BWC Board of Directors

Executive Summary

Opioid Prescribing, Peer Review, and Provider Decertification Rules
OAC 4123-6-02.7, 4123-6-21.2, 4123-6-21.7, 4123-6-22

Introduction

Chapter 4123-6 of the Administrative Code contains BWC rules implementing the Health Partnership Program (HPP), including reimbursement for outpatient medication by BWC in State Insurance Fund claims.

BWC is proposing to adopt new opioid prescribing rule OAC 4123-6-21.7, 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, and to revise rules OAC 4123-6-02.7, 4123-6-21.2, and 4123-6-22 to:

- Encourage the incorporation of best current clinical practices in the utilization of opioids in the treatment of injured workers;
- Establish provisions and criteria for the treatment of opioid dependence that arose secondary to treatment with opioid medications covered by BWC;
- Provide and strengthen BWC peer review processes for opioid prescribing that can be implemented to address serious non-compliance with these best practices; and
- Clarify that BWC provider decertification pursuant to peer review shall be conducted in accordance with Chapter 119 hearing procedures, but is exempt from BWC progressive compliance procedures.

Background Law

R.C. 4123.66(A) provides that the BWC Administrator "shall disburse and pay from the state insurance fund the amounts for medical, nurse, and hospital services and medicine as the administrator deems proper," and that the Administrator "may adopt rules, with the advice and consent of the [BWC] board of directors, with respect to furnishing medical, nurse, and hospital service and medicine to injured or disabled employees entitled thereto, and for the payment therefore."

Ohio Revised Code 4121.441(A)(1)(e) and (l) provide that the Administrator, with the advice and consent of the BWC Board of Directors, shall adopt rules for implementation of the HPP "to provide medical, surgical, nursing, drug, hospital, and rehabilitation services and supplies to an employee for an injury or occupational disease" which shall include, but are not limited to:

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> (e) Adequate methods of peer review, utilization review, quality assurance, and dispute resolution to prevent, and provide sanctions for, inappropriate, excessive or not medically necessary treatment;
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> (l) Standards for the bureau to utilize in penalizing or decertifying a health care provider from participation in the health partnership program.

Proposed Changes

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

Proposed new opioid prescribing rule OAC 4123-6-21.7 provides standards and criteria governing BWC'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.

Upon proposed rule OAC 4123-6-21.7 taking effect, BWC 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 OAC 4731-21-02 and proposed BWC rule OAC 4123-6-21.7 are followed. BWC shall not reimburse for any further prescriptions for opioids, and prescribers should discontinue prescribing opioids, if the applicable criteria of the rules are not met.

Furthermore, a prescriber's failure to comply with the requirements of OAC 4731-21-02 and OAC 4123-6-21.7 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 BWC Pharmacy and Therapeutics (P&T) Committee, the BWC Health Care Quality Assurance Advisory Committee (HCQAAC), or such other peer review committee established by BWC.

- **OAC 4123-6-21.2 Pharmacy and therapeutics committee**
- **OAC 4123-6-22 Stakeholders' health care quality assurance advisory committee**

The proposed changes to OAC 4123-6-21.2 and 4123-6-22 provide that any decertification or sanction of a provider by BWC pursuant to peer review recommendation of the HCQAAC or the P&T committee shall be conducted in accordance with the Chapter 119 hearing procedures set forth in BWC rule OAC 4123-6-17 of the Administrative Code.

- **4123-6-02.7 Provider access to the HPP - provider decertification procedures**

The proposed changes to OAC 4123-6-02.7 provide that the progressive compliance procedures of that rule do not apply to, and the BWC Administrator may proceed directly to enrollment termination and/or decertification of a provider upon, peer review recommendation of the HCQAAC, the P&T committee, or other peer review committee established by BWC.

Stakeholder Involvement

BWC's proposed new rule OAC 4123-6-21.7 and revisions to rules OAC 4123-6-02.7, 4123-6-21.2, and 4123-6-22 were e-mailed to stakeholders on April 15, 2016 with comments due back by May 9, 2016. Stakeholder responses received by BWC were summarized on the attached Stakeholder Feedback Summary Spreadsheet for the second reading of the rules.

