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 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. The parties may utilize the medical motion procedure in G.S. 97-25 and Rule 04 NCAC 10A .0609A if a dispute arises regarding treatment covered by these 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.

(c) The rules in this Subchapter shall apply to all claims arising under the provisions of the Workers’ Compensation Act. Notwithstanding the previous sentence, 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.

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) “Pain” means pain from an injury by accident or occupational disease.

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

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

(4) “Targeted controlled substance” means any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d).

(5) “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, available at https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html.

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

(7) “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 less than 12 hours, including but not limited to immediate-release morphine, hydromorphone, oxymorphone, codeine, hydrocodone, oxycodone, and hydromorphone. Drugs classified by the United States Food and Drug Administration as long-acting or extended release opioids are listed at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm.

(8) “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, including, but not limited to, methadone, transdermal fentanyl, and extended-release formulations of morphine, oxycodone, oxymorphone, and hydrocodone. Drugs classified by the United States Food and Drug Administration as long-acting or extended release opioids are listed at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm.

(9) “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.

(10) “Opioid antagonist” means naloxone hydrochloride that is approved by the United States Food and Drug Administration for the treatment of a drug overdose.

History Note: Authority G.S. 90-12.7(a); 90-87(26a); 90-106(a4)(1) and (2); 97-25.4; 97-80(a); Session Law 2017-203, Section 4.
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 TARGETED CONTROLLED SUBSTANCE OR OTHER MEDICATION FOR PAIN IN AN ACUTE PHASE

(a) This rule applies to the first prescription of any targeted controlled substance or other medication to an employee for pain in an acute 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 prescribe the lowest number of days’ supply of a targeted controlled substance necessary to treat an employee’s pain, not to exceed a five-day supply. Notwithstanding the previous sentence, the first prescription of any targeted controlled substance for post-operative pain immediately following a surgical procedure shall not exceed a seven-day supply.

(d) 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 short-acting opioids only.

(e) 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.

(f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in the health care provider’s medical record of the inadequacy of oral opioid dosing 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 in addition to a targeted controlled substance in an acute phase.

(j) If an employee is taking benzodiazepines or carisoprodol at the time of the first prescription of a targeted controlled substance, the health care provider shall exercise extreme caution in prescribing the targeted controlled substance to the employee and shall advise the employee of the potential risks of combining opioids 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 an opioid.

(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.

(l) Notwithstanding Paragraph (d) of this Rule, 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
already being prescribed more than a 50 mg morphine equivalent dose per day for the injury or occupational disease immediately prior to surgery.

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 TARGETED CONTROLLED SUBSTANCE OR OTHER MEDICATION IN AN ACUTE PHASE FOLLOWING THE FIRST PRESCRIPTION

(a) This rule applies to prescriptions for targeted controlled substances or other medication 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 in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the employee’s pain when prescribing a targeted controlled substance to an employee.
(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 to treat an employee’s pain, not to exceed the prescription of one 30-day supply at a time.
(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 short-acting opioids only.
(f) Notwithstanding Paragraph (e) of this Rule, 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 therefor, including, but not limited to, 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 shall consider whether to continue the higher dosage and shall document the medical record accordingly.
(g) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in the prescribing health care provider’s medical record of the inadequacy of oral opioid dosing for the employee.
(h) A health care provider shall not prescribe fentanyl for pain in an acute phase.
(i) 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.
(j) 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 minimum requirements:

(1) The health care provider shall administer and document in the medical record the results of a presumptive urine drug test. The health care provider shall use a presumptive urine drug test that
is billed using the American Medical Association’s Current Procedural Terminology code 80305 or its successor. 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 controlled substances or other potentially harmful drugs or negative for prescribed controlled substances, the health care provider shall obtain confirmatory urine drug testing. A health care provider may also order 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 shall use a confirmatory urine drug test that is billed using the Centers for Medicare and Medicaid’s Healthcare Common Procedure Coding System code G0480, G0481, or G0482 only. The health care provider shall consider whether to obtain the confirmatory 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 test. The results of any confirmatory 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 clinically validated tool for screening and assessing opioid risk, such as one of 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; or

(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 (i) 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.

(k) A health care provider shall not prescribe carisoprodol in addition to a targeted controlled substance in an acute phase.

