4123-6-21.7 **Utilization of opioids in the subacute or chronic phases of pain treatment for a work-related injury or occupational disease.**

(A) Definitions.

For purposes of this rule:

(1) "Chronic phase of pain treatment" means that an injured worker is considered to be experiencing chronic pain or pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than twelve continuous weeks after the date of injury or occupational disease, or after a surgical intervention related to the allowed conditions of the claim.

(2) "Clinically meaningful improvement in pain and function" or "CMIF" means a measured and meaningful improvement in the ability of the injured worker to engage in activities of daily living, or to make progress toward accomplishing any daily activity goals established at the onset of treatment with emphasis on a possible return to work.

(3) "Clinically validated and appropriate drug testing methodology" means a chemical analysis of a specimen (e.g. urine, blood, saliva, hair) to identify presence or absence of parent drugs or their metabolites. For purposes of this rule, it is inclusive of both the immunoassay and a confirmation test such as gas chromatography, mass spectrometry or high-performance liquid chromatography.

(4) "Informed consent" has the same meaning as defined in rule 4731-29-01 of the Administrative Code.

(5) "Morphine equivalent dose" or "MED" means the equivalent daily amount of morphine represented by all of the opioids prescribed for an injured worker as measured by the conversion factors used by the Ohio board of pharmacy at the time the opioids are prescribed. This metric is used to approximate the total opioid load of an individual injured worker.

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

(7) "Opioid" has the same meaning as "opiate" as defined in division (R) of section 3719.01 of the Revised Code.

(8) "Subacute phase of pain treatment" means that an injured worker is experiencing pain that has persisted after reasonable medical efforts have been made to relieve it and has continued, either continuously or episodically, for longer than six continuous weeks but less than twelve continuous weeks after the date of injury or occupational disease, or after a surgical intervention related to the allowed conditions of the claim.

(B) Current clinical literature has shown that long term utilization of opioids in workers' compensation claims is associated with an increased length of time until an injured worker returns to work. Therefore, it is highly recommended that prescribers consider and apply appropriate Ohio opioid prescribing guidelines prior to initially prescribing opioids to treat an injured worker, and continuously throughout the injured worker's course of opioid therapy.

This rule governs the bureau's reimbursement of opioid prescriptions used to treat a work related injury or occupational disease in the subacute phase of pain treatment, at high doses, or in the chronic phase of pain treatment, and for discontinuing opioids in the chronic phase of pain treatment. It is not meant to preclude, or substitute for, the prescriber's responsibility to exercise sound clinical judgment in light of current best medical practices and appropriate Ohio opioid prescribing guidelines when treating injured workers.

(C) Effective October 1, 2016 for claims with a date of injury on or after September 1, 2016 and for all claims on or after January 1, 2017, reimbursement for opioid prescriptions used to treat a work related injury or occupational disease shall be limited to claims in which current best medical practices as implemented by Ohio state medical board rule 4731-21-02 of the Administrative Code and this rule are followed.

The bureau shall not reimburse for any further prescriptions for opioids, and prescribers should discontinue prescribing opioids, if the applicable criteria of Ohio state medical board rule 4731-21-02 of the Administrative Code and this rule are not met. A prescriber's failure to comply with the requirements of these rules may constitute endangerment to the health and safety of injured workers, and claims involving opioid prescribing not in compliance with these rules may be subject to peer review by the bureau of workers' compensation pharmacy and therapeutics (P&T) committee pursuant to rule 4123-6-21.2 of the Administrative Code, the bureau of workers' compensation stakeholders' health care quality assurance advisory committee (HCQAAC) pursuant to rule 4123-6-22 of the Administrative Code, or other peer review committee established by the bureau.

(D) Opioid utilization in the subacute phase of pain treatment.

(1) Reimbursement for opioid prescriptions for an injured worker during the subacute phase of pain treatment shall only be provided in claims where a prescriber has documented the following actions prior to either escalating the dosing regimen beyond fifty milligrams morphine equivalent dose (MED) per day, or prescribing opioids more than six weeks after the injured worker's date of injury or occupational disease or surgery related to allowed conditions in the claim, whichever occurs first:

(a) Development of an individualized treatment plan that is justified with

clinical rationale.

(b) Establishment of a risk assessment through the use of a clinically validated tool for screening and assessment, the OARRS prescription reporting system, and a clinically validated and appropriate drug testing methodology.

(c) Documented response to treatment as demonstrated by CMIF in the injured worker.

(2) Because continuous utilization of opioid medications in the chronic phase of pain treatment is associated with substantial risk for harm, opioid prescribing or dose increases that do not result in CMIF are considered not medically necessary or appropriate in the Ohio workers' compensation system.

