STATE OF CALIFORNIA

**DEPARTMENT OF INDUSTRIAL RELATIONS**

**Division of Workers’ Compensation**

### NOTICE OF PROPOSED RULEMAKING

**Subject Matter of Regulations: Workers’ Compensation – Official Medical Fee Schedule: Physician and Non-Physician Practitioner Fee Schedule and Pharmaceutical Fee Schedule**

**TITLE 8, CALIFORNIA CODE OF REGULATIONS**

**Section 9789.12.1 et seq.**

**NOTICE IS HEREBY GIVEN** that the Administrative Director of the Division of Workers’ Compensation, pursuant to the authority vested in him by Labor Code sections 59, 133, 4603.5, 5307.1 and 5307.3 proposes to amend sections 9789.12.1, 9789.13.2, 9789.13.3, 9789.40, 9789.111 and adopt new sections 9789.40.1 through 9789.40.6, in Article 5.3 of Division 1, Chapter 4.5, Subchapter 1, of title 8, California Code of Regulations, relating to the Official Medical Fee Schedule – Physician and Non-Physician Practitioner Services and Pharmaceutical Services.

## PROPOSED REGULATORY ACTION

The Division of Workers’ Compensation proposes to modify existing regulations and adopt new regulations, related to the physician and non-physician practitioner fee schedule and the pharmaceutical services fee schedule by amending Article 5.3 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations. The following regulations are proposed for amendment or adoption:

| **Section to Amend/Adopt** | **Title of Section** |
| --- | --- |
| Section 9789.12.1 | Physician Fee Schedule: Official Medical Fee Schedule for Physician and Non-Physician Practitioner Services – For Services Rendered On or After January 1, 2014 [amend] |
| Section 9789.13.2 | Physician-Administered Drugs, Biologicals, Vaccines, Blood Products [amend] |
| Section 9789.13.3 | Physician-Dispensed Drugs [amend] |
| Section 9789.40 | Pharmacy – Pharmaceuticals Dispensed and Pharmaceutical Services Rendered Prior to [Month Day, 2024] [amend] |
| Section 9789.40.1 | Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy on or after [Month Day, 2024] [adopt] |
| Section 9789.40.2 | Compounded Pharmaceuticals Dispensed By a Pharmacy on or after [Month Day, 2024] [adopt] |
| Section 9789.40.3 | Compounding Fee and Sterility Fee: Route of Administration Compounding Fee / Sterility Fee Table; and Dosage Form Compounding Fee Table: Pharmacy Dispensed Compounded Drugs on or after [Month Day, 2024] [adopt] |
| Section 9789.40.4 | Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after [Month Day, 2024] [adopt] |
| Section 9789.40.5 | Pharmaceuticals Dispensed By a Physician on or after [Month Day, 2024] [adopt] |
| Section 9789.40.6 | Compounded Pharmaceuticals Dispensed By a Physician on or after [Month Day, 2024] [adopt] |
| Section 9789.111 | Effective Date of Fee Schedule Provisions [amend] |

**AN IMPORTANT PROCEDURAL NOTE ABOUT THIS RULEMAKING:**

The Official Medical Fee Schedule "establish(es) or fix(es) rates, prices, or tariffs" within the meaning of Government Code Section 11340.9, subdivision (g), and is therefore not subject to Chapter 3.5 of the Administrative Procedure Act (APA) (commencing at Government Code Section 11340) relating to administrative regulations and rulemaking.

This rulemaking proceeding to amend the Physician and Non-Physician Practitioner Fee Schedule, and the Pharmacy Fee Schedule and to adopt a new Pharmaceutical Fee Schedule is being conducted under the Administrative Director’s rulemaking power under Labor Code sections 133, 4603.5, 5307.1 and 5307.3. This regulatory proceeding is subject to the procedural requirements of Labor Code Section 5307.4.

This Notice and the accompanying Initial Statement of Reasons are being prepared to comply with the procedural requirements of Labor Code Section 5307.4 and for the convenience of the regulated public to assist the regulated public in analyzing and commenting on this non-APA rulemaking proceeding.

## TIME AND PLACE OF PUBLIC HEARING

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, oral or in writing, with respect to the proposed regulatory action, on the following date:

Date: April 11, 2024

Time: 11:00 a.m. to 5:00 p.m., or until conclusion of business

Place: Elihu Harris State Office Building – 2nd Floor, Room 1

 1515 Clay Street

 Oakland, CA 94612

Please note that public comment will begin promptly at 11:00 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 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.