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

(m) If an employee is taking benzodiazepines or carisoprodol at the time of a prescription of a targeted controlled substance, the health care provider shall exercise extreme caution in prescribing the targeted controlled substance to the employee and shall advise the employee of the potential risks of combining opioids 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 an opioid.
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 TARGETED CONTROLLED SUBSTANCE OR OTHER MEDICATION IN A CHRONIC PHASE

(a) This rule applies to prescriptions for targeted controlled substances or other medication 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 when prescribing a targeted controlled substance to an employee.

(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 not prescribe more than a 30-day supply of a targeted controlled substance at a time in the chronic phase.

(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.

(f) Notwithstanding Paragraph (e) of this Rule, 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 therefor, including, but not limited to, 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 any subsequent evaluations whether the employee experienced the expected benefits and shall consider whether to continue the higher dosage and shall document the medical record accordingly.

(g) Notwithstanding Paragraphs (e) and (f) of this Rule, 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 shall consider whether to continue the higher dosage and shall document the medical record accordingly.

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

(i) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in the prescribing health care provider’s medical record of the inadequacy of oral opioid dosing for the employee. A health care provider shall seek preauthorization from the employer or carrier before prescribing transdermal fentanyl.
(j) A health care provider shall review the information in the CSRS pertaining to the employee for the preceding 12-month period at least as often as every appointment with the employee 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.

(k) 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. The health care provider may meet this requirement by requiring that the employee take a random, unannounced urine drug test. If the test result is positive for non-disclosed controlled substances or other potentially harmful drugs or negative for prescribed controlled substances, the health care provider shall obtain confirmatory urine drug testing. A health care provider may also order 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 shall consider whether to obtain the confirmatory 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 test. The results of any confirmatory test shall be documented in the medical record.

(l) Following compliance with Paragraph (k) of this Rule, a health care provider shall administer a presumptive urine drug test 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 health care provider may meet this requirement by requiring that the employee take random, unannounced urine drug tests. If a presumptive test result is positive for non-disclosed controlled substances or other potentially harmful drugs or negative for prescribed medications, the health care provider shall obtain confirmatory urine drug testing. The health care provider shall consider whether to obtain the confirmatory 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 test. The results of any confirmatory test shall be documented in the medical record.

(m) A presumptive urine drug test administered pursuant to Paragraphs (k) or (l) of this Rule shall be a presumptive urine drug test that is billed using the American Medical Association’s Current Procedural Terminology code 80305 or its successor. Notwithstanding the previous sentence, a health care provider who is providing primarily pain management treatment to an employee may administer a presumptive urine drug test that is billed using the American Medical Association’s Current Procedural Terminology code 80306 or 80307 or their successors if the health care provider believes a more sensitive presumptive urine drug test is appropriate and may reduce the need for a confirmatory urine drug test. A confirmatory urine drug test administered pursuant to Paragraphs (k) or (l) of this Rule shall be a confirmatory urine drug test that is billed using the Centers for Medicare and Medicaid Services’ Healthcare Common Procedure Coding System code G0480, G0481, or G0482.

(n) 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 Subparagraph (2) of Paragraph (j) of Rule .0202 of this Section, the new health care
provider shall administer and document in the medical record the results of a clinically validated tool for screening and assessing opioid risk, such as one of 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;
3. SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org;

(o) A health care provider shall document in the medical record whether the information obtained by complying with Paragraphs (j), (k), (l), and/or (n) 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.

(p) A health care provider shall seek preauthorization from the employer or carrier before prescribing carisoprodol in addition to a targeted controlled substance in a chronic phase.

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

(r) If an employee is taking benzodiazepines or carisoprodol at the time of a prescription of a targeted controlled substance, the health care provider shall exercise extreme caution in prescribing the targeted controlled substance to the employee and shall advise the employee of the potential risks of combining opioids 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 an opioid.

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 employees:

(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 whose prescribing health care provider is aware 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, to include 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 including, but not limited to, 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 DEPENDENCE ON OR ADDICTION TO A TARGETED CONTROLLED SUBSTANCE

04 NCAC 10M .0501 TREATMENT FOR DEPENDENCE ON OR ADDICTION TO A TARGETED CONTROLLED SUBSTANCE

(a) If a health care provider believes that an employee may benefit from an evaluation for discontinuation or tapering of a targeted controlled substance or treatment for dependence or addiction to a targeted controlled substance, the health care provider may refer the employee to an appropriate health care provider 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.