

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

***NOTICE OF PROPOSED RULEMAKING  
AND INFORMATIVE DIGEST***

**Subject Matter of Regulations: Official Medical Fee Schedule - Pharmaceuticals**

**NOTICE IS HEREBY GIVEN** that the Administrative Director of the Division of Workers' Compensation (hereinafter "Administrative Director"), exercising the authority vested in the Administrative Director by Labor Code sections 59, 133, 4603.5, 5307.1, and 5307.3, proposes to adopt the proposed regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

**PROPOSED REGULATORY ACTION**

The Department of Industrial Relations, Division of Workers' Compensation ("DWC"), proposes to amend Article 5.3 of Chapter 4.5, Subchapter 1, of Title 8, California Code of Regulations, commencing with Section 9789.40:

Amend Section 9789.40      Pharmacy

**TIME AND PLACE OF PUBLIC HEARING**

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, either orally or in writing, with respect to the subjects noted above. The hearing will be held at the following time and place:

**Date: October 31, 2006**  
**Time: 10:00 a.m. to 5:00 pm or conclusion of business**  
**Place: Auditorium**  
**Elihu Harris State Building**  
**1515 Clay Street**  
**Oakland, California 94612**

The State Office Building and its Auditorium are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or any other type of reasonable accommodation to facilitate effective communication and program access for persons with disabilities, are available upon request. Please contact the Statewide Disability Accommodation Coordinator at 1-866-681-1459 (toll free), or through the California Relay Service by dialing 711 or 1-800-735-2929 (TTY/English) or 1-800-855-3000 (TTY/Spanish) as soon as possible to request assistance.

**Please note that public comment will begin promptly at 10:00 a.m. and will conclude when the last speaker has finished his or her presentation or 5:00 p.m., whichever is earlier. If public comment concludes before the noon recess, no afternoon session will be held.**

The Administrative Director requests, but does not require, that any persons who make oral comments at the hearing also provide a written copy of their comments. Equal weight will be accorded to oral comments and written materials.

## AUTHORITY AND REFERENCE

The Administrative Director is undertaking this regulatory action pursuant to the authority vested in the Administrative Director by Labor Code sections 59, 133, 4603.5, 5307.1, and 5307.3.

Reference is to Labor Code Sections 4600, 4603.2, and 5307.1.

## INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of his or her employment. Labor Code section 5307.1 requires the Administrative Director to adopt an official medical fee schedule that establishes maximum fees paid for medical services under the workers' compensation system.

Existing law, commencing January 1, 2004, requires the Administrative Director to adopt these fees in accordance with the fee-related structure and rules of the relevant Medicare and Medi-Cal payment systems. The existing § 9789.40 provides that for drugs not covered by the Medi-Cal payment system, the Official Medical Fee Schedule (OMFS) of 2003 applies. Many drugs which are commonly dispensed by physicians are not covered by the Medi-Cal payment system. This regulation amendment is intended to provide a pricing scheme for those drugs.

This proposed regulatory change implements, interprets, and makes specific Sections 4600, 4603.2, and 5307.1 of the Labor Code as follows:

### **Section 9789.40. Pharmacy.**

This section sets forth the maximum reasonable fees for pharmacy services.

(a) This subdivision sets forth the maximum reasonable fees for pharmacy services after January 1, 2004. The word *pharmaceuticals* is added before the phrase *pharmacy services*, to clarify that the entire regulation applies both to drugs dispensed by a pharmacy, and drugs dispensed directly by a physician. The word *fee* is changed to *reimbursement*, to mirror the language used in the Medi-Cal statutes. The phrase *including the Medi-Cal professional fee for dispensing* is added at the end of the first sentence.

(b) This subdivision is changed to provide that if a pharmacy service or drug is not covered by Medi-Cal, the maximum reasonable fee is to be determined according to the rules of this subdivision, plus the professional dispensing fee of \$7.25, or \$8.00 for nursing home patients.

(b) (1) This subdivision provides that if the National Drug Code (NDC) for the product as dispensed, is not in the Medi-Cal database, but the NDC for the underlying drug product from the original labeler is in the Medi-Cal database, then the maximum reasonable fee is the fee that would be allowed pursuant to Welfare and Institutions Code section 14105.45, using the NDC for the underlying drug product, calculated on a per unit basis.

(b) (2) This subdivision provides that if neither the NDC of the drug as dispensed, nor the NDC for the underlying drug from the original labeler is in the Medi-Cal database, then the reimbursement is 83% of the average wholesale price of the lowest priced therapeutically equivalent drug, calculated on a per unit basis.

