



December 6, 2017

Via email: meredith.henderson@ic.nc.gov

Meredith Henderson
North Carolina Industrial Commission

Re: Optum Workers' Compensation and Auto No-Fault Comments on Proposed Draft Opioid Utilization Rules

Thank you for the opportunity to provide comments on the proposed opioid utilization rules. The Optum Workers' Compensation & Auto No-Fault Division (OWCA) is a result of the integration of several workers' compensation pharmacy services providers, including former companies such as PMSI, Progressive Medical and Healthcare Solutions.

The OWCA Government Affairs and Clinical teams have seasoned experience in working with both public sector policy makers and private sector clients on development of treatment guidelines and drug formularies. Additionally, our expertise in workers' compensation has enabled us to fully understand and provide insight on the growing opioid crisis. We support the Commission in their efforts to implement policies to deter future opioid addiction and assist providers and patients currently utilizing opioids in properly managing their care. However, we have concerns over language in the current proposal and subsequent potential impact of unintended consequences of enacting specific language found in the proposed rule.

Additionally, we offer insight on language in the proposed rule which we believe will streamline delivery of care and support the Commission's underlying desire to reduce opioid utilization.

For these reasons, OWCA respectfully offers the following comments on and suggested changes to proposed rule language. Where we suggest language for removal, this language will appear as ~~strikethrough~~. Where we suggest language for addition, this language will appear as underlined.

Section .0100 – General Provisions

While we understand the Commission's desire is to provide a bifurcated timeframe for separately handling treatment provided to new claimants and legacy claimants, we believe the current language to be vague. An effective policy would be better achieved by tying implementation of all proposed opioid controls to the date of rule adoption.

Additionally, we believe that the proposed effective date – tied to the underlying Session Law from 2017 – of May 1, 2018 is too soon and will not provide enough lead time for all impacted stakeholders to properly prepare and implement these important opioid utilization protocols. We suggest the overall effective date of rule requirements should be no sooner than six months **after** final rule adoption.



The rules in this Subchapter shall apply to all claims . . . Section .0200 of this subchapter shall not apply to claims in which the employee received treatment with an opioid a targeted controlled substance for more than 12 consecutive weeks immediately preceding the effective date of the rules. Additionally, the requirements of Section .0200 shall apply to any new opioid treatments which shall not include continuation of existing dosage(s).

Section .0102 – Definitions

OWCA supports the Commission for having foresight to parse out the rules into specific segments. We also support the Commission’s efforts in addressing initial prescribing and treatment with an opioid as a key step in controlling future opioid utilization and abuse. However, we remain concerned with specific inclusion of “*targeted controlled substance*” as a definition and inclusion of specific drug names in the definition(s) for both “*short-acting*” and “*long-acting*” opioids. Including a definition of targeted controlled substance and tying this definition to controlled substance statutes cedes the ability of the Commission to determine and properly apply implemented controls on drugs which are of specific concern in workers’ compensation. Further, linking these proposed rules to a non-workers’ compensation statute creates the potential for unnecessary future rule-making on drugs not pertinent to workers’ compensation but defined by the controlled substance statutes. The Commission may find themselves in a situation – outside their scope of control – which mandates rule changes any time a change is made to statutes which have no bearing on the provision of care to injured workers.

For these reasons we strongly suggest removal of this language both in Section .0102 and elsewhere throughout the **entire** proposed rule, and we strongly suggest replacing the term “targeted controlled substance” with opioid(s) as grammatically correct.

04 NCAC 10M.0102(4)

~~*Targeted controlled substance means any controlled substance included in G.S. 90-90(1) or (2) or G.S. 90-91(d).*~~

In a similar vein we are concerned with inclusion of specific drug names under .0102(7) *Short-acting opioid* and .0102(8) *Long-acting opioid*. We believe that specific inclusion of these drug names creates a default drug formulary where these medications, and **only these named medications**, will fall into the requirements for review and authorization under the proposed rules. We have experienced, in other jurisdictions which have implemented formularies and treatment guidelines, the exposure of unintended consequences leading to exploitation and increased costs. We desire to assist the Commission in avoiding a similar situation in North Carolina. Additionally, by including specific drug names, we believe the Commission may limit future application of rule requirements to **only these medications** which could weaken the ability of the rule to work effectively. For these reasons we strongly suggest the removal of these specific drug names in Section .0102.



