**STATE OF CALIFORNIA**

**DEPARTMENT OF INDUSTRIAL RELATIONS**

**DIVISION OF WORKERS’ COMPENSATION**

**INITIAL STATEMENT OF REASONS**

**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**

**SECTIONS 9789.12.1 et seq.**

# INTRODUCTION

This Initial Statement of Reasons (“ISOR”) describes the purposes, rationale, and necessity of the proposed amendments to the Official Medical Fee Schedule to be codified at title 8, California Code of Regulations §9789.12.1 through 9789.111.

# AN IMPORTANT PROCEDURAL NOTE ABOUT THIS RULEMAKING:

The Physician and Non-Physician Practitioner Fee Schedule and Pharmaceutical Fee Schedule regulations within the Official Medical Fee Schedule "establish or fix rates, prices, or tariffs" within the meaning of Government Code section 11340.9, subdivision (g), and are 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 Pharmaceutical Fee Schedule is being conducted pursuant to the rulemaking power vested in the Division of Workers’ Compensation Administrative Director by Labor Code sections 133, 4603.5, 5307.1 and 5307.3. This regulatory proceeding is subject to the procedural requirements of Labor Code sections 5307.1 and 5307.4.

This Initial Statement of Reasons and the accompanying Notice of Rulemaking 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 in analyzing and commenting on this non-APA rulemaking proceeding.

# BACKGROUND TO REGULATORY PROCEEDING

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 Director 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 be established by the Administrative Director and 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 the 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 (FUL), or the Maximum Allowable Ingredient Cost (MAIC).

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*](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_Merc_Rpt_170127.pdf), 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) minus 17% 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. The attestation for the prior calendar year determines the eligibility for the higher dispensing fee for the following California state fiscal year.

DHCS submitted [State Plan Amendment 17-002](https://www.dhcs.ca.gov/formsandpubs/laws/Documents/17-002ApvOct.pdf) to CMS to obtain approval for the selected “actual acquisition cost” and two-tier 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 (FUL), or the Maximum Allowable Ingredient Cost (MAIC). DHCS, through its pharmacy benefit administrator, began to implement the revised methodology in February 2019, and subsequently commenced retroactive adjustments for pharmaceuticals dispensed on or after April 1, 2017.

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”]. Under the proposed regulations, the new Medi-Cal methodology would apply prospectively for pharmaceuticals dispensed on or after the effective date and will not be retroactive to April 1, 2017. Medi-Cal has a single Medi-Cal pharmacy benefit administrator that handles all pharmacy claims, and is able to retroactively adjust reimbursement for the drug ingredients and dispensing fees. In workers’ compensation, 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.

The proposed regulations would revise the Administrative Director’s pharmaceutical fee schedule to align the workers’ compensation pharmacy drug reimbursement and dispensing fee reimbursement with the new Medi-Cal pharmacy fee methodology so that the maximum pharmacy fees do not exceed 100% of the Medi-Cal fees for pharmacy services. In addition, the proposed regulations implement the statutory provision to set maximum prices for pharmacy goods that are not Medi-Cal benefits at rates that Medi-Cal would pay for pharmacy goods requiring “comparable resources.”

The proposed regulations set forth separate sections to govern maximum fees for pharmacy dispensed and physician-dispensed pharmaceuticals. This is necessary in light of the fact that Medi-Cal does not pay for physician-dispensed drugs, and due to statutory changes to Labor Code section 5307.1. Amendments to Labor Code section 5307.1 adopted by AB 378 (Statues 2011, Chapter 545) created rules for physician-dispensed pharmacy goods and medical devices, and adopted enhanced provisions to address physician referrals where the physician has a financial interest in the entity that receives the referral. The legislative intent provisions of the bill express the legislature’s concern with physician dispensing of “costly and questionable” compounded drugs. In addition, the Labor Code provides caps on fees for physician-dispensed non-legend drugs that do not apply to pharmacy-dispensed products. To account for these differences, the proposed regulations provide separate sections to govern pharmaceutical reimbursement for pharmacies and physicians for drugs dispensed on or after the effective date.

The proposed regulations diverge from the Medi-Cal methodology as specified in Labor Code section 5307.1. Pursuant to subdivision (e) of Labor Code section 5307.1, compounded drug ingredients with no NDC are not reimbursable although some inactive ingredients lacking an NDC may be reimbursed by the Medi-Cal program. Subdivision (e) also provides that a physician-dispensed non-legend drug and a physician-dispensed compounded drug product are subject to a cap based upon documented paid cost.

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

# SUMMARY OF PROPOSED CHANGES

This rulemaking action implements the Labor Code requirements related to the workers’ compensation pharmaceutical fee schedule, including updating the fee methodology to reflect changes to the Medi-Cal pharmaceutical payment structure and Labor Code amendments. In addition, amendments are proposed to align the Physician and Non-Physician Practitioner Services Fee Schedule (hereafter “Physician Fee Schedule”) with the revised and new pharmaceutical fee schedule regulations. The specific purpose of each adoption, and the rationale for the determination that each adoption is reasonably necessary to carry out the purpose for which it is proposed, are provided below.

# SPECIFIC PURPOSE OF, AND RATIONALE FOR, EACH PROPOSED AMENDMENT

## 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.

This section sets forth the scope and applicability of the Physician Fee Schedule. Subdivision (a) is revised to add an additional Labor Code reference to the provision indicating that the fee schedule does not govern contracted rates. This is necessary to increase the public awareness that the authority for contracted rates is contained within the fee schedule enabling statute, Labor Code section 5307.1, subdivision (h), as well as the separate statute relating to contracts in section 5307.11. The proposed amendment to subdivision (c) revises the cross-reference to the pharmaceutical regulation at “section 9789.40” to read “sections 9789.40, 9789.40.5, 9789.40.6.” This is necessary in order to coordinate the cross-reference with the expanded range of pharmaceutical fee regulation sections that are applicable to physician and non-physician practitioners dispensing medications.

## Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products.

This section of the Physician Fee Schedule sets forth the rules for determining the maximum fee for physician-administered (as opposed to physician-dispensed) drugs, biologicals, vaccines, and blood products and includes coding requirements needed to implement the fees.

Subdivision (a) is modified to state that the specified pharmaceuticals are separately payable “unless bundled or packaged into the procedure code pursuant to official medical fee schedule rules”. It is necessary to add the language to provide clarity and avoid misapplication of the “separately payable” concept. For example, some pharmaceuticals that are administered by a physician in a surgical facility are bundled into the facility payment pursuant to the Hospital Outpatient Department / Ambulatory Surgical Center Fee Schedule portion of the OMFS and would not be separately payable.

The existing language of subdivision (a)(1) sets forth a requirement to report “physician-administered drugs, biologicals and blood products” using the NDC and J code, however the language is too narrow. It is necessary to broaden the language to “NDC and Healthcare Common Procedure Coding System Level II code (HCPCS Level II code)” because the J codes are not the only applicable codes. For example, some drugs are listed in HCPCS Level II “J”, “Q”, or “S” codes, some biosimilar drugs are listed in HCPCS Level II “Q” codes and blood products are listed in HCPCS Level II “P” codes.