4123-6-02.7 Provider access to the HPP - provider decertification procedures.

(A) Except as otherwise provided in paragraph (C) of this rule, the administrator of the bureau of workers' compensation shall follow the procedures set forth in this rule to terminate the enrollment of and decertify a non-facility provider who has failed to comply with a workers' compensation statute or rule.

(1) If the bureau determines a provider has committed three or more reported violations of the same workers' compensation statute or rule in a six month period, or five or more reported violations of any workers' compensation statute or rule in a six month period, the bureau shall send the provider written notification of the violations by certified mail.

(2) If the bureau determines the provider has committed two or more subsequent reported violations of any workers' compensation statute or rule for which the provider previously received notice pursuant to paragraph (A)(1) of this rule, and the subsequent violations occurred any time within the twelve month period following the calendar month in which the provider received notice pursuant to paragraph (A)(1) of this rule, the bureau shall send the provider written notification of the violations by certified mail, which shall include a thirty day period within which the provider must submit and implement a correction plan to the bureau. The correction plan shall be entered into the provider's certification file and the provider's certification file shall have the notation "under correction plan" during the twelve month period following the calendar month in which the provider's thirty day implementation period provided above expires.

If the provider fails to submit a correction plan within the thirty day implementation period satisfactory to the bureau, which satisfaction shall not be unreasonably withheld, the bureau shall send the provider written notification of the failure by certified mail, which shall include a notice of proposed enrollment termination and decertification complying with rule 4123-6-17 of the Administrative Code.

(3) If the bureau determines the provider has committed two or more subsequent reported violations of the same workers' compensation statute or rule for which the provider previously received notice pursuant to paragraph (A)(2) of this rule and submitted a correction plan satisfactory to the bureau, and the subsequent violations occurred any time within the twelve month period following the calendar month in which the provider's thirty day implementation period provided in the notice sent pursuant to paragraph (A)(2) of this rule expires, the bureau shall send the provider written notification of the violations by certified mail, which shall include a notice of proposed enrollment termination and decertification complying with rule 4123-6-17 of the Administrative Code.

(4) If the bureau determines a provider who has twice received written notice pursuant to paragraph (A)(1) of this rule for violation of the same workers' compensation statute or rule has committed a subsequent reported violation of the same workers' compensation statute or rule within three years of the date written notification was first sent to the

provider by the bureau pursuant to paragraph (A) of this rule, the bureau shall send the provider written notification of the violation by certified mail, which shall include a notice of proposed enrollment termination and decertification complying with rule 4123-6-17 of the Administrative Code.

(5) The bureau may, in its discretion, may consider mitigating circumstances in its application of the procedures set forth in paragraphs (A)(1) to (A)(4) of this rule with regard to an individual provider. Mitigating circumstances may include, but are not limited to:

(a) The violations related to the provision of emergency treatment;

(b) At the time the violations occurred, the provider was not aware a workers' compensation claim was involved;

(c) The provider was initially bureau certified within six months prior to the violations;

(d) The violations were due to bureau or MCO error;

(e) The provider billed the bureau for goods or services in fewer than five workers' compensation claims in the twelve months prior to the violations;

(f) Other documented justification as deemed sufficient by the bureau.

(6) If any notice sent by certified mail pursuant to this rule is returned because the party fails to claim the notice, the bureau shall resend the notice by ordinary mail to the party at the party's last known address appearing in the bureau's records and shall obtain a certificate of mailing.

(B) Providers whose enrollment is terminated and who are decertified pursuant to paragraph (A)(3) or (A)(4) of this rule shall be eligible to apply for and be considered for recertification and reenrollment at any time after two years from the date of the final administrative or judicial order of enrollment termination and decertification.

(C) The procedures set forth in paragraphs (A)(1) to (A)(6) of this rule do not apply to, and the administrator may proceed directly to enrollment termination and/or decertification of a provider for, violation of the following:

(1) The minimum provider certification criteria set forth in rule 4123-6-02.2 of the Administrative Code.

