04 NCAC 10M .0101 is proposed for adoption as follows:

CHAPTER 10 - INDUSTRIAL COMMISSION

SUBCHAPTER 10M – RULES FOR THE UTILIZATION OF OPIOIDS, RELATED PRESCRIPTIONS, AND PAIN MANAGEMENT TREATMENT IN WORKERS' COMPENSATION CLAIMS

SECTION .0100 – GENERAL PROVISIONS

04 NCAC 10M .0101 PURPOSE AND APPLICABILITY OF THE RULES

(a) The Rules in this Subchapter shall apply to all claims arising under the provisions of the Workers' Compensation Act. However, Section .0200 of this Subchapter shall not apply to claims in which the employee received treatment with a targeted controlled substance for more than 12 consecutive weeks immediately preceding the effective date of the Rules.

(b) The Rules in this Subchapter apply to the prescription of targeted controlled substances as defined in Rule .0102 of this Section and the prescription of other modalities of pain management treatment for the outpatient treatment of non-cancer pain in claims in which the employer is providing medical compensation pursuant to the Workers' Compensation Act. The Rules in this Subchapter do not apply to prescriptions for medications to be administered in a health care setting.

(c) The Rules in this Subchapter are promulgated to ensure that employees are provided the services and care intended by the Workers' Compensation Act and that medical costs are adequately contained. The Rules are intended to facilitate the timely and effective delivery of appropriate medical treatment for pain management in workers' compensation claims. The Rules address the utilization of opioids, related prescriptions, and pain management treatment in workers' compensation claims. The Rules do not constitute medical advice or a standard of medical care. Disputes regarding the treatment addressed by these Rules shall be governed by G.S. 97-25 and Rule 04 NCAC 10A .0609A.

History Note: *Authority G.S. 97-25; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0102 is proposed for adoption as follows:

04 NCAC 10M .0102 DEFINITIONS

As used in this Subchapter:

(1) "Acute phase" means 12 weeks of treatment for pain following an injury by accident, occupational disease, surgery for an injury by accident or occupational disease, or subsequent aggravation of an injury by accident or occupational disease. There may be more than one acute phase during treatment for an injury or occupational disease.

(2) "Chronic phase" means continued treatment for pain immediately following a 12-week period of treatment for pain using a targeted controlled substance.

(3) "Confirmatory urine drug test" means a definitive urine drug test that verifies the results of a presumptive urine drug test. A confirmatory urine drug test identifies individual drugs and drug metabolites. Health care providers shall use a confirmatory drug test for the lowest number of drug classes necessary based on the results of the presumptive urine drug test, not to exceed 21 drug classes.

(4) "CSRS" means the Controlled Substances Reporting System as referenced in the North Carolina Controlled Substances Reporting System Act, Article 5E of Chapter 90 of the North Carolina General Statutes.

(5) "Long-acting opioid" or "extended-release opioid" means any targeted controlled substance that is formulated to release the drug gradually into the bloodstream or to have a long half-life for prolonged activity with an analgesic effect of 8-72 hours or longer.

(6) "Lowest effective dosage" means the lowest dose necessary to achieve the clinical goal.

(7) "Morphine equivalent dose" means conversion of various opioids to an equivalent morphine dose by using the most current conversion guidelines provided by the Centers for Disease Control and Prevention ("CDC"). The CDC Opioid Prescribing Guideline Mobile App and the CDC's guidelines for Calculating Total Daily Dose of Opioids for Safer Dosage are hereby incorporated by reference, including any subsequent amendments or editions. These materials are available online at no additional cost at https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf and https://www.cdc.gov/drugoverdose/pdf/App_Opioid_Prescribing_Guideline-a.pdf.

(8) "Opioid antagonist" means the term as defined in G.S. 90-12.7(a).

(9) "Pain" means pain resulting from an injury by accident or occupational disease.