Subdivision (a)(2) is amended to add clarity regarding coding, since “Physician-Administered Drugs, Biologicals, Vaccines, Blood Products” are represented by HCPCS Level I codes or HCPCS Level II codes. The current regulation refers to “HCPCS code”; the proposal adds “CPT code” or “HCPCS Level II” code for added clarity. The term “HCPCS” is colloquially thought of as the HCPCS Level II alpha-numeric codes. Although CPT is designated as HCPCS Level I code, it will provide greater specificity to identify CPT codes and HCPCS Level II codes in the regulation. CMS describes HCPCS coding as follows:

“[**HCPCS Codes**](https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/coding/overview-coding-classification-systems)

HCPCS is a standard, national medical code set specified for the purpose of ensuring that claims are processed in an orderly and consistent manner. HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. HCPCS Level I codes are part of the Current Procedural Terminology (CPT®) code set maintained by the CPT® Editorial Panel and copyrighted by the American Medical Association (AMA). HCPCS Level II codes are established and maintained by CMS...”

Subdivision (a)(2) is amended to remove language that provides background information but that does not provide regulatory direction. In addition, the background information regarding the Medi-Cal pharmacy rate is no longer correct due to the Medi-Cal methodology change. Removing the language will streamline the section and improve clarity.

Existing regulatory language in subdivision (a)(3) which references determining the injection administration fee “under the RBRVS” is revised to state “under the physician fee schedule”. The phrase “under the RBRVS” was initially intended to distinguish the drug reimbursement based upon Medi-Cal Rates from the drug administration fee which is based upon the Resource Based Relative Value Scale (RBRVS) methodology used in the physician fee schedule. To avoid confusion and improve clarity it is necessary to modify the section to substitute reference to the “physician fee schedule” in place of “the RBRVS.” Also, it is necessary to clarify that the drug injection fee of $4.46 is only deducted for *injectable* drugs since the Medi-Cal Rates list for physician-administered drugs includes some products that are not injectable.

It is necessary to amend the subparagraph (a)(4) relating to physician-administered drugs that are not contained in the Medi-Cal Rates file, to update the cross-references to include the new physician-dispensed pharmaceutical fee schedule sections 9789.40.5 and 9789.40.6. The proposed structure of the pharmaceutical fee schedule separates the new provisions related to pharmacies and those related to physicians in order to carry out the statutory differences in the treatment of physician-dispensed versus pharmacy-dispensed drugs. The replacement of the phrase “Medi-Cal Pharmacy Fee Schedule” with “pharmaceutical fee schedule applicable to physicians” harmonizes this section with the new provisions.

Revisions are made to correct the punctuation in subdivision (a)(1) by deleting the hyphen from “CPT-code”, and in subdivision (c) by adding a hyphen to “low osmolar.”

## Section 9789.13.3. Physician-Dispensed Drugs.

This section is amended to add cross-reference to the two new sections (9789.40.5 and 9789.40.6) which will govern maximum reimbursement for physician-dispensed drugs dispensed on or after the effective date. The amendment is necessary in order to coordinate the cross-reference with the expanded range of pharmaceutical fee regulation sections that may apply to physician-dispensed pharmaceuticals.

## 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 heading of the current section 9789.40 is amended to add the language “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]. This is intended to make it clear that this existing regulation will only govern the pharmaceutical fees for drugs dispensed prior to the effective date of the amended regulation. The clarity of the regulation is improved by making the end date of the section prominent.

Language is also added to subdivision (a) so that the codified text itself makes it clear that the current methodology and rate file will not be used after the effective date. Specifically, language is added to clarify that the Medi-Cal data file updated 3/8/2019 and the current dispensing fees of $7.25 or $8.00 for a nursing home patient will continue in effect for services rendered prior to the effective date of the new and amended regulations. This is necessary to ensure that there is no ambiguity regarding the fact that the new regulations and methodology are prospective only. Retroactive payment methodology change would be untenable, creating extreme disruption and expense to the workers’ compensation system, which is composed of a multitude of different payers.

It is necessary to revise subdivision (a) and (c)(1) to update web page references for clarity and accuracy.

The proposal deletes subdivision (d) which states that regulatory changes made to the section in February 2007, shall be applicable to all pharmaceuticals dispensed or provided on or after March 1, 2007. This proposed amendment is intended to delete an obsolete provision. The February 2007 change added the current subdivision (b), which sets forth the methodology for determining the maximum fee for a repackaged drug product that is not covered by a Medi-Cal payment system. The subdivision (d) was intended to avoid retroactive effect of the February 2007 change. It is highly unlikely that any bill for a pharmaceutical dispensed prior to February of 2007 is still pending payment. Therefore, the subdivision (d) language is obsolete and unnecessary. The clarity of the regulation is improved by the deletion of the subdivision, and is not expected to impact any pending matters.

The proposal adds a new subdivision (d) which states that the section applies to pharmaceuticals dispensed and pharmaceutical services rendered prior to the effective date. This provision is necessary for clarity regarding the applicability of the section.

The proposed regulations include a new subdivision (e) which states that the Medi-Cal data file dated 03/08/2019 posted on the internet website by the Division will remain in effect for pharmaceuticals dispensed prior to the effective date of the amended regulation. Since the new methodology is prospective it is necessary to make it clear that the current fee schedule data file is applicable until the new file/methodology becomes effective. This is necessary so that the public is aware that the prior fee schedule is in effect during the period allowed for implementation of the new methodology. Medi-Cal payments are handled by a single pharmacy benefit administrator, and the “go live” date for Medi-Cal was followed at a later time by retroactive adjustments to payments (both drug ingredient and dispensing fee). ([*Retroactive Claims Adjustments*](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_RetroactiveClaimAdj.pdf), DHCS, March 26, 2019.) The Division has determined that it would cause extreme disruption to the workers’ compensation system, and would be overly burdensome and costly to adopt retroactive adjustments since there are numerous payers in workers’ compensation rather than a single payer as there is for Medi-Cal fee-for-service claims.

At the time of Medi-Cal system implementation, the DHCS ceased sending the Division updated files with the “old” AWP-based methodology. Due to the need to allow the workers’ compensation stakeholders adequate time to become familiar with the new file and prepare for implementation of the new methodology, there cannot be an immediate switch between the old methodology and the new methodology. Therefore, it is necessary for workers’ compensation to specify that the last “old” methodology file will remain in place until the workers’ compensation effective date of the new file.

