December 4, 2017

Via Email to: MEREDITH.HENDERSON@IC.NC.GOV

Re: 04 NCAC 10M .0101 – PRE-PROPOSED RULES FOR THE UTILIZATION OF OPIOIDS, RELATED PRESCRIPTIONS AND PAIN MANAGEMENT TREATMENT IN WORKERS' COMPENSATION CLAIMS

Dear Ms. Henderson,

Please accept these comments from Healthesystems as it relates to the draft proposal to adopt rules for Utilization of Opioids, Related Prescriptions, and Pain Management Treatment in Workers' Compensation Claims. Healthesystems is a pharmacy benefit manager supporting large national carriers, regional insurers, self-insureds, state insurance funds and third party administrators. In reading the proposal, it is clear that the Industrial Commission and the distinguished members of the Workers' Compensation Opioid Task Force have proposed a regulatory framework which can work in tandem with the 2016 STOP Act. Overall, we support this pre-proposal; upon consultation with our Chief Medical Officer and staff clinical pharmacists, we wish to share our perspective and provide some recommended language changes which may clarify sections of the rule.

First, we commend the Commission and the task force for incorporating a number of recommendations which appear in both the CDC Guidelines for Prescribing Opioids for Chronic Pain and the ACOEM Practice Guideline Chapter on Opioids for Treatment of Acute, Subacute, Chronic, and Postoperative Pain. Incorporating a 50 MED threshold for treatment of acute pain and chronic pain and instating a limitation on initial dosing limits at five days for the initial opioid and seven days for post-operative pain is a sound approach endorsed by both of these guidelines. We also support placing limits on long acting opioids, Fentanyl, benzodiazepines for pain and muscle relaxation and Carisprodol during the acute phase of care. The Commission also recommended ongoing urine drug monitoring and mandatory checks of the prescription monitoring program for patients who are on opioids for longer than thirty days. We support both of these measures as well.

We must also voice our concerns about some of the language within the proposal. There is a need to expand the applicability of this rule to all claims and all accident dates, more specificity in relation to prescriber documentation requirements and limits on subsequent opioid fills.

Applicability of the Rule

We note the absence of any guidance on managing patients who have been on > 50 MED of opioids for more than twelve weeks prior to the adoption of this rule. We are asking the Commission to expand applicability of these rules to all injured workers, regardless of accident date or duration of care. Workers who have been on opioids for greater than twelve weeks are as much in need of stringent monitoring and oversight as injured workers with new injuries.

In relation to long term use of opioids, The National Institutes of Health says:

> *"Despite what is commonly done in current clinical practice, there appear to be few data to support the long-term use of opioids for chronic pain management."*[1]

Given the high risks associated with long term use of opioids for chronic pain, we strongly believe the rule should be applicable to all injured workers.

Prescriber Documentation Requirements

Throughout the rule there are various documentation requirements for prescribers. We support these initial requirements and also suggest this be taken one step further to better protect injured workers from risk associated with overutilization. Modification to this section is recommended as follows:

04 NCAC 10M .0202 PRESCRIPTION OF TARGETED CONTROLLED SUBSTANCE OR OTHER MEDICATION IN AN ACUTE PHASE FOLLOWING THE FIRST PRESCRIPTION

> *(f) Notwithstanding Paragraph (e) of this Rule, the health care provider may prescribe a morphine equivalent dose higher than 50 mg per day, but not higher than 90 mg per day, after documenting the medical justification therefor, including, but not limited to, a comparison of the expected functional improvement as ~~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 clinically significant functional improvement and shall consider whether to continue the higher dosage and shall document the medical record accordingly.*

We recommend this change because the original language which states "expected benefits" is ambiguous, and replacing this with the term "functional improvement" makes it clear that documentation must specify the objective gains the patient has made as a result of the increase in dosing, i.e.; patient has increased his lifting capacity by 20 lbs. since last visit, able to stand for 30 minutes, etc.

We also recommend the physician document the medical record to specify the "exit strategy" for weaning the patient off opioids during the acute phase of care and utilization of Opioid and/or Pain Agreements between the physician and the patient. This mechanism will allow the physician to establish treatment goals with the patient for both pain and function. These kinds of agreements often delineate the expectations for appropriate use, tapering and the risks and potential consequences for misuse.

Supply Limitations

Also in *04 NCAC 10M .0202* there is guidance on prescribing of controlled substances after the first prescription, and a limitation to a 30-day supply at a time. Current state and federal law prohibits more than a 30-day supply be written at any office visit for controlled substances. In the case of opioids, we recommend subsequent opioid prescriptions after the initial fill be reduced from a 30-day supply to a 7-day supply in the acute phase. All current medical literature recommends tapering of opioids at 1-2 weeks'

[1] Pathways to Prevention Workshop: The Role of Opioids in the Treatment of Chronic Pain, National Institute of Health, Executive Summary, accessed November 29, 2017 https://prevention.nih.gov/docs/programs/p2p/ODPPainPanelStatementFinal_10-02-14.pdf

post-acute onset of pain, so we urge that the patient be provided only the minimum required amount of opioids and then be re-evaluated frequently. This requirement may increase the number of office visits at the onset of the claim, but the importance of more physician-patient interaction at the onset of the claim will surely outweigh the additional expense over the life of the claim. For this reason, we recommend the follow language change to subparagraph (d) in this section:

> *(d) A health care provider shall prescribe the lowest number of days' supply of a targeted controlled substance necessary to treat an employee's pain, not to exceed the prescription of one seven ~~30~~-day supply at a time.*

Decreasing the subsequent supply during the acute phase of care will reduce the risk of injured workers continuing on opioids beyond what is recommended in medical literature, and will prevent members of their household from being exposed to unused surplus of medications should the patient self-taper or discontinue use.

Management of patients on opioids prior to rule effective date

Conspicuously absent from the proposed rule, is guidance on what steps can be taken to help patients who have been on >50 MED in the chronic phase of care prior to this rule adoption. We urge the Commission develop rules for this subset of patients. Many states have set timelines to help injured workers and their physicians to plan for reducing or eliminating long term opioid use for treatment of chronic pain. We recommend a six-month period to be written into the rule, to allow insurers and physicians to work together with injured employees to 1) identify patients who may be in need of weaning 2) educate those individuals about the ongoing risks associated with inappropriate long term opioid therapy for chronic pain management and 3) to develop an action plan for weaning which includes alternative therapies (physical therapy, massage, acupuncture, biofeedback, cognitive behavioral therapy).

We want to express our support for the intent of this language, and we appreciate the extensive time and effort the Commission and Task Force have devoted towards developing this proposal. Our aim in providing these comments is to further ensure injured workers and their physicians are working as a team to prevent the risks associated with overutilization of opioids and other controlled substances. By implementing these recommendations, we can reduce inappropriate use of medications for all injured workers, regardless of their accident date. Thank you for considering our input on this issue and please do not hesitate to contact me directly should you have any questions or comments on this information.

Sincerely,

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