McDowell, Robert

From: David Price <dprice@prium.net>
Sent: Wednesday, December 06, 2017 4:41 PM
To: Henderson, Meredith
Subject: [External] Comments to draft utilization rules for opioid and pain management
Attachments: PRIUM Comments -- NC IC Utilization Rules on Opioids and Pain Management.pdf

Executive Secretary Henderson,

I'm attaching PRIUM's comments to the draft opioid and pain management utilization rules.

Overall, we feel that the WC Opioid Task Force did an excellent job, and we're looking forward to seeing the final rules.

Thank you.

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Meredith Henderson, Executive Secretary
North Carolina Industrial Commission
via email to Meredith.Henderson@ic.nc.gov

RE: Public Comments on the Draft Rules for the Utilization of Opioids and Pain Management Treatment in Workers' Compensation Claims

Executive Secretary Henderson,

These comments on Draft Rules for the Utilization of Opioids and Pain Management Treatment in Workers' Compensation Claims are respectfully submitted on behalf of PRIUM. PRIUM is a nationwide peer review and utilization review entity with a URAC-accredited workers' compensation utilization review program. PRIUM has assisted workers' compensation stakeholders in implementing newly-adopted treatment guidelines and utilization rules in multiple states including Arizona, California, Colorado, New York, Tennessee, and Texas. PRIUM also assisted stakeholders in implementing North Carolina's preauthorization process for surgeries and inpatient procedures under 04 NCAC 10A.1001 when that rule was introduced in 2014.

We are in support of the Industrial Commission's decision to adopt rules for the utilization of opioids and pain management of treatment in workers' compensation claims. The draft rules represent a great effort in ensuring the responsible practice of medicine in North Carolina workers' compensation claims. We commend the Industrial Commission and, in particular, the Workers' Compensation Opioid Task Force for the time and thought put into these draft rules, as well as the Executive Summary presentation.

We have organized our comments into two general suggestions with specific references to how each suggestion may be applied to specific cited draft rules.

Again, PRIUM appreciates the time and effort that the Commission and, in particular, the Workers' Compensation Opioid Task force have put into the draft rules.

Sincerely,

David Price
Compliance Counsel
PRIUM

GENERAL COMMENTS

COMMENT #1: INTENT OF RULES – VOLUNTARY OR ACTIONABLE

It is unclear whether the draft rules were intended to serve as voluntary guidelines for prescribers or as actionable rules. The draft rules currently suggest both – stating that they "do not constitute medical advice or a standard of medical care," while also mandating preauthorization for certain treatments and using mandatory language ("shall" and "shall not") rather than permissive language ("should" and "should not").

Typically, when a state agency adopts treatment guidelines or utilization rules, they are adopted either as voluntary guidelines – suggested protocols which providers are encouraged to follow but may ignore without consequence – or as actionable rules – protocols which, if not followed, will permit some additional action that would not otherwise have been available (such as a denial by the payer).

- An example of a state with voluntary guidelines would be Kansas. The Kansas Division of Workers' Compensation's website[1] announced adoption of the Official Disability Guidelines (ODG) published by the Work Loss Data Institute, and the ODG are referenced in the Division's fee schedule.[2] Even so, neither the Division's rules nor the worker's compensation statutes provide any recourse in the event that a prescriber ignores the guidelines, and the Division's fee schedule clearly states that "the medical treatment guidelines are not requirements, nor are they mandates or standards; they simply provide advice by identifying the care most likely to benefit injured workers."

- Examples of states with actionable rules would include:
  - States with mandatory preauthorization requirements (such as Texas, Ohio, and Mississippi, among others);
  - States that require the adopted treatment guidelines to be applied in a statutory utilization review or preauthorization process (such as Tennessee, California, and Arizona, among others);
  - States that permit the use of the adopted treatment guidelines as evidence in administrative hearings when medical necessity/appropriateness of treatment is disputed (such as New York, Tennessee, and Texas, among others).

The Commission's draft rules should be changed to clearly and consistently indicate either that they are intended to function merely as voluntary guidelines or, alternatively, that they are intended to serve as actionable rules. Failing to clearly demonstrate the intent will result either in unnecessary litigation (when payers improperly deny treatment that fails to comply with rules that, in reality, are merely voluntary guidelines) or in reduced effectiveness (when providers and payers decline to apply the rules, seeing them as merely voluntary).

Depending on the Commission's intent, we suggest the following.

[1] https://www.dol.ks.gov/WorkComp/odg.aspx
[2] https://www.dol.ks.gov/Files/PDF/med_fees_2017.pdf

If the Commission intends for the rules to serve as voluntary guidelines:

- References to preauthorization requirements should be removed so as not to suggest that payers may deny treatment that is not preauthorized.
    - See 04 NCAC 10M .0203(g),(h),(i), (l),and (p).

