Companion Guide to the North Carolina Industrial Commission Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management in Workers' Compensation Claims

Adopted by the North Carolina Industrial Commission

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North Carolina Industrial Commission

Important Note

The North Carolina Industrial Commission would like to thank the members of the North Carolina Workers' Compensation Opioid Task Force who generously volunteered their time and expertise to help research, discuss, and provide recommendations for rules and guidelines for opioid use, related prescriptions, and pain management in workers' compensation claims.

The North Carolina Industrial Commission is also grateful to the other states who shared their expertise and insights on opioid rules and guidelines for workers' compensation claims, particularly Dr. Robert B. Snyder, M.D., Medical Director at the Tennessee Bureau of Workers' Compensation, Dr. Jaymie Mai, Pharm.D., Pharmacy Manager at Washington State Department of Labor & Industries, Dr. Stephen T. Woods, M.D., former Chief Medical Officer at the Ohio Bureau of Workers' Compensation, Johnnie L. Hanna, R.Ph., M.B.A., former Pharmacy Program Director at the Ohio Bureau of Workers' Compensation, Dr. Nicholas D. Trego, Pharm.D., R.Ph., Interim Pharmacy Director at the Ohio Bureau of Workers' Compensation, and Jacqueline Kurth, Manager of the Medical Resource Office at the Industrial Commission of Arizona.

The North Carolina Industrial Commission also reviewed and studied the opioid and pain management rules and guidelines of many other states, including Arizona, California, Colorado, Connecticut, Delaware, Louisiana, Massachusetts, Minnesota, New York, Ohio, Oregon, Tennessee, Washington, and West Virginia.

Purpose of the Companion Guide to the Industrial Commission Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management in Workers' Compensation Claims

This Companion Guide is intended to assist employees, employers, carriers, health care providers, pharmacists, attorneys, and other stakeholders in the North Carolina workers' compensation system in understanding and implementing the Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management in Workers' Compensation Claims. This Companion Guide does not cover every aspect of the Rules, but rather provides guidance on rule provisions or topics as deemed necessary by the North Carolina Industrial Commission. The Companion Guide also contains some additional guidelines established by the North Carolina Industrial Commission that are not contained in, but complement, the Rules.

Reading this Companion Guide is **not** a substitute for reviewing the Rules for Utilization of Opioids, Related Prescriptions, and Pain Management in Workers' Compensation Claims in detail.

Documentation Change Control

The Companion Guide content is subject to change. Documentation change control is maintained in this document through the Change Control Table shown below. Each change made to this Companion Guide after the adoption date is noted, along with the date and reason for the change.

Change Control Table			
Date	Page(s)	Change	Reason
June 2018	All	Citations	Recodification of NCIC Rules from 04 NCAC 10 to 11 NCAC 23

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Methodology for Updating Companion Guide Document

Please contact the Industrial Commission's Rulemaking Coordinator regarding instructions for submitting change requests, recommendations, and document updates.

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Executive Summary

In Session Law 2017-203, Section 4.(a), the General Assembly directed the North Carolina Industrial Commission ("Industrial Commission" or "Commission") to adopt rules and guidelines for the utilization of opioids, related prescriptions, and pain management treatment. After several months of research, stakeholder collaboration, and preliminary public comment, the Industrial Commission developed rules in response to the General Assembly's directive. The Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management in Workers' Compensation Claims ("Opioid Utilization Rules" or "Rules"), effective May 1, 2018,[1] were adopted into the North Carolina Administrative Code in conformance with the North Carolina Administrative Procedure Act. See the Rules at Exhibit A. The Industrial Commission developed this Companion Guide to assist with the implementation and application of the Rules. As such, the information set forth in this Companion Guide is intended to supplement the Opioid Utilization Rules.

Similar to the Opioid Utilization Rules, this Companion Guide was drafted with consideration to the North Carolina STOP Act (Session Law 2017-74), the Centers for Disease Control and Prevention ("CDC") Guidelines for Prescribing Opioids for Chronic Pain, other professional opioid guidelines, and the opioid utilization rules and guidelines promulgated by other states for workers' compensation claims.

Neither the Opioid Utilization Rules, nor this Companion Guide, are intended to replace physician expertise and professional medical judgment. The Rules and this Companion Guide 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 and this Companion Guide are intended to facilitate the timely and effective delivery of appropriate medical treatment for pain in workers' compensation claims. The Rules and this Companion Guide do not constitute medical advice or a standard of medical care.

Chapter 1 provides an introduction to the Opioid Utilization Rules and this Companion Guide and addresses several aspects of the purpose and application of the Rules. This chapter explains which claims are affected by the Rules and provides guidelines for transitioning ongoing treatment into compliance with the Rules. Issues relating to communication with health care providers about the Rules are also addressed. Lastly, this chapter provides guidelines for the implementation

[1] Please note that while the Rules go into effect on May 1, 2018, the requirements related to reviewing the Controlled Substances Reporting System in 11 NCAC 23M .0201(k), .0202(k), and .0203(k) have a specific effective date of November 1, 2018 or the date of application of Session Law 2017-74, Section 15.(e), whichever is earlier.

of Rules 11 NCAC 23M .0101-.0103, which apply to all workers' compensation claims.

Chapter 2 reviews and provides guidelines for Section .0200 of the Rules, which encompasses the utilization rules for opioids and other medications for pain. In particular, this chapter covers the first prescription, acute phase, and chronic phase by rule topic, highlighting the differences between the rules for each phase. In addition to the text of Chapter 2, Exhibit B to the Companion Guide provides a one-page reference table for Rules 11 NCAC 23M .0201-.0203.

Chapter 3 addresses Rule 11 NCAC 23M .0301 regarding the co-prescription of an opioid antagonist and offers additional details regarding the requirement for a health care provider to consider co-prescribing an opioid antagonist under certain conditions. The information in this Chapter is applicable to all workers' compensation claims, regardless of the date of injury or whether there has been a period of treatment with a targeted controlled substance.

Chapter 4 reviews Rule 11 NCAC 23M .0401 and elaborates on the requirement for consideration of non-pharmacological treatments for pain. The information in this Chapter is applicable to all workers' compensation claims, regardless of the date of injury or whether there has been a period of treatment with a targeted controlled substance. The Rule includes a list of examples of non-pharmacological treatments for pain, but providers are not limited to the examples listed. To facilitate communication between the health care provider and the parties, Exhibit C to the Companion Guide provides a non-mandatory form that may be used to request additional information as allowed in the Rule.

Chapter 5 discusses Rule 11 NCAC 23M .0501 which addresses treatment for substance use disorder involving a targeted controlled substance. The information in this chapter is applicable to all workers' compensation claims, regardless of the date of injury or whether there has been a period of treatment with a targeted controlled substance. To facilitate communication between the health care provider and the parties, Exhibits D and E provide two non-mandatory forms that may be used to request additional information as allowed in the Rule.

The complete guidelines are set forth in the Companion Guide and all Exhibits attached hereto.

Chapter One
Introduction and Application

1.1 Authority

The North Carolina Industrial Commission is a quasi-judicial administrative agency created by statute to administer the North Carolina Workers' Compensation Act (Chapter 97 of the North Carolina General Statutes). The Industrial Commission has exclusive jurisdiction over claims arising under the Workers' Compensation Act. In addition to administering and adjudicating the claims, the Industrial Commission has the authority to make rules as needed to implement the Workers' Compensation Act. Pursuant to N.C. Gen. Stat. § 97-25.4, the Industrial Commission may adopt utilization rules and guidelines for medical treatment in workers' compensation claims.

In Session Law 2017-203, the North Carolina General Assembly directed the Industrial Commission to "adopt rules and guidelines, consistent with N.C. Gen. Stat. § 97-25.4, for the utilization of opioids, related prescriptions, and pain management treatment." Using its authority and in accordance with the legislative directive, the Industrial Commission engaged in formal rulemaking to develop permanent rules and created this Companion Guide to the Rules to assist with rule implementation and provide additional guidelines.