**ACCESSIBILITY**

The State Office Building and its Auditorium are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or other type of reasonable accommodation to facilitate effective communication 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.

**WRITTEN COMMENT PERIOD**

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department of Industrial Relations, Division of Workers’ Compensation. The written comment period closes **on April 11, 2024.** Equal weight will be accorded to oral comments presented at the hearing and written materials.

Submit written comments concerning the proposed regulations prior to the close of the public comment period to:

Maureen Gray

Regulations Coordinator

Department of Industrial Relations

Division of Workers’ Compensation

Post Office Box 420603

San Francisco, CA 94142

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

Submit written comments prior to the close of the public comment period at 11:59 p.m. on April 11, 2024**.**

## AUTHORITY AND REFERENCE

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

Reference is to Labor Code sections 4600, 5307.1 and 5307.11.

## INFORMATIVE DIGEST AND 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 injury or illness arising out of, and occurring in the course of employment. Labor Code section 4600 requires an employer to provide medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury or illness. Under existing law, payment for medical treatment shall be no more than the maximum amounts set by the Administrative Directive in the Official Medical Fee Schedule (OMFS) or the amounts set pursuant to a contract. (Labor Code sections 5307.1, 5307.11.)

Labor Code section 5307.1 was amended effective January 1, 2004 to specify that the maximum fee schedule for drugs and pharmacy services will be based upon 100% of the fees prescribed in the Medi-Cal payment system. The statute also states that for a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum fee shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources. The statute was amended effective January 1, 2012 by Assembly Bill 378 (Statutes 2011, Chapter 545) to add additional provisions relating to compounded drugs and physician-dispensed drugs and physician-dispensed devices. The statute specifies that a compounded drug shall be billed by the compounding pharmacy or dispensing physician at the ingredient level, with each ingredient identified using the applicable National Drug Code (NDC). Ingredients without an NDC are not separately reimbursable.

For many years the Medi-Cal pharmacy fee schedule formula for legend (prescription) and non-legend (non-prescription) drugs was the lower of “usual and customary charge” or “estimated acquisition cost”, plus a dispensing fee of $7.25 (or $8.00 if the patient resided in a nursing home.) The “estimated acquisition cost” was the lower of Average Wholesale Price (AWP) minus 17%, the Federal Upper Limit, or the Maximum Allowable Ingredient Cost.

On February 1, 2016, the Centers for Medicare & Medicaid Services (CMS) published the Covered Outpatient Drug final rule (Federal Register (81 FR 5170)) requiring Medicaid programs to adopt a new methodology for legend and non-legend drugs that replaces “estimated acquisition cost” with “actual acquisition cost”, and also requiring review and update of the professional dispensing fee. The California Department of Health Care Services (DHCS), the department that administers the California Medicaid program (known as “Medi-Cal”), contracted with an independent consultant, Mercer Government Human Services Consulting (Mercer), to prepare an analysis of options to revise the Medi-Cal Pharmacy Fee Schedule based on “actual acquisition cost” methodology and options to update the professional dispensing fee. The Mercer report, *Professional Dispensing Fee and Actual Acquisition Cost Analysis for Medi-Cal – Pharmacy Survey Report*, dated January 4, 2017, set forth options for a revised methodology for the drug cost reimbursement and the professional dispensing fee. In light of the Mercer study, DHCS selected the actual acquisition cost alternative utilizing the National Average Drug Acquisition Cost (NADAC) (or Wholesale Acquisition Cost (WAC) +0% for drugs lacking a NADAC price) in place of the Average Wholesale Price (AWP) in the drug ingredient formula. For the professional dispensing fee, DHCS selected the two-tier dispensing fee model: $10.05 for pharmacies with total annual prescription volume of 90,000 or more, and $13.20 for pharmacies with total annual prescription volume of less than 90,000. A Medi-Cal-enrolled pharmacy wishing to receive the higher dispensing fee submits a “self-attestation” of total claim volume for the prior calendar year during a prescribed attestation period.

