AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 10A .0107

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

<u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 5, consider striking "by" before "order" and "any"

On line 6, I recommend replacing "is" with "shall be" or "shall not be" both places the term "is" is used.

On line 7, established how? Do you want to incorporate the SHRC rule on this into your Rule by reference pursuant to G.S. 150B-21.6? If so, the citation is 25 NCAC 01E .0901.

On line 8, could you not just state "until the end of the next State business day." and delete everything else in the sentence from lines 8 to 9?

If you need to retain the language, please insert a comma after "Sunday" on line 8.

In (b), line 13, you do not make it clear here that this is service by the Commission, like you do in (c), line 19. Is this intentional? If not, you may want to include "upon the Commission's sending" here.

In (b)(1), line 15, I recommend replacing "is" with "shall be"

In (b)(2), line 17, is "business days" known? I ask because of the language you use in (a), lines 6 through 9.

In (b)(2), the individual must notify the Commission of the unreadability because the Commission sent it, correct?

In (c), line 19, I recommend replacing "is" with "shall be"

In the History Note, line 23, why are you citing to G.S. 97-84?

Also in the History Note, I do not think you need to cite to SL 2017-57, s. 15-17. After all, what that session law did was rewrite 97-86, which you also cite to.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

2 3 04 NCAC 10A .0107 COMPUTATION OF TIME AND NOTICE BY THE COMMISSION 4 (a) Except as otherwise provided by statute or rule, in computing any period of time prescribed or allowed by the 5 Commission Rules, by order of the Commission, or by any applicable statute, the day of the act, event, or default after 6 which the designated period of time begins to run is not included. The last day of the period so computed is included, 7 unless it is a Saturday, a Sunday, or a holiday established by the State Personnel Human Resources Commission, in 8 which event the period runs until the end of the next day that is not a Saturday, a Sunday or a holiday established by 9 the State Personnel Human Resources Commission. When the period of time prescribed or allowed is less than seven 10 days, intermediate Saturdays, Sundays, and holidays shall be excluded in the computation. Whenever a party has the 11 right to do some act or take some proceedings within a prescribed period after the service of any document, document 12 by mail, three days shall be added to the prescribed period. 13 (b) If service is provided by electronic mail, notice pursuant to G.S. 97-86 is complete one hour after it is sent, 14 provided that: 15 (1) notice sent after 5:00 p.m. is complete at 8:00 a.m. the following business day; and notice sent by electronic mail that is not readable by the recipient is not complete. Within five 16 (2) 17 business days of receipt of an unreadable document, the receiving party shall notify the Commission 18 of the unreadability of the document. 19 (c) If service is provided by U.S. Mail, notice pursuant to G.S. 97-86 is complete upon the Commission's placing the 20 item to be served, enclosed in a wrapper addressed to the party to be served, in the custody of the Mail Service Center 21 or an official depository of the United States Postal Service. 22 23 History Note: Authority G.S. 97-80; 97-81; 97-84; 97-86; S.L. 2017-57 s. 15.17; 24 Eff. November 1, 2014; 25 Amended Eff. May 1, 2018.

04 NCAC 10A .0107 is amended as published in 32:14 NCR 1333 as follows:

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0101

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 11, (b), lines 15 and 18, and (c), line 20, please make "Rules" lowercase. Since you published it this way in the Register, you don't need to show it as a change.

In (b), line 17, are you excluding non-cancer pain due to G.S. 90-106(a4)(1)?

Why do you need most of (c), specifically lines 20 through 23, and then the sentence on line 24? The language is aspirational and does not convey any standards. In addition, on lines 20-21, you are simply reciting G.S. 97-25.4. Please delete the language.

If you need to retain the language:

Lines 20-21, this is a recitation of statute, but what is "intended" and who determines it? And what is adequately?

On line 21, if the rules are intended to do this, who will determine this?

On line 22, define "timely" "effective" and "appropriate"

On lines 23 through 24, it appears that the sentence "The Rules..." belongs in Paragraph (a).

On line 24, why do you say "workers' compensations claims" when in (a), you refer only to claims?

What do you mean on line 24 regarding medical advice or a standard of care? Does the Industrial Commission have the authority to create these, such that you have to expressly disclaim them?