1.2 Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment

The Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims were adopted into the North Carolina Administrative Code and became effective May 1, 2018. The Opioid Utilization Rules, which are cited as 11 NCAC 23M .0101-.0501, are available in the North Carolina Administrative Code. The Rules, which are quoted in part throughout, may also be found in Exhibit A of this Companion Guide. The Rules are law and are mandatory for the claims to which they apply. (See Section 1.4 for guidance regarding application of the Rules.)

The list of Rules with their citations and titles are below:

11 NCAC 23M .0101	Purpose and Applicability of the Rules
11 NCAC 23M .0102	Definitions
11 NCAC 23M .0103	Waiver of Rules
11 NCAC 23M .0201	First Prescription of Medication for Pain in an Acute Phase
11 NCAC 23M .0202	Prescription of Medication for Pain in an Acute Phase following the First Prescription
11 NCAC 23M .0203	Prescription of Medication for Pain in a Chronic Phase
11 NCAC 23M .0301	Co-Prescription of Opioid Antagonist
11 NCAC 23M .0401	Non-Pharmacological Treatment for Pain
11 NCAC 23M .0501	Treatment for Substance Use Disorder Involving a Targeted Controlled Substance

1.3 Companion Guide to the Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims

This Companion Guide to the North Carolina Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims was developed to assist with the implementation and understanding of the Rules and to provide additional guidelines regarding opioids, related prescriptions, and pain management. The information and guidelines in this Companion Guide are intended as guidance and recommendations, but they are not rules.

1.4 Purpose and Application of the Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims

Rule 11 NCAC 23M .0101 addresses the purpose and application of the Opioid Utilization Rules.

1.4.1 What is the purpose of the Opioid Utilization Rules?

The Rules were developed to address the problems that can arise at the intersection of the current opioid epidemic and related issues in workers' compensation claims. The Rules are proactive measures aimed at curtailing opioid misuse and addiction in workers' compensation claims, which can lead to poor physical and mental health outcomes, prolonged disability from work and other life activities, overdose, and death. The Rules encourage the use of non-opioid and non-pharmacological means of treating pain, as well as the evaluation and treatment of employees with substance use disorder.

The Rules 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 also intended to facilitate the timely and effective delivery of appropriate medical treatment for pain management in workers' compensation claims. Patient safety is a priority of the Industrial Commission on behalf of the State of North Carolina for any treatment received for a work-related injury.

1.4.2 To whom do the Rules apply? Which Rules apply to which employees?

Rule 11 NCAC 23M .0101(a) states that the Opioid Utilization Rules shall apply to all claims, <u>but</u> that Rules 11 NCAC 23M .0201-.0203 (rules regarding the prescription of opioids and other medications for pain) shall not apply to claims in which the employee received treatment with a targeted controlled substance (Schedule II or III opioid) <u>for more than 12 consecutive weeks immediately prior</u> to the effective date of May 1, 2018.

If an employee received 12 or fewer consecutive weeks of treatment with a targeted controlled substance immediately prior to May 1, 2018, then <u>all</u> of the Rules apply to that employee's claim.

If an employee received more than 12 consecutive weeks of treatment with a targeted controlled substance immediately prior to May 1, 2018, the following Rules apply to that employee's claim:

11 NCAC 23M .0101	Purpose and Applicability of the Rules
11 NCAC 23M .0102	Definitions
11 NCAC 23M .0103	Waiver of Rules
11 NCAC 23M .0301	Co-Prescription of Opioid Antagonist

11 NCAC 23M .0401	Non-Pharmacological Treatment for Pain
11 NCAC 23M .0501	Treatment for Substance Use Disorder Involving a Targeted Controlled Substance

The date of February 6, 2018, is 12 weeks prior to May 1, 2018. Please see the illustrative examples below:

Example 1: Worker A was injured on or after February 6, 2018.

All of the Rules apply to Worker A.

Example 2: Worker B was injured before February 6, 2018. Worker B saw a physician for the injury and was first prescribed a targeted controlled substance on or after February 6, 2018.

All of the Rules apply to Worker B.

Example 3: Worker C was injured before February 6, 2018. Worker C saw a physician for the injury and was prescribed a targeted controlled substance before February 6, 2018. Worker C continued to receive treatment with a targeted controlled substance through May 1, 2018.

Rules .0101, .0102, .0103, .0301, .0401, .0501 apply to Worker C. Rules .0201, .0202, and .0203 (limitations on prescription of pain medication) do not apply to Worker C.

Example 4: Worker D was injured before February 6, 2018. Worker D was prescribed a targeted controlled substance for over 12 consecutive weeks, but not during all of the period from February 6 to May 1, 2018.

All of the Rules apply to Worker D.

1.4.3 Transitioning Ongoing Treatment into Compliance with the Rules

If an employee received 12 or fewer consecutive weeks of treatment with a targeted controlled substance immediately prior to May 1, 2018, then all of the Rules apply to that employee's claim.[2] There will be situations where a health care provider has been treating an employee with a targeted controlled substance for some duration less than 12 consecutive weeks immediately prior to the effective date of the Rules. For those claims, all of the Rules would then need to be applied to the prospective treatment of that employee. However, if the treatment for that employee in the time prior to May 1, 2018, went beyond the limitations set in the Rules, then the prescriber should consider the safest effective measures to wean the employee into compliance with the Rules as soon as possible within a reasonable period of time. This determination should be case-specific with the best interest of the injured worker in mind.

The Industrial Commission recommends that the treatment of that employee come into compliance with the Rules within 6 months. Examples of when this situation may arise include prescriptions of targeted controlled substances higher than the MED limits established in the Rules, prescriptions of long acting opioids in an acute phase, and prescriptions of various drug combinations which would not be allowed under the Rules.

[2] See Footnote 1 regarding the effective date of the Rules and the specific effective date for the requirements regarding the Controlled Substances Reporting System.

1.4.4 "Legacy" Claims

As discussed in Section 1.4.2, Rules .0101-.0103 and .0301-.0501 apply to all claims, which includes claims in which an employee received a prescription for a targeted controlled substance for more than 12 consecutive weeks prior to May 1, 2018. Therefore, all health care providers treating workers' compensation patients should be familiar with the Rules. In particular, Rule .0301 allows for the prescription of Naloxone and Rule .0401 addresses non-pharmacological modalities of treatment for pain. Rule .0501 also addresses evaluation and treatment for substance use disorder. Rules .0401 and .0501 may assist in reducing or discontinuing the use of a targeted controlled substance.

Even though Rules .0201-.0203 do not apply to claims where the employee received treatment with a targeted controlled substance for more than 12 consecutive weeks immediately preceding May 1, 2018, the Industrial Commission encourages health care providers to review each workers' compensation patient individually to determine whether there is a safe and effective way to transition the "legacy" patient to treatment consistent with the spirit of the Rules. Providers are encouraged to consider tapering or weaning employees on high doses of a targeted controlled substance down to the safest effective levels or off the targeted controlled substance in their professional medical judgment based upon an assessment of improvements in pain, function, and quality of life.

1.4.5 In what settings do the Rules apply?

Rule 11 NCAC 23M .0101(a) states that the Opioid Utilization Rules shall apply to the prescription of targeted controlled substances and other modalities of pain management for the outpatient treatment of non-cancer pain and shall not apply to prescriptions to be administered in a health care setting.

> Example: Worker E did not have 12 consecutive weeks of treatment with a targeted controlled substance immediately prior to May 1, 2018. Therefore, all of the Rules apply to Worker E.
>
> Worker E has surgery for a non-cancer-related work injury at a health care facility.
>
> The Rules do not apply to any pain medications administered to Worker E at the facility before, during, or after surgery.
>
> The Rules do apply to any prescriptions for pain given to Worker E to be taken after leaving the facility or hospital.