DHCS submitted State Plan Amendment 17-002 to CMS to obtain approval for the selected actual acquisition cost and two-tiered dispensing fee methodologies. CMS approved the State Plan Amendment on August 25, 2017, with an effective date of April 1, 2017. Pursuant to the State Plan Amendment, the drug ingredient cost is reimbursed at the lower of usual and customary charge or the drug ingredient cost plus the professional dispensing fee. The “drug ingredient cost” is defined as the lowest of: NADAC of the drug (or WAC +0% when no NADAC is available), or the Federal Upper Limit, or the Maximum Allowable Ingredient Cost. DHCS, through its pharmacy benefit administrator, began to implement the revised methodology beginning in February 2019, and thereafter commenced retroactive payments and adjustments for pharmaceuticals dispensed on or after April 1, 2017.

The proposed regulations revise the Administrative Director’s pharmaceutical fee schedule to align the workers’ compensation drug reimbursement and dispensing fee reimbursement with the revised Medi-Cal pharmacy fee methodology, and adopt modifications to implement statutory changes relating to compounded drugs and physician-dispensed drugs.

For workers’ compensation, the new fee method is proposed to become effective for pharmaceuticals dispensed on or after [Month Day, 2024] [a date that is 90 days after the regulations are filed with the Secretary of State], hereafter “the effective date”, and will not be retroactive to April 1, 2017. Under the proposed regulations, the Medi-Cal methodology would apply prospectively for pharmaceuticals dispensed on or after the effective date; the new methodology would not be retroactive. Medi-Cal has a single pharmacy benefit administrator that handles all pharmacy claims, and is able to retroactively adjust reimbursement. In the workers’ compensation system there are hundreds of payers and other entities involved in bill payment and retroactive bill adjustment would be overly burdensome and costly. Therefore, the regulations propose prospective application of the new methodology for services on or after the effective date, and include a period to allow for programming and related activities to implement the new method.

In addition, the proposed regulations diverge from the Medi-Cal methodology as specified in the Labor Code section 5307.1. These provisions relate to compounded drugs and physician-dispensed drugs.

The proposed regulations also make minor amendments to the Physician and Non-Physician Practitioner portion of the Official Medical Fee Schedule to align cross references for physician-dispensed drugs to the new pharmaceutical fee schedule sections and to clarify codes for physician-administered drugs.

The Administrative Director now proposes to amend the fee schedule for physician and non-physician practitioner services, amend the pharmaceutical fee schedule, and adopt new pharmaceutical fee schedule regulations for services rendered on or after the effective date. The proposed regulations implement, interpret, and make specific Labor Code section 5307.1 as follows:

**Section 9789.12.1. Physician Fee Schedule: Official Medical Fee Schedule for Physician and Non-Physician Practitioner Services – For Services Rendered on or after January 1, 2014**: sets forth the scope and applicability of the Physician Fee Schedule. The proposed amendment to subdivision (a) adds language referencing Labor Code section 5307.1 as an additional statutory authority for contracted rates outside of the fee schedule. The proposed amendment to subdivision (c) revises the cross-reference to the pharmaceutical regulations.

**Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products**: sets forth rules to determine the maximum fee for physician-administered drugs, biologicals, vaccines, and blood products and includes coding requirements for specified pharmaceuticals. Amendments are proposed to clarify coding rules, clarify applicability of the section, streamline the language, and update cross references to other regulatory provisions.

**Section 9789.13.3. Physician-Dispensed Drugs**: This section of the Physician and Non-Physician Practitioner Fee Schedule contains a cross-reference to the Pharmaceutical Fee Schedule regulation section 9789.40 for physician-dispensed drugs. The citation is amended to add reference to the new sections that govern physician-dispensed drugs after the effective date.

**Section 9789.40. Pharmacy – Pharmaceuticals Dispensed and Pharmaceutical Services Rendered Prior to [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: The proposed amendment deletes an obsolete provision relating to regulation changes made in February of 2007. A new subdivision is proposed to specify that the section is applicable to pharmaceuticals dispensed and pharmaceutical services rendered prior to the effective date. Language is also added to indicate that for services prior to the effective date, the current Medi-Cal data file updated 3/8/2019, and current dispensing fees of $7.25, or $8.00 for a nursing home patient, will remain in effect. The fee schedule web address is updated.

**Section 9789.40.1. Pharmaceuticals Dispensed and Pharmaceutical Services Rendered by a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: A new section is proposed to govern reasonable maximum fees for pharmaceutical services rendered and pharmaceuticals dispensed by a pharmacy on or after the effective date. The changes align the legend and non-legend drug ingredient cost reimbursement and the professional dispensing fee with the new Medi-Cal methodology adopted by the State Plan Amendment 17-002. The drug ingredient cost formula caps the drug ingredient at the “lowest cost” utilizing the lowest of the National Average Drug Acquisition Cost (or Wholesale Acquisition Cost if a NADAC does not exist), the Federal Upper Limit, or Maximum Allowable Ingredient Cost. The regulation also provides for a “no substitution” drug ingredient fee methodology where the physician has indicated “Dispense as Written” or “Do Not Substitute” on the prescription for a brand name drug.

