STATE OF CALIFORNIA DEPARTMENT OF INDUSTRIAL RELATIONS DIVISION OF WORKERS' COMPENSATION

ADDENDUM TO FINAL STATEMENT OF REASONS

Subject Matter of Regulations: Workers' Compensation – Medical Treatment Utilization Schedule – Formulary

TITLE 8, CALIFORNIA CODE OF REGULATIONS ADOPT SECTIONS 9792.27.1 – 9792.27.23

The Administrative Director of the Division of Workers' Compensation (hereinafter "Administrative Director") issues the following Addendum to the Final Statement of Reasons.

UPDATE OF INITIAL STATEMENT OF REASONS AND INFORMATIVE DIGEST

Problem Addressed / Specific Purpose, Rationale, and Necessity of Each Section of the Adopted Regulations

Section 9792.27.8. Physician-Dispensed Drugs.

The regulation requires physician-dispensed drugs to be authorized through prospective review, except as specified. As originally proposed, the section allowed the physician to dispense up to a 7-day supply of an Exempt drug "on a one-time basis", and Non-Exempt drugs as allowed by the Perioperative Fill and Special Fill provisions. In the first 15-day comment modified proposal, the regulation was changed to delete "one-time basis" and instead allows the dispensing without prospective review "at the time of an initial visit that occurs within 7 days of the date of injury." The provision restricting the dispensing without prospective review to the initial visit within 7 days of injury is necessary to balance the interests of ensuring that pharmaceuticals are medically appropriate and the goal of providing needed medication quickly at the outset of an injury. The RAND study, *Implementing a Drug Formulary for California Workers' Compensation Program*, 2016, Wynn et al, reviews studies that highlight evidence of physician dispensing practices influenced by financial incentives. (See Chapter Two.) The RAND report sets forth options to address issues with physician dispensing and states in pertinent part as follows:

"Physician dispensing represents a trade-off among patient convenience and compliance, protections against dispensing of medically inappropriate drugs, and reasonable fee schedule allowances for medically appropriate drugs. DWC might consider a multipronged approach to achieve this balance:

- Patient convenience could be addressed through policy that exempts prescriptions immediately following an injury from UR (as discussed earlier, under "First-Fill Policy")....
- The prescribing of medically unnecessary drugs for the patient's condition could be addressed by requiring PR for any physician-dispensed drug unless the prescription is exempt from UR based on a first-fill policy...."

Implementing a Drug Formulary for California Workers' Compensation Program, 2016, Wynn, et al, page 88.

The Division determined it is necessary to restrict the physician dispensing of exempt drugs without prospective review to the initial visit within 7 days of the date of injury to serve as a convenience to the patient as a kind of "first fill", while retaining the prospective review if the visit is beyond 7 days. The physician can provide a prescription for the patient to obtain medication at a pharmacy if the physician-dispensing criteria are not met. If the physician seeks to dispense outside of the specified conditions, he or she can seek and obtain prospective review through the usual utilization review process, which is beneficial as it serves as a confirmation that the treatment is medically necessary.

Section 9792.27.22. Pharmacy and Therapeutics Committee – Meetings.

<u>Subdivision (c).</u> The provisions of section 9792.27.22, subdivision (c), which set forth the time requirement for advance notice of meetings, and which identify how the notice shall be distributed, constitute a non-substantive adoption, because the provisions re-state existing law contained in the Bagley-Keene Open Meeting Act (California Government Code section 11120 et seq.) The provision is necessary and does not violate the non-duplication standard, as including the provisions is necessary for the convenience of the public and enhances clarity of the procedural rules relating to the Pharmacy and Therapeutics Committee meetings.

<u>Subdivision (d).</u> The provision of subdivision (d) which places a per-speaker limit on the time allotted for speakers to address the P&T Committee is authorized by the Bagley-Keene Open Meeting Act section which allows an agency to establish reasonable regulations to limit the time allotted for public comment. (Government Code section 11125.7 subdivision (b).) The provision allotting 3 minutes per speaker is necessary to ensure adequate time for the committee to complete the business scheduled on the agenda and to ensure that all interested members of the public have the opportunity to speak. There may be a large number of public members who wish to address the committee, and if there is no time limit on each public presentation, lengthy presentations could undermine the effective conduct of business, or interfere with the ability of all members of the public to speak. Establishing a 3-minute per speaker limit will balance the need for efficient operation of the committee, with the goal of supporting public participation.

STATEMENT REGARDING SUMMARY OF COMMENTS RECEIVED AND RESPONSES THERETO CONCERNING THE REGULATIONS ADOPTED

The Notice of Modification of Proposed Regulations issued in July 2017, and the Notice of Modification of Proposed Regulations issued in September 2017, specified addresses (mail, hand delivery, FAX, e-mail) to use to submit comments, and indicated comments to other addresses would not be accepted. While use of the specified addresses is efficient for ensuring comments are recognized and properly routed within the department, the department did not exclude any comments received based upon the address to which the comment was submitted.

The comments received by the department were summarized and responded to in the Comment Charts, which are incorporated by reference.

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