1.4.6 What if a provider does not know about the work-related nature of the injury?

There may be situations in which an employee is injured and receives treatment for pain before the health care provider, or even the employee or employer, knows that the injury is or may be work related. These situations can be problematic if the health care provider's treatment does not comply with one or more of the Rules. Examples of such situations include prescriptions of a targeted controlled substance that exceed the MED limits established in the Rules, prescriptions of long-acting opioids for acute pain, and prescriptions of various drug combinations that would not be allowed under the Rules. In such situations, once the health care provider is aware of the workers' compensation injury, the provider should consider the safest effective measures to bring the

employee's treatment into compliance with the Rules within a reasonable period of time, ideally within 6 months or less. See also Section 1.4.3.

1.4.7 What if the provider does not know about the Rules?

In most cases, adherence to these Rules will be monitored by the employer/carrier through its authorization of treatment. There may be situations in which the health care provider is not aware of the Rules, or is not fully aware of all the requirements in the Rules. The following two sections provide guidance for communications with the health care provider and the injured worker in these contexts.

1.4.7.1 Communications by the Employer or Carrier

In order to facilitate efficient and timely treatment, a carrier or employer may, for purposes of education and awareness, provide the health care provider with a copy of or electronic URL link to the Rules, the Companion Guide, and any Exhibits attached hereto. However, in providing these materials, if the carrier or employer makes any interpretive statements, tailors the communication in any way to the treatment in a specific case, or makes any other request for information, then the communication may be subject to the requirements of N.C. Gen. Stat. § 97-25.6.

Furthermore, should a controversy arise regarding the application of the Rules in a workers' compensation claim, at that point in communications between the payer and the health care provider, the employee should also be provided a copy of or electronic URL link to the Industrial Commission Rules, the Companion Guide, and any Exhibits attached hereto.

1.4.7.2 Communications by the Rehabilitation Professional

In order to facilitate efficient and timely treatment related to the Rules, a rehabilitation professional may communicate with the health care provider as permitted by the Rules for Utilization of Rehabilitation Professionals in Workers' Compensation Claims (11 NCAC 23C). Nothing in the Opioid Utilization Rules changes what a rehabilitation professional is permitted to do pursuant to 11 NCAC 23C.

For example, if a rehabilitation professional is present at an appointment where a health care provider writes an opioid prescription that may exceed the prescription limitations of the Rules and, therefore, may not be authorized by the employer or carrier, the rehabilitation professional may inquire as to whether the health care provider is aware of the Rules, and if not, provide a copy of or an electronic URL link to the Rules, the Companion Guide, and any Exhibits attached hereto to the provider and the employee. The rehabilitation professional may inform the provider and employee of any potential issues that may arise with regard to employer or carrier authorization of the prescription.

Similarly, if a health care provider appears to be unaware of certain requirements in the Rules, such as review of the Controlled Substances Reporting System ("CSRS") and/or urine drug testing, preauthorization, or documentation of medical justification in the medical record, the rehabilitation professional may provide a copy of the Rules to the provider and employee and indicate any potential issues with authorization of a prescription.

If the rehabilitation professional provides a copy of the Rules outside of a joint meeting with the employee and the health care provider, the rehabilitation professional must notify the employee as required by 11 NCAC 23C. Provision of the Rules to the health care provider should also be reflected in the rehabilitation professional's reports to the parties. The rehabilitation professional

should provide only an unaltered and complete copy of the Rules, the Companion Guide, and any Exhibits attached hereto. A copy should be provided to the employee contemporaneously, and, when possible, by the same means.

1.4.8 What if there is a dispute about appropriate treatment under the Rules?

There may be situations in which the treating health care provider orders a prescription or other pain treatment and the order is not authorized by the employer or carrier. The lack of authorization may be for a variety of reasons. In most cases, additional medical documentation or communication between the parties can resolve the issue. If the issue cannot be resolved, the employee is entitled to file a motion for medical treatment with the Industrial Commission to request an Order authorizing the denied treatment. The employer or carrier is entitled to respond to the motion within a certain period of time. The procedures for medical motions and emergency medical motions are outlined in N.C. Gen. Stat. § 97-25(f) and Rule 11 NCAC 23A .0609A. Such medical motions may be filed with the Industrial Commission in the manner directed in Rules 11 NCAC 23A .0108 and.0609A.

The Rules do not prohibit a carrier from filling a prescription up to the dosage limits in the Rules if the prescription, as written, exceeds the limitations in the Rules. The carrier may then request medical documentation justifying the dosage. The parties should communicate and attempt to resolve such issues in a timely manner.

> Example: The provider prescribes a targeted controlled substance at 90 mg MED/day in an acute phase (after the first prescription). The carrier may authorize filling the prescription at 50 mg MED/day until it obtains documentation of the medical justification for the higher dosage.

Further, an employer or carrier may authorize treatment outside of the Rules based on medical documentation and communication with the health care provider. Nothing in the Rules prevents the parties from reaching an agreement for safe recommended treatment outside the Rules. It is recommended that documentation of such an agreement be preserved in writing by the parties (employee and employer/carrier).

1.5 Definitions of Important Terms Used in the Opioid Utilization Rules

Rule 11 NCAC 23M .0102 provides definitions for important terms as used throughout the Opioid Utilization Rules. Below is a list of the terms defined.

(1) Acute phase
(2) Chronic phase
(3) Confirmatory urine drug test
(4) CSRS
(5) Long-acting opioid
(6) Lowest effective dosage
(7) Morphine equivalent dose
(8) Opioid antagonist
(9) Pain
(10) Presumptive urine drug test
(11) Short-acting opioid
(12) Targeted controlled substance

Most of the definitions provided in Rule 11 NCAC 23M .0102 do not require supplementary guidance. However, additional information is provided for the following provisions:

- **Rule 11 NCAC 23M .0102(1), Acute Phase, and Rule 11 NCAC 23M .0102(2), Chronic Phase**

  "'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." [emphasis added]

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

  To illustrate a scenario including more than one acute phase of treatment, please see the example below.

  Example:

  Day 1: "First Prescription"

  Date of injury or some date after date of injury when Worker F is treated and receives first prescription of 5-day supply of targeted controlled substance.

  Days 1-84: Acute Phase

  Worker F continues to be prescribed a targeted controlled substance for 12 weeks after the first prescription.

  Day 85+: Chronic Phase

  Worker F continues to be prescribed a targeted controlled substance for more than 12 consecutive weeks.

  Day 150: Treatment with a targeted controlled substance ends because Worker F does not need it anymore or another modality for pain is attempted.

  Day 180: Worker F experiences a reaggravation of the injury or the trial of another pain modality is determined unsuccessful such that the health care provider issues a new prescription for a targeted controlled substance. This is a new "first prescription."

  Days 180-263: Acute Phase

  Worker F continues to be prescribed a targeted controlled substance for 12 weeks after the first prescription.

  Day 264+: Chronic Phase

Worker F continues to be prescribed a targeted controlled substance for more than 12 consecutive weeks.

- **Rule 11 NCAC 23M .0102(3), Confirmatory Urine Drug Test**

  The current Centers for Medicare and Medicaid Services ("CMS") Healthcare Common Procedure Coding System("HCPCS") codes for the confirmatory urine drug tests referenced in 11 NCAC 23M .0102(3) are G0480 (1-7 drug classes), G0481 (8-14 drug classes), and G0482 (15-21 drug classes). The Rule directs the health care provider to use the test for the lowest number of drug classes necessary. HCPCS code G0483 (22+ drug classes) is not included in the definition of confirmatory urine drug test for the purposes of the Opioid Utilization Rules. If a health care provider feels that urine drug testing with HCPCS code G0483 is medically necessary in relation to pain management or opioid use for a workers' compensation claimant, the provider may contact the employer or carrier regarding authorization.

  The billing codes cited in this guideline will be updated in the future if they are changed by CMS.

- **Rule 11 NCAC 23M .0102(7), Morphine Equivalent Dose**

  "'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."