## 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].

The proposal adds section 9789.40.1 to set forth the rules to determine maximum reasonable fees for pharmacy services and pharmaceuticals dispensed by a pharmacy on or after the effective date, which will be 90 days after the regulations are filed with the Secretary of State. The section provides that the maximum fee for legend and non-legend drugs dispensed by a pharmacy is the lower of the drug’s ingredient cost plus the professional dispensing fee or the usual and customary charge to the public. “Drug’s ingredient cost” is defined to mean the lowest of: 1) the NADAC or when no NADAC is available, the WAC plus 0%, or 2) the FUL or 3) the MAIC. This definition of the “drug’s ingredient cost” is necessary to implement Labor Code section 5307.1 by setting the maximum pharmaceutical fee at 100% of the updated Medi-Cal pharmacy fee rate specified in Welfare and Institutions Code section 14105.45. The approved State Plan Amendment 17-002 changes the pharmacy fee methodology by eliminating the prior formula for “estimated acquisition cost” that uses the AWP -17%, the FUL and the MAIC, and adopting the new formula for “actual acquisition cost” using NADAC (or WAC when there is no NADAC), the FUL, and the MAIC. In regard to the WAC + 0% part of the formula, it is helpful to follow the Medi-Cal State Plan Amendment language of “plus zero percent” to make it clear that workers’ compensation is following the Medi-Cal implementation.

The proposed regulation sets forth the method for determining the maximum fee for a pharmacy-dispensed brand name drug where a physician has written “Do Not Substitute”, or “Dispense as Written” in accordance with the Business and Professions Code. Under California law, a pharmacist may substitute a generic equivalent of a brand name drug unless the physician indicates that the brand name is required by writing “Do Not Substitute”, or “Dispense as Written” (DAW) on the prescription. For multi-sourced brand name drugs that have an FUL or MAIC, the lowest price is likely to be less than the price of the brand name drug. However, when the physician has documented that the brand name product is medically necessary, and has complied with the formulary regulations by documenting the medical necessity and obtaining authorization, the reimbursement for the brand name drug product may exceed the FUL or MAIC. The proposed regulation provides that the payment for the branded drug dispensed by a pharmacy pursuant to a DAW prescription as set forth, is the lower of: 1) the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0% (the “no substitution” fee), plus the professional dispensing fee pursuant to (a)(2), or 2) the pharmacy’s usual and customary charge to the public.

This formula is necessary in order to align with the Medi-Cal methodology, which allows a multiple source brand name drug to be paid at a rate higher than the “lowest price” where the branded product is medically necessary. The Medi-Cal Pharmacy Provider Manual, Reimbursement chapter, states in pertinent part:

“When medically necessary for a specific recipient, approval of reimbursement at the NADAC or, if no NADAC, the WAC may be obtained for a product whose price exceeds the MAIC or FUL price limits by requesting authorization from a Medi-Cal consultant. Reimbursement of the prescription ingredient cost may require the use of a brand of a multiple-source drug and may not exceed the statutory reimbursement limits.”
[*Medi-Cal Pharmacy Provider Manual, Reimbursement*](https://mcweb.apps.prd.cammis.medi-cal.ca.gov/file/manual?fn=reimbursement.pdf), page 3, December 2021 revision.

In addition, the proposed formula supports the goal of promoting the availability of medically necessary brand name products to improve injured workers’ health outcomes. The Division anticipates that pricing the medically necessary multi-source brand name drug at its NADAC cost rather than the lowest price using the FUL/MAIC will help maintain access to the drug.

The data file to be posted by the Division will include the “lowest cost”, and “no substitution” cost that will be used to determine maximum reasonable fees. The calculation of the “lowest cost” (based on lowest of NADAC (or WAC + 0% if NADAC does not exist), FUL, and MAIC) and “no substitution cost” (based on NADAC or WAC if NADAC does not exist) will be embedded in the “lowest cost” and “no substitution cost” fields in the posted data file, thus reducing the programming burden on payers and other stakeholders.

The proposed section adopts the Medi-Cal two-tiered professional dispensing fee, which results in a substantial increase from the current dispensing fee of $7.25 (or $8.00 for drugs dispensed to a nursing home patient.) The proposed new maximum dispensing fee is $10.05 for all pharmacies except those that qualify under the Medi-Cal program for the higher tier dispensing fee of $13.20. The regulation provides that eligibility for the higher dispensing fee is designated by inclusion of the pharmacy’s National Provider Identifier in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed. Pharmacies that qualify are those Medi-Cal enrolled pharmacies that have a total prescription volume (Medi-Cal and non-Medi-Cal) of less than 90,000 claims a year. It is necessary to adopt the two-tier dispensing fee methodology in order to implement the directive in Labor Code section 5307.1, subdivision (a)(1), that pharmacy service and drug “…fees shall be in accordance with the fee-related structure and rules of the relevant … Medi-Cal payment systems….”

The Medi-Cal professional dispensing fee of $7.25 had not been updated in many years. Based upon the surveys conducted and analysis, Mercer set forth three options for consideration by DHCS: a single dispensing fee across all retail community pharmacies and long term care pharmacies, the two-tiered dispensing fee structure based upon total annual prescription volume, or a four-tiered dispensing fee based upon total annual prescription volume. The Mercer study found a significant effect of prescription volume on the cost of dispensing. The volume for a surveyed pharmacy included *total* number of prescriptions filled by the pharmacy at the location including Medicaid, Medicare, and all other prescriptions. DHCS selected the two-tier dispensing fee model from the three options suggested by its consultant. The Mercer report notes the following factors in favor of the two-tier dispensing fee model: “Balances rewards for efficiency with improved access to rural and underserved areas” and “Efficiently distributes Med-Cal funds with reimbursement levels closely reflecting costs.” ([Professional Dispensing Fee and Actual Acquisition Cost Analysis For Medi-Cal — Pharmacy Survey Report](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_Merc_Rpt_170127.pdf), page 29.)

The proposed regulation also sets forth the rule for repackaged drugs. Medi-Cal does not pay for “repackaged drugs.” Therefore, the proposal implements the directive in Labor Code 5307.1, subdivision (d): “If the administrative director determines that a pharmacy service or drug is not covered by a Medi-Cal payment system, the administrative director shall establish maximum fees for that item. However, the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources.” Since Medi-Cal does not pay for a repackaged drug, the proposed formula sets the maximum using the Medi-Cal price for the underlying drug product where the NDC for the underlying product appears in the Pharmaceutical Fee Data File. The Administrative Director has determined that if the underlying drug NDC is not in the Pharmaceutical Fee Data File, an appropriate proxy for what Medi-Cal would pay is the WAC of the lowest priced therapeutically equivalent drug.

The proposal specifies that the NDC of the dispensed repackaged drug and the NDC of the underlying drug shall both be identified on the bill in accordance with the billing regulations. It is necessary to identify pharmaceuticals by the NDC because that is the identifier used in the Pharmaceutical Fee Data File database of drugs, and is universally used in the pharmaceutical industry.

It is necessary to define “therapeutically equivalent drugs” by reference to the Food and Drug Administration’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”), as it is the definitive and authoritative source of the status of drug products as therapeutic equivalents.

The proposal defines “National Drug Code for the underlying drug product from the original labeler” to be the NDC of the drug product actually utilized. This is necessary to ensure that the drug product dispensed can be accurately benchmarked to the Medi-Cal price for the product.

