

March 16, 2018

Ms. Kendall M. Bourdon, J.D.
Rulemaking Coordinator & Legislative Liaison
North Carolina Industrial Commission
1240 Mail Service Center
Raleigh, NC 27699-1240

Via email to kendall.bourdon@ic.nc.gov

Re: NCMS Comments on NC Industrial Commission's Proposed Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims

Dear Ms. Bourdon,

The North Carolina Medical Society is pleased to submit the following comments on the North Carolina Industrial Commission's proposed rules for the utilization of opioids, related prescriptions, and pain management treatment in workers' compensation claims. NCMS commends the Commission for taking steps to address the opioid crisis in our state, and we likewise appreciate the multiple opportunities to engage the Commission and suggest changes to improve the effectiveness of the proposed rules.

04 NCAC 10M .0101 – Purpose and Applicability of the Rules

The Commission proposes in paragraph (b) of Rule .0101 to exclude from the scope of the rules targeted controlled substances ("TCS") prescribed for the treatment of cancer-related pain and prescriptions for medications administered in a health care setting. NCMS agrees with this approach and appreciates the Commission's willingness to directly address the matter of opioid administration in health care settings.

NCMS recommends that the Commission exclude from the scope of these rules TCS prescriptions for employees requiring pain management for palliative and hospice care. Since these individuals often receive treatment at home, it does not appear these scenarios are currently addressed by paragraph (b). Our recommendation is largely consistent with provisions in the Strengthen Opioid Misuse Prevention Act of 2017 (hereinafter "STOP Act"). For example, the STOP Act excludes pain "treated as part of cancer care, hospice care, palliative care . . ." from the definition of "acute pain,"¹ and encourages, but does not require, prescribers to review the Controlled Substance Reporting System

¹ N.C. Sess. Law 2017-74, sec. 6.

("CSRS") prior to prescribing for hospice and palliative care patients.² Accordingly, the second sentence of Rule .0101(b) could be revised as follows:

The rules in this Subchapter do not apply to prescriptions for medications to be administered in a health care setting, or to prescriptions for an employee in hospice care or palliative care.

NCMS also supports the statements in paragraph (c) that the Commission's utilization rules do not constitute a standard of medical care, and that an employee may request relief from the Commission pursuant to § 97-25 and medical motion procedures in the event of a dispute over the appropriate pain management treatment.

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

Paragraph (d) of this rule makes clear that if a provider determines a TCS to be the only sufficient method for treating an employee's acute pain, the first prescription must be for "the lowest number of days' supply . . . not to exceed a five-day supply." A maximum seven-day supply of a TCS may be prescribed "for post-operative pain immediately following a surgical procedure." We find these limitations appropriate and largely consistent with the STOP Act's quantity limits on TCS prescriptions at the initial consultation for acute pain.³

Paragraph (e) addresses the strength of this first acute phase prescription, requiring "the lowest effective dosage . . . not to exceed 50 mg morphine equivalent dose per day, using only short-acting opioids." The Commission then proposes an exception to this dosing maximum, which NCMS interprets as an acknowledgement that opioid-tolerant or -experienced patients may require higher doses to properly manage new or additional pain in the acute phase. The ability to exceed the 50 mg morphine equivalent ("MME") dose per day is available "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."

As drafted, the Commission proposes a narrow exception that is problematic in multiple respects, but primarily: (1) it only addresses opioid-tolerance in post-operative contexts; and (2) it is unclear how, if at all, the MME dose per day of the employee's pre-existing TCS prescriptions should factor in to the dosage for the prescription authorized by this rule. The NCMS requests an alternative approach that acknowledges the broader potential needs of all opioid-tolerant employees experiencing acute pain, and that allows for reconciliation or coordination of their pre-existing medications. The following sentence, offered to replace the second sentence of paragraph (e), accomplishes this:

However, if the employee was using targeted controlled substances immediately prior to the start of the acute phase, a health care provider may

² N.C. Sess. Law 2017-74, sec. 12.

³ N.C. Sess. Law 2017-74, sec. 6.

prescribe a targeted controlled substance pursuant to this rule that, when taking into account the employee's prior prescription(s), results in a total morphine equivalent dose higher than 50 mg per day, after documenting the medical justification for the additional prescription.

The Required CSRS Review of 04 NCAC 10M .0201, .0202, and .0203

Paragraph (k) of proposed Rules .0201, .0202, and .0203 contain substantially similar requirements that a provider "shall review" an employee's prescription history in the CSRS as part of the provider's decision-making process in prescribing a TCS in acute and chronic phases of treatment. NCMS is satisfied that this is mostly consistent with STOP Act requirements,⁴ and that it creates the possibility that providers must consult the CSRS more frequently than the STOP Act requires when treating employees on continuing courses of opioid therapy.