  Health care providers are encouraged to download and use the CDC's Mobile Application. Health care providers may also find helpful information on calculating opioid dosages here. These materials include an estimated conversion chart of the most commonly prescribed opioids as illustrated below.[3]

Calculating morphine milligram equivalents (MME)

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

[3] The conversion chart is from "Calculating Total Daily Dose of Opioids for Safer Dosage," U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, available at https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

- **Rule 11 NCAC 23M .0102(10), Presumptive Urine Drug Test**

  The current American Medical Association ("AMA") Current Procedural Terminology ("CPT") code for the presumptive urine drug test required by the Rule is 80305. The Rule also allows for the presumptive urine drug tests with current AMA CPT codes 80306 and 80307 if the 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.

  Example: Some providers treating in the chronic phase may not consider the results of a dipstick test or drug test cup (billed with CPT 80305) to be adequate to provide appropriate treatment for a particular employee. In such situations, rather than ordering both a dipstick test and a confirmatory urine drug test, a provider may order a more sensitive presumptive urine drug test that would be billed using CPT codes 80306 or 80307 if it is likely that this testing will reduce the need to order confirmatory testing.

  The billing codes cited in this guideline will be updated in the future if they are changed by the AMA.

- **Rule 11 NCAC 23M .0102(12), Targeted Controlled Substance**

  This definition refers to Chapter 90-90(1) and (2) and Chapter 90-91(d) of the General Statutes for rulemaking format reasons. The drugs listed in those provisions may be viewed by clicking on the Chapter numbers. These provisions refer specifically to Schedule II and Schedule III opioid drugs. The phrase "targeted controlled substance" as used throughout the Rules and the Companion Guide means Schedule II and Schedule III opioid drugs. The phrase "opioid" is also used in the Rules and the Companion Guide where appropriate and refers to opioids in general.

1.6 Is there a way to request a waiver of the Rules?

In most cases, it is expected that the parties will be able to resolve disputes about treatment for pain and the application of the Opioid Utilization Rules or that the Industrial Commission will enter an Order resolving the dispute if requested. An employer or carrier may authorize treatment outside of the Rules based on medical documentation and communication with the health care provider. Nothing in the Rules prevents the parties from reaching an agreement for safe recommended treatment outside the Rules. It is recommended that documentation of such an agreement be preserved in writing by the parties (employee and employer/carrier). Rule 11 NCAC 23M .0103, Waiver of Rules, outlines the procedure to request a waiver of the Rules in a particular case pending before the Industrial Commission based on the circumstances in that case.

Chapter Two
Utilization Rules for Opioids and Other Pharmacological Pain Management Treatment

*(**REMINDER**: Section .0200 of the Rules and this chapter of the Companion Guide apply only to employees who received 12 or fewer consecutive weeks of treatment with a targeted controlled substance immediately prior to May 1, 2018.)*

2.1 Prescription of Medication for Pain in Acute and Chronic Phases

Rule 11 NCAC 23M .0201 addresses the **first prescription** of medication to an employee for pain in an acute phase.

Rule 11 NCAC 23M .0202 addresses prescriptions for medication to an employee for pain **in an acute phase** that are written **after a first prescription** as described in Rule 11 NCAC 23M .0201.

Rule 11 NCAC 23M .0203 addresses prescriptions for medication to an employee for pain **in a chronic phase**.

Please refer to Section 1.5 above for details about the treatment phases. Additionally, see Exhibit B for a one-page reference table illustrating a basic overview of the phases of treatment.

These guidelines only address certain parts of Rules 11 NCAC 23M .0201-.0203 where additional guidance is deemed necessary. Users are encouraged to review the Rules in detail.

2.2 Documentation Justifying Prescribing an Opioid

Paragraph (b) of Rules 11 NCAC 23M .0201-.0203 states, "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."

Providers are encouraged to specify what non-pharmacological or non-opioid treatment has been attempted or considered. Include details regarding duration and outcome of trial(s). It is acknowledged that there may be situations where trials of non-pharmacological or non-opioid treatments are not appropriate. However, in other situations, an adequate trial of non-pharmacological and/or non-opioid treatments should be attempted and documented.

See Chapter 4 regarding Rule 11 NCAC 23M .0401, Non-Pharmacological Treatment for Pain.

2.3 Dosage (MED) Limitations When Prescribing Targeted Controlled Substances

2.3.1 First Prescription in an Acute Phase

Rule 11 NCAC 23M .0201(e) states, "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, if the employee was being prescribed a targeted controlled substance immediately prior to the first prescription. The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule."

Under this Rule, when prescribing a targeted controlled substance for the initial prescription in an acute phase, if the employee is already taking a targeted controlled substance, the health care provider may prescribe more than a 50 mg MED per day if necessary, using the lowest effective dosage. In these circumstances, the provider should communicate to the employee the significant risks associated with high dosages of opioids.

The Industrial Commission encourages the health care provider to communicate with any other provider prescribing the employee a targeted controlled substance to determine the necessity of prescribing additional opioids. In making this determination, the provider should balance patient safety with treating the employee's pain. Consideration should be given to non-opioid medications and non-pharmacological therapies for pain, when appropriate in the provider's professional medical judgment.

> Example: Worker G takes 30 mg MED/day of a targeted controlled substance for chronic pain from a non-work-related injury. Worker G has a work-related injury. The health care provider treating the work-related injury believes that Worker G needs an additional 60 mg MED/day to treat the acute pain of the new injury. The health care provider for the work-related injury may prescribe up to a 5-day supply of the additional 60 mg MED/day of a targeted controlled substance under the Rule for the first prescription. The health care provider should coordinate with the provider who is already prescribing the 30 mg MED/day dose and advise Worker G of the risks of taking high doses of opioids.

> Example: Worker H takes 50 MED/day of a targeted controlled substance for pain from a work-related injury. Worker H has surgery for his injury. The surgeon believes that Worker H needs an increase in his dosage for a brief period after surgery. The surgeon may prescribe up to a 7-day supply of more than 50 MED/day of a targeted controlled substance. The surgeon should advise Worker H of the risks of taking high doses of opioids.

2.3.2 Acute Phase Prescriptions

Rule 11 NCAC 23M .0202(e) states, "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. The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule."

Rule .0202(e) continues the emphasis in the acute phase on keeping an employee's dosage of a targeted controlled substance as low as possible while still treating the employee's pain. A health care provider may prescribe up to 90 mg MED/day if the medical justification is documented in the

medical record. Importantly, a dosage exceeding 50 mg MED/day must be reviewed at every appointment to determine whether the employee received the expected benefits and the dosage should be continued or lowered. The provider must document this review and the outcome in the medical record.

2.3.3 Chronic Phase Prescriptions

Rule 11 NCAC 23M .0203(e) states, "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." Rule 11 NCAC 23M .0203(e)(1) contains an exception for prescribing up to 90 mg MED/day under certain conditions similar to Rule .0202(e). Rule 11 NCAC 23M .0203(e)(2) indicates that a health care provider may seek preauthorization from the employer or carrier to prescribe higher than 90 mg MED/day. In order to allow for flexibility, the Rules and the Companion Guide do not outline a specific preauthorization procedure to use. Health care providers are encouraged to include specific medical information and justification in the initial preauthorization request to the employer or carrier.

2.4 Non-Oral Preparations of Targeted Controlled Substances

Rules 11 NCAC 23M .0201-.0203(f) address the prescription of transcutaneous, transdermal, transmucosal, or buccal preparations of targeted controlled substances. **In an acute phase**, neither Schedule II nor Schedule III transcutaneous, transdermal, transmucosal, or buccal opioid preparations may be prescribed without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.

In a chronic phase, Schedule II transcutaneous, transdermal, transmucosal, or buccal opioid preparations may not be prescribed without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee. Schedule III non-oral opioid preparations may be prescribed in a chronic phase.

