchased pharmacy bills from a pharmacy provider for subsequent submission to the bureau for payment. Pharmacy providers are required to submit for billing the NDC number of the stock bottle from which the dispensed medication is obtained. Drugs may be dispensed in unit dose packaging, but the NDC number of the closest comparable bulk package listed in the bureau or the bureau's pharmacy benefit manager's payment system must be used for billing purposes. The pharmacy provider shall:

(1) Include prescriber information within bills submitted electronically to the bureau or the bureau's pharmacy benefits manager for payment. The prescriber information must include the national provider identifier (NPI) or the drug enforcement administration (DEA) number;

(2) Not pay, allow, or give, or offer to pay, allow, or give, any consideration, money, or other thing of value to an injured worker, or to any other person, firm, or corporation (including but not limited to free or discounted medications or other goods or services) as an inducement to or in return for the injured worker ordering or receiving from the provider any medications or other goods or services for which payment may be made by the bureau, the bureau's pharmacy benefits manager, or MCO under Chapter 4121., 4123., 4127., or 4131. of the Revised Code;

(3) Comply with all applicable billing instructions contained in the bureau's provider billing and reimbursement manual in effect on the billed date(s) of service.

(I) The bureau may establish a maximum allowable cost for single source or multi-source medications which

are pharmaceutically and therapeutically equivalent, that is, contain identical doses of the active ingredient and have the same biological effects as determined by the FDA and designated by an "A" code value in the FDA publication, "Approved Drug Products With Therapeutic Equivalence Evaluations" in effect on the billed date(s) of service. The methodology used to determine a maximum allowable cost for a qualified drug product shall be determined by the bureau. The bureau may ~~choose to~~ utilize the maximum allowable cost list of a vendor or develop its own maximum allowable cost list.

(J) Injured workers who request a brand name drug or whose physician specifies a brand name drug designated by "dispense as written" on the prescription for a medication for which pharmaceutically and therapeutically equivalent medication exist, as defined in paragraph (I) of this rule, shall be liable for the product cost difference between the AWP of the dispensed brand name drug minus ~~fifteen per cent~~ the percentage determined by the bureau pursuant to paragraph (G)(1) of this rule and the established maximum allowable cost price of the drug product. However, the bureau may approve reimbursement of the dispensed brand name drug at the AWP of the drug minus ~~fifteen per cent~~ the percentage determined by the bureau pursuant to paragraph (G)(1) of this rule if the following circumstances are met:

(1) The injured worker has a documented, systemic allergic reaction as a result of taking the generic equivalent which is consistent with known symptoms or clinical findings of a medication allergy; or

(2) The injured worker has been prescribed, and has tried, another generic equivalent and the intended therapeutic benefit has not been achieved or an unacceptable adverse event has occurred.

(K) The following dispensing limitations may be adopted by the bureau:

(1) The bureau may publish supply limitations for drugs which represent the maximum number of days supply that may be dispensed at any one time for a single prescription.

(2) The bureau may publish maximum prescription quantities which represent the largest number of units per drug that may be dispensed at any one time for a single prescription.

(3) Requests submitted that exceed any published days supply limit or maximum quantity limit shall be denied. Denials may be overridden by the bureau in cases where medical necessity and appropriateness have been determined.

(4) Refills of drugs not scheduled by the DEA requested before eighty per cent of any published days supply limit has been utilized will be denied.

(5) Refills of drugs scheduled by the DEA requested before ninety per cent of any published days supply limit has been utilized will be denied.

(6) Denials may be overridden by the bureau for the following reasons with supporting documentation:

(a) The injured worker's pharmacy is submitting an early refill for a shortened days supply to support synchronizing the filling or refilling of the prescription in a manner that allows the dispensed drug to be obtained on the same date each month;

(b) The injured worker is traveling out of the country and will be unable to refill medications during that time;

(c) The injured worker's pharmacy will be closed for more than two days.

(d) An emergency or disaster, as defined in division (O) of section 4123.511 of the Revised Code, is declared by the governor of Ohio or the president of the United States.

(L) Except as otherwise provided in paragraph (F) of this rule, outpatient medications shall be billed to and reimbursed through the bureau's pharmacy benefits manager. Pharmacy providers must submit bills for medication by an on-line point-of-service authorization terminal or a host-to-host link with the bureau's pharmacy benefits manager's established bill processing system as a condition of provider enrollment or reimbursement. Submission by paper or by tape-to-tape will not be accepted by the bureau or the bureau's pharmacy benefits manager.

