NC Industrial Commission's Proposed Rules Addressing the Opioid Epidemic in Workers' Compensation Cases

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On December 20, 2017, the North Carolina Industrial Commission announced its proposed rules for the workers' compensation system addressing the opioid crisis. The rules are designed to be proactive measures to curtail opioid misuse and addiction in workers' compensation claims. If implemented, these rules will impose several limitations and requirements on medical providers who prescribe outpatient opioid and pharmacological medications to manage the pain of workers' compensation patients. This article highlights provisions in the proposed rules that would directly impact how medical care providers prescribe opioid and pharmacological medications to manage pain in workers' compensation cases. Before the Commission can implement final rules, it must publish a notice of text in the North Carolina Register, hold a public hearing on the proposed rules, and accept oral or written comments on the proposed rules. The proposed rules were published in the North Carolina Register on January 16, 2018. A public hearing on the proposed rules is scheduled for March 2, 2018, at 2:30 p.m. in Room 240, 2nd Floor, Department of Insurance, Albemarle Building, 325 North Salisbury Street, Raleigh, NC 27603. Comments regarding the proposed rules may be submitted to Kendall Bourdon, 1233 Mail Service Center, Raleigh, NC 27699-1233; phone (919) 807-2644; email Kendall.Bourdon@ic.nc.gov. The proposed effective date for the rules is May 1, 2018.

Scope of Rules:

The proposed rules would apply to all claims arising under the NC Workers' Compensation Act. However, the Utilization Rules for Opioid and Other Pharmacological Pain Management Treatment would not apply to claims in which the employee received treatment with a targeted controlled substance more than 12 consecutive weeks before the effective date of the Rules. The proposed rules also do not apply to prescriptions for medications to be administered in a health care setting.

The Proposed Rules:

The proposed rules are designed to reduce the risk of the misuse of opioids in workers' compensation cases and to reduce the incidence of employees in workers' compensation cases becoming addicted to opioids. Medical cost containment is an additional goal of the proposed rules. The rules seek to achieve these goals by putting into place detailed protocols to be followed by medical care providers who prescribe opioid medications on an outpatient basis in treating injured or ill workers under the NC Workers' Compensation Act. The rules do not apply to prescriptions for medication to be administered in a health care setting. The proposed rules assert that they do not constitute medical advice or a standard of medical care.

The proposed rules do not specifically address the consequences to health care providers for failing to follow the proposed rules. Presumably, a failure to comply with the mandatory provisions would increase the risk of fee disputes with employers and carriers under G.S. §97-26(e) and potentially create an exposure to penalties under §97-88.3(b) in cases where the health care provider's actions can be construed as willfully or intentionally failing or refusing to timely file required reports or records and/or knowingly violating the rules with the intention to deceive or to gain improper advantage of a patient, employee, insurer or the Commission. The maximum penalty under G.S. §97-88.3(b) is $1,000.00. Whether or not evidence of noncompliance with the rules would be inadmissible in a negligence/malpractice action arising out of an employee's addiction or overdose is uncertain.

The proposed rules set out both strict prohibitions on the prescribing of certain drugs at certain times in the course of treatment of patients under the Workers' Compensation Act and procedural requirements for prescribing certain drugs at certain times during the course of treatment. A provision allows the Commission to waive or vary the rules in particular cases pending before the Commission upon written application by a party or upon the Commission's own initiative. The proposed rules differ based on whether the employee's treatment is in an "acute phase" or a "chronic phase". Within the acute phase, a distinction is made between the first prescription of a targeted controlled substance and subsequent prescriptions. The acute phase is defined as 12 weeks of treatment for pain following an injury by accident, occupational disease, or surgery, or subsequent aggravation of an injury by accident or occupational disease. Chronic phase is defined as continued treatment for pain immediately following a 12-week period of pain treatment using a targeted controlled substance. A targeted controlled substance means any controlled substance included in G.S. §90-90(1) or (2) or G.S. §90-91(d). See Exhibit 1.