The regulation states that the “lowest cost” and “no substitution cost” drug ingredient rates file and dispensing fee file will be made available on the Division’s website and sets forth a link. This is necessary to alert the public that the necessary data files will be available, and where to access them. By posting the drug ingredient cost file with the “lowest cost” and “no substitution” cost, the public will not have to set up the calculation of the lowest of the NADAC (or WAC if there is no NADAC), the FUL, or the MAIC. This calculation is already embedded in the “lowest cost” column, and follows the format of the current file, reducing the amount of programming adjustments that may be needed. Similarly, the “no substitution" cost is set forth in its own column, and does not require separate listing of NADAC and WAC.

## 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 proposed regulation sets forth the methodology for determining the maximum fee for compounded drugs dispensed by a pharmacy to implement the statutory directive in Labor Code section 5307.1, subdivision (e)(2), which states:

“The ingredient-level reimbursement shall be equal to 100 percent of the reimbursement allowed by the Medi-Cal payment system and payment shall be based on the sum of the allowable fee for each ingredient plus a dispensing fee equal to the dispensing fee allowed by the Medi-Cal payment systems.”

Pharmacy-dispensed compounded drugs and physician-dispensed compounded drugs are governed by different regulation sections, in order to implement Labor Code section 5307.1, subdivision (e)(2), which provides a different methodology for determining the maximum fee for a physician-dispensed compounded drug:

“If the compounded drug product is dispensed by a physician, the maximum reimbursement shall not exceed 300 percent of documented paid costs, but in no case more than twenty dollars ($20) above documented paid costs.”

For pharmacies, the proposed regulation uses the Medi-Cal methodology for determining the maximum compounded drug ingredient fee for compounded drug ingredients covered by Medi-Cal, except that ingredients without a valid NDC number are not reimbursable. This is necessary to conform to the provisions of Labor Code section 5307.1, subdivision (e)(2), which provides that “[i]ngredients with no NDC shall not be separately reimbursable.” To provide guidance on what qualifies as a valid NDC, the regulation provides a presumption that an NDC is valid if it is listed in the FDA’s NDC directory as a finished or unfinished drug product, and is not listed on the excluded drugs database file. The regulation also provides that the presumption is rebuttable by a showing that the product is not legally eligible for assignment of an NDC. It is necessary to provide the rebuttable presumption, because the [FDA indicates limitations on the NDC Directory listings](https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory):

“Inclusion in the NDC Directory does not indicate that FDA has verified the information provided or that the products are FDA approved. The content of each NDC Directory entry is the responsibility of the labeler submitting the SPL file.

Assignment of an NDC number does not in any way denote FDA approval of the product. Any representation that creates an impression of FDA approval because a product has an NDC number is misleading and violates federal law.

Inclusion in the NDC Directory or assignment of an NDC number does not mean a product is a drug as defined by federal law

Inclusion in the NDC Directory does not mean a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers. Assignment of NDC number to non-drug products is prohibited.”

For pharmacy-dispensed compounded drugs utilizing finished drug products, the regulation specifies that the maximum fee is based on (1) drug ingredient costs, and (2) professional dispensing fee, and (3) compounding fees and sterility fees if applicable. Drug ingredient costs are calculated in accordance with Medi-Cal which pays the lowest of the billed amount or calculated amount for each ingredient, i.e. lesser of NADAC (or WAC + 0% if NADAC not available), FUL, or MAIC, for compound ingredients that are finished drug products.

It is necessary for the regulation to set forth a different formula for determining the drug ingredient fee for ingredients that are active pharmaceutical ingredients that are “unfinished drug products”. The Medi-Cal program does not pay for compounded drugs created from active pharmaceutical ingredients (bulk chemicals) which are unfinished drug products, as the ingredients do not meet the definition of “covered outpatient drug” in section 1927(k)(2) of the Social Security Act. ([*Medi-Cal Provider Manual, Part 2 General Medicine, Physician-Administered Drugs- NDC*](https://mcweb.apps.prd.cammis.medi-cal.ca.gov/file/manual?fn=physicianndc.pdf), updated November 2023, p. 1.)

Although Medi-Cal does not pay for dispensed compounds composed of unfinished active pharmaceutical ingredients, compounds using these ingredients can be payable through workers’ compensation if medically necessary. Therefore, it is necessary that the regulation adopt a method for pricing bulk active pharmaceutical ingredients used in a compounded drug dispensed by a pharmacy. Since these products are not “covered outpatient drugs” under the federal Medicaid program, they do not have surveyed NADAC prices, and are not covered by the Medi-Cal pharmacy fee schedule. Therefore, the Administrative Director has determined that a drug ingredient cost based on the pharmacy’s documented paid cost for the unfinished drug products plus 10%, “not to exceed the unfinished drug product’s WAC...”, would be an appropriate proxy for what Medi-Cal would pay for a drug using comparable resources. The regulation defines “documented paid cost” to mean the price paid by the pharmacy net of discounts and rebates, and requires submission of documentation of the actual paid costs upon request by the claims administrator. These provisions are necessary to avoid inappropriately inflated invoices that do not reflect actual costs in circumstances where discounts or rebates are not reflected in the invoiced price. The regulation provides related information necessary to clarify that the quantity/units billed for each ingredient is the total amount within the compound regardless of the number of containers.

It is necessary in subdivision (d) to adopt the Medi-Cal pharmacy two-tier dispensing fee structure to implement Labor Code section 5307.1’s directive to set the maximum fee “based on the sum of the allowable fee for each ingredient plus a dispensing fee equal to the dispensing fee allowed by the Medi-Cal payment systems.”

Proposed subdivision (e) defines “compounding and sterility fees” by cross reference to section 9789.40.3. The clarity of the regulations is enhanced by setting forth the compounding fee and sterility fee rules and tables in a separate section.

The definition of “documented paid cost” in subdivision (f) is necessary in order to implement the maximum fee methodology for unfinished drug products. In addition, to reduce ambiguity, subdivision (f) itemizes the types of documents that will satisfy the requirement for “documentation.” Many pharmacy bills are submitted electronically utilizing the National Council on Prescription Drug Programs (NCPDP) transaction standards, which do not include a method to submit documentation. Therefore, it is not feasible to require documentation at the time the bill is submitted. The proposed section includes a requirement for the pharmacy to submit documentation upon request by the claims administrator. This will improve efficiency since the pharmacy bills can continue to be submitted electronically without impediment, and the claims administrator will have the option to request documentation in cases where that is deemed necessary.

The proposal, at subdivision (g), states that a compounded drug that is “essentially a copy of a commercially available product” as defined in federal law and regulation is not reimbursable. The FDA’s Guidance for Industry publication, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, January 2018 sets forth the policy rationale for restrictions on compounding drugs that are essentially copies of commercially available drug products as follows.

“The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP [current good manufacturing practice] requirements, was available.

In addition to these immediate public health risks, section 503A’s limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound “substitutes” that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA [abbreviated new drug application] for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA’s drug monograph process … for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.”

*Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Guidance For Industry,* January, 2018, page 3.