(2) Acts of misrepresentation, misstatement, or omission of a relevant fact or other acts involving dishonesty, fraud, or deceit on the provider’s provider application and agreement or recertification application and agreement.

(3) Acts involving breach of the bureau's confidentiality and sensitive data requirements, including but not limited to failure to maintain the confidentiality of injured worker medical or claim information.

(4) Acts involving misuse of information obtained from the bureau by means of electronic account access for a purpose other than facilitating treatment, including but not limited to engaging in advertising or solicitation directed to injured workers.

(5) Acts involving advertising or solicitation directed to injured workers in violation of rule 4123-6-02.9 of the Administrative Code.

(6) Acts of intentional misrepresentation, misstatement, or omission of a relevant fact or other acts involving false, fraudulent, deceptive, or misleading information on reports, information, and/or documentation submitted by the provider, the provider's employees, or the provider's agents to the bureau, industrial commission, claimant, employer, or their representatives, MCO, QHP, or self-insuring employer in connection with a workers' compensation claim.

(7) Upon peer review recommendation of the bureau of workers' compensation stakeholders' health care quality assurance advisory committee (HCQAAC) pursuant to rule 4123-6-22 of the Administrative Code**,** the bureau of workers' compensation pharmacy and therapeutics (P&T) committee pursuant to rule 4123-6-21.2 of the Administrative Code, or other peer review committee established by the bureau.

(8) The reasons for immediate revocation or suspension of a provider's certification set forth in paragraph (C) of rule 4123-6-02.5 of the Administrative Code.

Effective: 11/13/15
Prior Effective Dates: 2/16/96, 2/14/05, 2/1/10, 1/1/13

4123-6-21.2 Pharmacy and therapeutics committee.

The bureau of workers' compensation pharmacy and therapeutics (P&T) committee is hereby created to advise the administrator and the chief medical officer with regard to issues involving medication therapy for injured workers. A list of physician and pharmacist providers, each holding a professional license in good standing, who have agreed to serve on the P&T committee and who would add credibility and diversity to the mission and goals of the committee shall be developed and maintained by the chief medical officer. Providers may also be nominated for inclusion on the list by provider associations and organizations including but not limited to: deans of Ohio's allopathic and osteopathic medical schools, deans of Ohio's colleges of pharmacy, presidents of Ohio's various allopathic and osteopathic medical associations, the Ohio pharmacists association, the Ohio state medical board, and the Ohio state pharmacy board.

(A) The P&T committee shall consist of the bureau pharmacy program director and not more than thirteen nor less than five voting members who shall be licensed physicians and licensed pharmacists representing the diverse group of providers that provide care to the injured workers of Ohio as administered through the bureau. The committee may create any subcommittees that the committee determines are necessary to assist the committee in performing its duties. Any subcommittee recommendations shall be submitted to the P & T committee.

(B) P&T committee members must meet the following requirements:

(1) Each provider must be familiar with issues relating to the prescribing or dispensing of medications in the Ohio workers' compensation system.

(2) Physicians must be a doctor of medicine (MD) or doctor of osteopathic medicine (DO).

(3) Providers must possess significant clinical or administrative experience in health care delivery, including but not limited to pain management, pharmacy practice, medical quality assurance, disease management and utilization review.

(4) Providers must have experience with and an understanding of the concepts of evidence based medicine as well as contemporary best practices in appropriate prescribing, dispensing, and monitoring of outpatient medications.

(5) Providers must not be, or within the previous twenty-four months have been, an employee of any pharmaceutical manufacturer, pharmacy benefits manager, or any non-governmental firm or entity administering state purchased health care program benefits or pharmaceutical rebates.

(C) The appointing authority for members of the P&T committee shall be the administrator or the administrator's designee(s), who shall appoint members of the committee from the list of qualified providers developed and maintained by the chief medical officer. Terms of membership

for individual members of the P&T committee shall be for one year. Individuals may be reappointed to subsequent terms as determined by the administrator. Vacated terms shall be filled in a like manner as for the full term appointments and shall be for the remaining term of the vacated member.