The following sections of the proposed rules impose prohibitions on specific prescribing practices:

04 NCAC 10M .0201 First Prescription of Medication for Pain in an Acute Phase

A health care provider shall not:

- prescribe more than one targeted controlled substance at the time of the first prescription.
- provide at the time of the first prescription any additional prescription for a targeted controlled substance to be dispensed at a later time.
- prescribe more than a five-day supply of a targeted controlled substance. However, the first prescription of a targeted controlled substance for post-operative pain immediately following a surgical procedure may exceed five days, but shall not exceed a seven-day supply.
- prescribe more than a 50 mg morphine equivalent dose per day, using only short-acting opioids, except for post-operative pain immediately following a surgical procedure if the employee was being prescribed more than a 50 mg morphine equivalent dose per day for the injury or occupational disease immediately prior to surgery.
- prescribe fentanyl for pain in an acute phase.
- prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.
- prescribe carisoprodol and a targeted controlled substance in an acute phase.

04 NCAC 10M .0202 Prescription of Medication for Pain in an Acute Phase Following the First Prescription

A health care provider shall not:

- prescribe more than one targeted controlled substance at a time during an acute phase.
- prescribe fentanyl for pain in an acute phase.
- prescribe benzodiazepines for pain or as muscle relaxers in an acute phase.
- prescribe carisoprodol and a targeted controlled substance in an acute phase.

04 NCAC 10M .0203 Prescription of Medication for Pain in a Chronic Phase

A health care provider shall not:

- prescribe benzodiazepines for pain or as muscle relaxers in a chronic phase.
- A health care provider shall not prescribe more than two targeted controlled substances at a time in a chronic phase, to include more than one short-acting opioid and one long-acting or extended-release opioid.

The following sections of the proposed rules impose conditions on specific prescribing practices:

04 NCAC 10M .0201 First Prescription of Medication for Pain in an Acute Phase

- 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.
- 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.
- 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.
- A health care provider shall review the information in the Controlled Substances Reporting System (hereafter "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.

04 NCAC 10M .0202 Prescription of Medication for Pain in an Acute Phase Following the First Prescription

- 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.
- A 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.
- 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.
- 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.
- 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.
- After an employee has received the first prescription of a targeted controlled substance 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:
    - The health care provider shall administer and document in the medical record the results of a presumptive urine drug test, which may be met by requiring the employee to 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. 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 test results of any confirmatory urine drug test shall be documented in the medical record.
    - 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. See Exhibit 2.
- The health care provider shall review and document in the medical record whether the information obtained from CSRS, urine drug test, or opioid risk screening 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 despite any increased risks identified, the health care provider shall document in the medical record the reasons justifying the continued prescription.

04 NCAC 10M .0203 Prescription of Medication for Pain in a Chronic Phase

- 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.
- 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 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.

- If the 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 authorized (or ordered by the Commission), 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.
- 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.
- 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.
- 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.
- 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.
- 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 3 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.
- 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.
- A health care provider shall administer a presumptive urine drug test and document the results in the medical records 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 of the employer or carrier shall not apply where a patient is being prescribed targeted controlled substances for the purpose of substance use disorder in addition to pain management.
    - A health care provider may meet the urine drug testing requirements by requiring the employee to take random, unannounced urine drug tests.
- 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. 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 test results of any confirmatory urine drug test shall be documented in the medical record.
- 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, 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.
- A health care provider shall document in the medical record if the results from searching CSRS, presumptive urine drug tests, and/or opioid risk screening and assessment tools 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.

Other Provisions:

In addition to the restrictions and procedural requirements imposed by the proposed rules on the prescription of medications to workers' compensation patients, the rules require health care providers to consider co-prescribing an opioid antagonist to certain classes of employees with heightened risk profiles. The proposed rules further encourage medical care providers to consider non-pharmacological treatments for pain such as physical therapy, chiropractic, acupuncture, massage, cognitive behavioral therapy, biofeedback, and functional restoration programs. The proposed rules do not impose an obligation on employers and carriers to approve such care if ordered by the health care provider.

The proposed rules note that if a health care provider believes an employee may benefit from an evaluation for discontinuation or tapering of a targeted controlled substance or treatment of a 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 proposed rules do not impose an obligation on employers and carriers to approve such evaluation or any treatment recommended following the evaluation. However, like other medical authorization disputes arising under the Workers' Compensation Act, a claimant could seek an order from the Commission requiring the employer or carrier to authorize the evaluation or treatment.

