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

FINAL STATEMENT OF REASONS AND UPDATED INFORMATIVE DIGEST

Subject Matter of Regulations: Official Medical Fee Schedule - Pharmaceuticals

TITLE 8, CALIFORNIA CODE OF REGULATIONS
Section 9789.40

The Acting Administrative Director of the Division of Workers' Compensation, pursuant to the authority granted by Labor Code Sections 59, 133, 4603.5, 5307.1, and 5307.3 has amended Section 9789.40 of Article 5.3 of Chapter 4.5, Subchapter 1, of Title 8, California Code of Regulations:

Section 9789.40 Pharmacy

UPDATED INFORMATIVE DIGEST

The Administrative Director incorporates the Informative Digest prepared in this matter. There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Regulatory Action.

UPDATE OF INITIAL STATEMENT OF REASONS

The Administrative Director incorporates the Initial Statement of Reasons prepared in this matter. The purposes and rationales for the regulations as set forth in the Initial Statement of Reasons continue to apply. The proposed regulations changes are summarized below.

THE FOLLOWING SECTIONS WERE AMENDED FOLLOWING THE PUBLIC HEARING:

Modifications to Section 9789.40 Pharmacy

Subdivision (b) was modified to make the text more clear. Subdivision (c) was modified to delay the effective date of the changes to March 1, 2007.

Specific Purpose of these modifications to Section 9789.40:

The purpose of the changes to Section 9789.40 was to remove possible ambiguities in the language, and to delay the date on which the fee changes would become effective.

Necessity:

It was necessary to eliminate possible ambiguities, and to change the date on which the changes would become effective. The change in the date on which the fee changes become effective will give the regulated public approximately one hundred seventy days notice since the Notice of proposed Rulemaking was mailed, and one hundred twenty days notice since the date of the public hearing.

Modifications to Section 9789.40 subdivision (b)

Subdivision (b) was changed by moving the sentence, "The maximum fee shall include only a single professional dispensing fee for dispensing for each dispensing," from subparagraph (1) to the initial portion of the subdivision, and adding the phrase, "of a drug" at the end of that sentence. The changes makes clear that only a single professional fee (for dispensing) is payable for each dispensing of a drug, regardless whether the fee is paid under subdivision (b), subdivision (b)(1), or subdivision (b)(2).

The initial part of subdivision (b) was changed by inserting the modifying phrase, "drug cost portion of the" immediately before the word "fee."

The initial part of subdivision (b) was changed for clarity by inserting the word "in" into the clause, "if the patient is in a skilled nursing facility or an intermediate care facility," immediately before the words "an intermediate care facility."

Paragraph (2) of subdivision (b) was changed for clarity by changing the word "reimbursement" to "maximum fee."

Specific Purpose of changes to Section 9789.40:

The pharmacy fee schedule relates closely to the fees prescribed by statute and regulations of the Department of Health Services applicable to fees paid to Medi-Cal pharmacy providers. The Medi-Cal statute, Welfare & Institutions Code §14105.45, uses the term ***reimbursement*** in speaking of what Medi-Cal pharmacy providers are to be paid, and Labor Code §5307.1 refers to *maximum reasonable* ***fee***, in addressing the fees to be set by the Administrative Director for workers' compensation pharmacy payments. The use of the different terms, *reimbursement* and *fee*, when addressing the same payment of money, is confusing. The possible confusion in terms is further enhanced by the provision in Welfare & Institutions Code §14105.45 that the *reimbursement* is to include both a cost of drug and a "professional *fee* for dispensing."

The regulation is intended to provide for the Medi-Cal professional fee, and only one Medi-Cal professional *fee*, no matter how the basis for the cost of the drug is determined. This was accomplished by moving the language about the professional fee from the end of paragraph (1) of subdivision (b) to within the body of the initial portion of subdivision (b).

To avert possible confusion in the regulated public as to the intent of the regulation, the word *fee* in subdivision (a) was changed to *reimbursement*, because it refers to the Medi-Cal payment system, which uses the term *reimbursement* to mean the same thing that Labor Code §5307.1 means by the use of the term *fee*. For the same reason, in paragraph (2) of subdivision (b), the term *maximum fee* was substituted for the term *reimbursement* in the originally proposed text. With this substitution, the term *maximum fee* is now used in both paragraphs (1) and (2) of subdivision (b) and intended to have the same meaning in each paragraph. For the same reason, the phrase, "*plus the professional fee allowed by subdivision (b) of this section*," was added to both paragraphs (1) and (2). The addition of this phrase eliminates any possible ambiguity that the maximum reasonable *fee* provided for in Labor Code §5307.1 includes both a drug cost and the professional *fee* which is part of the *reimbursement* provided for in Welfare & Institutions Code §14105.45.

Necessity:

It was necessary to make these language changes in subdivision (b) in order that the regulation would be clear and without possible ambiguity in how the fee is to be determined.

UPDATE OF MATERIAL RELIED UPON

The document cited as *Study of the Cost of Pharmaceuticals in Workers' Compensation* by Frank Neuhauser, *et. al.*, is dated June, 2000, instead of November, 1993. Additional documents beyond those identified in the Initial Statement of Reasons, relied upon by the Administrative Director or taken into consideration when finalizing the regulation, include:

1. Wilson L, Gitlin M. New Workers' Compensation Legislation: Expected Pharmaceutical Cost Savings. *American Journal of Industrial Medicine*. 2005; 48(4):239-48.

2. Matthew Gitlin, Pharm.D., Leslie Wilson, Ph.D. The Pricing and Distribution of Repackaged Drugs: Cost Effects to the California Workers' Compensation System, Payers and Providers. Department of Clinical Pharmacy, University of California, San Francisco, San Francisco 94143.

3. Gitlin M., Wilson L. Repackaged Pharmaceuticals in the California Workers' Compensation System: From Distribution and Pricing Options to Physician and Retail Dispensing. *American Journal of Industrial Medicine*. Pending Revisions.

4. Neuhauser, Frank, Alex Swedlow, and Barbara O. Wynn, *Impact of Physician-Dispensing of Repackaged Drugs on California Workers' Compensation, Employers Cost, and Workers' Access to Quality Care,* prepared for the California Commission on

Health and Safety and Workers' Compensation, July, 2006; available on the internet website of the Commission at: www.dir.ca.gov/CHSWC .

5. Public comments submitted before the end of the public comment period.

6. Transcript of Hearing of testimony, October 31, 2006.

Although documents numbered 1 through 4, above, as well as the documents listed in the Initial Statement of Reasons are listed as documents relied upon by the Administrative Director in proposing the regulations, no document was relied on in total, and no specific conclusion nor finding of any document was conclusive or determinative of the action taken by the Administrative Director in adopting this regulation.

CONSIDERATION OF ALTERNATIVES

The Division considered all comments submitted during the public comment periods, and made modifications based on those comments to the regulations as initially proposed. The Administrative Director has now determined that no alternatives proposed by the regulated public or otherwise considered by the Division of Workers' Compensation would be more effective in carrying out the purpose for which these regulations were proposed, nor would they be as effective as and less burdensome to affected private persons and businesses than the regulations that were adopted.

SUMMARY OF COMMENTS RECEIVED AND RESPONSES THERETO CONCERNING THE REGULATIONS ADOPTED

The summaries and responses to comments of each organization or individual which were received during the 45 day comment period or testified at the public hearing are contained in the rulemaking file and are incorporated by reference herein.

The public comment period was as follows:

A 45-day comment period on proposed regulations: September 15, 2006 through October 31, 2006.