04 NCAC 10M.0102(7)

“Short-acting opioid” means any opioid ~~targeted-controlled substance~~ with a quick onset of action and short duration of analgesic activity that is formulated for dosing at intervals of less than 12 hours, ~~including but not limited to immediate-release morphine, hydromorphone, oxycodone, codeine, hydrocodone, oxycodone, and codeine in combination with acetaminophen or a nonsteroidal anti-inflammatory drug.~~

04 NCAC 10M.0102(8)

*“Long-acting opioid” or “extended-release opioid” means any opioid ~~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 8-72 hours or longer. ~~including, but not limited to, methadone, transdermal fentanyl, and extended-release formulations of morphine, oxycodone, oxycodone, and hydrocodone.~~ Drugs *For reference, drugs classified by the United States Food and Drug Administration as long-acting or extended release opioids are listed at . . .**

Section .0201 – First Prescription of Targeted Controlled Substance or Other Medication for Pain in an Acute Phase

As stated earlier in our comments we believe use of the definition and language found in Section .0102(4) *“targeted controlled substance”* should be removed throughout the entirety of Section .0200 and Section .0201 and replaced with opioid(s) as grammatically correct. We also suggest the title for 04 NCAC 10M.0201 should be revised to address these concerns and similar language in the title be replaced with opioid(s) as grammatically correct.

Additionally, we believe language in 04 NCAC 10M.0201(a) should be revised to provide better clarification for following subsections of .0201.

04 NCAC 10M.0201(a)

(a) This rule, and all included subsections, applies to the first prescription of any opioid ~~targeted-controlled substance or other medication to an employee for pain in an acute phase~~

Section .0202 – Prescription of Targeted Controlled Substances or Other Medication in an Acute Phase Following the First Prescription

As stated earlier in our comments we believe usage of the definition and language found in Section .0102(4) *“targeted controlled substance”* should be removed throughout the entirety of Section .0202 and replaced with opioid(s) as grammatically correct. We also suggest the title for 04 NCAC 10M.0202 should be revised to address these concerns and similar language in the title be replaced with opioid(s) as grammatically correct

Additionally, we believe a few minor revisions to proposed language in Section .0202 will help streamline implementation and ongoing compliance with requirements in this section. We have outlined these proposed changes below.



04 NCAC 10M.0202

- (a) This rule, and all included subsections, applies to prescriptions for an opioid ~~targeted controlled substances~~ or other medication for pain during an acute phase that are subsequent to written ~~after~~ the first prescription as described in Rule .0201 of this Section.
- (b) Before . . . are insufficient to treat the employee's pain ~~when prescribing a targeted controlled substance to an employee~~.

Section .0203 – Prescription of Targeted Controlled Substances or Other Medication in a Chronic Phase

As stated earlier in our comments we believe usage of the definition and language found in Section .0102(4) "*targeted controlled substance*" should be removed throughout the entirety of Section .0203 and replaced with opioid(s) as grammatically correct. We also suggest the title for 04 NCAC 10M.0203 be revised to address these concerns and that similar language in the title be replaced with opioid(s) as grammatically correct.

Additionally, we believe a few minor revisions to the proposed language in Section .0203 will help streamline implementation and ongoing compliance with requirements of this section. We have outlined these proposed changes below.

04 NCAC 10M.0203

- (a) This rule, and all included subsections, applies to prescriptions for an opioid ~~targeted controlled substances~~ or other medication for pain during a chronic phase.
- (f) Notwithstanding Paragraph (e) of this Rule, and after seeking preauthorization, the health care provider may prescribe a morphine equivalent dose higher than 50 mg per day, but not exceeding higher than 90 mg per day, after documenting the medical justification therefor . . .
- (g) Notwithstanding Paragraph (e) and (f) of this Rule, . . . the health care provider shall seek specific written preauthorization from the employer or carrier.

Supporting the Solution

As a leader in provision of pharmacy care services for workers' compensation claims, OWCA supports the proposed changes. We believe efforts by the Commission will help reduce the abuse of opioids in the workers' compensation system and implement reasonable levels of safety for prescribing opioids. We respectfully submit our comments and suggest changes as a direct result of our concern(s) over the currently proposed shortened implementation time frame of May 1, 2018 and the envisioned unintended consequences of using definitions found in Section .0102, specifically subparagraphs (4), (7) and (8).

We applaud the Commission in moving forward with much needed change and giving us the ability to provide feedback as a knowledgeable and experienced stakeholder. We look forward to discussing this issue in the future and supporting your efforts to provide the best workers' compensation system possible for employers and workers in North Carolina. We stand ready to



provide any documentation, data and support needed as you move forward with the rule-making process.

Sincerely,

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke extending to the right.

Kevin C. Tribout
Executive Director of Government Affairs, OWCA
kevin.tribout@optum.com