The excerpted material from the Guidance for Industry document related to pharmacy and physician compounders under section 503A of the Federal Food, Drug, and Cosmetic Act mirrors the information set forth in the Guidance for Industry document related to outsourcing facility compounders under section 503B of the Federal Food, Drug, and Cosmetic Act. The FDA policy recognizes that compounding can fill an important need for individual patients with a special clinical need, such as a patient with an allergy to a dye in the FDA-approved product, or a patient who needs a medicine in liquid form that is not available in an approved product. The restriction on compounding a drug that is essentially a copy of a commercially available drug balances the need for patient-specific formulations with the safeguards afforded by the FDA drug approval process. The proposed regulation section is beneficial as it alerts workers’ compensation system participants to this important aspect of compounding law.

## 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] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

In order to mirror Medi-Cal’s compounding and sterility fee structure for pharmacy-dispensed compounded drugs, it is necessary for the regulations to set forth tables and related rules. Subdivision (a) sets out the instructions for the compounding fee, which is determined on the “Route of Administration Compounding Fee / Sterility Fee Table”, or if listed as zero, then determined based on the “Dosage Form Compounding Fee Table”. Subdivision (b) provides that the sterility fee is the fee designated in the “Route of Administration Compounding Fee / Sterility Fee Table”. In order to clarify that the sterility fee is not automatic, the section specifies that the sterility fee is only allowed if sterility testing is actually performed, and requires that the pharmacy maintain documentation. Subdivisions (a) and (b) provide that the compounding and sterility fees are the lesser of the billed amount or the calculated amount in order to align with the Medi-Cal methodology.

Subdivision (c) adopts the Medi-Cal dispensing fee for each “allowed” container by cross-referencing to the section setting forth the dispensing fee formula applicable to compounded drugs. Medi-Cal’s fee structure allows the compounding, sterility, and dispensing fee to be applied *per container* (up to 20 containers) *only* for the injection or infusion route of administration. In order to follow this Medi-Cal billing rule, it is necessary for subdivision (d) to set forth the allowed container count.

The existing regulatory language in section 9789.40 states that the maximum reasonable fee is 100% of the Medi-Cal reimbursement and states that Medi-Cal Rates will be made available on the Division of Workers’ Compensation website. The DWC website sets forth the “MMIS 2024 Compound Dosage Fee Table” and Medi-Cal formula. However, the current regulation text itself does not explicitly address pharmacy compounding. Therefore, it is necessary for clarity to augment the regulatory language to set forth the pharmacy compounding fee, sterility fee, and dispensing fee methodology and the fee tables. The Route of Administration Compounding Fee / Sterility Fee Table in subdivision (e) and the Dosage Form Compounding Fee Table in subdivision (f) are based on the Medi-Cal structure and set forth the Medi-Cal quantities and applicable fees. Notably, the Medi-Cal fees in these tables are unchanged from the current Medi-Cal MMIS 2024 Compound Dosage Fee Table available on the DWC website (although the format is modified slightly and the information is broken into two separate tables for clarity.)

## 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 regulation specifies that the pharmaceutical fee schedule provisions of the article apply to determine the 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. This provision is necessary to provide a level playing field so that the fee schedule limits are applicable to mail order pharmacies serving California injured workers.

The regulation states that the cost of shipping and handling of pharmaceuticals is included in the reimbursement for the drug ingredient and is not separately payable. This provision is necessary to implement the Labor Code section 5307.1, subdivision (a) provision which states that “all fees shall be in accordance with the fee-related structure and rules of the relevant … Medi-Cal payment systems….” Medi-Cal does not pay a separate fee for shipping and handling of pharmaceuticals.

The regulation sets forth a “catch-all” provision to cap payment for a pharmacy-dispensed drug at the Wholesale Acquisition Cost applicable to the NDC, for a drug that is not set forth in the Pharmaceutical Fee Data File, and that is not covered by, or bundled into, a facility fee or physician fee payment, unless otherwise specified in the Article. This is needed to provide a maximum fee benchmark for the rare circumstances that may occur where a drug is not in the Medi-Cal data file, or otherwise addressed in the pharmacy fee schedule regulations set forth in the article.

## 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 regulations propose two sections to govern the maximum fee for physician-dispensed drugs that are distinct from the sections that govern the maximum fee for pharmacy-dispensed drugs. This is necessary in light of Labor Code section 5307.1, which sets forth provisions specifically directed to physician-dispensed drugs in subdivision (e), which was adopted by Assembly Bill 378 (Statutes 2011, Chapter 545) effective January 1, 2012. This bill added a provision making it a criminal offense for a physician to refer a patient for “pharmacy goods” if the physician or his/her immediate family member has a financial interest in the entity receiving the referral, except in specified circumstances. The bill also added provisions to the fee schedule statute placing additional caps on physician-dispensed pharmaceuticals and dangerous devices. The Legislature’s concern with physician drug dispensing practices is evidenced by the legislative findings set forth in the bill. Section 1 of Assembly Bill 378 states in part:

“(b) 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.”

The legislative findings reference the 2007 Administrative Director regulation that capped repackaged drug fees at the same fee schedule rate applicable to the same drug distributed through pharmacies, which was adopted to address the physician practice of billing at inflated rates by repackaging the drug so that it would not have a fee schedule price. The bill’s legislative findings further state that “once the abusive repackaging practice was outlawed, the practice of physicians prescribing or dispensing compounded medications, creams, copacks, and medical foods expanded rapidly.”

“(e) The percentage of California workers’ compensation medication dollars that are used toward compounded drugs, copacks, and medical foods has increased from 2.3 percent in 2006 to 12 percent in 2009. This increase in compounded drugs, copacks, and medical foods has increased costs for insurers and led to rising premiums for employers. For example, the State Compensation Insurance Fund reports that what was rarely billed prior to 2007 rapidly escalated to over $58 million in billings in a 16-month period. Another insurer reported a 16-fold increase in less than a two-year period.

(f) Compounded drugs are not evaluated for safety or efficacy by the federal Food and Drug Administration (FDA). According to the FDA, compounded drugs carry significant health risks that can lead to permanent injury or death.

(g) In order to alleviate California’s employers and insurers from this significant increase in costs, to enhance the efficiency of the workers’ compensation system, and to ensure that injured workers receive safe, appropriate health care, the Legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, copacks, and medical foods and to create a new process for the prescription of compounded drugs, copacks, and medical foods.”
Assembly Bill 378 (Statutes 2011, Chapter 545).

Labor Code section 5307.1 generally caps maximum pharmaceutical fees to 100% of the Medi-Cal fees. Labor Code section 5307.1, subdivision (a) states that “…all fees shall be in accordance with the fee-related structure and rules of the relevant … Medi-Cal payment systems…” and “Pharmacy services and drugs shall be subject to the requirements of this section, whether furnished through a pharmacy or dispensed directly by the practitioner…” Subdivision (d) states in part: “If the administrative director determines that a pharmacy service or drug is not covered by a Medi-Cal payment system, the administrative director shall establish maximum fees for that item. However, the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources.”