(D) The pharmacy program director of the bureau shall be the chairperson of the P&T committee and shall provide notice of meetings to the members and be responsible for the meeting agenda. In addition, the pharmacy program director may be self-designated as an ad hoc member of any subcommittees of the P&T committee; however, the pharmacy program director shall be a voting member of the P&T committee and any subcommittees only in the case of tie votes. The bureau chief medical officer and bureau staff pharmacist may participate in discussions; however, they shall not be voting members.

(E) The P&T committee shall develop and establish bylaws for the organization and operations of the committee and subcommittees, subject to the requirements of this rule and approval by the administrator.

(F) The P&T committee may make such recommendations as it deems necessary to address any issue impacting the bureau related to pharmacy or medication therapeutics. The committee shall be responsible to respond to requests for action on any such issue submitted by the bureau's administrator, chief of medical services, chief medical officer or pharmacy director, including but not limited to:

(1) Development, approval and annual review of a formulary of approved medications.

(2) Development, approval and annual review of a list of non-covered, non-reimbursable medications.

(3) Development and approval of prior authorization criteria.

(4) Review and approval of proposed medication treatment guidelines.

(5) Review and approval of bureau policies and procedures related to drug 4123-6-21.2 2 utilization review or specific medication issues.

(6) Review of the bureau's pharmacy providers' professional performance. The P&T committee shall perform peer review according to generally accepted standards of pharmacy practice and may recommend sanctions as well as termination of any pharmacy provider determined to have consistently failed to meet those standards of care.

(7) Review of any of the bureau's medical providers' medication prescribing patterns and practices. The P&T committee shall perform peer review according to generally accepted standards of medical practice applicable to medication prescribing and may recommend sanctions as well as decertification of any provider determined to have consistently failed to meet those standards of care. Any decertification or sanction of a provider by the

bureau pursuant to recommendation of the P&T committee shall be conducted in accordance with rule 4123-6-17 of the Administrative Code.

(8) Review of the performance of the bureau's pharmacy benefit manager and conduct regarding its management of prescription benefit services for the bureau.

(G) The P&T committee shall hold at least three meetings annually. The P&T committee and all subcommittees shall keep written records of the agenda and minutes of each meeting. The records of all committees shall remain in the custody of the chief medical officer.

(H) The P&T committee shall submit an annual report of its activities and recommendations to the administrator. In addition to inclusion in the annual report, all recommendations from the P&T committee and subcommittees shall be submitted to the chief medical officer in a timely fashion upon completion and approval by the respective subcommittees and P & T committee.

(I) Each member of the P&T committee and its respective subcommittees may be paid such fees as approved by the administrator or the administrator's designee. The expenses incurred by the P&T committee and its subcommittees and the fees of their members shall be paid in the same manner as other administrative costs of the bureau.

Effective: 2/1/12
Prior Effective Dates: 1/10/11

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 50 milligrams (mg) 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 80 mg 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 80 mg 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 120 mg 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 120 mg 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 (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 120 mg 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: 10/1/2016
Prior Effective Dates:

4123-6-22 Stakeholders' health care quality assurance advisory committee.

The bureau of workers' compensation stakeholders' health care quality assurance advisory committee (HCQAAC) was created to advise the administrator, the chief of medical services, and the chief medical officer with regard to medical quality issues. A list of medical providers, each holding a professional license in good standing, who have agreed to serve on the HCQAAC, and who would add credibility and diversity to the mission and goals of the HCQAAC shall be developed and maintained by the chief medical officer. Providers may be nominated for inclusion on the list by provider associations and organizations including but not limited to: deans of Ohio's allopathic and osteopathic medical schools, deans of Ohio's colleges of pharmacy, deans of Ohio's dental schools, the dean of the Ohio college of podiatric medicine, the Ohio state medical association, the Ohio state osteopathic association, the Ohio state chiropractic association, specialty board associations of Ohio, the Ohio podiatric medical association, the Ohio psychological association, the Ohio dental association, the Ohio pharmacists association, the Ohio hospital association, the Ohio state medical board, the Ohio state chiropractic board, the Ohio state psychology board, the Ohio state pharmacy board, and the Ohio state dental board.