The challenge that the Commission's CSRS review requirement presents for the provider community involves timing. The Commission proposes an effective date for all components of its opioid utilization rules of May 1, 2018. The effective date for the STOP Act's CSRS review requirement is a to-be-determined date that is driven by a series of technological upgrades to the state's database itself that are underway. This was a carefully considered and heavily negotiated aspect of the STOP Act, and was instrumental in gaining broad stakeholder support and eventual passage of the legislation. For providers that are not yet consistently using the CSRS, the timing of the Commission's requirement will create inconsistent implementation dates, which we believe could create confusion and a low initial rate of compliance with the new rules.

To resolve this operational inconsistency, we request the Commission amend paragraph (k) in each of Rules .0201, .0202, and .0203 so as to match the effective date with that established in the STOP Act. We offer the following opening clause to address this issue in all three rules:

(k) Upon the effective date specified in Section 15.(e) of N.C. Session Law 2017-74, a health care provider shall review the information in the CSRS pertaining to the employee for the preceding 12-month period . . .

Many providers already review the CSRS, and doing so is widely considered a "best practice" for opioid prescribing. The NCMS holds the view that physicians should consult the CSRS whenever necessary to understand and track a patient's history with controlled substances. But the levels of preparedness and capability within the provider community still vary. With passage of the STOP Act, the provider community entered a transition period to allow those providers adequate time to prepare (and allow the CSRS adequate time to make its changes) before the review mandate takes effect. This was a pragmatic and reasonable approach the General Assembly chose, and we urge the Commission to adopt the same course.

⁴ N.C. Sess. Law 2017-74, sec. 12.

The “Differs Substantially” Provision of N.C.G.S. § 150B-21.2

At the conclusion of an agency’s public comment period for a proposed permanent rule, North Carolina’s Administrative Procedure Act provides, in pertinent part:

An agency shall not adopt a rule that differs substantially from the text of a proposed rule published in the North Carolina Register unless the agency publishes the text of the proposed different rule in the North Carolina Register and accepts comments on the proposed different rule for the time set in subsection (f) of this section.

An adopted rule differs substantially from a proposed rule if it does one or more of the following:

- (1) Affects the interests of persons who, based on the proposed text of the rule published in the North Carolina Register, could not reasonably have determined that the rule would affect their interests.
- (2) Addresses a subject matter or an issue that is not addressed in the proposed text of the rule.
- (3) Produces an effect that could not reasonably have been expected based on the proposed text of the rule.

N.C.G.S. § 150B-21.2(g). Considerable discussion focused on this provision at the Commission’s public hearing, including whether the recommendations of the NCMS, if incorporated into the Commission’s adopted permanent rules, would result in rules that “differ substantially” from those originally proposed. This is important since adopted rules that “differ substantially” require republication and a new notice and comment period.

Should the recommendations advanced by NCMS in this letter be incorporated and adopted by the Commission, NCMS’s position is that the resulting rules would not differ substantially from the proposed versions. NCMS’s recommendations do not affect the interests of any person not already on notice about the Commission’s proposed rules, do not introduce new issues or subject matter into this series of opioid rules, nor would adopting our recommendations produce an effect that could not have been reasonably anticipated given what the Commission originally proposed.

In NCMS’s recent experience as a stakeholder in agency rulemaking initiatives across state government, we cannot recall an example of a rule being returned to an agency by the N.C. Rules Review Commission for this reason. This is not to say that rulemaking problems under § 150B-21.2(g) *never* arise, only that in our experience it is exceedingly rare.

In fact, agencies commonly adjust their proposed rules following (and in response to) public comments, and are typically successful in finally adopting those revised rules within the strictures of

§ 150B-21.2(g). So while the Commission should, of course, monitor compliance with § 150B-21.2(g) as it contemplates adoption of its opioid rules, the Commission *should not* view this provision as an absolute bar from considering and incorporating otherwise meritorious suggestions collected during the comment period.

Thank you again for the opportunity to respond to the Industrial Commission's draft rules on opioid utilization. NCMS looks forward to the Commission's continued development of these rules.

Respectfully,

A handwritten signature in black ink, appearing to read "Conor Brockett". The signature is fluid and cursive, with the first name "Conor" being more prominent.

Conor Brockett
Vice President, Legal & Regulatory Affairs