In the History Note for this and all other Rules, I assume you want to retain the reference to S.L. 2017-203 because it expressly directed the creation of rules on this topic?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 2	04 NCAC 10M .0101 is adopted as published in 32:14 NCR 1334 as follows:
3	CHAPTER 10 - INDUSTRIAL COMMISSION
4	
5	SUBCHAPTER 10M – RULES FOR THE UTILIZATION OF OPIOIDS, RELATED PRESCRIPTIONS,
6	AND PAIN MANAGEMENT TREATMENT IN WORKERS' COMPENSATION CLAIMS
7	
8	SECTION .0100 – GENERAL PROVISIONS
9	
10	04 NCAC 10M .0101 PURPOSE AND APPLICABILITY OF THE RULES
11	(a) The Rules in this Subchapter shall apply to all claims arising under the provisions of the Workers' Compensation
12	Act. However, Section .0200 of this Subchapter shall not apply to claims in which the employee received treatment
13	with a targeted controlled substance for more than 12 consecutive weeks immediately preceding the effective date of
14	the Rules.
15	(b) The Rules in this Subchapter apply to the prescription of targeted controlled substances as defined in Rule .0102
16	of this Section and the prescription of other modalities of pain management treatment for the outpatient treatment of
17	non-cancer pain in claims in which the employer is providing medical compensation pursuant to the Workers'
18	Compensation Act. The Rules in this Subchapter do not apply to prescriptions for medications to be administered in
19	a health care setting.
20	(c) The Rules in this Subchapter are promulgated to ensure that employees are provided the services and care intended
21	by the Workers' Compensation Act and that medical costs are adequately contained. The Rules are intended to
22	facilitate the timely and effective delivery of appropriate medical treatment for pain management in workers
23	compensation claims. The Rules address the utilization of opioids, related prescriptions, and pain management
24	treatment in workers' compensation claims. The Rules do not constitute medical advice or a standard of medical care
25	Disputes regarding the treatment addressed by these Rules shall be governed by G.S. 97-25 and Rule 04 NCAC 10A
26	<u>.0609A.</u>
27	
28	History Note: Authority G.S. 97-25; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
29	Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0102

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In Item (3), line 11, what is "definitive"? Is there only one of these?

On line 14, what are these 21 drug classes? Is this known to your regulated public?

In Item (4), line 16, consider replacing "referenced in" with "established by"

In Item (5), line 21, consider stating "8 to 72" to be consistent with Item (11).

In Item (6), line 22, is "clinical goal" known to your regulated public?

In Item (7), line 28, delete "additional"

In Item (10), line 33, is it not "presumptive" negative specimens like it is presumptively positive? Or is that not how the nomenclature works?

Line 34. who does the visual examination? The administrator?

In Item (11), Page 2, line 3, is the term "quick onset" known to your regulated public?

On line 4, is "short duration" a known term?

In the History Note, line 8, delete the references to 90-12.7, 90-90, and 90-91, as they are not part of your rulemaking authority, but instead references to statutes stated in the Rule.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 04 NCAC 10M .0102 is adopted as published in 32:14 NCR 1334 as follows: 2 3 04 NCAC 10M .0102 **DEFINITIONS** 4 As used in this Subchapter: 5 (1) "Acute phase" means 12 weeks of treatment for pain following an injury by accident, occupational 6 disease, surgery for an injury by accident or occupational disease, or subsequent aggravation of an 7 injury by accident or occupational disease. There may be more than one acute phase during 8 treatment for an injury or occupational disease. 9 (2) "Chronic phase" means continued treatment for pain immediately following a 12-week period of 10 treatment for pain using a targeted controlled substance. 11 (3) "Confirmatory urine drug test" means a definitive urine drug test that verifies the results of a 12 presumptive urine drug test. A confirmatory urine drug test identifies individual drugs and drug 13 metabolites. Health care providers shall use a confirmatory drug test for the lowest number of 14 drug classes necessary based on the results of the presumptive urine drug test, not to exceed 21 15 drug classes. "CSRS" means the Controlled Substances Reporting System as referenced in the North Carolina 16 (4) 17 Controlled Substances Reporting System Act, Article 5E of Chapter 90 of the North Carolina 18 General Statutes. 19 "Long-acting opioid" or "extended-release opioid" means any targeted controlled substance that is (5) 20 formulated to release the drug gradually into the bloodstream or to have a long half-life for 21 prolonged activity with an analgesic effect of 8-72 hours or longer. 22 "Lowest effective dosage" means the lowest dose necessary to achieve the clinical goal. (6) 23 **(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 24 25 Prevention ("CDC"). The CDC Opioid Prescribing Guideline Mobile App and the CDC's 26 guidelines for Calculating Total Daily Dose of Opioids for Safer Dosage are hereby incorporated 27 by reference, including any subsequent amendments or editions. These materials are available 28 online at no additional cost at 29 https://www.cdc.gov/drugoverdose/pdf/calculating total daily dose-a.pdf and 30 https://www.cdc.gov/drugoverdose/pdf/App Opioid Prescribing Guideline-a.pdf. "Opioid antagonist" means the term as defined in G.S. 90-12.7(a). 31 (8) 32 (9) "Pain" means pain resulting from an injury by accident or occupational disease. 33 (10)"Presumptive urine drug test" means an initial urine drug test that identifies negative specimens 34 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 35 36 management treatment in the chronic phase to an employee may administer a presumptive urine 37 drug test that is qualitative and interpreted or analyzed with instrumental or chemical assistance if