(10) "Presumptive urine drug test" means an initial urine drug test that identifies negative specimens and presumptive positive specimens, and is interpreted through visual examination. Examples include dipstick tests and drug test cups. A health care provider who is providing pain management treatment in the chronic phase to an employee may administer a presumptive urine drug test that is qualitative and interpreted or analyzed with instrumental or chemical assistance if

the health care provider believes, in his or her medical opinion, that a more sensitive presumptive urine drug test is appropriate and is likely to reduce the need for a confirmatory urine drug test.

(11) "Short-acting opioid" means any targeted controlled substance with a quick onset of action and short duration of analgesic activity that is formulated for dosing at intervals of two to six hours.

(12) "Targeted controlled substance" means any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d).

History Note: *Authority G.S. 90-12.7(a); 90-90; 90-91; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0103 is proposed for adoption as follows:

04 NCAC 10M .0103 WAIVER OF RULES

In the interests of justice or to promote judicial economy, the Commission may, except as otherwise provided by the rules in this Subchapter, waive or vary the requirements or provisions of any of the Rules in this Subchapter in a case pending before the Commission upon written application of a party or upon its own initiative. Factors the Commission shall use in determining whether to grant the waiver are:

(1) the necessity of a waiver;

(2) the party's responsibility for the conditions creating the need for a waiver;

(3) the party's prior requests for a waiver;

(4) the precedential value of such a waiver;

(5) notice to and opposition by the opposing parties; and

(6) the harm to the party if the waiver is not granted.

History Note: *Authority G.S. 97-25; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0201 is proposed for adoption as follows:

SECTION .0200 – UTILIZATION RULES FOR OPIOID AND OTHER PHARMACOLOGICAL PAIN MANAGEMENT TREATMENT

04 NCAC 10M .0201 FIRST PRESCRIPTION OF MEDICATION FOR PAIN IN AN ACUTE PHASE

(a) This Rule applies to the first prescription of any medication to an employee for pain in an acute phase.

(b) Before prescribing a targeted controlled substance, a health care provider shall document his or her medical opinion in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the employee's pain.

(c) A health care provider shall not prescribe more than one targeted controlled substance at the time of the first prescription. A health care provider shall not provide at the time of the first prescription any additional prescription for a targeted controlled substance to be dispensed at a later time.

(d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance necessary in his or her medical opinion to treat an employee's pain, not to exceed a five-day supply. However, the first prescription of any targeted controlled substance for post-operative pain immediately following a surgical procedure may exceed five days but shall not exceed a seven-day supply.

(e) A health care provider shall prescribe the lowest effective dosage of a targeted controlled substance, not to exceed a 50 mg morphine equivalent dose per day, using only short-acting opioids. However, a health care provider may prescribe more than a 50 mg morphine equivalent dose per day for post-operative pain immediately following a surgical procedure if the employee was being prescribed more than a 50 mg morphine equivalent dose per day for the injury or occupational disease immediately prior to surgery.

(f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.

(g) A health care provider shall not prescribe fentanyl for pain in an acute phase.

(h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.

(i) A health care provider shall not prescribe carisoprodol and a targeted controlled substance in an acute phase.

(j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to inform that health care provider of the prescription of a targeted controlled substance.

(k) A health care provider shall review the information in the CSRS pertaining to the employee for the 12-month period preceding the first prescription. The health care provider shall document in the medical record the review and any potential contraindications to prescribing a targeted controlled substance found in the CSRS.

History Note: *Authority 90-106(a3); G.S. 90-113.74C(a); 97-25; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0202 is proposed for adoption as follows:

04 NCAC 10M .0202 PRESCRIPTION OF MEDICATION FOR PAIN IN AN ACUTE PHASE FOLLOWING THE FIRST PRESCRIPTION

(a) This Rule applies to prescriptions for medication to an employee for pain during an acute phase that are written after a first prescription as described in Rule .0201 of this Section.

(b) Before prescribing a targeted controlled substance, a health care provider shall document his or her medical opinion in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the employee's pain.