The legislative findings in AB 378 evidence the legislature’s intent to amend Labor Code section 5307.1 to add separate provisions directed specifically at physician-dispensed drugs to address the “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”. (AB 378, Statutes 2011, Chapter 545, Section 1 (b).) Labor Code section 5307.1, subdivision (e)(2), includes a provision specifically related to physician-dispensed compounded drugs; subdivision (e)(3) relates to a physician-dispensed “dangerous drug” (defined as a drug requiring a prescription, also known as a “legend” drug) that is a finished drug product approved by the FDA; subdivision (e)(4) relates to a physician-dispensed “dangerous device” (defined as a device requiring a prescription) and subdivision (e)(5) relates to any pharmacy good dispensed by a physician that is not subject to subdivisions (e)(2), (e)(3), or (e)(4). In addition, subdivision (e), paragraphs (7) and (8) give the Administrative Director additional authority to adopt fee schedule provisions explicitly directed at physician dispensed pharmaceuticals.

The proposed regulation section 9789.40.5, subdivision (a), specifies that the maximum fee payable for a legend drug dispensed by a physician on or after the effective date, is the lower of the physician’s usual and customary charge to patients under the physician’s care or the drug’s ingredient cost based on the formula set forth. This subdivision implements Labor Code section 5307.1, subdivision (e)(3), which states: “For a dangerous drug dispensed by a physician that is a finished drug product approved by the federal Food and Drug Administration, the maximum reimbursement shall be according to the official medical fee schedule adopted by the administrative director.” The section uses the same definition of “drug’s ingredient cost” that is used for pharmacy-dispensed drugs in section 9789.40.1: “Drug’s ingredient cost” means the lowest of: 1) the NADAC or when no NADAC is available, the WAC plus 0%, or 2) the FUL or 3) the MAIC. This brings the definition into alignment with the revised Medi-Cal pharmacy fee schedule definition of “drug’s ingredient cost” used for pharmacies as adopted by the State Plan Amendment 17-002. Although Medi-Cal does not pay physicians for dispensing drugs, in workers’ compensation the physician may lawfully dispense to their patients; the Administrative Director has determined that the pharmacy formula for the “drug ingredient cost” is appropriate for physician-dispensed legend drugs.

The proposed regulation section 9789.40.5, subdivision (b), sets forth a different methodology for a legend brand name drug dispensed by a physician where the physician has fulfilled the requirements set forth in the Medical Treatment Utilization Schedule formulary regulation sections 9792.27.7 and 9792.27.8. Where the physician has determined that a brand name drug is medically necessary instead of a generic therapeutic equivalent, Section 9792.27.7 indicates that the physician must document the medical necessity of the brand name drug where a less costly therapeutically equivalent drug exists and must obtain prospective authorization. Section 9792.27.8 sets forth rules specifically related to physician dispensing, and sets forth exceptions to the requirement to obtain prospective authorization.

In order to provide cost effective care, a generic therapeutic equivalent to a brand name drug should be dispensed if it is less costly. However, it is important that an injured worker have access to brand name drugs where they are medically necessary to treat the injury or illness, even if the brand name drug is more expensive than the generic equivalent. Therefore, to support access to brand name drugs where medically necessary and dispensed in accordance with sections 9792.27.7 and 9792.27.8, the regulation specifies the maximum payment is the lower of 1) the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0% (this is the “No Substitution” price), or 2) the physician’s usual and customary charge to patients under the physician’s care.

The proposed regulation section 9789.40.5, subdivision (c) sets forth the methodology for determining the maximum fee for a repackaged drug dispensed by a physician. Medi-Cal does not pay for drugs dispensed by a physician, and also does not pay for “repackaged drugs.” AB 378’s legislative finding evidences the need for a regulation to address repackaged drugs as follows:

“(c) One of the ways that these physicians accomplished the goal of billing at inflated rates was by repackaging common medications from bulk supplies so that the packages did not have fee schedule codes, and dispensing them in common amounts at prices far above the fee schedule for the same products sold through pharmacies. This practice continued until the Administrative Director of the Division of Workers’ Compensation adopted a regulation in 2007 that required any repackaged medication to be reimbursed at the same fee schedule as the same drug distributed through pharmacies and not reimbursed based on arbitrary prices associated with unscheduled packages.”

The proposed regulations continue to use the basic structure of the 2007 repackaged drug regulation, by utilizing the NDC of the underlying drug product if the repackaged drug NDC is not in the Pharmaceutical Fee Data File. The underlying drug NDC maximum fee is determined based on the applicable physician-dispensed formula set forth in subdivision (a) (legend drug), (b) (legend brand name drug where branded product is medically necessary and prospectively authorized) or (d) (non-legend drugs). This language is necessary so that the underlying drug product used in a repackaged drug is subject to the same formula that it would have been subject to if it were not repackaged.

If the NDC for a repackaged drug is not in the Pharmaceutical Fee Data File, and the underlying drug NDC is not in the Pharmaceutical Fee Data File, then the maximum drug ingredient fee shall not exceed the drug ingredient cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis pursuant to subdivisions (a) or (d). The Administrative Director has determined that this would be an appropriate methodology to approximate what Medi-Cal would pay for a drug that requires comparable resources, and also implements the physician-specific statutory provisions of Labor Code section 5307.1, subdivision (e) to the extent possible.

The proposal specifies that the NDC of the dispensed repackaged drug and the NDC of the underlying drug shall both be identified on the bill in accordance with the billing regulations. It is necessary to include both NDC numbers on the bill for accuracy of reporting the dispensed product and to allow determination of the fee based on the actual underlying drug product utilized.

It is necessary to define “therapeutically equivalent drugs” by reference to the Food and Drug Administration’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”), as it is the definitive and authoritative source of the status of drug products as therapeutic equivalents.

The proposal defines “National Drug Code for the underlying drug product from the original labeler” to be the NDC of the drug product actually utilized. This is necessary to ensure that the drug product dispensed can be accurately benchmarked and to avoid the potential for artificially inflated prices.

The proposed regulation section 9789.40.5, subdivision (d) sets forth the formula for the maximum reasonable fee for a non-legend drug dispensed by a physician, at the lower of the physician’s usual and customary charge to patient’s under the physician's care, or the lowest drug ingredient cost pursuant to subdivision (a) (the Medi-Cal methodology), 120% of documented paid cost, or 100% of documented paid cost plus $250.00. This subdivision implements the Labor Code directive to adopt additional caps for physician-dispensed non-legend drugs. Although these caps may be applied to physician-dispensed non-legend drugs directly from the statute, including them in this subdivision specifically addressing non-legend drugs adds clarity.

Subdivision (e) is proposed as a catch all to set maximum fee formula for any pharmacy good dispensed by a physician that does not fall within the sections governing legend drugs, medically necessary brand name drugs, repackaged drugs or compounded drugs. This “catch all” provision for physician-dispensed drugs that do not fall within the other specified provisions is necessary to implement the provisions of Labor Code section 5307.1, subdivision (e)(5) that prices these products at the same maximum fee applicable to non-legend drugs. The section cross references to subdivision (d) to set the maximum fee.