The professional dispensing fee is based on the Medi-Cal two-tier dispensing fee. The regulation changes the pharmacy professional dispensing fee from the current rate of $7.25 (or $8.00 for drugs dispensed to a nursing home patient) to $10.05 for all pharmacies except those that qualify under the Medi-Cal program for the higher tier dispensing fee of $13.20.

The proposed regulation sets forth the method to determine the fee for repackaged drugs, which are products that are not paid for by Medi-Cal, and sets forth relevant definitions.

The section states that the Pharmaceutical Fee Data file and dispensing fee file will be made available on the Division’s web pages.

**Section 9789.40.2. Compounded Pharmaceuticals Dispensed by a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: The new section adopts a maximum reasonable fee formula for compounded drugs dispensed by a pharmacy on or after the effective date and sets forth rules applicable to calculation of the fee. The maximum fee is calculated as the sum of the ingredient cost as defined, the dispensing fee, and applicable compounding and sterility fees. The section cross-references to the pharmacy compounding and sterility fees section. The regulation provides that a compounded drug that is “essentially a copy of a commercially available drug product”, as defined by federal law, is not reimbursable.

**Section 9789.40.3. Compounding Fee and Sterility Fee: Route of Administration Compounding Fee / Sterility Fee Table; and Dosage Form Compounding Fee Table; Pharmacy Dispensed on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]:** The new section sets forth the Medi-Cal based tables and rules to determine compounding and sterility fees for pharmacy-dispensed compounded drugs.

**Section 9789.40.4. Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: The proposed section specifies that the provisions of the article apply to determine maximum fees for pharmaceuticals dispensed by a mail order pharmacy to an injured worker for treatment of a California workers’ compensation injury or illness, whether the injured worker resides within the state of California or outside the state of California. The rule states that shipping and handling is included in the drug ingredient and is not separately payable. The section also provides that the drug ingredient’s maximum reasonable fee shall not exceed the Wholesale Acquisition Cost applicable to the NDC if the NDC does not appear on the Pharmaceutical Fee Data file, and is not otherwise covered or bundled into another fee schedule provision.

**Section 9789.40.5. Pharmaceuticals Dispensed by a Physician on or after [Month, Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: The proposed section sets forth rules to govern the maximum reasonable fee for pharmaceuticals dispensed by a physician.

The drug ingredient reimbursement for a legend (prescription) drug dispensed by a physician would be the lower of the physician’s usual and customary charge or the rate that is 100% of the Medi-Cal drug ingredient fee which is the lowest of: the National Average Drug Acquisition Cost (or Wholesale Acquisition Cost if a NADAC does not exist), the Federal Upper Limit, or the Maximum Allowable Ingredient Cost. The regulation also provides that the maximum fee for a legend brand name drug shall be the “no substitution” rate where specified requirements of the Medical Treatment Utilization Schedule are met.

The proposed regulation sets forth the method to determine the fee for repackaged drugs utilizing the NDC of the underlying drug product and sets forth relevant definitions.

The regulation sets forth a formula for determining the maximum reasonable fee for a non-legend drug dispensed by a physician, and for any other drug product not covered by the rules for legend drugs, repackaged drugs, or compounded drugs. The maximum is set at the lowest of: (1) the drug’s ingredient cost as defined in subdivision (a), or (2) 120% of the documented paid cost to the physician, or (3) 100% of the documented paid cost to the physician plus two hundred fifty dollars ($250.00).

The section states that a dispensing fee is not payable for a drug dispensed by a physician. The regulation defines “documented paid costs”. The rule states that a physician shall not bill for a drug that the physician obtained for free, such as a sample. The section states that the Pharmaceutical Fee Data file containing drug ingredient rates will be made available on the Division’s web pages.

