Property Casualty Insurers
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Trey Gillespie
AVP, Workers Compensation

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Meredith R. Henderson
General Counsel
North Carolina Industrial Commission
4333 Mail Service Center
Raleigh, NC 27699-4333
meredith.henderson@ic.nc.gov

Re: Proposed Rules for the Utilization of Opioids and Pain Management in Workers Compensation

Dear Ms. Henderson,

Property Casualty Insurers Association of America (PCI) respectfully submits the following comments to the formal proposal to create new 04 NCAC 10M Rules for the Utilization of Opioids, Related Prescriptions, and Pain Management Treatments in Workers Compensation Claims.

Property Casualty Insurers Association of America (PCI) is a trade association representing over 1000 property and casualty insurance companies. PCI members write over $220 billion in annual premium including 35% of the commercial insurance market and 37% of the private workers compensation insurance market.

PCI supports the adoption of evidence-based medical treatment guidelines and pharmaceutical formulary to facilitate the timely and effective delivery of appropriate medical care to injured workers in North Carolina. The Workers Compensation Opioid Task Force has made significant recommendations worthy of praise and support. Nevertheless, there are some areas of concern, as outlined below.

1. **Proposed 04 NCAC 10M .0101 Purpose and Applicability of the Rules**

Proposed Section .0200 Utilization Rules for Opioid and Other Pharmacological Pain Management Treatment (acute phase and chronic phase) would not apply to claims in which the employee received treatment with a targeted controlled substance for more than 12 consecutive weeks immediately preceding the effective date of the rules. Yet these are the injured workers that are at the greatest risk of drug dependence, addiction, and overdose and are in the greatest need for regulatory protection. Granted, some of these workers may be at levels of drug dependency or addiction that immediate application of these proposed rules could create a health emergency. Consideration should be given to providing a transition period for these legacy claims to come into compliance, if possible, with the standards set forth in Section .0200. A reasonable transition period of six months would allow prescribers and payors to come up with a treatment plan to wean these injured workers off the targeted drugs or achieve a reduction in dosage to a less dangerous level of utilization.

2. **Utilization of Compounded Pain Medications/Preparations in Acute or Chronic Phase**

The proposal allows for the prescription of transcutaneous, transdermal, transmucosal, or buccal opioid preparations if there is documentation in the medical record that oral opioid dosing is medically contraindicated for the employee. In addition, there are no restrictions on the prescription of transcutaneous, transdermal, transmucosal, or buccal preparations that do not contain opioids but are prescribed for the treatment of pain.

All non-emergency out-patient prescriptions of compounded medications or preparations should be subject to appropriate evidence-based pharmaceutical formulary regulation. See Comment 4 below.

3. **Section .0500 Utilization Rules for Treatment of Substance Use Disorder**

PCI supports health care provider referrals for evaluation from a specialist to determine if an employee may benefit from discontinuation or tapering of a targeted controlled substance or for treatment for substance use disorder. This proposed rule potentially applies to claims in which the employee received treatment with a targeted controlled substance for more than twelve weeks immediately preceding the effective date of the rules in addition to new claims. As outlined in Comment 1, this is very important.

However, the proposed rule is silent as to whether the employer or carrier may refer an employee to a specialist for such an evaluation. In some cases, the health care provider may not want to make such a referral to avoid a determination that the prescribing behavior of the health care provider may have created the substance use disorder. Nevertheless, it is critical to patient safety that such an evaluation take place especially if the employee is on opioid dosage at 90 MED or higher. The rule should clearly allow the employer or carrier to make such a referral for evaluation.

4. **Evidence-Based Pharmaceutical Formulary**

The proposed rules are a good starting point for addressing a very difficult health crisis that impacts injured workers and the public. There does not appear to be a single solution to this problem. The International Association of Industrial Accident Boards and Commissions (IAIABC) and the National Conference of Insurance Legislators (NCOIL) have recognized that a more comprehensive legislative and regulatory approach should be utilized to address this problem. Adoption of an evidence-based pharmaceutical formulary is one of the recommended tools for addressing the issue and has proven effectiveness.

PCI supports state adoption of evidence-based pharmaceutical formularies which can be integrated with evidence-based medical treatment guidelines to ensure timely delivery of appropriate medical care to injured workers to achieve optimum health and return-to-work outcomes.

Texas was the first state to adopt an evidence-based workers compensation pharmaceutical formulary which became effective September 1, 2011. The Texas Legislature required the Texas Department of Insurance, Workers Compensation Research and Evaluation Group to monitor the use and effectiveness of the adopted formulary since that time.

The adopted Texas pharmaceutical formulary has proven to be very effective in providing injured workers with access to the most appropriate medication based on evidence-based medicine (“Y” drugs) while protecting injured workers from utilization of non-recommended medicine (“N” drugs) including high-dosage opioids and benzodiazepines and carisoprodol which have driven the national opioid crisis.

Key findings from the 2016 Texas Workers Compensation Research and Evaluation Group study include the following:

- Between 2011-2014 the number of injured employees receiving N-drugs fell by 83%;
- N-drug costs fell by 80%;
- N-drug prescriptions decreased by 80+ percent in all drug groups;
- There are no N-drugs in the top ten most prescribed drugs; and
- The number of claims receiving N-drug opioids with greater than 90 morphine equivalents per day decreased from almost 15,000 in 2009 to less than 500 in 2015.

With the proven success in Texas, other states have adopted, or are in the process of adopting, evidence-based pharmaceutical formularies for workers compensation including Arkansas, California, Montana, New York, Ohio, Oklahoma, Tennessee, and Washington.

Thank you for considering these comments.

Respectfully submitted,

Trey Gillespie
512-366-5430 direct line
trey.gillespie@pciaa.net