(A) The HCQAAC shall consist of the bureau's chief medical officer, the chief of medical services and not more than thirteen nor less than five voting members representing the diverse group of providers that provide medical care to the injured workers of Ohio as administrated through the bureau. The committee may create any subcommittees that the committee determines are necessary to assist the committee in performing its duties. Any subcommittee recommendations shall be submitted to the HCQAAC committee.

(B) HCQAAC members must meet the following requirements:

(1) Providers must be familiar with issues relating to the treatment of injured workers in the Ohio workers' compensation system.

(2) Providers must possess significant clinical or administrative experience in health care delivery, including but not limited to, medical quality assurance, disease management, and utilization review.

(3) Providers must have experience with and an understanding of the concepts of evidence based medicine as well as contemporary best practices in their respective areas of practice.

(C) The appointing authority for members of the HCQAAC shall be the administrator or the administrator's designee(s), who shall appoint members of the HCQAAC from the list of qualified providers developed and maintained by the chief medical officer. Terms of membership for individual members of the HCQAAC shall be for one year. Individuals may be reappointed to subsequent terms as determined by the administrator. Vacated terms shall be filled in a like

manner as for the full term appointments and shall be for the remaining term of the vacated member.

(D) The chief medical officer of the bureau shall be the chairperson of the HCQAAC and shall provide notice of meeting to the members and be responsible for the meeting agenda. In addition, the chief medical officer and chief of medical services may be self-designated as an ad hoc member of any subcommittees of the HCQAAC,. However, the chief of medical services shall not be a voting member of the HCQAAC or any subcommittee, and the chief medical officer shall be a voting member of the HCQAAC and any subcommittees only in the case of tie votes. The bureau's medical director, the industrial commission's medical director, and one physician chosen by the MCOs may participate in discussions; however, they shall not be voting members.

(E) The HCQAAC shall develop and establish bylaws for the organization and operations of the committee and subcommittees, subject to the requirements of this rule and approval by the administrator and the chief medical officer.

(F) The HCQAAC shall be responsible to respond to requests for action on any medical quality assurance issue submitted by the bureau's administrator, chief of medical services, or chief medical officer including, but not limited to:

(1) Review of medical treatment guidelines referred to the bureau;

(2) Review of any of the bureau's policies and procedures related to medical quality assurance issues;

(3) Review of any of the bureau's medical providers' professional performance and conduct, including bureau certification and malpractice issues. The HCQAAC shall perform peer review according to generally accepted standards of medical practice and may recommend sanctions as well as decertification of any provider determined to have consistently failed to meet those standards of care. Any decertification or sanction of a provider by the bureau pursuant to recommendation of the HCQAAC shall be conducted in accordance with rule 4123-6-17 of the Administrative Code;

(4) Review of any of the bureau's managed care organizations' professional performance and conduct regarding the management of medical services for the bureau. This may include interfacing with any quality assurance committee of any of the individual managed care organizations.

The HCQAAC may make such recommendations as it deems necessary to address any medical quality assurance issue impacting the bureau.

(G) The HCQAAC shall hold at least quarterly meetings. The HCQAAC and all subcommittees shall keep written records of the agenda and minutes of each meeting. The records of all committees shall remain in the custody of the chief medical officer.

(H) The HCQAAC shall submit an annual report of its activities and recommendations to the administrator. In addition to inclusion in the annual report, all recommendations from the HCQAAC and subcommittees shall be submitted to the chief medical officer in a timely fashion upon completion and approval by the respective subcommittees and HCQAAC committee.

(I) Each member of the HCQAAC and its respective subcommittees may be paid such fees as approved by the administrator or administrator's designee. The expenses incurred by the HCQAAC and its subcommittees and the fees of their members shall be paid in the same manner as other administrative costs of the bureau.