- All instances of mandatory language ("shall" or "shall not") should be changed to language that indicates a suggestion rather than a mandate ("should" or "should not").

- 04 NCAC 10M .0101(c) should be removed, as limiting the application of the rules is unnecessary when compliance with the rules is purely voluntary and cannot be enforced.

Alternatively, if the Commission intends for the rules to serve as actionable standards:

- References to preauthorization requirements should be supplemented with language clearly indicating that "the workers' compensation payer may deny reimbursement for this treatment if preauthorization is not obtained."
    - See 04 NCAC 10M .0203(g),(h),(i), (l),and (p).

- Additional language should be added to 04 NCAC 10M. 0101 to clearly state how the Executive Secretary or Deputy Commissioner shall consider the utilization rules and how much weight shall be applied to the requirements/recommendations in the rules within the medical motion process.
    - Examples:
        - Mere evidence – "In the event of a dispute, the clinical recommendations in these rules shall be considered in addition to other evidence."

        - Presumptive evidence -- "In the event of a dispute, the clinical recommendations of these rules shall be presumed correct; treatment that deviates from the recommendations of these rules shall be supported by documented findings supporting a deviation from the utilization rules."

COMMENT #2: EASE OF IMPLEMENTATION

We suggest that the draft rules be supplemented with educational resources developed by the Commission to better ease implementation of the rules by health care providers and workers' compensation payers.

This will be particularly important if the rules are intended to be merely voluntary guidelines. Any difficulty that providers face in discerning when the rules apply and how to apply them may result in their misapplication or may even deter prescribers from trying to familiarize themselves with the rules. Prescribers will be even less inclined to attempt to discern complex rules if it is commonly understood that the rules cannot or will not be enforced by the Commission.

We have identified three potential problem areas.

1. Determining whether a claim is affected by the rules

   Rather than simply looking to the date of injury to determine application of the guidelines (as is the process in Texas, Oklahoma, Tennessee, and others), draft rule 10M .0101(c) requires one to:

   - First -- determine whether the injured worker was prescribed at least one "targeted controlled substance" (TCS) upon the effective date of the rules.

   - Second – review the pharmaceutical history of the claim for the 12 weeks immediately prior to the effective date of the rules in order to determine whether there was any point within that period of 12 consecutive weeks at which the injured worker was not being prescribed at least one TCS.
     - If so, the rules apply.
     - If not, the rules do not apply.

   This more complex approach to determining applicability of the rules may create some confusion amongst payers and prescribers.

2. Determining which medications are affected.
   Often, adopted guidelines include an appendix or list of medications that are affected by the guidelines.

   The definition of "targeted controlled substance" provided in draft rule 10M. 0102(4) does not provide a list of medications or categories of medications that meet the definition; rather, it refers to two paragraphs and one subsection of two separate statutes.

   From a rulemaking standpoint, this "incorporation by reference" approach makes sense, as it will allow the definition in the rule to be updated automatically as those statutory provisions are updated.

From a clinical standpoint, this approach makes it more difficult to determine which medications are affected by the rules, as prescribers may not be familiar with paragraphs (1) and (2) of G.S. § 90-90 or subsection (d) of G.S. § 90-91.

While it is not necessary that the definition in draft rule 10M. 0102(4) be revised to re-state in full the provisions of G.S. § 90-90(1)-(2) and G.S. 90-91(d), educational materials that re-state those provisions of the referenced statutes may be very helpful to prescribers.

We also note that draft rules 10M.0201 through 10M.0203 may create additional confusion, as they claim to apply to any prescription for a TCS "or other medication" for pain. The inclusion of the phrase "or other medication" renders the reference to targeted controlled substances unnecessary. If these rules are intended to apply to any prescribed for pain – regardless of whether it is a TCS or not – the rules should be changed to state that they apply to "prescriptions of any medication prescribed for pain."

3. Similar language surrounding different requirements.
   In their current form, the draft rules include separate rules for:
   - initial prescriptions of a TCS in the acute phase (04 NCAC 10M .0201),
   - subsequent prescriptions of a TCS in the acute phase (04 NCAC 10M .0202); and
   - prescriptions of a TCS in the chronic phase (04 NCAC 10M .0203).

   These three rules contain some parallel recommendations that are identical across each rule (such as the prohibition against prescribing benzodiazepines or muscle relaxers found in draft rules 10M .0201(h), 10M .0202(l), and 10M .0203(q)); however these rules also contain recommendations that are very similar but not quite identical. (For example, both rule 201(f) and 202(g) prohibit the prescription of transdermal opioid preparations without certain supporting documentation; rule 203(i) repeats this prohibition but also adds that preauthorization is required for transdermal fentanyl).

   Without supporting educational documentation, it is likely that the nuances between similar (but not identical) rules may go unnoticed by prescribers.