1		the health care provider believes, in his or her medical opinion, that a more sensitive presumptive
2		urine drug test is appropriate and is likely to reduce the need for a confirmatory urine drug test.
3	<u>(11)</u>	"Short-acting opioid" means any targeted controlled substance with a quick onset of action and
4		short duration of analgesic activity that is formulated for dosing at intervals of two to six hours.
5	(12)	"Targeted controlled substance" means any controlled substance included in G.S. 90-90(1) or (2)
6		or G.S. 90-91(d).
7		
8	History Note:	Authority G.S. 90-12.7(a); 90-90; 90-91; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
9		Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0103

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On line 5, please make "Rules" lowercase. Since you published it this way in the Register, you do not have to show it as a change; simply do it.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1	04 NCAC 10M	.0103 is adopted as published in 32:14 NCR 1334 as follows:
2		
3	04 NCAC 10M	.0103 WAIVER OF RULES
4	In the interests of	of justice or to promote judicial economy, the Commission may, except as otherwise provided by the
5	rules in this Sub	chapter, waive or vary the requirements or provisions of any of the Rules in this Subchapter in a
6	case pending be	fore the Commission upon written application of a party or upon its own initiative. Factors the
7	Commission sha	all use in determining whether to grant the waiver are:
8	(1)	the necessity of a waiver;
9	(2)	the party's responsibility for the conditions creating the need for a waiver;
10	(3)	the party's prior requests for a waiver;
11	<u>(4)</u>	the precedential value of such a waiver;
12	<u>(5)</u>	notice to and opposition by the opposing parties; and
13	<u>(6)</u>	the harm to the party if the waiver is not granted.
14		
15	History Note:	Authority G.S. 97-25; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
16		Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0201

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

What is the point of the sentence on lines 23-24?

04 NCAC 10M .0201 is adopted with changes as published in 32:14 NCR 1334 as follows:

1 2 3

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

456

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

- 7 (a) This Rule applies to the first prescription of any medication to an employee for pain in an acute phase.
- 8 (b) Before prescribing a targeted controlled substance, a health care provider shall document his or her medical
- 9 opinion in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the
- 10 employee's pain.
- 11 (c) A health care provider shall not prescribe more than one targeted controlled substance at the time of the first
- 12 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.
- 14 (d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance
- 15 necessary in his or her medical opinion to treat an employee's pain, not to exceed a five-day supply. However, the
- 16 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.
- 18 (e) A health care provider shall prescribe the lowest effective dosage of a targeted controlled substance, not to exceed
- 19 a 50 mg morphine equivalent dose per day, using only short-acting opioids. However, a health care provider may
- 20 prescribe more than a 50 mg morphine equivalent dose per day for post operative pain immediately following a
- 21 surgical procedure if the employee was being prescribed more than a 50 mg morphine equivalent dose per day for the
- 22 injury or occupational disease immediately prior to surgery. day, if the employee was being prescribed a targeted
- 23 controlled substance immediately prior to the first prescription. The dosage limits in this Paragraph apply only to an
- 24 opioid prescription being prescribed pursuant to this Rule.
- 25 (f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations
- 26 without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.
- 27 (g) A health care provider shall not prescribe fentanyl for pain in an acute phase.
- 28 (h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.
- 29 (i) A health care provider shall not prescribe carisoprodol and a targeted controlled substance in an acute phase.
- 30 (j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health
- 31 care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the
- 32 potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care
- 33 provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to
- 34 inform that health care provider of the prescription of a targeted controlled substance.
- 35 (k) A health care provider shall review the information in the CSRS pertaining to the employee for the 12-month
- 36 period preceding the first prescription. The health care provider shall document in the medical record the review and
- 37 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),
- 2 and any amendments thereto, whichever is earlier.