The proposed regulation section 9789.40.5, subdivision (f) provides that a dispensing fee is not payable for a drug dispensed by a physician. The Administrative Director has determined that the professional dispensing fee that would be payable to a pharmacy under the Medi-Cal system is not warranted where a physician dispenses a drug to their workers’ compensation patient. The Medi-Cal payment system does not pay for physicians to dispense pharmaceuticals, and therefore does not pay a dispensing fee to a physician. The dispensing fees calculated for Medi-Cal are based on services and costs of dispensing by pharmacies, not physicians. Physicians will dispense drugs to their patients as part of an office visit, and will be reimbursed for an evaluation and management code, which includes time spent counseling the patient (such as advising on medication usage), and documenting the patient record. Many of the tasks involved in dispensing a drug to a patient are already included in the physician’s reimbursement.

The proposed regulation section 9789.40.5, subdivision (g) provides that the physician shall not bill for a drug he/she dispenses to a patient that was obtained for free, such as a sample, or which was otherwise obtained by the physician without payment. This is necessary to avoid inappropriate payment to a physician where costs were not incurred.

The definition of “documented paid cost” is set forth in subdivision (h), specifying that it means the net price actually paid by the physician for the drug product(s), after discounts or rebates. In order to implement the Labor Code’s provision that specified physician fees be based upon *documented* paid cost, it is necessary for the regulation to require the physician to submit documentation of paid costs together with the bill. These provisions are necessary to define an important term used as a benchmark in the formulas, in order to avoid highly inflated bills for physician-dispensed drugs.

Subdivision (i) of the proposed regulation states that the “lowest cost” and “no substitution cost” drug ingredient rates file and dispensing fee file will be made available on the Division’s website and sets forth a link. This is necessary to alert the public that the necessary data files will be available, and where to access them. By posting the drug ingredient cost file with the “lowest cost” and “no substitution” cost, the public will not have to independently set up the calculations, reducing the amount of programming adjustments that may be needed.

AB 378 clearly expresses the legislature’s concern with physician-dispensing practices. The bill adopted new provisions restricting physician’s pharmaceutical referrals where the physician has a financial interest in the entity receiving the referral. And the legislative findings directly express the concerns regarding physician dispensing as set forth above.

The Administrative Director is cognizant of the fact that physician dispensing of drugs can be a convenience to patients. However, this convenience is weighed against the potential harms of physician dispensing that may be influenced, either consciously or unconsciously, by financial incentives. Researchers have found that physician selection of medication may differ depending on whether the physician is writing a prescription for a drug to be filled at a pharmacy or is dispensing the drug directly to the patient.

Research conducted by the Workers’ Compensation Research Institute (WCRI) raises the concern that some physician dispensing may be driven by financial incentives, increasing costs, but not improving patient care. In a 2014 study, *The Impact of Physician Dispensing on Opioid Use*, Thumula, WCRI examined reforms in Florida that prohibited dispensing of Schedule II and Schedule III opioids by physicians. The major findings included the following:

* “When we compare pre- and post-reform prescribing practices, it appears that physician-dispensers not only reduced *dispensing* of strong opioids, but also reduced *prescribing* of strong opioids. This raises concerns that a significant proportion of pre-reform physician-dispensed strong opioids may not have been necessary.
* Of the 3.4 percentage point drop in the percentage of workers receiving physician-dispensed strong opioids, we found the following:
* Few workers received strong opioids at pharmacies. The legislation banned physician dispensing but did not limit the physician from prescribing strong opioids and sending the patient to a local pharmacy. Somewhat surprisingly, there was very little increase in the percentage of patients receiving strong opioid prescriptions at pharmacies after the reform – 12.2 percent pre-reform versus 12.5 percent post-reform.”

(Thumula, 2014, page 4.)

These findings raise troubling questions regarding whether physicians prescribe more addictive opioids if the drugs are physician-dispensed rather than pharmacy-dispensed. WCRI noted that “The findings of this study are based on Florida data but the lessons may apply to other states where physician dispensing is common.” *Impact of Physician Dispensing on Opioid Use*, Thumula, WCRI, page 4.

A subsequent WCRI report, *Physician Dispensing of Higher-Priced New Drug Strengths and Formulation*, Wang et al., April 2016, examines data of prescribing changes that occurred with the marketing of “new” strengths of commonly prescribed drugs. Most often these new strengths cost substantially more than the common strengths that had been available previously. For example, the WCRI report discusses the trend observed with the prescription of the muscle relaxant cyclobenzaprine HCL:

“Table 4.1 shows a substantial shift in prescriptions from existing strengths to the new strengths, which is true for all three drugs, especially for 7.5 milligram cyclobenzaprine HCL….For example, before generic cyclobenzaprine HCL of 7.5 milligrams was introduced in 2012, there were two prescription strengths for the drug – 5 milligrams and 10 milligrams. Once the new strength was introduced, it was quickly picked up by physicians in California. In the first quarter of 2012, physician-dispensed prescriptions for the 7.5 milligram new strength accounted for 6 percent of cyclobenzaprine prescriptions dispensed by physicians, an increase from none. The figure increased dramatically in subsequent quarters. By the first quarter of 2014, the frequency of physicians dispensing the new strength increased to 55 percent.

When the 7.5 milligram cyclobenzaprine HCL prescriptions were dispensed by physicians in California, the price paid was about $3.01 per pill in the first quarter of 2014, much higher compared with the prices paid for physician-dispensed existing strengths ($0.38 for 5 milligrams and $0.39 for 10 milligrams). By contrast, a vast majority of pharmacy-dispensed cyclobenzaprine HCL was still 5 and 10 milligrams.”

(Wang, 2016, p. 40.)

The WCRI reported similar findings for tramadol HCL, a synthetic opioid. WCRI’s data analysis revealed a substantial increase in physician dispensing of an extremely costly new 150-milligram strength extended release formulation of tramadol HCL which was not seen in pharmacy-dispensed tramadol prescriptions. The average price paid per pill for the new 150-milligram extended release was $8.05 in the first quarter of 2014, whereas the price of the 50-milligram regular release product was $0.24. (Wang, 2016, 40.)

The WCRI’s summary of its findings in California evidences the necessity for ensuring that physician-dispensed drugs are appropriately being used to maximize quality of care. The WCRI report states:

“There is strong evidence that physician dispensing of higher-priced new drug products was prevalent in California. The frequent physician dispensing of these new-strength and new-formulation products outweighed the price reductions seen in the existing strengths of the same drugs, driving up the physician prices in California. The result is unintended and inconsistent with the goals of the reforms in the state. The question is whether these new drug products provide certain clinical benefits that may justify the additional costs. The fact that the higher-priced new drug products were essentially dispensed only by physicians and not by pharmacies suggests that financial incentives and not therapeutic value drove the growth in dispensing these new products.”

(Wang, 2016, p. 43.)

