August 16, 2016

Paul Tauriello, Director
Division of Workers' Compensation
633 17th Street, Suite 400
Denver, CO 80202

Via email: paul.tauriello@state.co.us

RE: Proposed Pharmacy Related Changes to Rule 18, Medical Fee Schedule

Dear Director Tauriello,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) consisting of nearly 1500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, industry professional societies, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

NCPDP creates the standards that facilitate the interchange of data amongst pharmacies, physicians, pharmacy benefits managers, payers, processers and manufacturers—including the Universal Claim Form (UCF), the Workers' Compensation/Property & Casualty Universal Claim Form (WC/PC UCF) and the HIPAA-named Telecommunication Standard Version D.0. NCPDP's Work Group 16 (WG16) Property and Casualty/Workers' Compensation is responsible for maintaining the standards and guidance specific to workers' compensation and other property/casualty lines of insurance.

NCPDP appreciates this opportunity to submit written comments on the Division of Workers' Compensation proposed amendments to Rule 18 as they pertain to pharmacy. Though we believe we understand the Division's intent in proposing the new language, there are concerns with the ability to comply with this language and at the same time adhere to the NCPDP pharmacy billing and processing standards adopted by the Division.

<u>Reimbursement for Drugs & Medications: (3) (b) Co-Pack</u>
Clarification of the definition for co-packaged is needed within the rule.

- Multiple drugs may be packaged by the manufacturer, with or without supplies, as a kit. Do these kits fall under your definition of co-pack or are they excluded? If not excluded, where does the Division expect the provider to obtain the underlying National Drug Code (NDC)?
- Does co-pack apply to dispenser-created packages of multiple drugs, i.e. a convenience pack? If so, these drugs would not have a distinct NDC for the pack.

The pricing and billing differs for these two dispensed products. For the kit, the product has a single NDC at the kit level and is normally priced and billed based on that NDC. For the co-pack/convenience pack, the drug components are billed separately.

The proposed solution presents multiple problems for billing. Presently there is no way to identify a billed product as a co-pack or convenience pack within the standards. In addition, there is no way within the standards to report multiple original NDCs for a single product.

NCPDP encourages the use of standard transactions and is available to work with you to develop a viable way to accomplish your intent for the proper billing and reimbursement of these products. Within the standards, we cannot support the proposed language as written.

"Approved" Compound Active Ingredients

WG16 is concerned with the practical limitations that may be inherent in attempting to apply the Division's proposed methodology at the point of sale. In proposed Rule 18-6(N)(4), the Division has added language which would require the parties (both provider and payer) to review the "approved" status in the Division's treatment guidelines of individual active ingredients within a particular compound before being able to calculate the applicable billing and reimbursement category.

First, we are unclear as to what is meant by stating the guidelines "approve" of certain ingredients. As we understand them, the Division's guidelines provide recommendations for medications to be used for treatment of certain injuries and conditions, but not necessarily automatic approval of them. We request the Division clarify what is meant by this wording.

Second, the 'real time' nature of electronic pharmacy transactions is not conducive to a thorough clinical assessment of narrative-form treatment guidelines. The NCPDP Telecommunication Standard is adopted by the Division, mandated under HIPAA, and used by most pharmacy chains and processors in Colorado and throughout the country to submit and process pharmacy transactions electronically. This is done at point-of-sale in a 'real time' environment, providing the dispensing pharmacy necessary coverage information and payment assurance and enabling the patient to receive their medication in a timely fashion.

For point-of-sale transactions, formularies are typically instituted to 'flag' certain medications as covered, not covered or subject to prior authorization. This is an automated process that directs the transaction through the appropriate channels in order to reach a prompt resolution and decision. We do not believe the Division's guidelines lend themselves to such a process. Without an expeditious determination, these types of transactions may be shifted to a more manual, paper billing process – which may create extra burdens of time and expense for providers and payers. Any determination as to the approval of a medication or the reimbursement for a medication would be retrospective, after the injured worker has already received and likely used the medication. If it is the Division's intent that these types of medications be billed on paper rather than electronically, we understand this proposed language. But, if it is not, we believe a slower paper billing process may be the end result should this proposed language be adopted. We recommend the Division reassess this language to determine if it is needed.

Additional "Z" Codes

Of more concern is the continued use and proposed expansion of Colorado Division of Worker's Compensation "Z" codes. In proposed Rule 18-6(N)(5), the Division has created two new "Z" codes to

specifically apply to certain topical muscle relaxant, analgesic, anti-inflammatory and/or neuritic medications containing only over-the-counter (OTC) active ingredients based on whether the product is a patch or is not a patch.

These state-specific codes are not currently supported by the NCPDP electronic billing standard (Telecommunication Standard). This has created a situation in which pharmacies and payers/processors are forced to utilize manual methods in order to successfully process a pharmacy bill as required by Division rules using state-specific codes. A recently identified solution to accommodate the compound-related state-specific codes in electronic billing is undergoing the approval process for inclusion in the Telecommunication Standard. However, this change will not accommodate the addition of the proposed new "Z" codes for non-compounds.

NCPDP recommends the state-specific billing codes be omitted from the requirements as it is not possible for providers and payers to use these codes to identify products when using our industry-adopted standards. Reimbursement could still be based on the Division's proposed methodology to cap expenditures on these products without the use of the state specific codes, just as with any other maximum fee schedule set by rules. Pharmacy providers and payers/processors rely on our standards for the submission and processing of pharmacy transactions. If these state-specific codes are adopted, the industry would be forced to use the alternate and more time-consuming one-off manual process, adding to delays in the processing of billings for medications and additional time and costs for both sides of the transaction (provider and payer).

Should the Division want to add new state-specific codes or make other types of unsupported billing-related changes as part of this or future rule-making, we encourage Division staff to reach out to NCPDP and our Work Group well in advance of proposed changes so that we can work together toward standards-compliant solutions. This will avoid the adoption of new state-specific billing requirements with which pharmacies cannot comply while using the billing standard adopted by the Division.

Thank you for your consideration of our comments and recommendations. For direct inquiries or questions related to this letter, please contact:

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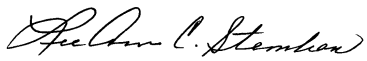
Sincerely,



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