**Section 9789.40.6. Compounded Pharmaceuticals Dispensed By a Physician on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]**: The proposal sets forth a formula for maximum fees for a compounded pharmaceutical dispensed by a physician. The maximum fee is the lowest of: the physician’s usual and customary charge for the compounded drug to patients under the physician’s care; 300% of documented paid costs, but not more than $20 above documented paid costs; or the drug ingredient cost determined pursuant to the specified formula. The term “documented paid cost” is defined to be the net price paid by the physician for the drug ingredients after discounts and rebates. The proposed rule specifies the documentation that must be presented with the bill. The proposed rule specifies that dispensing, compounding and sterility fees are not payable for a compounded drug dispensed by a physician. The regulation provides that a compounded drug that is “essentially a copy of a commercially available drug product”, as defined by federal law, is not reimbursable.

**Section 9789.111. Effective Date of Fee Schedule Provisions**: This section of the Official Medical Fee Schedule sets forth an overview of the effective dates applicable to the various sections of the fee schedule. The proposal makes a technical amendment to conform to a change to the Physician Fee Schedule which added 9789.19.1 (relating to anesthesia conversion factor) effective January 1, 2019. The proposal also adds new language specifying that the new pharmaceutical fee schedule regulations at sections 9789.40.1 through 9789.40.6 are effective for services rendered on or after [Month Day, 2024], [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL.]

**Objective and Anticipated Benefits of the Proposed Regulation**

The objective of the rulemaking action is to adopt updates to the pharmaceutical fee schedule, including updates to account for changes to the Medi-Cal payment system. The regulations are also intended to implement Labor Code section 5307.1 provisions that provide additional caps on pharmaceutical fees for physician-dispensed drugs. Moving away from the AWP-based fee schedule to the new Medi-Cal fee schedule based primarily on the NADAC is anticipated to be beneficial as reimbursement will be more closely aligned with actual costs of drug acquisition. Pharmacies will benefit by the increase to the dispensing fee which has not been adjusted in many years.

Another important objective of the regulations is to implement the physician dispensing provisions of Labor Code section 5307.1, in order to address the legislature’s concern expressed in the legislative findings in AB 378:

“Since the creation of the official medical fee schedule governing pharmaceuticals, there has been a growing practice by some prescribing physicians to utilize medications that are not covered by the fee schedule, to dispense these medications directly to workers’ compensation patients, and to bill employers and insurers at highly inflated rates. These practices unfairly enrich the physicians who engage in these efforts, cost employers and insurers millions of dollars, and prevent these wasted dollars from being used to enhance benefits for injured workers.”

(Assembly Bill 378, Section 1 (b) (Statutes 2011, Chapter 545).)

The regulations relating to physician dispensing are anticipated to better align reimbursement with reasonable costs, and avoid improper financial incentives that may impact prescribing practices. This is anticipated to produce higher quality and safer health care, and may also reduce system costs.

**DETERMINATION REGARDING INCONSISTENCY/INCOMPATIBILITY
WITH EXISTING STATE REGULATIONS**

The Administrative Director has determined that this proposed regulation is not inconsistent or incompatible with existing regulations.

**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.
1. Adoption of these regulations will not: (1) create or eliminate 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.
2. Effect on Housing Costs: None.
3. The Division of Workers’ Compensation is aware of cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. Claims administrators, medical bill review companies, medical providers or their billing services, pharmacy benefit managers, will incur one-time up-front costs to modify medical billing and payment systems to accommodate the revised pharmaceutical fee schedule, including the two-tiered Medi-Cal dispensing fee. The programming for adoption of the revised Medi-Cal-based structure for legend and non-legend pharmacy drug ingredient cost, is expected to be straightforward. The price file will have the same basic structure, with “lowest cost” and “no-substitution” fields provided in the data. The data elements which form the basis of the “lowest cost” and “no-substitution” fields (NADAC, WAC, FUL, MAIC) will not need to be separately programmed. For the two-tier dispensing fee, some programming will be required, but it will not be overly complicated. The Division will post the file listing NPIs of pharmacies entitled to receive the higher fee. The NPI of the dispensing pharmacy will be readily available on the mandated paper billing form or electronic billing format. Some system adjustments will also be needed in relation to physician-dispensed pharmaceuticals. The statutory caps on physician-dispensed non-legend drugs have been in effect since 2012, and will now be included in the regulatory text. A legend/non-legend indicator will be added to the posted data file which facilitates identification of NDCs that are subject to the statutory fee cap on non-legend drugs dispensed by a physician. For pharmacy and physician-dispensed compounded drugs, there will be some programming required to accommodate the portion of the formula that utilizes “documented paid cost +10%” for products that are not finished drug products. Since Medi-Cal does not pay for these products in a compounded drug, the Administrative Director proposes “documented paid cost +10%” as part of the maximum reasonable fee calculation for these products used in a compounded drug. The Administrative Director will provide an updated pharmaceutical fee calculator which will assist many users in calculating maximum reasonable fees.