The medical contraindication may be based on an employee's medical condition(s) or history or based on an unsuccessful trial of oral opioid dosing.

See Section 2.5 below for specific information about the prescription of fentanyl.

2.5 Limitations on Utilization of Fentanyl

Rules 11 NCAC 23M .0201(g) and .0202(g) do not allow the prescription of Fentanyl **in an acute phase**. However, Rule 11 NCAC 23M .0203(g) allows such a prescription **in a chronic phase**, if preauthorized by the employer or carrier. In order to allow for flexibility, the Rules and the Companion Guide do not outline a specific preauthorization procedure to use. Health care providers are encouraged to include specific medical information and justification in the initial preauthorization request to the employer or carrier.

2.6 Limitations on Utilization of Methadone

The Rules do not allow the prescription of methadone **in an acute phase** because it is a long-acting opioid. Only short-acting opioids may be prescribed in an acute phase. However, Rule 11 NCAC 23M .0203(g) allows the prescription of methadone **in a chronic phase**, if preauthorized by

the employer or carrier. In order to allow for flexibility, the Rules and the Companion Guide do not outline a specific preauthorization procedure to use. Health care providers are encouraged to include specific medical information and justification in the initial preauthorization request.

2.7 Limitations on Utilization of Benzodiazepines

Paragraph (h) of Rules 11 NCAC 23M .0201-.0203 do not allow the prescription of benzodiazepines for pain or as muscle relaxers in an acute or a chronic phase. If a muscle relaxer is needed in addition to an opioid, health care providers are encouraged to prescribe other muscle relaxers that can be safely administered along with an opioid.

2.8 Limitations on Utilization of Carisoprodol

Rules 11 NCAC 23M .0201(i) and .0202(i) do not allow the prescription of carisoprodol and a targeted controlled substance **in an acute phase**. Rule 11 NCAC 23M .0203(i) provides, "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." [emphasis added]

It is preferred that opioids not be prescribed in combination with carisoprodol due to the increased risk for abuse and overdose. However, in a chronic phase the health care provider may prescribe carisoprodol and an opioid by obtaining preauthorization and communicating the potential risks to the employee.

2.9 Prescribing Targeted Controlled Substances When Employee is Taking Benzodiazepines or Carisoprodol

Paragraph (j) of Rules 11 NCAC 23M .0201-.0203 states, "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."

It is preferred that opioids not be prescribed in combination with a benzodiazepine or carisoprodol **AT ALL** due to the increased potential for overdose. However, the Industrial Commission does not have jurisdiction over treatment unrelated to a workers' compensation claim. Therefore, the limitations and prohibitions of various prescriptions in the Rules apply only to the prescribed treatment within the jurisdiction of the workers' compensation claim. If an injured worker is receiving separate, unrelated treatment, the Industrial Commission Rules do not extend to that health care provider.

While the Rules explicitly preclude the prescription of benzodiazepines for pain or as muscle relaxers in an acute phase as well as the prescription of carisoprodol in addition to opioids in an acute phase, it is possible that the injured worker is being prescribed a benzodiazepine or carisoprodol by another health care provider, e.g., for a depression-related and/or anxiety-related diagnosis. In anticipation of these potential overlapping treatments, the Rules offer flexibility and

guidance to the physician treating the employee's workers' compensation injury. With the understanding that a disproportionate number of overdose deaths result from dangerous combinations of these drugs, the Rules are intended to encourage communication between the employee and the providers in these situations for the sake of patient safety. The communication between these providers can be accomplished by any means or manner convenient to the providers.

2.10 Reviewing the Controlled Substances Reporting System

Paragraph (k) of Rules 11 NCAC 23M .0201-.0203 requires that a health care provider review the CSRS when prescribing a targeted controlled substance. Reviewing a patient's controlled substance prescription history is a cornerstone of every set of established rules or guidelines for opioid use reviewed by the Industrial Commission when developing the Rules. Therefore, the Industrial Commission determined that it was necessary to include requirements to review the CSRS in the Rules.

The Industrial Commission is aware that the requirements to review the CSRS under the North Carolina STOP Act do not become effective until certain conditions stated in the North Carolina STOP Act are met. Based on feedback received from medical associations during the development of the Rules, the Industrial Commission set the effective date of the CSRS requirements in the Opioid Utilization Rules for **November 1, 2018, or the date of application of the relevant provision in the North Carolina STOP Act, whichever is earlier**. Health care providers are encouraged to comply with the requirement at the earliest possible date for the sake of patient safety and to help combat the opioid epidemic. Please see the Home Page of the CSRS.

In addition, health care providers should consider registering with and reviewing the prescription drug monitoring programs in **border states**. In determining whether to review a border state's system in addition to the North Carolina CSRS, a health care provider should take into consideration the individual facts and circumstances. Examples of factors for consideration are the location of the provider's practice and the history or residence of the injured worker.

The home pages of the prescription drug monitoring programs in states bordering North Carolina are provided below:

- Virginia Prescription Monitoring Program
- Tennessee Controlled Substance Monitoring Database
- Georgia Prescription Drug Monitoring Program
- South Carolina Reporting and Identification Prescription Tracking System

2.10.1 Reviewing the CSRS before the First Prescription in an Acute Phase

Rule 11 NCAC 23M .0201(k) provides, "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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier."

The Rule requires health care providers to review the information in the North Carolina Controlled Substances Reporting System **prior to the first prescription** of a targeted controlled substance in an acute phase, including a prescription for post-operative pain immediately following a surgical procedure.

2.10.2 Reviewing the CSRS in an Acute Phase

Rule 11 NCAC 23M .0202(k) provides, "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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier." [emphasis added]

The Industrial Commission understands that Rule 11 NCAC 23M .0202(k) requires reviewing the CSRS more often than Section 12 of the North Carolina STOP Act. However, it is important to safeguard patient safety at the earliest point possible in treating an employee with opioid medication. Frequent reviewing of the CSRS in an acute phase may also help detect any issues with opioid diversion or other similar risks.

2.10.3 Reviewing the CSRS in a Chronic Phase

Rule 11 NCAC 23M .0203(k) provides, "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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier." [emphasis added]

The Industrial Commission understands that Rule 11 NCAC 23M .0203(k) may require reviewing the CSRS more often than required under the North Carolina STOP Act. However, it is important to ensure patient safety throughout the treatment of an employee with opioid medication. Reviewing the CSRS at every appointment at which a targeted controlled substance is prescribed in the chronic phase may also help detect any issues with opioid diversion or other similar risks.

2.11 Additional Requirements for Prescriptions in the Acute and Chronic Phases

Rule 11 NCAC 23M .0202(l) contains additional risk assessment requirements for prescribing a targeted controlled substance **beyond 35-37 days in an acute phase**. A health care provider may not continue to prescribe a targeted controlled substance beyond the first prescription (maximum 5-7 days) and another 30 days of a targeted controlled substance without conducting urine drug testing, administering an opioid risk assessment tool, and assessing the employee's risk of opioid-related harm.

Rule 11 NCAC 23M .0203 contains several provisions regarding additional risk assessment requirements for prescribing a targeted controlled substance **in the chronic phase**. These also include conducting urine drug testing, administering an opioid risk assessment tool, and assessing the employee's risk of opioid-related harm.

Providers should review these Rules in detail. The Rules describe the minimum risk assessment requirements. Providers may choose, in their professional medical judgment, to use additional means of risk assessment.

2.11.1 Urine Drug Testing

Rule 11 NCAC 23M .0202(l)(1) describes the urine drug testing required **in an acute phase**:

> 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.

This presumptive urine drug testing must occur before the health care provider continues to prescribe a targeted controlled substance beyond the initial 35-37 days of treatment with a targeted controlled substance. The Rule allows the health care provider to use his or her professional medical judgment in deciding whether to prescribe a targeted controlled substance after receiving unexpected results on a presumptive urine drug test but before receiving the confirmatory urine drug test results.