(c) A health care provider shall not prescribe more than one targeted controlled substance at a time in an acute phase.

(d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance necessary in his or her medical opinion to treat an employee's pain.

(e) A health care provider shall prescribe the lowest effective dosage of a targeted controlled substance, not to exceed 50 mg morphine equivalent dose per day, using only short-acting opioids. However, the health care provider may prescribe a morphine equivalent dose higher than 50 mg per day, but not higher than 90 mg per day, after documenting the medical justification for the prescription, including a comparison of the expected benefits to the employee versus any potential risks of increasing the employee's dosage. If the health care provider prescribes a morphine equivalent dose higher than 50 mg per day in an acute phase, the health care provider shall review at all subsequent evaluations whether the employee experienced the expected benefits and consider whether to continue the higher dosage and document the medical record accordingly.

(f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.

(g) A health care provider shall not prescribe fentanyl for pain in an acute phase.

(h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.

(i) A health care provider shall not prescribe carisoprodol and a targeted controlled substance in an acute phase.

(j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to inform that health care provider of the prescription of a targeted controlled substance.

(k) A health care provider shall review the information in the CSRS pertaining to the employee for the preceding 12-month period every time the health care provider prescribes a targeted controlled substance in an acute phase. The health care provider shall document in the medical record the review and any potential contraindications to prescribing a targeted controlled substance found in the CSRS.

(l) After an employee has received the first prescription of a targeted controlled substance as described in Rule .0201 of this Section and an additional 30 days of treatment with a targeted controlled substance, the health care provider may only continue treatment with a targeted controlled substance after fulfilling the following requirements:

(1) The health care provider shall administer and document in the medical record the results of a presumptive urine drug test as defined in Rule .0102 of this Subchapter. The health care provider may meet this requirement by requiring that the employee take a random, unannounced urine drug test. If the test results are positive for non-disclosed drugs or negative for prescribed controlled substances, the health care provider shall obtain confirmatory urine drug testing as defined in Rule .0102 of this Section. Nothing herein prevents a health care provider from ordering confirmatory urine drug testing for a medical reason other than the presumptive urine drug test results if the medical reason is documented in the medical record. The health care provider may obtain the confirmatory urine drug test results before prescribing a targeted controlled substance. Alternatively, the health care provider may order a limited supply of a targeted controlled substance pending the results of the confirmatory urine drug test. The results of any confirmatory urine drug test shall be documented in the medical record.

(2) The health care provider shall administer and document in the medical record the results of a tool for screening and assessing opioid risk that has been validated by clinical studies. Examples of these tools include the following:

(A) NIDA Quick Screen V1.0 and NIDA-Modified ASSIST V2.0 (National Institute on Drug Abuse), available at https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated_2013(1).pdf;

(B) Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 (Inflexxion, Inc.), available at http://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf;

(C) SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org; and

(D) Opioid Risk Tool (ORT) (Lynn Webster, MD), available at http://agencymeddirectors.wa.gov/Files/opioidrisktool.pdf.

(3) The health care provider shall review and document in the medical record whether the information obtained by complying with Paragraph (k) of this Rule or Subparagraphs (1) or (2) of this Paragraph, or any other aspects of the employee's medical records or examination, indicate an increased risk for opioid-related harm. If the health care provider continues the prescription of a targeted controlled substance despite any increased risks identified, the health care provider shall document in the medical record the reasons justifying the continued prescription.

History Note: *Authority 97-25; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0203 is proposed for adoption as follows:

04 NCAC 10M .0203 PRESCRIPTION OF MEDICATION FOR PAIN IN A CHRONIC PHASE

(a) This Rule applies to prescriptions for medication to an employee for pain during a chronic phase.

(b) Before prescribing a targeted controlled substance, a health care provider shall document in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the employee's pain.

