

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

INITIAL STATEMENT OF REASONS

Subject Matter of Regulations: Official Medical Fee Schedule - Pharmaceuticals

**TITLE 8, CALIFORNIA CODE OF REGULATIONS
SECTION 9789.40**

Section 9789.40 Pharmacy

BACKGROUND TO REGULATORY PROCEEDING

In 2003, the Legislature enacted S.B. 228 (Alarcon) as part of workers' compensation reform legislation intended to reduce unnecessary medical and litigation expenses, among other things, in workers' compensation cases in California. [Stats. 2003, ch. 639] As one of its provisions, the bill substantially amended Labor Code section 5307.1, which provided for the Administrative Director to adopt a medical fee schedule for workers' compensation claims which would establish maximum reasonable fees. Commencing January 1, 2004, maximum reasonable fees for pharmacy services and drugs not covered by a Medicare fee schedule payment for inpatient hospital stays, were to be 100 percent of fees prescribed in the relevant Medi-Cal payment system. For pharmacy services or drugs not covered by a Medi-Cal payment system, the Administrative Director could establish maximum fees. However, the maximum fees paid could not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that required comparable resources. For pharmacy services and drugs that were not covered by a Medi-Cal payment system, the maximum reasonable fee paid shall not exceed the fee specified in the Official Medical Fee Schedule (OMFS) in effect on December 31, 2003.

In 2003, the Administrative Director adopted regulation 9789.40, effective January 1, 2004, which provided that the maximum fees for pharmacy services were 100% of the fee prescribed by Medi-Cal, and which provided that for pharmacy services and drugs not covered by Medi-Cal, the maximum fee was the fee specified in the 2003 OMFS.

This amendment is intended to establish fees for those drugs not now covered by the Medi-Cal payment system. Medi-Cal does not cover drugs dispensed by physicians directly to patients. Many of the most commonly used drugs in California workers' compensation cases are dispensed by physicians. The National Drug Code for most of these drugs is not within Medi-Cal's payment database, because the drugs have been repackaged and relabeled by a repackager and given a new National Drug Code. The repackager supplies the relabeled drugs to the dispensing physicians. The repackager normally establishes a new average wholesale price for the drugs as repackaged which is much higher on a per unit basis than the average wholesale price for the drugs which was

set by the original labeler of the drugs. Under the 2003 OMFS, it is the average wholesale price set by the repackager which determines the maximum reasonable charge for the drugs.

NECESSITY

Labor Code section 5307.1 provides for the Administrative Director to prescribe a fee schedule for medical treatment. It also provides that until the Administrative Director adopts a fee schedule for pharmacy services and drugs, the maximum reasonable fee is to be 100% of the fees prescribed in the Medi-Cal payment system, and for pharmacy services and drugs that are not covered by a Medi-Cal payment system, the maximum reasonable fee paid shall not exceed the fee specified by the OMFS in effect on December 31, 2003. This regulation is necessary to prescribe fees for drugs not covered the Medi-Cal payment system.

TECHNICAL, THEORETICAL, OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

The Division relied upon the following technical, theoretical, or empirical studies, reports, or similar documents in proposing the above-identified regulations:

(1) *Paying for Repackaged drugs Under the California Workers' Compensation Official Medical Fee Schedule*, Barbara O. Wynn, a Rand Institute for Civil Justice Working Paper, prepared for the California Commission on Health and Safety and Workers' Compensation, May, 2005; available on the internet website of the Commission at: www.dir.ca.gov/CHSWC .

(2) *Study of the Cost of Pharmaceuticals in Workers' Compensation*, Frank Neuhauser, Alex Swedlow, Laura Gardner, and Ed Edelstein, prepared for the California Commission on Health and Safety and Workers' Compensation, November, 1992; available on the internet website of the Commission at: www.dir.ca.gov/CHSWC .