Rule 11 NCAC 23M .0203(l), (m), (n), and (o) describe the urine drug testing required **in the chronic phase**. The requirements for presumptive and confirmatory testing are similar to those for the acute phase, but some additional frequency provisions apply. Rule 11 NCAC 23M .0203(m) requires urine drug testing to be administered before first prescribing a targeted controlled substance in a chronic phase. Rule 11 NCAC 23M .0203(m) requires urine drug testing to be administered thereafter 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 Industrial Commission strongly urges health care providers to use random and unannounced tests. In order to allow for flexibility, the Rules and the Companion Guide do not outline a specific preauthorization procedure to use. Health care providers are encouraged to include specific medical information and justification in the initial preauthorization request supporting the necessity of additional testing.

Please note that Rule 11 NCAC 23M .0203(m) further provides that 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.

2.11.2 Opioid Risk Assessment Tools

Rule 11 NCAC 23M .0202(l)(2) requires **in the acute phase** that 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." This testing must occur before the health

care provider continues to prescribe a targeted controlled substance beyond the initial 35-37 days of treatment with a targeted controlled substance. The Rule provides a list of examples of risk assessment tools that may be used to comply with this Rule:

- 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
- 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
- SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org.
- Opioid Risk Tool (ORT) (Lynn Webster, MD), available at http://agencymeddirectors.wa.gov/Files/opioidrisktool.pdf.

Importantly, the list contains four examples of risk assessment tools, but providers are not limited to the examples listed. Providers may use any tools for screening and assessing opioid risk that have been validated by clinical studies. Additionally, for the examples provided in the Rule, providers are encouraged to use any later updated version available at the time of testing.

In a chronic phase, Rule 11 NCAC 23M .0203(p) requires that an opioid risk assessment tool be re-administered and the results documented whenever the treatment of an employee is transferred to a new health care practice. There is nothing in the Rules preventing a provider from administering a risk assessment tool more often in the provider's professional medical judgment.

Rule 11 NCAC 23M .0203(p) provides the same list of examples of risk assessment tools that may be used to comply with this Rule. Again, providers are not limited to the examples listed.

2.11.3 Assessing Risk of Opioid-Related Harm and Documenting Medical Record

For the **acute phase**, Rule 11 NCAC 23M .0202(l)(3) requires that the health care provider review and document in the medical record whether the information obtained from the CSRS, urine drug testing, or opioid risk assessment tool, 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 beyond the 35-37 day point despite any increased risks identified, the health care provider shall document in the medical record the reasons justifying the continued prescription.

In the **chronic phase**, Rule 11 NCAC 23M .0203(q) contains a similar requirement for assessment and documentation. Reviewing the CSRS, administering urine drug testing, and administering an opioid risk tool may occur several times depending on the length of the chronic phase. If an increased risk of opioid-related harm is detected at any point, the health care provider must document the medical record accordingly, including the reasons for any continuation of the prescription.

2.12 Other Measures for Managing Treatment with a Targeted Controlled Substance

In addition to the requirements in the Rules, providers may consider implementing an opioid treatment plan, creating a pain contract with the employee, and/or engaging the employee in a discussion regarding the risks associated with opioid therapies. The extent to which such plans or contracts are appropriate will depend on the nature and extent of the injury, the length of recovery, and other case-by-case factors.

Chapter Three
Utilization Rules for Opioid Antagonists

3.1 When must co-prescription of an opioid antagonist be considered?

Rule 11 NCAC 23M .0301 requires health care providers to consider co-prescribing an opioid antagonist when prescribing a targeted controlled substance if the provider identifies certain risks with respect to an employee either by the patient's history or by making an active diagnosis. The Rule lists potential risks to consider, including:

(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.

Of note, (3) through (6) above involve risks related to an employee's medical or substance use history. A provider need not make a diagnosis related to these risks to consider co-prescription of an opioid antagonist.

If one or more of the risks listed in the Rule is present, the health care provider is encouraged to consider alternative non-opioid treatments for pain in lieu of opioids. These can include non-opioid pharmacological or non-pharmacological treatments, or a combination thereof. See Chapter 4 regarding Rule 11 NCAC 23M .0401, Non-Pharmacological Treatment for Pain.

3.2 What formulation of an opioid antagonist may be prescribed?

Rule 11 NCAC 23M .0301(b) states that a 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. The Industrial Commission understands that intranasal formulations of an opioid antagonist may be easier to administer, and therefore potentially more effective in saving lives.

3.3 To whom does this Rule apply?

Rule 11 NCAC 23M .0301 applies to **all claims** regardless of the date of injury or period of treatment with a targeted controlled substance. See Section 1.4 for information on the applicability of the Rules.

Chapter Four
Utilization Rules for Non-Pharmacological Treatment for Pain

Rule 11 NCAC 23M .0401 provides as follows:

> (a) A health care provider shall consider and may prescribe non-pharmacological treatments for pain. Examples of these treatments include the following: physical therapy, chiropractic services, acupuncture, massage, cognitive behavioral therapy, biofeedback, and functional restoration programs.
>
> (b) 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.

4.1 Encouraging Non-Pharmacological Treatments for Pain

Rule 11 NCAC 23M .0401 states that the provider "shall consider" non-pharmacological treatments for pain. It may appear that there is an inconsistency with the requirements set forth in Rules .0201-0203(b), which state that "[b]efore 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." See Section 2.2 above. However, these provisions are not inconsistent because of the varying nature and severity of injuries in workers' compensation claims. Some cases may require opioid medication right away, while in other situations, pain can be managed appropriately through non-opioid or non-pharmacological treatments. In some cases, concurrent opioid and non-pharmacological treatment may be appropriate. The intention of Rule 11 NCAC 23M .0401 is to require consideration of non-pharmacological treatments to be used alone or in conjunction with other therapies for the treatment of pain with the ultimate goal of reducing or eliminating opioid use to the extent possible for the sake of patient safety.

4.2 What non-pharmacological treatments for pain may be prescribed?

Rule 11 NCAC 23M .0401 provides a list of examples of non-pharmacological treatments that may be used in lieu of or in conjunction with opioids or other medications for pain. Importantly, this list contains seven examples of treatments, but providers are not limited to the examples listed. Providers may recommend any treatment that the provider believes, in his or her professional medical judgment, would be therapeutic in treating the employee. Additionally, the provider is encouraged to consider the most current medical guidance and literature for non-pharmacological modalities.

It is preferred that non-pharmacological modalities be used instead of opioids, where possible. However, non-pharmacological treatments may also be used in conjunction with opioids when necessary. Different treatment modalities may be appropriate at different points and phases of treatment. If opioids are prescribed in the acute phase, it is encouraged that the prescriber try to transition the employee to non-opioid treatment at the earliest time possible in the provider's professional medical judgment.

4.3 Why and how may an employer or carrier request additional information about a recommended non-pharmacological treatment for pain?

Rule 11 NCAC 23M .0401 indicates that if a provider prescribes a non-pharmacological treatment for pain, the carrier may request additional information. This Rule is not intended to create a significant change in the way recommendations for treatment are currently reviewed and authorized in workers' compensation claims. If an employer or carrier receives a prescription for physical therapy or biofeedback, for example, and does not have any questions about the recommendation in light of the circumstances of the injury, the employer or carrier may choose to authorize the treatment by its usual means. However, if a non-pharmacological treatment for pain is recommended and the employer or carrier wants additional information before proceeding to authorize the treatment, the employer or carrier may request it from the provider.

The employer or carrier may request the additional information by any method allowed pursuant to the Workers' Compensation Act. To assist employees, employers, carriers, and health care providers, the Industrial Commission has developed a non-mandatory form that may be used to request the additional information and respond to the request. This non-mandatory form can be found in Exhibit C of this Companion Guide. Click here to access the form.