**EFFECT ON SMALL BUSINESS**

The Administrative Director has determined that the proposed regulations will affect small business, primarily medical providers. One-time up-front costs may be incurred by providers to modify their billing systems, although many physicians use billing services that will be performing the adjustments. Physicians who derive profit from dispensing drugs to their patients may experience a decrease in revenue.

FISCAL IMPACTS

* Costs or savings to state agencies: The state will experience the same costs and savings as other employers.
* Costs/savings in federal funding to the State: None.
* Local Mandate: None. The proposed amendments to the 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 amendments, 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 amendments 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 amendments, 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.
* Other nondiscretionary costs/savings imposed upon local agencies: None. To the extent that local agencies and school districts are self-insured employers who must reimburse physicians, pharmacies or other providers for medical treatment for industrially injured employees, they will be subject to the same cost impacts as all other employers in the state.

# **CONSIDERATION OF ALTERNATIVES**

The Administrative Director invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

**AVAILABILITY OF INITIAL STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, RULEMAKING FILE AND DOCUMENTS SUPPORTING THE RULEMAKING FILE / INTERNET ACCESS**

An Initial Statement of Reasons and the text of the proposed regulations have been prepared and are available from the contact person named in this notice. The rulemaking file including documents relied upon will be made available for inspection at the address indicated below.

As of the date of this notice, the rulemaking file consists of the notice; the initial statement of reasons; the proposed text of the regulations; a sample Pharmaceutical Fee Data File; a sample National Provider Identifier List, a Word background document regarding the sample data files, and the documents relied upon.

Rulemaking File Access / Internet Access

The Notice, Initial Statement of Reasons, proposed text of regulations, sample Pharmaceutical Fee Data File, and sample National Provider Identifier List may be accessed and downloaded from the Division’s [Proposed Regulations webpage](http://www.dir.ca.gov/dwc/rulemaking/dwc_rulemaking_proposed.html), or copies may be obtained from the contact person named in this notice.

Any interested person may inspect a copy or direct questions about the proposed regulations and any supplemental information contained in the rulemaking file. The rulemaking file, including the documents relied upon in preparing this proposal, will be made available for inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 18th Floor, Oakland, California, between 9:00 a.m. and 4:30 p.m., Monday through Friday, unless the state office is closed for a state holiday.

**CONTACT PERSON**

Inquiries concerning this proposed action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed amendments or the Initial Statement of Reasons, or requests to review any supplemental information contained in the rulemaking file may be submitted in writing at the same address. The contact person is:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
Division of Workers’ Compensation
Post Office Box 420603
San Francisco, CA 94142
E-mail: mgray@dir.ca.gov

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

##### BACKUP CONTACT PERSON

In the event the contact person is unavailable, inquiries should be directed to the following backup contact person:

Jacqueline Schauer, DWC Legal Counsel
Department of Industrial Relations
Division of Workers’ Compensation
Post Office Box 420603
San Francisco, CA 94142
E-mail: (jschauer@dir.ca.gov)

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

##### FORMAT OF REGULATORY TEXT

Format note:

Plain text is current codified language.

Blue text indicates a hyperlink is provided in the text.

Proposed 45-day changes are shown in single underline and single ~~strikeout~~.

# **AVAILABILITY OF CHANGES FOLLOWING PUBLIC HEARING**

If the Administrative Director makes changes to the proposed regulations 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 regulations are adopted. The Notice of Modification of Proposed Rulemaking will be sent to persons who have submitted written comments to the agency during the comment period or at the public hearing, to persons who testified at the public hearing, and to persons who have requested notification of modifications to the proposal.

# **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 [Approved Regulations webpage](https://www.dir.ca.gov/dwc/rulemaking/dwc_rulemaking_approved.html) or rulemaking archive webpage.

## AUTOMATIC MAILING

A copy of this Notice will automatically be sent to those interested persons on the Administrative Director’s mailing list.

If adopted, the regulations as adopted will appear in Article 5.3 of Division 1, Chapter 4.5, Subchapter 1, title 8, California Code of Regulations commencing with section 9789.12.1.