Medical providers who prescribe opioid and other controlled substances to workers' compensation patients for the management of pain should be aware of the North Carolina Industrial Commission's proposed rules regulating the utilization of opioid and other pharmacologic pain management treatment in workers' compensation cases. The proposed effective date for the rules is May 1, 2018. A public hearing on the proposed rules is scheduled for March 2, 2018, at 2:30 p.m. in Room 240, 2nd Floor, Department of Insurance, Albemarle Building, 325 North Salisbury Street, Raleigh, NC 27603. Comments regarding the proposed rules will be accepted through March 19, 2018, and may be submitted to Kendall Bourdon, 1233 Mail Service Center, Raleigh, NC 27699-1233; phone (919) 807-2644; email Kendall.Bourdon@ic.nc.gov.

EXHIBIT 1. Targeted Controlled Substances

§ 90-90(1) & (2). (Effective December 1, 2017) Schedule II controlled substances

(1) Any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, unless specifically excepted or unless listed in another schedule:
   a. Opium, opiate, or opioid and any salt, compound, derivative, or preparation of opium and opiate, excluding apomorphine, nalbuphine, dextrorphan, naloxone, naltrexone and nalmefene, and their respective salts, but including the following:
      1. Raw opium.
      2. Opium extracts.
      3. Opium fluid extracts.
      4. Powdered opium.
      5. Granulated opium.
      6. Tincture of opium.
      7. Codeine.
      8. Ethylmorphine.
      9. Etorphine hydrochloride.
      10. Any material, compound, mixture, or preparation which contains any quantity of hydrocodone.
      11. Hydromorphone.
      12. Metopon.
      13. Morphine.
      14. Oxycodone.
      15. Oxymorphone.
      16. Thebaine.
      17. Dihydroetorphine.
   b. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph 1 of this subdivision, except that these substances shall not include the isoquinoline alkaloids of opium.
   c. Opium poppy and poppy straw.
   d. Cocaine and any salt, isomer, salts of isomers, compound, derivative, or preparation thereof, or coca leaves and any salt, isomer, salts of isomers, compound, derivative, or preparation of coca leaves, or any salt, isomer, salts of isomers, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocanized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
   e. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy).

(2) Any of the following opiates or opioids, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation unless specifically exempted or listed in other schedules:
   a. Alfentanil.
   b. Alphaprodine.
   c. Anileridine.
   d. Bezitramide.
   e. Carfentanil.
   f. Dihydrocodeine.
   g. Diphenoxylate.
   h. Fentanyl.
   i. Isomethadone.
   j. Levo-alphacetylmethadol. Some trade or other names: levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.
   k. Levomethorphan.
   l. Levorphanol.
   m. Metazocine.
   n. Methadone.
   o. Methadone -- Intermediate, 4-cyano-2-dimethylamino-4, 4- diphenyl butane.
   p. Moramide -- Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid.
   q. Pethidine.
   r. Pethidine -- Intermediate -- A, 4-cyano-1-methyl-4/y-phenylpiperidine.
   s. Pethidine -- Intermediate -- B, ethyl-4-phenylpiperidine-4-carboxylate.
   t. Pethidine -- Intermediate -- C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
   u. Phenazocine.
   v. Piminodine.
   w. Racemethorphan.
   x. Racemorphan.
   y. Remifentanil.
   z. Sufentanil.
   aa. Tapentadol.

§ 90-91(d). (Effective December 1, 2017) Schedule III controlled substances

(d) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof unless specifically exempted or listed in another schedule:
   1. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium.
   2. Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
   3. Repealed by Session Laws 2017-115, s. 5, effective December 1, 2017, and applicable to offenses committed on or after that date.
   4. Repealed by Session Laws 2017-115, s. 5, effective December 1, 2017, and applicable to offenses committed on or after that date.
   5. Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
   6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
   7. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
   8. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
   9. Buprenorphine.

Exhibit 2 Approved opioid risk screening and assessment tools.

1. NIDA Quick Screen V1.0 and NIDA-Modified ASSIST V2.0 (National Institute on Drug Abuse) Available at : https://www.drugabuse.gov/sites/default/files/files/QuickScreen_Updated2013(1).pdf;
2. Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0 (Inflexxion, Inc.) Available at http://nhms.org/sites/default/files/Pdfs/SOAPP-14.pdf;
3. SOAPP-Revised (Inflexxion, Inc.), available at https://www.painedu.org; and
4. Opioid Risk Tool (ORT) (Lynn Webster, MD), available at http://agencymeddirectors.wa.gov/Files/opioidrisktool.pdf.