(c) A health care provider shall not prescribe more than one targeted controlled substance at a time in a chronic phase without documentation of justification in the medical record. A health care provider shall not prescribe more than two targeted controlled substances at a time in a chronic phase, to include no more than one short-acting opioid and one long-acting or extended-release opioid.

(d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance necessary in his or her medical opinion to treat an employee's pain.

(e) A health care provider shall prescribe the lowest effective dosage of a targeted controlled substance, not to exceed 50 mg morphine equivalent dose per day.

(1) However, the health care provider may prescribe a morphine equivalent dose higher than 50 mg per day, but not higher than 90 mg per day, after documenting the medical justification for the prescription, including a comparison of the expected benefits to the employee versus any potential risks of increasing the employee's dosage. If the health care provider prescribes a morphine equivalent dose higher than 50 mg per day in the chronic phase, the health care provider shall review at all subsequent evaluations whether the employee experienced the expected benefits and consider whether to continue the higher dosage and document the medical record accordingly.

(2) If a health care provider considers it necessary to prescribe a morphine equivalent dose higher than 90 mg per day to treat an employee's pain, the health care provider shall seek preauthorization from the employer or carrier. If the employer or carrier authorizes, or the Commission orders, authorization of a prescription of a morphine equivalent dose higher than 90 mg per day, the health care provider shall review at all subsequent evaluations whether the employee experienced the expected benefits of the increased dosage and consider whether to continue the higher dosage and document the medical record accordingly.

(f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations included in G.S. 90-90(1) or (2) without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.

(g) A health care provider shall seek preauthorization from the employer or carrier before prescribing transdermal fentanyl. A health care provider shall seek preauthorization from the employer or carrier before prescribing methadone for pain in a chronic phase.

(h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in a chronic phase.

(i) A health care provider shall seek preauthorization from the employer or carrier before prescribing carisoprodol and a targeted controlled substance in a chronic phase. A health care provider shall advise the employee of the potential risks of combining a targeted controlled substance and carisoprodol if both medications are prescribed.

(j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to inform that health care provider of the prescription of a targeted controlled substance.

(k) A health care provider shall review the information in the CSRS pertaining to the employee for the preceding 12-month period at every appointment with the employee at which a targeted controlled substance is prescribed or every three months, whichever is more frequent. The health care provider shall document in the medical record the review and any potential contraindications to prescribing a targeted controlled substance found in the CSRS.

(l) Before first prescribing a targeted controlled substance in a chronic phase, a health care provider shall administer and document in the medical record the results of a presumptive urine drug test as defined in Rule .0102 of this Subchapter.

(m) Following compliance with Paragraph (l) of this Rule, a health care provider shall administer a presumptive urine drug test as defined in Rule .0102 of this Subchapter and document the results in the medical record a minimum of two times per year and a maximum of four times per year during a chronic phase, unless additional urine drug tests are authorized by the employer or carrier at the request of the health care provider. The limitation on the number of urine drug tests to be conducted per year without authorization by the employer or carrier for additional urine drug tests shall not apply in those cases where a patient is being prescribed targeted controlled substances for the purpose of substance use disorder treatment in addition to pain management.

(n) The health care provider may meet the requirements of Paragraphs (l) and (m) by requiring that the employee take random, unannounced urine drug tests.

(o) If the result of a presumptive urine drug test administered pursuant to this Rule is positive for non-disclosed drugs or negative for prescribed medications, the health care provider shall obtain confirmatory urine drug testing as defined in Rule .0102 of this Subchapter. The health care provider may obtain the confirmatory urine drug test results before prescribing a targeted controlled substance. Alternatively, the health care provider may order a limited supply of a targeted controlled substance pending the results of the confirmatory urine drug test. The results of any confirmatory urine drug test shall be documented in the medical record. Nothing herein prevents a health care provider from ordering a confirmatory urine drug test for a medical reason other than the presumptive urine drug test results if the medical reason is documented in the medical record.