(M) A claimant may request outpatient medication reimbursement in accordance with rule 4123-6-26 of the Administrative Code using form C-17 or equivalent. Claimant reimbursement may be limited to the following situations:

(1) Claimants whose medication is not payable under division (I) of section 4123.511 of the Revised Code on the date of service, but later becomes payable;

(2) Emergency situations where an enrolled pharmacy provider is not available;

(3) Claimants who reside out of the country.

(N) A "pharmacy provider" designation and provider number can be obtained by a provider who meets all the following criteria:

(1) Has a valid "terminal distributor of dangerous drugs" as defined in section 4729.01 of the Revised Code if located within Ohio; or an equivalent state license if located outside of Ohio; and,

(2) Has a valid DEA number; and,

(3) Has a licensed registered pharmacist in full and actual charge of a pharmacy; and,

(4) Has the ability and agrees to submit bills at the point of service.

All state and federal laws and regulations relating to the practice of pharmacy and the dispensing of medication by a duly licensed pharmacist must be observed.

(O) The bureau may contract with a pharmacy benefit manager to perform drug utilization review and on-line bill processing, maintain a pharmacy provider network and prior authorization program for medications, and provide management reports. The bureau or its vendor may also contract rebate agreements with drug manufacturers. The bureau may utilize other services or established procedures of the pharmacy benefits manager which may enable the bureau to control costs and utilization and detect fraud.

(P) The bureau may identify circumstances under which it may consider reimbursement for pharmacist professional services (also known as cognitive services) when payment for such services results in a measurable, positive outcome. The bureau shall be responsible for developing the criteria which will be used to assess the compensability of billed pharmacist professional services. The bureau shall be responsible for developing the structure of the reporting of the measurable outcomes used to justify the payment of pharmacist professional services, which may include reimbursement for the dispensing fee component. The amount that could be reimbursed for pharmacist professional services shall be determined by the bureau.

(Q) The bureau shall retain a registered pharmacist licensed in the state of Ohio to act as the full-time pharmacy program director to assist the bureau in the review of drug bills. The pharmacy program director may assist the bureau in determining the appropriateness, eligibility, and reasonableness of compensation payments for drug services. The bureau may adopt a drug formulary with the recommendation of the bureau's pharmacy and therapeutics committee established by rule 4123-6-21.2 of the Administrative Code, and may consult with the committee on the development and ongoing annual review of the drug formulary and other issues regarding medications.

4123-6-21.1 Payment for outpatient medication by self-insuring employer.

(A) Medication must be for treatment of a work related injury or occupational disease in a claim either allowed by an order of the bureau or the industrial commission, or recognized by a self-insuring employer.

(B) Medication may be prescribed by any treating provider authorized by law to prescribe such medication.

(C) Drugs covered in self-insuring employer claims are limited to those that are approved for human use in the United States by the food and drug administration (FDA) and that are dispensed by a registered pharmacist from a pharmacy provider.

(D) A self-insuring employer may approve and reimburse for various drugs as a part of a comprehensive treatment plan submitted by the physician of record or a treating physician when reasonably related to and medically necessary for treatment of the allowed conditions in the claim, provided that such approval and reimbursement shall not constitute the recognition of any additional conditions in the claim even if such drugs are used to treat conditions that have not been allowed in the claim.

(E) Payment for medications to pharmacy providers shall include both a product cost component and a dispensing fee component.

(1) Except as provided in this paragraph, product cost component shall be the lesser of the following: maximum allowable cost established under paragraph (N) of this rule, if applicable, or the average wholesale price (AWP) of the commonly stocked package size minus ~~fifteen per cent~~ a percentage determined by the bureau pursuant to paragraph (G)(1) of rule 4123-6-21 of the Administrative Code, subject to annual review.

(a) For repackaged brand name medications, the product cost component shall be calculated using the AWP of the original labeler.

(b) For compounded prescriptions, the product cost component shall be limited to the lesser of the the maximum allowable cost, if applicable, for each ingredient or the AWP of the commonly stocked package size minus ~~fifteen per cent~~ the percentage determined by the bureau for each ingredient pursuant to paragraph (G)(1) of rule 4123-6-21 of the Administrative Code.

(c) The maximum product cost component reimbursement for any one non-sterile compounded prescription will be ~~four~~ one hundred dollars.

(2) The dispensing fee ~~component~~ components for non-compounded prescriptions, non-sterile compounded prescriptions, and sterile compounded prescriptions shall be ~~three dollars and fifty cents~~ flat rate fees determined by the bureau pursuant to paragraph (G)(2) of rule 4123-6-21 of the Administrative Code, subject to annual review, unless the self-insuring employer has negotiated a payment rate with the pharmacy provider pursuant to rule 4123-6-46 of the Administrative Code. Only pharmacy providers are eligible to receive a dispensing fee.