The information requested in the non-mandatory form includes the clinical goals and measurable objectives of the treatment, the estimated length of treatment, and the projected outcome upon completion of the treatment. The health care provider should try to include this information in the medical record. If a health care provider has already documented this information in the medical record, it may be unnecessary for the carrier/employer to send a request for additional information.

4.4 What if there is a dispute about a treatment recommendation?

There may be situations in which the treating health care provider recommends a non-pharmacological treatment for pain and the order is not authorized by the employer or carrier, whether additional information was requested or not. The lack of authorization may be for a variety of reasons. In most cases, additional medical documentation or communication between the parties can resolve the issue.

If the issue cannot be resolved, the employee is entitled to file a motion for medical treatment with the Industrial Commission to request an Order authorizing the denied treatment. The employer or carrier is entitled to respond to the motion within a certain period of time. The procedures for medical motions and emergency medical motions are outlined in N.C. Gen. Stat. § 97-25(f) and Rule 11 NCAC 23A .0609A. Such medical motions may be filed with the Industrial Commission in the manner directed in Rules 11 NCAC 23A .0108 and.0609A. See also Sections 1.4.8 and 1.6. Under the Workers' Compensation Act, the Industrial Commission may authorize any treatment that is reasonable and appropriate under the circumstances.

4.5 To whom does this Rule apply?

Rule 11 NCAC 23M .0401 applies to **all claims** regardless of the date of injury or whether there has been a period of treatment with a targeted controlled substance. See Section 1.4.2 for information on the applicability of the Rules.

Chapter Five
Utilization Rules For Treatment For Substance Use Disorder Involving a Targeted Controlled Substance

Rule 11 NCAC 23M .0501 provides as follows:

> (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.

5.1 Must a health care provider make a diagnosis of substance use disorder to refer the employee for evaluation for substance use disorder?

Rule 11 NCAC 23M .0501 is intended to encourage employees, employers, carriers, and health care providers to be aware of and consider whether an employee may need to reduce or eliminate the use of a targeted controlled substance or need treatment for substance use disorder involving a targeted controlled substance. Many health care providers prescribing targeted controlled substances may not be specialists in substance use disorder. It is not required that a health care provider make a diagnosis of substance use disorder before referring an employee for evaluation.

5.2 Additional Information Requests

This Rule provides that if a health care provider refers an employee to a specialist for evaluation for tapering or discontinuation of a targeted controlled substance or treatment for substance use disorder, 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.

Additionally, after the evaluation, if treatment is recommended, 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. The "recommending health care provider" is a provider who recommends treatment based on the evaluation. This can be the evaluating health care provider or the referring health care provider.

To assist employees, employers, carriers, and health care providers, the Industrial Commission has developed two <u>non-mandatory</u> forms that may be used to request additional

information pursuant to 11 NCAC 23M .0501(b). The non-mandatory form specific to treatment for tapering or discontinuation of a targeted controlled substance can be found in Exhibit D of this Companion Guide. The non-mandatory form specific to treatment for substance use disorder can be found in Exhibit E of this Companion Guide.

The information requested in the non-mandatory forms includes the clinical goals and measurable objectives of the treatment, the estimated length of treatment, whether medication assisted treatment will be used, and the projected outcome upon completion of the treatment. The health care provider should try to include this information in the medical record. If a health care provider has already documented this information in the medical record, it may be unnecessary for the carrier/employer to send a request for additional information.

5.3 To whom does this Rule apply?

Rule 11 NCAC 23M .0501 applies to **all claims** regardless of the date of injury or when the period of treatment with a targeted controlled substance began. See Section 1.4.2 for information on the applicability of the Rules.

Exhibit A

Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims (11 NCAC 23M)

CHAPTER 23 - INDUSTRIAL COMMISSION

SUBCHAPTER 23M – RULES FOR THE UTILIZATION OF OPIOIDS, RELATED PRESCRIPTIONS, AND PAIN MANAGEMENT TREATMENT IN WORKERS' COMPENSATION CLAIMS

SECTION .0100 – GENERAL PROVISIONS

11 NCAC 23M .0101 PURPOSE AND APPLICABILITY OF THE RULES

(a) The rules in this Subchapter address the utilization of opioids, related prescriptions, and pain management treatment in 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 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 11 NCAC 23A .0609A.

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

11 NCAC 23M .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 established by 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 to 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 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. 97-25.4; 97-80(a); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

11 NCAC 23M .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); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

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

11 NCAC 23M .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, if the employee was being prescribed a targeted controlled substance immediately prior to the first prescription. The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule.

(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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier.

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

11 NCAC 23M .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. The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule.

(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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier.

(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); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

11 NCAC 23M .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 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 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.

The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule.

(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. The effective date of this Paragraph is November 1, 2018, or shall coincide with the date of application in S.L. 2017-74, Section 15.(e), and any amendments thereto, whichever is earlier.

(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, including those in Rule .0202(l)(1)(A) through (D) of this Section.

(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; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

SECTION .0300 – UTILIZATION RULES FOR OPIOID ANTAGONISTS

11 NCAC 23M .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; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

SECTION .0400 – UTILIZATION RULES FOR NON-PHARMACOLOGICAL TREATMENT FOR PAIN

11 NCAC 23M .0401 NON-PHARMACOLOGICAL TREATMENT FOR PAIN

(a) A health care provider shall consider and may prescribe non-pharmacological treatments for pain. Examples of these treatments include the following: physical therapy, chiropractic services, acupuncture, massage, cognitive behavioral therapy, biofeedback, and functional restoration programs.

(b) 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); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