(c) (1) This subdivision provides a definition of therapeutically equivalent drugs.

(c) (2) This subdivision provides a definition of the phrase *National Drug Code for the underlying drug product from the original labeler*.

(d) This subdivision provides that these changes are to become effective December 1, 2006.

## DISCLOSURES REGARDING THE PROPOSED REGULATORY ACTION

The Administrative Director has made the following initial determinations:

- **Significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states:** None.
- **Adoption of this regulation will not:** (1) create jobs within the State of California; (2) create new businesses or eliminate existing businesses within the State of California; or (3) affect the expansion of businesses currently doing business in California.
- **Adoption of this regulation may possibly eliminate jobs within the State of California.**
- **Effect on Housing Costs:** None.
- **Cost impacts on representative private person or business:** The Administrative Director has made an initial determination that the proposed regulations will have the following cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed regulations: To the extent that the representative private person or business is a medical office which dispenses drugs directly to workers' compensation patients, the medical office will experience a decrease in income, due to a much smaller profit on the dispensed drugs. As it cannot be known what is the current dollar volume of physician dispensed drugs, nor the dollar volume of such drugs for a typical medical office, there cannot be an estimate of the actual cost impact for any such representative private person or business. The Administrative Director has made an initial determination that the proposed regulations may have a significant adverse economic impact on representative private persons or directly affected businesses. The entities directly affected by the regulation, which governs payments for pharmaceuticals in workers' compensation cases, include: (1) employers who are large and financially secure enough to be permitted to self-insure their workers' compensation liability and who administer their own workers' compensation claims; (2) private insurance companies which are authorized to transact workers' compensation insurance in California; (3) large pharmaceutical manufacturers and repackagers; and (4) medical offices which dispense drugs directly to workers' compensation patients. Only the last two categories, manufacturers, repackagers, and medical offices, will experience an economic impact which is adverse.

## FISCAL IMPACTS

- **Costs or savings to state agencies or costs/savings in federal funding to the State:** Minimal costs to state agencies in their capacity as employers, which may result from the need to revise computer programs, if any, for determining correct pharmaceutical maximum fees. Some savings to state agencies in their capacity as employers, which will result from lower prices paid for some pharmaceuticals provided to employees in workers' compensation cases.
- **Mandate on Local Agencies:** None. The proposed regulations will not impose any new mandated programs or increased service levels on any local agency or school district. The potential costs imposed on all public agency employers by these proposed regulations, although not a benefit level increase, are not a new State mandate because the regulations apply to all employers, both public and private, and not uniquely to local governments. The Administrative Director has determined that the proposed regulations will not impose any new mandated programs on any local agency or school district. The California Supreme Court has determined that an increase in workers' compensation benefit levels does not constitute a new State mandate for the purpose of local mandate claims because the increase does not impose unique requirements on local governments. See County of Los Angeles v. State of California (1987) 43 Cal.3d 46. The potential costs imposed on all public agency employers and payors by these proposed regulations, although not a benefit level increase, are similarly not a new State mandate because the regulations apply to all employers and payors, both public and private, and not uniquely to local governments.
- **Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code:** None. (See "Local Mandate" section above.)
- **Other nondiscretionary costs/savings imposed upon local agencies:** None. (See "Local Mandate" section above.)

## EFFECT ON SMALL BUSINESS

The Administrative Director has determined that the proposed regulation will affect small business.

## CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Administrative Director must determine that no reasonable alternative considered or that has otherwise been identified and brought to the Administrative Director's attention would be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposed actions.

The Administrative Director invites interested persons to present reasonable alternatives to the proposed regulation at the scheduled hearing or during the written comment period.

## PUBLIC DISCUSSIONS OF PROPOSED REGULATION

Proposed regulatory language was posted on the forum website of DWC, and public comment was received and considered.

**AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF  
PROPOSED REGULATION / INTERNET ACCESS**

An Initial Statement of Reasons and the text of the proposed regulation have been prepared and are available from the contact person named in this notice. The entire rulemaking file will be made available for inspection and copying at the address indicated below or a copy will be provided upon written request.

In addition, this Notice, the Initial Statement of Reasons, and the text of regulations may be accessed and downloaded from the Department of Industrial Relations' Internet site at [www.dir.ca.gov](http://www.dir.ca.gov) under the heading "Rulemaking-proposed regulations." Any subsequent changes in regulation text and the Final Statement of Reasons will be available at that Internet site when made.