(~~3) The dispensing fee component for non-sterile compounded prescriptions shall be eighteen dollars and seventy five cents.~~

~~(4) The dispensing fee component for sterile compounded prescriptions shall be thirty seven dollars and fifty cents.~~

(F) The pharmacy provider is required to bill medication at their usual and customary charge. The amount paid to the provider will be the lesser of the provider's usual and customary charge or the reimbursement allowed as determined in paragraph (E) of this rule, unless the self-insuring employer has negotiated a payment rate with the provider pursuant to rule 4123-6-46 of the Administrative Code. Pharmacy providers are required to submit for billing the national drug code (NDC) number of the stock bottle from which the dispensed medication is obtained. Drugs may be dispensed in unit dose packaging, but the NDC number of the closest comparable bulk package listed in the bureau or vendor payment system must be used for billing purposes.

(G) The pharmacy provider shall:

(1) Include prescriber information within bills submitted electronically to the self-insuring employer or its vendor for payment. The prescriber information must include the national provider identifier (NPI) or the drug enforcement administration (DEA) number;

(2) Not pay, allow, or give, or offer to pay, allow, or give, any consideration, money, or other thing of value to an injured worker, of to any other person, firm, or corporation (including but not limited to free or discounted medications or other goods or services) as an inducement to or in return for the injured worker ordering or receiving from the provider any medications or other goods or services for which payment may be made by the self-insuring employer or its vendor or QHP under Chapter 4121., 4123., 4127., or 4131. of the Revised Code;

(3) Comply with all applicable billing instructions contained in the bureau's provider billing and reimbursement manual in effect on the billed date(s) of service.

(H) Claimant reimbursement for medications shall be in accordance with rule 4123-6-26 of the Administrative Code and shall at least be equal to the bureau's established rate for the medication, unless the self-insuring employer has negotiated a payment rate with the pharmacy provider utilized by the claimant pursuant to rule 4123-6-46 of the Administrative Code, in which case the claimant reimbursement shall be at least the rate negotiated with the provider. Requests for reimbursement must be paid within thirty days of receipt of the request.

(I) Self-insuring employers must obtain a drug utilization review from a physician before terminating payment for current medications, as follows:

(1) Except as otherwise provided in paragraph (I)(7) of this rule, before terminating payment for current medications, the self-insuring employer shall notify all parties to the claim (including authorized representatives) and the prescribing physician, in writing, that a physician drug review is being performed, or has been performed, regarding the necessity and appropriateness of the continued

use of current medications (by therapeutic drug class).

(2) The written notice shall inform all parties to the claim (including authorized representatives) and the prescribing physician that they have twenty-one days from receipt of the notice to provide additional information and/or medical documentation to justify the need for continued use of the medications (by therapeutic drug class).

(3) The self-insuring employer shall provide all medically related information regarding the medications to an independent physician reviewer for review and opinion as to the necessity or appropriateness of the medications. If the self-insuring employer has obtained an independent physician reviewer's report prior to sending the notice required by paragraph (I)(1) of this rule and subsequently receives additional information and/or medical documentation pursuant to paragraph (I)(2) of this rule, the self-insuring employer shall provide the additional information and/or medical documentation to the independent physician reviewer and obtain an addendum. The independent physician reviewer's report (and addendum, if applicable) shall address the medical rationale, necessity and appropriateness of the drug treatment in the control of symptoms associated with the allowed conditions in the claim.

(4) When the independent physician reviewer's report (and addendum, if applicable) indicates the drug treatment is not medically necessary or appropriate for treatment or in the control of symptoms associated with the allowed conditions in the claim, the self-insuring employer may terminate reimbursement for the medications (by therapeutic drug class) effective as of the date of receipt of the independent physician reviewer's report, or addendum if one is obtained, or in the case that a drug is in a therapeutic class that requires a "weaning-off" period, in accordance with the tapering schedules set forth in ~~the appendix to~~ rule 4123-6-21.5 of the Administrative Code or such other date as agreed to by the prescribing physician and self-insuring employer.

(5) In the event the self-insuring employer terminates reimbursement for the medications as set forth in paragraph (I)(4) of this rule, the self-insuring employer or its authorized representative shall provide all parties to the claim (including authorized representatives) and the prescribing physician with a copy of the independent physician reviewer's report (and addendum, if applicable) and the self-insuring employer shall notify the injured worker and the injured worker's representative in writing of its decision to terminate. The employer's notification to the injured worker and injured worker's representative shall indicate that the injured worker has the right to request a hearing before the industrial commission.