- 4 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;
- 5 <u>Eff. May 1, 2018.</u>

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0202

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

What is the point of the sentence on lines 20-21? If the intent is to make it clear that these dosage limits are only for this Rule, why doesn't Paragraph (a) suffice for the notice?

In Subparagraph (I)(1), Page2, line 6, so that I am clear, does this mean that the provider can meet the requirement by doing an announced drug test?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

04 NCAC 10M .0202 is adopted with changes as published in 32:14 NCR 1334 as follows:

1 2 3

4

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

- 5 (a) This Rule applies to prescriptions for medication to an employee for pain during an acute phase that are written 6
- 7 (b) Before prescribing a targeted controlled substance, a health care provider shall document his or her medical
- 8 opinion in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the
- 9 employee's pain.
- 10 (c) A health care provider shall not prescribe more than one targeted controlled substance at a time in an acute phase.
- 11 (d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance
- 12 necessary in his or her medical opinion to treat an employee's pain.

after a first prescription as described in Rule .0201 of this Section.

- 13 (e) A health care provider shall prescribe the lowest effective dosage of a targeted controlled substance, not to exceed
- 14 50 mg morphine equivalent dose per day, using only short-acting opioids. However, the health care provider may
- 15 prescribe a morphine equivalent dose higher than 50 mg per day, but not higher than 90 mg per day, after documenting
- 16 the medical justification for the prescription, including a comparison of the expected benefits to the employee versus
- 17 any potential risks of increasing the employee's dosage. If the health care provider prescribes a morphine equivalent
- 18 dose higher than 50 mg per day in an acute phase, the health care provider shall review at all subsequent evaluations
- 19 whether the employee experienced the expected benefits and consider whether to continue the higher dosage and
- 20 document the medical record accordingly. The dosage limits in this Paragraph apply only to an opioid prescription
- 21 being prescribed pursuant to this Rule.
- 22 (f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations
- 23 without documentation in the medical record that oral opioid dosing is medically contraindicated for the employee.
- 24 (g) A health care provider shall not prescribe fentanyl for pain in an acute phase.
- 25 (h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.
- 26 (i) A health care provider shall not prescribe carisoprodol and a targeted controlled substance in an acute phase.
- 27 (j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health
- 28 care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the
- 29 potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care
- 30 provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to
- 31 inform that health care provider of the prescription of a targeted controlled substance.
- 32 (k) A health care provider shall review the information in the CSRS pertaining to the employee for the preceding 12-
- 33 month period every time the health care provider prescribes a targeted controlled substance in an acute phase. The
- 34 health care provider shall document in the medical record the review and any potential contraindications to prescribing
- 35 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. 36

- (1) 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.
 - 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.

(3)

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0203

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

What is the point of the sentence on line 30? If the intent is to make it clear that these dosage limits are only for this Rule, why doesn't Paragraph (a) suffice for the notice?

In Paragraph (f), line 32, so that I'm clear, you are intentionally not referring to targeted controlled substances here?

In Paragraph (k), you are requiring a review every three months or at every visit, whichever is more frequent. However, G.S. 90-113.74C requires review only every three months. Is the intention here to further regulate the check because you are regulating the use of the Workers Compensation system?

In Paragraph (n), so that I am clear, the healthcare provider may also satisfy the requirement through an announced drug test?

In Paragraph (p), Page 3, why do you need to recite Rule 04 NCAC 10M .0202(I)(2)? Can't you just state on line 2 "that has been validated by clinical studies, including those in Rule .0202(I)(1)(A) through (D) of this Section."?

