4123-6-21 **Payment for outpatient medication.**

(A) Medication must be for the 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. 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: ~~Reimbursement~~

(1) Reimbursement for prescriptions written by providers who are not enrolled with the bureau and who refuse to become enrolled shall be denied. ~~Reimbursement for prescriptions written by providers who are enrolled but non-certified shall be denied except in the following situations:~~

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

~~(1)~~(a) The prescription is written by a non-bureau certified provider during initial or emergency treatment of the claimant if the claimant's claim and treated conditions are subsequently allowed.

~~(2)~~(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.

~~(3)~~(c) The prescription is written by a non-bureau certified provider for a claimant with a date of injury prior to October 20, 1993, the provider was the claimant's physician of record prior to October 20, 1993, and the claimant has continued treatment with that non-bureau-certified provider.

(3) Reimbursement for prescriptions of controlled substances written by Ohio providers who are not enrolled in OARRS and refuse to become enrolled shall be denied if the provider has written prescriptions for controlled substances for the purpose of providing chronic care. For purposes of this provision:

(a) "Controlled substance" has the same meaning as in section 3719.01 of the

Revised Code.

(b) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(c) "Written for the purpose of providing chronic care" means the provider has written three or more prescriptions for controlled substances for the same injured worker in a twelve week period.

(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, and shall publish a list of all such drugs or therapeutic classes of drugs for which prior authorization is required.

(E) Drugs which fall into one of the following categories may be prior authorized by and reimbursed through the bureau's pharmacy benefits manager:

(1) Compounded sterile parenteral drug products.

(a) "Parenteral" drugs are injectable medications. They may include those intended for use by the intrathecal, intravenous, intramuscular, or subcutaneous routes of administration.

(b) All compounded sterile parenteral drug products must be prepared and dispensed by a licensed and enrolled pharmacy provider that is able to demonstrate compliance with the standards contained in chapter 797 of the United States pharmacopeia (USP) in effect on the billed date of service.

(2) Drug efficacy study implementation (DESI) drugs or drugs that may have been determined to be identical, similar, or related;

(3) Extemporaneous ~~or simple~~ compounded prescriptions.

(a) Reimbursement for non-sterile compounded prescriptions shall only be considered for preparations that contain not less than one nor more than three FDA approved active pharmaceutical ingredients, and that contain only one prescription drug from any specific therapeutic class of drugs (as defined in the edition of the "American Hospital Formulary Service

Drug Information" in effect on the billed date(s) of service).

(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 and indicates the usual and customary cost of the prescription.

(c) Approval for reimbursement of non-sterile compounded prescriptions will be for an initial period of ninety days with subsequent approvals contingent upon clinical documentation of improvement in both pain and function.

(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 injectable drugs not intended for self-administration;

(4) Drugs used to aid in smoking cessation;

(5) Drugs dispensed to a claimant while the claimant 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) ~~The~~Except as provided below, 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 nine per cent. ~~For~~

(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 per cent for each ingredient.

(c) The maximum reimbursement for any one compunded prescription will be six hundred dollars.

(2) The dispensing fee component for non-compounded prescriptions shall be three dollars and fifty cents.

(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) Except as provided below, dispensing fees shall be limited to one dispensing fee per patient per generic code number (GCN) 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) Cases where the medication has been lost, stolen or destroyed;

(v) Controlled substances (which are limited to two dispensing fees per twenty-five days).

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

(4) The dispensing fee component for sterile compounded prescriptions shall be twenty-five dollars.

(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. 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 national drug code 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) Maintain a signature log verifying receipt by the injured worker of applicable covered medications;

(2) 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;

(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 bureau, the bureau's pharmacy benefits manager, or MCO 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.

(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 food and drug administration (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. For multi-source drugs, the bureau may choose to utilize the maximum allowable cost list of a vendor or develop its own maximum allowable cost list. For single source drugs, the maximum allowable cost shall be the drug's average wholesale price minus nine per cent.

(J) 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 (I) 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 of the dispensed brand name drug minus nine percent. However, the bureau may approve reimbursement of the dispensed brand name drug at the average wholesale price of the drug minus nine 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.

(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 requested before seventy-five per cent of any published days supply limit 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 bureau for the following documented reasons:

(a) Previous supply was lost, stolen or destroyed;

(b) Pharmacist entered previous wrong day supply;

(c) Out of country vacation or travel;

(d) Hospital or police kept the medication;

(e) Pharmacy will be closed for more than two days.

(f) 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) Claimant reimbursement for medications shall be in accordance with rule 4123-6-26 of the Administrative Code. 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. Claimant reimbursement may be limited to the following situations:

(1) Claimants whose claims are not allowed on the date of service, but are subsequently allowed;

(2) Emergency situations where an enrolled pharmacy provider with point-of-service capabilities is not available;

(3) Claimants who reside out of the country.

(N) The bureau may formulate medication utilization protocols for select conditions or diseases consistent with current medical texts and peer reviewed medical literature.

Compliance with the established protocols shall be monitored through the on-line, point-of-service adjudication system. 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 refusal to reimburse for such medications.

(O) 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 drug enforcement agency (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 relating to the practice of pharmacy and the dispensing of medication by a duly licensed pharmacist must be observed.

(P) 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.

(Q) 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 included reimbursement for the dispensing fee component. The amount that could be reimbursed for pharmacist professional services shall be determined by the bureau.

(R) 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.

Effective:

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Certification

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Date

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