Effective: 11/13/15
Prior Effective Dates: 1/27/97, 1/15/99, 6/1/05, 1/10/11

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Stakeholder Feedback Recommendations for OAC 4123-6-02.7, 4123-6-21.2, 4123-6-21.7, 4123-6-22 Opioid Prescribing, Peer Review and Provider Decertification Rules

Line #	Rule #/ Subject Matter	Stakeholder	Draft Rule Suggestions	Stakeholder Rationale	BWC Response	Resolution
1	OAC 4123-6-21.7	Julie L. Ehemann, R.Ph Commissioner, Shelby County	Commended BWC on the effort to rein in overuse of opioids and to support weaning of patients who are receiving them, in order for the patient to return to work. Asked about mandates that would require physicians to communicate any changes in drug regimen to the patient. Also asked why there was no monetary penalty being assessed against prescribers who did not follow the rule.		Thanked Commissioner Ehemann for her support. Explained that BWC had no authority to levy a monetary penalty against prescribers who do not comply with the rule. Also explained that BWC cannot mandate specific communications between a prescriber and their patient.	None required
2	OAC 4123-6-21.7	John Van Doorn Ohio Association for Justice	The Ohio Association for Justice consulted with a pain management physician to provide comments on the rule. The physician agreed with much of the		Thanked Mr. Van Doorn as well as the physician reviewer for their comments regarding the proposed rule. Explained that our referral triggers were taken	None required

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			rule but recommended a requirement for an earlier referral to a pain management specialist. He recommended a referral trigger based on both a shorter time frame as well as a lower daily opioid dose.		from published national and Ohio guidelines. BWC felt that such verifiable public sources provided the best foundation for our rule.	
3	OAC 4123-6-21.7	Ernest Boyd, R.Ph., MBA Executive Director Ohio Pharmacists Association	The Ohio Pharmacists Association did not have any problems with the rule a proposed but did have questions regarding implementation. Specifically whether the rule would apply to only new injured workers. What would the role of the Prescription Benefit Manager (PBM) be in applying the rule? Would a Prior Authorization (PA) request be needed in order for a prescriber to go beyond the stated daily opioid loads?		Thanked Mr. Boyd for his comments and questions. Responded that the rule would apply to all injured workers, but noted that paragraph G gives the Administrator the ability to exclude claims based on specific clinical situations. Explained that the PBM would only block payment of prescriptions in the claim after an extensive communication process between BWC, the injured worker and the prescriber. Additionally if reimbursement for a prescription were blocked under this rule, the pharmacist would receive an electronic message explaining why. Further	None required

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					explained that the PA process was not involved with application of this rule.	
4	OAC 4123-6-21.7	Stephen Northrup Rampy Northrup LLC Washington DC and Srinivas G. Rao MD, PhD, Chief Medical Officer Depomed, Inc.	Dr. Rao's letter indicates that Depomed supports the efforts of BWC to incorporate best clinical practices into the treatment of injured workers. However, he indicates that Depomed takes exception to the use of Morphine Equivalent Dose (MED) as a measure of daily opiod load. The company feels that use of this metric could result in an underdosing of their tapentadol product.		Thanked both Mr. Northrup and Dr. Rao for their support. Explained that national opioid prescribing guidelines, clinical literature as well as FDA package inserts clearly state that a patient's daily opioid load as measured by an aggregate MED is not an appropriate metric for conversion between different opioids. The specific pharmacological attributes of each medication and dosage form must always direct the clinical decision making process. Our rule references the MED metric purely from the intent to trigger a review and evaluation of the patient's drug regimen by the clinician, certainly not to direct selection of one medication over another.	None required

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5	OAC 4123-6-21.7	Matthew S. Whitehead, Director Legislative Affairs Governmental Policy Group, Inc.	Mr. Whitehead indicated that their client Pfizer, Inc had no issues with the proposed opiate prescribing rule.		Thanked Mr. Whitehead for his comment.	None required