I am just asking – why do you not cite to G.S. 97-25 in the History Note for this Rule? You cite to it for the other .0200 rules.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

04 NCAC 10M .0203 is adopted with changes as published in 32:14 NCR 1334 as follows:

1 2 3

14

16

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

- 4 (a) This Rule applies to prescriptions for medication to an employee for pain during a chronic phase.
- 5 (b) Before prescribing a targeted controlled substance, a health care provider shall document his or her medical
- 6 opinion in the medical record that non-pharmacological and non-opioid therapies are insufficient to treat the
- 7 employee's pain.
- 8 (c) A health care provider shall not prescribe more than one targeted controlled substance at a time in a chronic phase
- 9 without documentation of justification in the medical record. A health care provider shall not prescribe more than two
- 10 targeted controlled substances at a time in a chronic phase, to include no more than one short-acting opioid and one
- 11 long-acting or extended-release opioid.
- 12 (d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance
- 13 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
- 15 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
- 18 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
- 20 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
- 22 whether to continue the higher dosage and document the medical record accordingly.
- 23 (2) If a health care provider considers it necessary to prescribe a morphine equivalent dose higher than
- 24 90 mg per day to treat an employee's pain, the health care provider shall seek preauthorization from
- 25 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
- 27 care provider shall review at all subsequent evaluations whether the employee experienced the
- 28 expected benefits of the increased dosage and consider whether to continue the higher dosage and
- 29 document the medical record accordingly.
- The dosage limits in this Paragraph apply only to an opioid prescription being prescribed pursuant to this Rule.
- 31 (f) A health care provider shall not prescribe transcutaneous, transdermal, transmucosal, or buccal opioid preparations
- 32 included in G.S. 90-90(1) or (2) without documentation in the medical record that oral opioid dosing is medically
- 33 contraindicated for the employee.
- 34 (g) A health care provider shall seek preauthorization from the employer or carrier before prescribing transdermal
- 35 fentanyl. A health care provider shall seek preauthorization from the employer or carrier before prescribing methadone
- 36 for pain in a chronic phase.
- 37 (h) A health care provider shall not prescribe benzodiazepines for pain or as muscle relaxers in a chronic phase.

- 1 (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
- 3 potential risks of combining a targeted controlled substance and carisoprodol if both medications are prescribed.
- 4 (j) If an employee is taking benzodiazepines or carisoprodol prescribed by another health care provider, the health
- 5 care provider shall not prescribe a targeted controlled substance to the employee without advising the employee of the
- 6 potential risks of combining a targeted controlled substance and benzodiazepines or carisoprodol. The health care
- 7 provider shall also communicate with the health care provider prescribing the benzodiazepines or carisoprodol to
- 8 inform that health care provider of the prescription of a targeted controlled substance.
- 9 (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
- 14 15.(e), and any amendments thereto, whichever is earlier.
- 15 (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
- 17 Subchapter.
- 18 (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
- 20 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
- 22 urine drug tests to be conducted per year without authorization by the employer or carrier for additional urine drug
- 23 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.
- 25 (n) The health care provider may meet the requirements of Paragraphs (l) and (m) by requiring that the employee take
- 26 random, unannounced urine drug tests.
- 27 (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
- 29 in Rule .0102 of this Subchapter. The health care provider may obtain the confirmatory urine drug test results before
- 30 prescribing a targeted controlled substance. Alternatively, the health care provider may order a limited supply of a
- 31 targeted controlled substance pending the results of the confirmatory urine drug test. The results of any confirmatory
- 32 urine drug test shall be documented in the medical record. Nothing herein prevents a health care provider from ordering
- 33 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.
- 35 (p) If an employee's medical treatment involving the prescription of targeted controlled substances is transferred to a
- 36 health care provider in a different health care practice from the one that administered the opioid risk screening and
- 37 assessment tool required by Rule .0202(1)(2) of this Section, the new health care provider shall administer and

1	document in the	medical record the results of a tool for screening and assessing opioid risk that has been validated by
2	clinical studies.	Examples of these tools include the following:
3	(1)	NIDA Quick Screen V1.0 and NIDA-Modified ASSIST V2.0 (National Institute on Drug Abuse),
4		available at
5		https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated_2013(1).pdf;
6	(2)	Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0 (Inflexxion, Inc.),
7		available at http://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf;
8	(3)	SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org; and
9	(4)	Opioid Risk Tool (ORT) (Lynn Webster, MD), available at
10		http://agencymeddirectors.wa.gov/Files/opioidrisktool.pdf.
11	(q) A health can	re provider shall document in the medical record whether the information obtained by complying with
12	Paragraphs (k),	(l), (m), (o) or (p) of this Rule indicates an increased risk for opioid-related harm. If the health care
13	provider continu	nes the prescription of a targeted controlled substance despite any increased risks identified, the health
14	care provider sh	all document in the medical record the reasons justifying the continued prescription.
15		
16	History Note:	Authority 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
17		Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0301

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

What is the need for the language on line 19 relating to intranasal formulation?