(p) If an employee's medical treatment involving the prescription of targeted controlled substances is transferred to a health care provider in a different health care practice from the one that administered the opioid risk screening and assessment tool required by Rule .0202(l)(2) of this Section, the new health care provider shall administer and document in the medical record the results of a tool for screening and assessing opioid risk that has been validated by clinical studies. Examples of these tools include the following:

(1) NIDA Quick Screen V1.0 and NIDA-Modified ASSIST V2.0 (National Institute on Drug Abuse), available at https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated_2013(1).pdf;

(2) Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 (Inflexxion, Inc.), available at http://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf;

(3) SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org; and

(4) Opioid Risk Tool (ORT) (Lynn Webster, MD), available at http://agencymeddirectors.wa.gov/Files/opioidrisktool.pdf.

(q) A health care provider shall document in the medical record whether the information obtained by complying with Paragraphs (k), (l), (m), (o) or (p) of this Rule indicates an increased risk for opioid-related harm. If the health care provider continues the prescription of a targeted controlled substance despite any increased risks identified, the health care provider shall document in the medical record the reasons justifying the continued prescription.

History Note: *Authority 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0301 is proposed for adoption as follows:

SECTION .0300 – UTILIZATION RULES FOR OPIOID ANTAGONISTS

04 NCAC 10M .0301 CO-PRESCRIPTION OF OPIOID ANTAGONIST

(a) A health care provider prescribing a targeted controlled substance shall consider co-prescribing an opioid antagonist to the following:

(1) employees taking benzodiazepines and a targeted controlled substance;

(2) employees whose dosage exceeds a 50 mg morphine equivalent dose per day;

(3) employees with a history of drug overdose;

(4) employees with a history of substance use disorder;

(5) employees with a history of an underlying mental health condition that places them at an increased risk for overdose;

(6) employees with a medical condition such as respiratory disease, sleep apnea, or other comorbidities that places them at an increased risk for opioid toxicity, respiratory distress, or opioid overdose.

(b) If a health care provider prescribes an opioid antagonist pursuant to one or more of the conditions listed in Paragraph (a) of this Rule, the health care provider shall write the prescription to allow for product selection by the employer or carrier, including an intranasal formulation approved by the United States Food and Drug Administration.

History Note: *Authority 97-25.3; 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0401 is proposed for adoption as follows:

SECTION .0400 – UTILIZATION RULES FOR NONPHARMACOLOGICAL TREATMENT FOR PAIN

04 NCAC 10M .0401 NONPHARMACOLOGICAL TREATMENT FOR PAIN

A health care provider shall consider and may prescribe non-pharmacological treatments for pain. Examples of these treatments include the following physical therapy, chiropractic, acupuncture, massage, cognitive behavioral therapy, biofeedback, and functional restoration programs. The employer or carrier may request additional information from the health care provider regarding the prescribed treatment by any method allowed pursuant to the Workers' Compensation Act.

History Note: *Authority 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.

04 NCAC 10M .0501 is proposed for adoption as follows:

SECTION .0500 – UTILIZATION RULES FOR TREATMENT FOR SUBSTANCE USE DISORDER

04 NCAC 10M .0501 TREATMENT FOR SUBSTANCE USE DISORDER INVOLVING A TARGETED CONTROLLED SUBSTANCE

(a) If a health care provider believes, in his or her medical opinion, that an employee may benefit from an evaluation for discontinuation or tapering of a targeted controlled substance or for treatment for substance use disorder involving a targeted controlled substance, the health care provider may refer the employee to a health care provider specializing in such treatment for evaluation. The employer or carrier may request additional information from the health care provider regarding the referral by any method allowed pursuant to the Workers' Compensation Act.

(b) If treatment is recommended following the evaluation referenced in Paragraph (a) of this Rule, the employer or carrier may request additional information from the recommending health care provider regarding the treatment by any method allowed pursuant to the Workers' Compensation Act.

History Note: *Authority 97-25.4; 97-80(a); Session Law 2017-203, Section 4.*
Eff. May 1, 2018.