**PRESENTATION OF ORAL AND/OR WRITTEN COMMENTS, USE OF  
PHOTOGRAPHY AT HEARING, AND DEADLINE  
FOR SUBMISSION OF WRITTEN COMMENTS**

Members of the public are invited to present oral and/or written statements, arguments or evidence at the public hearing. If you provide a written comment, it will not be necessary to present your comment as oral testimony at the public hearing. To provide everyone a chance to speak, public testimony will be limited to 10 minutes per speaker and should be specific to the proposed regulations. Testimony which would exceed 10 minutes may be submitted in writing. In order to ensure unimpeded access for disabled individuals wishing to present comments and to facilitate the accurate transcription of public comments, camera usage will be allowed in only one area of the hearing room.

Any person may submit written comments on the proposed regulation to the DWC contact person:

Ms. Maureen Gray  
Regulations Coordinator  
Division of Workers' Compensation  
Post Office Box 420603  
San Francisco, CA 94142

Written comments may also be submitted by facsimile transmission (FAX), addressed to the contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail), using the following e-mail address: [dwcrules@hq.dir.ca.gov](mailto:dwcrules@hq.dir.ca.gov)

Unless submitted prior to or at the public hearing, all written comments must be received by the agency contact person, no later than 5:00 p.m. on October 31, 2006. Equal weight will be accorded to oral and written materials.

**COMMENTS TRANSMITTED BY E-MAIL OR FACSIMILE**

Due to the inherent risks of non-delivery by facsimile transmission and email transmission, the Administrative Director suggests, but does not require, that a copy of any comments transmitted by facsimile transmission or email transmission also be submitted by regular mail.

**Comments sent to other e-mail addresses or other facsimile numbers will not be accepted.**

**Comments sent by e-mail or facsimile are subject to the deadline set forth above for written comments.**

**AVAILABILITY OF RULEMAKING FILE AND LOCATION  
WHERE RULEMAKING FILE MAY BE INSPECTED**

Any interested person may inspect a copy or direct questions about the proposed regulation, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file.

The rulemaking file, including the Initial Statement of Reasons, the complete text of the proposed regulation and any documents relied upon in this rulemaking may be inspected during normal business hours (8:00 a.m. to 5:00 p.m., Monday through Friday, excluding public holidays) at the following location:

Division of Workers' Compensation  
1515 Clay Street, 17th Floor  
Oakland, California 94612

**AVAILABILITY OF RULEMAKING DOCUMENTS ON THE INTERNET**

Documents concerning this proceeding are available on the Division's website: [www.dir.ca.gov](http://www.dir.ca.gov). To access them, click on the "Rulemaking - proposed regulations" link, then click on the "Division of Workers' Compensation regulations" link and scroll down the list of rulemaking proceedings to find the rulemaking link, "Official medical fee schedule – pharmaceuticals."

**CONTACT PERSON:**

Nonsubstantive inquiries concerning this action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed regulation, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file may be directed to the contact person. The contact person is:

Ms. Maureen Gray  
Regulations Coordinator  
Division of Workers' Compensation  
Post Office Box 420603  
San Francisco, CA 94142

The telephone number of the contact person is (510) 286-7100.

**BACK-UP CONTACT PERSON / CONTACT PERSON FOR  
SUBSTANTIVE QUESTIONS**

To obtain responses to questions regarding the substance of the proposed regulation, or in the event the contact person is unavailable, inquiries should be directed to: Richard Starkeson, Counsel, at the same address and telephone number as noted above for the contact person.

**AVAILABILITY OF CHANGES FOLLOWING PUBLIC HEARING**

If the Administrative Director makes changes to the proposed regulation as a result of the public hearing and public comment received, the modified text with changes clearly indicated will be made available for public comment for at least 15 days prior to the date on which the regulation is adopted. The modified text will be made available on the Division's website: [www.dir.ca.gov](http://www.dir.ca.gov) and may be located by following the direction provided above.

#### **AVAILABILITY OF THE FINAL STATEMENT OF REASONS**

Upon its completion, the Final Statement of Reasons will be available and copies may be requested from the contact person named in this notice or may be accessed on the Division's website: [www.dir.ca.gov](http://www.dir.ca.gov) by following the directions provided above.

#### **AUTOMATIC MAILING**

A copy of this Notice, including the Informative Digest, will automatically be sent to those interested persons on the Administrative Director's mailing list.

If adopted, the regulations will appear in Title 8, California Code of Regulations, commencing with section 9789.40.