In the History Note, why are you citing to G.S. 97-25.3? That statute authorizes preauthorization for the following:

(a) An insurer may require preauthorization for inpatient admission to a hospital, inpatient admission to a treatment center, and inpatient or outpatient surgery.

That does not appear to apply here. Why are you including it?

1	04 NCAC 10M .0301 is adopted as published in 32:14 NCR 1334 as follows:
2	
3	SECTION .0300 – UTILIZATION RULES FOR OPIOID ANTAGONISTS
4	
5	04 NCAC 10M .0301 CO-PRESCRIPTION OF OPIOID ANTAGONIST
6	(a) A health care provider prescribing a targeted controlled substance shall consider co-prescribing an opio-
7	antagonist to the following:
8	(1) employees taking benzodiazepines and a targeted controlled substance;
9	(2) employees whose dosage exceeds a 50 mg morphine equivalent dose per day;
10	(3) employees with a history of drug overdose;
11	(4) employees with a history of substance use disorder;
12	(5) employees with a history of an underlying mental health condition that places them at an increase
13	risk for overdose;
14	(6) employees with a medical condition such as respiratory disease, sleep apnea, or other
15	comorbidities that places them at an increased risk for opioid toxicity, respiratory distress, or
16	opioid overdose.
17	(b) If a health care provider prescribes an opioid antagonist pursuant to one or more of the conditions listed
18	Paragraph (a) of this Rule, the health care provider shall write the prescription to allow for product selection by the
19	employer or carrier, including an intranasal formulation approved by the United States Food and Drug Administration
20	
21	History Note: Authority 97-25.3; 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
22	Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0401

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Consider making this a two Paragraph rule, with (a) being lines 6-8, and (b) being lines 8 through 10.

On line 7, should this be "chiropractic services"?

On lines 8 through 10, what are these methods? Are they known?

1	04 NCAC 10M .0401 is adopted as published in 32:14 NCR 1334 as follows:
2	
3	SECTION .0400 – UTILIZATION RULES FOR NONPHARMACOLOGICAL TREATMENT FOR PAIN
4	
5	04 NCAC 10M .0401 NONPHARMACOLOGICAL TREATMENT FOR PAIN
6	A health care provider shall consider and may prescribe non-pharmacological treatments for pain. Examples of the
7	treatments include the following: physical therapy, chiropractic, acupuncture, massage, cognitive behavioral therap
8	biofeedback, and functional restoration programs. The employer or carrier may request additional information fro
9	the health care provider regarding the prescribed treatment by any method allowed pursuant to the Worker
10	Compensation Act.
11	
12	History Note: Authority 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
13	Eff. May 1, 2018.

AGENCY: Industrial Commission

RULE CITATION: 04 NCAC 01M .0501

DEADLINE FOR RECEIPT: Thursday, April 12, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On line 10, if the referral is made, will the employer or carrier have to pay for it?

On lines 11 through 12, and then lines 14-15, what are these methods? Are they known?

1	04 NCAC 10M .0501 is adopted as published in 32:14 NCR 1334 as follows:
2	
3	SECTION .0500 – UTILIZATION RULES FOR TREATMENT FOR SUBSTANCE USE DISORDER
4	
5	04 NCAC 10M .0501 TREATMENT FOR SUBSTANCE USE DISORDER INVOLVING A TARGETED
6	CONTROLLED SUBSTANCE
7	
8	(a) If a health care provider believes, in his or her medical opinion, that an employee may benefit from an evaluation
9	for discontinuation or tapering of a targeted controlled substance or for treatment for substance use disorder involving
10	a targeted controlled substance, the health care provider may refer the employee to a health care provider specializing
11	in such treatment for evaluation. The employer or carrier may request additional information from the health care
12	provider regarding the referral by any method allowed pursuant to the Workers' Compensation Act.
13	(b) If treatment is recommended following the evaluation referenced in Paragraph (a) of this Rule, the employer or
14	carrier may request additional information from the recommending health care provider regarding the treatment by
15	any method allowed pursuant to the Workers' Compensation Act.
16	
17	History Note: Authority 97-25.4; 97-80(a); S.L. 2017-203, s. 4;
18	Eff. May 1, 2018.