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

11 NCAC 23M .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); S.L. 2017-203, s. 4;*
Eff. May 1, 2018.

Exhibit B

Basic Overview of the Phases of Treatment under the Opioid Utilization Rules

Basic Overview of the Phases of Treatment Under the Opioid Utilization Rules

Phase	Acute Phase (12 weeks of treatment)		Chronic Phase (continued treatment after 12 weeks)
Rule Topic	**First Prescription in Acute Phase**	**Prescriptions in Acute Phase after First Prescription**	**Prescriptions in Chronic Phase**
Rule Citation	Rule 11 NCAC 23M .0201	Rule 11 NCAC 23M .0202	Rule 11 NCAC 23M .0203
Timeline	1 to 5-7 days	6-8 to 84 days (12 weeks)	>84 days (more than 12 weeks)
Prerequisite to prescribing an opioid	Document provider's medical opinion that non-pharmacological and non-opioid therapies are insufficient to treat the employee's pain.		
Number and type of opioids prescribed	Only one short-acting TCS may be prescribed at a time.		Only one short-acting TCS may be prescribed at a time without documentation of justification in medical record. If justification is documented in medical record, up to two TCS's may be prescribed at a time, to include only one short-acting opioid and one long-acting or extended-release opioid.
Number of days' supply	Lowest number of days' supply necessary to treat the pain. Maximum 5 days' supply for pain. Maximum 7 days' supply for post-operative pain.	Lowest number of days' supply necessary to treat the pain.	
Dosage	Lowest effective dosage necessary to achieve the clinical goal. Maximum 50 mg MED/day, using short-acting opioids only. May prescribe >50 MED per day if employee was taking TCS immediately prior to first prescription. Dosage limit applies to prescription issued pursuant to this Rule.	Lowest effective dosage necessary to achieve the clinical goal. Maximum 50 mg MED/day, using short-acting opioids only. If justification is documented in the medical record (see rule for details), provider may prescribe more than 50 mg MED/day, but not >90 mg MED/day. (See rule for details.) Dosage limit applies to prescription issued pursuant to this Rule.	Lowest effective dosage necessary to achieve the clinical goal, not to exceed 50 MED per day. If justification is documented in the medical record, provider may prescribe more than 50 mg MED/day, but not more than 90 mg MED/day. (See rule for details.) If necessary to prescribe >90 mg MED/day, provider must seek preauthorization from carrier. (See rule for details.) Dosage limit applies to prescription issued pursuant to this Rule.
Non-oral opioids	No Schedule II or III transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in medical record that oral opioids are medically contraindicated for employee.		No Schedule II transcutaneous, transdermal, transmucosal, or buccal opioid preparations without documentation in medical record that oral opioids are medically contraindicated for employee. Schedule III non-oral preparations may be prescribed if appropriate.
Fentanyl	No fentanyl may be prescribed.		A provider must seek preauthorization for transdermal fentanyl.
Methadone	No methadone may be prescribed because only short-acting opioids may be prescribed.		A provider must seek preauthorization for methadone.
Benzodiazepines	No benzodiazepines may be prescribed for pain or as muscle relaxers.		
Carisoprodol	Carisoprodol may not be prescribed with a TCS in an acute phase.		A provider must seek preauthorization before prescribing carisoprodol with a TCS. The provider must advise the employee of the risks of combining both medications.
Medications prescribed by other providers	If an employee is already taking benzodiazepines or carisoprodol prescribed by another provider, a provider must not prescribe a TCS without advising the employee of related risks and advising the other provider of the prescription of a TCS.		
CSRS (Controlled Substances Reporting System)	Provider must check the CSRS and document the findings before the first prescription.	Provider must check the CSRS and document the findings every time an opioid is prescribed in the acute phase.	Provider must check the CSRS and document the findings at every appointment at which a TCS is prescribed or every three months, whichever is more frequent.
	Effective 11/1/18 or the date of application in S.L. 2017-74 (NC STOP Act), Section 15.(e), and any amendments thereto, whichever is earlier.		
Urine Drug Testing	No requirement in rule.	Before prescribing a TCS beyond 35-37 days in the acute phase, the provider must administer and document the results of a presumptive urine drug test. If the results show inappropriate drug use or irregularities with the prescribed drug, the provider shall obtain a confirmatory urine drug test and document the results. (See rule for additional information.)	Before first prescribing a TCS in a chronic phase, the provider must administer and document the results of a presumptive urine drug test. After the first urine drug test, a provider must administer 2-4 presumptive urine drugs tests per year. Any additional testing must be authorized by the carrier. If the results of a presumptive urine drug test show inappropriate drug use or show irregularities with the prescribed drug, the provider shall obtain a confirmatory urine drug test and document the results. (See rule for additional information.)
Opioid risk evaluation tool	No requirement in rule.	Before prescribing a TCS beyond 35-37 days in the acute phase, the provider must administer and document the results of a tool for screening and assessing opioid risk. (See rule for examples.)	If an employee's care is transferred to a different health care practice than the one that administered an opioid risk tool in the acute phase, the new provider must administer and document the results of a tool for screening and assessing opioid risk. (See rule for examples.)
Review of increased opioid risk by provider	No requirement in rule.	If a CSRS check, urine drug test, or opioid risk tool indicates an increased risk of opioid-related harm and the provider prescribes an opioid, the provider must document in the medical record the reasons justifying the prescription.	

The abbreviation "TCS" used in this table stands for "targeted controlled substance" or Schedule II and III opioids. This table is provided for easy reference, but does not contain all the information in the Opioid Utilization Rules.

Exhibit C

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Non-Pharmacological Treatment Recommendation

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Non-Pharmacological Treatment Recommendation

TO BE COMPLETED BY THE CARRIER/EMPLOYER

Patient Name: _____ Today's Date: _____

Patient ID #: _____ Date of Injury: _____

Employer: _____ Carrier: _____

Treating Provider: _____ IC File #: _____

TO TREATING HEALTH CARE PROVIDER:
You recently recommended the following non-pharmacological treatment for pain for the above-named employee:

_____

Your prompt completion and return of this form to the following person is appreciated:

Name: _____ Telephone number: _____

Fax number: _____ Email address: _____

TO BE COMPLETED BY THE HEALTH CARE PROVIDER

Please provide the following additional information regarding the recommended treatment:

1. What are the specific clinical goals of the recommended treatment? _____

_____

2. What measurable objective(s) is the treatment expected to accomplish? (Check all that apply)

☐ Reduction of Pain

☐ Decreased Use of Opioid Medication

☐ Self-Management of Pain

☐ Increased Independence with ADLs

☐ Return to Work

☐ Increased Function

☐ Other benefits of recommended treatment: _____

3. What is the recommended length of treatment?

Number of weeks: _____

Number of visits per week: _____

Intervals at which progress will be measured: _____

4. What is the projected outcome upon completion of the recommended treatment? _____

_____

5. Please provide any other relevant information supporting the treatment recommendation: _____

_____

_____

_____

_____

_____

Provider Signature_____

Printed Name_____ **Date**_____

Exhibit D

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Recommendation for Opioid Tapering or Discontinuation

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Recommendation for Opioid Tapering or Discontinuation

TO BE COMPLETED BY THE CARRIER/EMPLOYER

Patient Name: _____ Today's Date: _____

Patient ID #: _____ Date of Injury: _____

Employer: _____ Carrier: _____

Treating Provider: _____ IC File #: _____

TO RECOMMENDING HEALTH CARE PROVIDER:
You recently recommended the following treatment(s) for the above-named employee:

_____

Your prompt completion and return of this form to the following person is appreciated:

Name: _____ Telephone number: _____

Fax number: _____ Email address: _____

TO BE COMPLETED BY THE HEALTH CARE PROVIDER

Please provide the following additional information regarding the recommended treatment:

1. What are the clinical goals of the recommended treatment(s)? _____

_____

2. What measurable objective(s) is/are the treatment(s) expected to accomplish? _____

_____

3. What is the estimated length of treatment(s)?

   Number of weeks: _____

   Number of visits per week, if applicable: _____

   Intervals at which progress will be measured: _____

4. Will medication assisted treatment be used in the tapering / weaning process? ☐ Yes ☐ No

   If yes, name and dosage of the medication(s) to be used:

   NAME OF MEDICATION: DOSAGE:

   _____ _____

   _____ _____

   _____ _____

   Estimated length of medication assisted treatment, if known: _____

5. What is the projected outcome upon completion of the recommended treatment(s)?_____

_____

6. Please provide any other relevant information supporting the treatment recommendation: _____

_____

_____

_____

_____

Provider Signature _____

Printed Name_____ **Date**_____

Exhibit E

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Recommendation for Substance Use Disorder Treatment

Employer/Carrier Request to Health Care Provider for Additional Information Regarding Recommendation for Substance Use Disorder Treatment

TO BE COMPLETED BY THE CARRIER/EMPLOYER

Patient Name: _____ Today's Date: _____

Patient ID #: _____ Date of Injury: _____

Employer: _____ Carrier: _____

Treating Provider: _____ IC File #: _____

TO RECOMMENDING HEALTH CARE PROVIDER:
You recently recommended the following treatment(s) for substance use disorder for the above-named employee:

_____

Your prompt completion and return of this form to the following person is appreciated:

Name: _____ Telephone number: _____

Fax number: _____ Email address: _____

TO BE COMPLETED BY THE HEALTH CARE PROVIDER

Please provide the following additional information regarding the recommended treatment:

1. What are the clinical goals of the recommended treatment(s)? _____

_____

2. What measurable objective(s) is/are the treatment(s) expected to accomplish? _____

_____

3. Will treatment(s) require in-patient or out-patient rehabilitation: ☐ Inpatient ☐ Outpatient ☐ Both

4. What is the estimated length of treatment(s)?

   Number of weeks: _____

   Number of visits per week, if applicable: _____

   Intervals at which progress will be measured: _____

5. Will medication assisted treatment be used? ☐ Yes ☐ No

   If yes, name and dosage of the medication(s) to be used:

NAME OF MEDICATION:	DOSAGE:
_____	_____
_____	_____
_____	_____

   Estimated length of medication assisted treatment, if known: _____

6. Please provide any other relevant information supporting the treatment recommendation: _____

_____

_____

_____

_____

Provider Signature _____

Printed Name_____ **Date** _____