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

(A) Medication must be for treatment of an occupational injury or 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 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) 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 (O) of this rule, if applicable, or the average wholesale price (AWP) of the commonly stocked package size minus ~~nine~~ fifteen per cent.

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

(b) For non-sterile compounded prescriptions, the product cost component shall be limited to the lesser of the usual and customary price or the AWP of the commonly stocked package size minus ~~nine~~ fifteen per cent for each ingredient.

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

(2) The dispensing fee component for non-compounded prescriptions shall be three dollars and fifty cents, unless the self-insuring employer has negotiated a payment rate with the pharmacy provider pursuant to rule 4123-6-46 of the Administrative Code.

(a) Only pharmacy providers are eligible to receive a dispensing fee.

~~(b) The dispensing fee may include an additional incentive component of two dollars and fifty cents for pharmacy providers that accept assignment.~~

~~(c)~~(b) Except as provided below, dispensing fees shall be limited to one dispensing fee per patient per generic code number (GCN), or other proprietary code that serves to group together pharmaceutically equivalent products (defined as products that contain the same active ingredients in the same strengths, dosage forms, and routes of administration), per rolling twenty-five days. Exceptions to the single dispensing fee are:

(i) Cases where the physician has prescribed a second round of medication within the twenty-five day period;

(ii) Cases where the physician has changed the dosage;

(iii) Cases where the medication did not last for the intended days supply;

~~(iv) Controlled substances (which are limited to two dispensing fees per twenty-five days;~~

~~(v)~~(iv) Cases where the self-insuring employer determines the limitations of this paragraph to be unnecessary under the specific circumstances.

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

(4) The dispensing fee component for sterile compounded prescriptions shall be ~~twenty-five~~ 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) Maintain a signature log verifying receipt of applicable covered medications;

(2) 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;

(3) Not pay, allow, or give, or offer to pay, allow, or give, any consideration, money, or other thing of value to an injured worker (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;

(4) 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. Claimant requests for reimbursement shall 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. 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) 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, 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 employee and the employee's representative in writing of its decision to terminate. The employer's notification to the employee and employee's representative shall indicate that the employee 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) of rule 4123-19-03 of the Administrative Code.

(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 utilize medication utilization protocols formulated by the bureau for select conditions or diseases consistent with current medical texts and peer reviewed medical literature.

Refusal to comply with the established protocols shall result in refusal of reimbursement for the medications which are not within the established protocols. This rule does not require the discontinuation of treatment with medications that are not within the established protocols, but simply states the bureau's or self-insured employer's refusal to reimburse for such medications.

(L) Through internal development or through vendor contracts, self-insuring employers may implement a point-of-service adjudication system. Upon implementation, a self-insuring employer 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 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 point-of-service adjudication system 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.

(M) Self-insuring employers utilizing a point of service adjudication system 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.

(N) Self-insuring employers utilizing a point-of-service adjudication system 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 maximum prescription quantities which represent the largest number of units per drug that may be dispensed at any one time for a single prescription.

(2) 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.

(3) Refills requested before seventy-five per cent of the days supply has been utilized will be denied, except in cases where the dosage of a drug has been changed and has a new prescription number. Denials may be overridden by the self-insured employer for the following documented reasons:

(a) Pharmacist entered previous wrong day supply;

(b) Out of country vacation or travel;

(c) 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.

(O) Self-insuring employers utilizing a point-of-service adjudication system may apply the maximum allowable cost list of the point-of-service adjudication system vendor for 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 ~~food and drug administration (FDA)~~ 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. For single source drugs, self-insuring employers utilizing a point-of-service adjudication system may utilize as a maximum allowable cost the drug's ~~average wholesale price~~ AWP minus ~~nine~~ fifteen per cent.

(P) Claimants 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 single source or multi-source medications exist that are pharmaceutically and therapeutically equivalent, as defined in paragraph (O) of this rule, shall be liable for the product cost difference between the established maximum allowable cost price of the drug product and the ~~average wholesale price~~ AWP of the dispensed brand name drug minus ~~nine~~ fifteen per cent. However, the self-insuring employer or its vendor may approve reimbursement of the dispensed brand name drug at the ~~average wholesale price~~ AWP of the drug minus ~~nine~~ fifteen per cent if the following circumstances are met:

(1) The injured worker has a documented, systemic allergic reaction which is consistent with known symptoms or clinical findings of a medication allergy; and

(2) The injured worker has been prescribed, and has tried, other A code drugs in the therapeutic class and the intended therapeutic benefit has not been achieved or an unacceptable adverse event has occurred.

(Q) 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.

Effective: 01/01/2017

Five Year Review (FYR) Dates: 08/25/2020

CERTIFIED ELECTRONICALLY

Certification

12/22/2016

Date

Promulgated Under:	119.03
Statutory Authority:	4121.12 , 4121.121 , 4121.30, 4121.31, 4121.44, 4121.441, 4123.05, 4123.35, 4123.66
Rule Amplifies:	4121.12, 4121.121, 4121.44 , 4121.441, 4121.35, 4123.66
Prior Effective Dates:	2/1/10, 9/1/11, 1/1/12, 12/1/13, 4/10/14, 11/13/15