(3) *Pharmaceutical Cost Management in California Workers' Compensation, a Report to the Industry*, California Workers' Compensation Institute, Oakland, California, November, 2002; available on the internet website of the Institute at: www.cwci.org.

(4) *Redbook; Pharmacy's Fundamental Reference, 2005 Edition*, Thomson Healthcare, Inc., Montvale, New Jersey, 2005.

(5) *The Cost and Use of Pharmaceuticals in Workers' Compensation: A Guide for Policymakers*, Richard A Victor and Petia Petrova, published by Workers' Compensation Research Institute, Cambridge, Massachusetts, June, 2006;

SPECIFIC TECHNOLOGIES OR EQUIPMENT REQUIRED (if applicable)

No specific technologies or equipment are required by these proposed regulations.

FACTS ON WHICH THE AGENCY RELIES IN SUPPORT OF ITS INITIAL DETERMINATION THAT THE REGULATIONS WILL NOT HAVE A SIGNIFICANT ADVERSE IMPACT ON BUSINESS

The Administrative Director has determined that these proposed regulations will not have a significant adverse impact on business. The regulations will generally reduce the cost of pharmaceuticals in workers' compensation claims. This will directly reduce costs to self-insured employer businesses and to workers' compensation insurance carriers. To the extent that insurance carriers may decide to pass on their reduced costs to their insureds, it will reduce costs to all California businesses. The regulations are expected to have an adverse impact on a few large pharmaceutical businesses which repackage drugs for dispensing by physicians. The regulations are expected to have an adverse impact on an unknown number of physicians who dispense large quantities of repackaged drugs to their workers' compensation patients. The extent of the impact on an affected physician office is dependent upon the combined value of repackaged drugs that the physician office annually dispenses to workers' compensation patients in California.

SECTION 9789.40

Specific Purpose of This Section:

The purpose of the section is establish fees for pharmaceuticals in workers' compensation treatment, which are not covered by a Medi-Cal payment system, in a manner by which the maximum fees would not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that required comparable resources.

Necessity:

This section is necessary to establish fees for pharmaceuticals in workers' compensation treatment, which are not covered by a Medi-Cal payment system. The maximum reasonable fee for pharmaceuticals in workers' compensation treatment is 100% of the fees prescribed in the Medi-Cal payment system. The Administrative Director is to establish maximum fees for drugs that are not covered by a Medi-Cal payment system. Those maximum fees are not to exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources. Until the Administrative Director adopts a fee schedule for pharmacy services and drugs that are not covered by a Medi-Cal payment system, the maximum reasonable fee for those drugs are the fees prescribed by the official medical fee schedule (OMFS) in effect on December 31, 2003. This regulation is necessary to prescribe fees for those drugs not covered the Medi-Cal payment system.

It is necessary to identify pharmaceuticals by the National Drug Code because that is the identifier used in Medi-Cal's database of drugs, and universally used in the Official Medical Fee Schedule -Pharmacy
Proposed Regulations
Initial Statement of Reasons (September, 2006)

8 CCR §§ 9789.40

pharmaceutical industry. For repackaged drugs that have a National Drug Code not in the Medi-Cal database, but for which the National Drug Code of the underlying drug product from the original labeler is in the Medi-Cal database, an equivalent Medi-Cal price can be determined by using the National Drug Code for the underlying drug product, calculated on a per unit basis. For drugs for which the underlying drug's National Drug Code cannot be identified, to determine a Medi-Cal price for a drug of comparable resources, the price is set at 83% of the average wholesale price of the lowest priced therapeutically equivalent drug, because Medi-Cal would pay 83% of the average wholesale price of a brand name drug, if it authorized the use of a brand name drug. The therapeutically equivalent drug is chosen, because it is a drug of comparable resources.

Consideration of Alternatives:

At this time, the Administrative Director has not identified any more effective nor any equally effective yet less burdensome alternative system for determining maximum reasonable fees for pharmaceuticals which are not covered by a Medi-Cal payment system.