(E) Opioid utilization at high doses or in the chronic phase of pain treatment.

(1) Reimbursement for opioid prescriptions for an injured worker at doses greater than eighty milligrams MED per day or in the chronic phase of pain treatment shall only be provided in claims where a prescriber has documented the following actions prior to either escalating the dosing regimen beyond eighty milligram MED per day, or prescribing opioids more than twelve weeks after the injured worker's date of injury or occupational disease or surgery related to allowed conditions in the claim, whichever occurs first:

(a) Verification that the requirements of paragraphs (D)(1)(a) through (D)(1)(c) of this rule have been met.

(b) Documentation that reasonable alternatives to opioids have been tried and failed.

(2) Reimbursement for opioid prescriptions for an injured worker at doses greater than one hundred twenty milligrams MED per day or in the chronic phase of pain treatment shall only be provided in claims where a prescriber has documented the following actions prior to either escalating the dosing regimen beyond one hundred twenty milligrams MED per day, or prescribing opioids more than twelve weeks after the injured worker's date of injury or occupational disease or surgery related to allowed conditions in the claim, whichever occurs first:

(a) Verification that the requirements of paragraphs (D)(1)(a) through (D)(1)(c) and paragraphs (E)(1) (a) and (E)(1)(b) of this rule have been met.

(b) Documentation of a risk benefit assessment of the injured worker to determine whether to continue opioid prescribing or to initiate weaning.

(c) Consultation with a pain management specialist if the injured worker's dose is above one hundred twenty milligrams MED per day and there is no demonstrated CMIF or special circumstance such as the need for compassionate care as defined in paragraph (G) of this rule.

(d) Evidence of the injured worker's informed consent and provision to the injured worker of written education materials regarding opioid analgesics.

(e) Appropriate additional consultations if the injured worker has a co-morbid substance use issue or poorly controlled mental health disorder.

(F) Discontinuing opioids in the chronic phase of pain treatment.

(1) Reimbursement for treatments required to assist an injured worker during the discontinuance of opioid prescriptions in the chronic phase of pain treatment shall only be provided in claims where the treatment record reflects the following actions more than twelve weeks after the injured worker's date of injury or occupational disease or surgery related to allowed conditions in the claim:

(a) Documentation in the medical record of an intent to discontinue opioid treatment of the injured worker in a timeframe consistent with the standard dose tapering schedules set forth in the appendix to rule 4123-6-21.5 of the Administrative Code in effect at the time the intent to discontinue opioid treatment of the injured worker is documented.

(b) Documentation in the medical record of a clear plan for tapering the injured worker's total opioid load as measured by daily MED.

(c) Monthly documentation of adherence with the plan.

(2) During the eighteen months subsequent to the date of the documented plan to discontinue opioid treatment, the bureau will reimburse appropriate and medically necessary formulary medications pursuant to an approved prior authorization request that documents use of such medications as adjuncts to withdrawal of opioid medications. During this eighteen month period, the bureau will also reimburse appropriate and medically necessary inpatient treatment for detoxification for up to thirty days and outpatient treatment for opioid use disorder, according to the version of patient placement criteria of the American society of addiction medicine (ASAM) in effect during this eighteen month period. Reimbursement is contingent on documentation of the following:

(a) Documentation of concurrence with the plan of treatment by the injured worker's physician of record or treating physician.

(b) All medications prescribed for treatment of pain and opioid withdrawal during this eighteen month period must be prescribed by a single designated prescriber selected by the injured worker. Any change in prescriber during this period must be approved by the administrator.

(c) Documentation of compliance by the injured worker as indicated by monthly OARRS reports and at least bi-monthly use of a clinically validated and appropriate drug testing method. Evidence of more than two events of non-compliance by the injured worker shall be cause for the bureau to cease reimbursement for all clinical interventions directed at treating opioid withdrawal.

(G) Compassionate care.

The administrator may grant an exemption to the requirements listed in paragraph (E) of this rule at the recommendation of either the bureau's chief medical officer or the P&T, HCQAAC, or other peer review committee established by the bureau, following review of the claim, if the injured worker's injuries or treatment history is such that strict application of this rule would offer no improvement in the injured worker's overall health, safety, or quality of life, or continuing care of the injured worker will require a prolonged course of surgeries or multiple surgical interventions.

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	4121.12, 4121.121, 4121.30, 4121.31, 4121.44, 4121.441, 4123.05
Rule Amplifies:	4121.12, 4121.121, 4121.44, 4121.441