(6) In the event there is a dispute as to whether the drug treatment is medically necessary or appropriate for treatment of the symptoms associated with the allowed conditions in the claim, the disputed matter shall be adjudicated in accordance with paragraph ~~(K)(5)~~ (L)(5) of rule 4123-19-03 of the Administrative Code.

(7) The self-insuring employer may terminate current medications that have been removed from the bureau's outpatient medication formulary set forth in the appendix to rule 4123-6-21.3 of the Administrative Code without obtaining a physician drug review. However, the tapering schedules set

forth in ~~the appendix to~~ rule 4123-6-21.5 of the Administrative Code would apply.

(J) Self-insuring employers may deny initial requests for a drug or therapeutic class of drugs as not being reasonably related to or medically necessary for the treatment of the allowed conditions in a claim.

(K) Self-insuring employers may contract with a pharmacy benefits manager. A self-insuring employer utilizing a pharmacy benefits manager may require pharmacy providers to submit bills for medication by an on-line point-of-service authorization terminal or a host-to-host link with the pharmacy benefits manager's established bill processing system as a condition of reimbursement, and may refuse submission by paper or by tape-to-tape. Self-insuring employers utilizing a pharmacy benefits manager may refuse to reimburse any third-party pharmacy biller that submits pharmacy bills on behalf of a pharmacy provider or that has purchased pharmacy bills from a pharmacy provider for subsequent submission to the self-insuring employer for payment.

(L) Self-insuring employers utilizing a pharmacy benefits manager may require prior authorization of drugs or therapeutic classes of drugs which appear on the bureau's published list of drugs or therapeutic classes of drugs for which prior authorization is required. Notwithstanding rule 4123-19-03 of the Administrative Code, the self-insuring employer shall approve or deny a prior authorization request within three business days of the request.

(M) Self-insuring employers utilizing a pharmacy benefits manager may apply the following dispensing limitations, adopted by the bureau, to medications approved and reimbursed by the self-insuring employer:

(1) The bureau may publish supply limitations for drugs which represent the maximum number of days supply that may be dispensed at any one time for a single prescription.

(2) The bureau may publish maximum prescription quantities which represent the largest number of units per drug that may be dispensed at any one time for a single prescription.

(3) Requests submitted that exceed either the days supply limit or maximum quantity limit shall be denied; provided, however, that the pharmacy provider may still fill the prescription up to the days supply limit or maximum quantity limit, as applicable. Denials may be overridden by the self-insured employer in cases where medical necessity and appropriateness have been determined.

(4) Refills of drugs not scheduled by the DEA requested before eighty per cent of any published days supply limit has been utilized will be denied.

(5) Refills of drugs scheduled by the DEA requested before ninety per cent of any published days supply limit has been utilized will be denied.

(6) Denials may be overridden by the self-insured employer for the following reasons with supporting documentation:

(a) The injured worker's pharmacy is submitting an early refill for a shortened days supply to support synchronizing the filling or refilling of the prescription in a manner that allows the dispensed

drug to be obtained on the same date each month;

(b) The injured worker is traveling out of the country and will be unable to refill medications during that time;

(c) The injured worker's pharmacy will be closed for more than two days.

(d) An emergency or disaster, as defined in division (O) of section 4123.511 of the Revised Code, is declared by the governor of Ohio or the president of the United States.

(N) Self-insuring employers utilizing a pharmacy benefits manager may apply the maximum allowable cost list of the pharmacy benefits manager.

(O) Injured workers who request a brand name drug or whose physician specifies a brand name drug designated by "dispense as written" on the prescription for a medication for which pharmaceutically and therapeutically equivalent medications exist, as defined in paragraph (I) of rule 4123-6-21 of the Administrative Code, shall be liable for the product cost difference between the AWP of the dispensed brand name drug minus ~~fifteen per cent~~ the percentage determined by the bureau pursuant to paragraph (G)(1) of rule 4123-6-21 of the Administrative Code and the established maximum allowable cost price of the drug product. However, the self-insuring employer or its vendor may approve reimbursement of the dispensed brand name drug at the AWP of the drug minus ~~fifteen per cent~~ the percentage determined by the bureau pursuant to paragraph (G)(1) of rule 4123-6-21 of the Administrative Code if the following circumstances are met:

(1) The injured worker has a documented, systemic allergic reaction as a result of taking the generic equivalent which is consistent with known symptoms or clinical findings of a medication allergy; or

(2) The injured worker has been prescribed, and has tried, another generic equivalent and the intended therapeutic benefit has not been achieved or an unacceptable adverse event has occurred.

(P) A self-insuring employer has sufficient grounds to refuse to pay for the dispensing of drugs and other medications when a pharmacy provider fails to observe any state or federal law relating to his or her professional licensure or to the dispensing of drugs and other medication.