The trend of increasing physician dispensing, and not pharmacy dispensing, of the costly “new strength” synthetic opioid tramadol HCL in California raises serious concerns regarding inappropriate financial incentives for physician dispensing.

More recently, a WCRI study looking at topical analgesics considered how pricing may affect physician prescribing and dispensing practices. WCRI examined a variety of topical analgesics, including “private label topical analgesics” which it describes as follows: “Private-label topical analgesics are independently-manufactured products that combine ingredients in topical pain relievers that are commonly available over the counter.” *Topical Analgesic Use in Workers’ Compensation*, August 2021, Workers’ Compensation Research Institute, Thumula and Liu, p. 19. The study found that “the PLT [private-label topical] analgesics have higher prices per prescription than comparable products of the same strength that are available at retail pharmacies without a prescription”, in some cases as much as 66 times higher price. (Thumula and Liu, p. 21) In light of the data, it appears that there may be financial incentives motivating some dispensing of the higher priced products, without medical benefit to the injured worker. WCRI indicated its finding as follows:

“In all, we did not find any evidence in the literature of the clinical benefits of [private-label topical] drug products, especially over comparable products available over the counter in retail pharmacies. Moreover, these products had higher prices per prescription, higher utilization, and higher rate of duplicate therapies… If there were convincing clinical reasons for using these drug products, one would expect to see a significant number of physicians writing prescriptions for these drugs to their patients, regardless of whether or not they dispense them. However, these products were predominantly dispensed by physician-dispensers in most study states.” (Thumula and Liu, p. 22.)

The Administrative Director proposes the fee regulations for physician-dispensing in light of the provisions of Labor Code section 5307.1, the legislative intent expressed in AB 378, and with patient safety and health care quality foremost in mind.

## 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 proposed regulation section 9789.40.6 sets forth the rules to implement Labor Code section 5307.1, subdivisions (e)(2), (e)(7), (e)(8), and carry out the legislative intent to regulate physician-dispensed compounded drugs to promote safe appropriate health care that is not influenced by financial incentives. The legislative findings of Assembly Bill 378 note the Administrative Director’s 2007 regulation which was adopted to curb highly inflated fees for repackaged drugs, and finds that the apparent reaction to the regulation was a shift to compounded drugs, and other products such as “medical foods”. The key legislative findings underpinning the express need to rein in inappropriate financial incentives for physician dispensing are set forth as follows:

“(d) Prior to the adoption of the physician dispensing regulation, compounded medications, creams, copacks, and other medical foods constituted a small percentage of the overall cost of prescription medications. However, once the abusive repackaging practice was outlawed, the practice of physicians prescribing or dispensing compounded medications, creams, copacks, and medical foods expanded rapidly.

(e) The percentage of California workers’ compensation medication dollars that are used toward compounded drugs, copacks, and medical foods has increased from 2.3 percent in 2006 to 12 percent in 2009. This increase in compounded drugs, copacks, and medical foods has increased costs for insurers and led to rising premiums for employers. For example, the State Compensation Insurance Fund reports that what was rarely billed prior to 2007 rapidly escalated to over $58 million in billings in a 16-month period. Another insurer reported a 16-fold increase in less than a two-year period.

(f) Compounded drugs are not evaluated for safety or efficacy by the federal Food and Drug Administration (FDA). According to the FDA, compounded drugs carry significant health risks that can lead to permanent injury or death.

(g) In order to alleviate California’s employers and insurers from this significant increase in costs, to enhance the efficiency of the workers’ compensation system, and to ensure that injured workers receive safe, appropriate health care, the Legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, copacks, and medical foods and to create a new process for the prescription of compounded drugs, copacks, and medical foods.”
Assembly Bill 378, Section 1 (Statutes 2011, Chapter 545.)

The “new process for the prescription of compounded drugs” is set forth in Labor Code section 5307.1, subdivision (e)(2). The statute provides a special cap for physician-dispensed compounded drugs based upon documented paid costs:

“Any compounded drug product 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) of the ingredient and the corresponding quantity, and in accordance with regulations adopted by the California State Board of Pharmacy. Ingredients with no NDC shall not be separately reimbursable. The ingredient-level reimbursement shall be equal to 100 percent of the reimbursement allowed by the Medi-Cal payment system and payment shall be based on the sum of the allowable fee for each ingredient plus a dispensing fee equal to the dispensing fee allowed by the Medi-Cal payment systems. **If the compounded drug product is dispensed by a physician, the maximum reimbursement shall not exceed 300 percent of documented paid costs, but in no case more than twenty dollars ($20) above documented paid costs.**” [Emphasis added.]

The proposed regulation section 9789.40.6 states that the compounded drug maximum fee is the lowest of 1) 300% of documented paid cost but not more than $20.00 above documented paid cost, 2) the drug ingredient cost pursuant to subdivision (c) for a finished or unfinished drug product, or 3) the physician’s usual and customary charge for the compounded drug to patients under the physician’s care. Subdivision (c) encompasses the same methodology as the pharmacy compounded drug ingredient cost and the additional statutory caps in order to carry out the legislative intent that physician-dispensed drugs not be paid at highly inflated rates.

The regulation subdivision (b) defines “documented paid cost” to mean the price paid by the physician for the drug ingredients, net of discounts and rebates. Subdivision (b) also requires documentation, specifies the types of records that would satisfy the requirement, and mandates that documentation and proof of authorization be submitted to support the bill. These provisions support and implement the legislative intent that compounded drugs are not billed or reimbursed at highly inflated prices. Currently, the Labor Code section 5307.1 subdivision (e) provision makes it clear that the maximum amount payable to a physician above documented paid cost is $20.00. The California Medical Billing and Payment Guide (MBPG), version 1.2.2, “complete bill rules” require submission of documentation to support bills. The MBPG states in pertinent part:

“(b) All required reports and supporting documentation sufficient to support the level of service or code that has been billed must be submitted as follows:

[\*\*\*]

(9) An invoice or other proof of documented paid costs must be provided when required by statute or by the OMFS for reimbursement.”

(MBPG, version 1.2.2, 3.0 Complete Bills, Title 8, Cal. Code Regs. section 9792.5.1(a))

The inclusion of the provisions regarding “documented paid costs” in section 9789.40.6 reinforces the requirement in Labor Code section 5307.1, subdivision (e), which benchmarks physician-compounded drugs to documented paid costs.

The proposed regulation, subdivision (d) requires drugs to be identified using the applicable NDC and corresponding quantity which is necessary to implement Labor Code section 5307.1, subdivision (e)(2). In addition, the regulation includes necessary language to conform to the provision of Labor Code section 5307.1, subdivision (e)(2), which states that “[i]ngredients with no NDC shall not be separately reimbursable.” To provide guidance on what qualifies as a “valid NDC”, the regulation provides a presumption that an NDC is valid if it is listed in the FDA’s NDC directory as a finished or unfinished drug product, and is not listed on the excluded drugs database file. It is necessary that the regulation provides that the presumption is rebuttable because listing on the NDC directory is necessary, but is not always sufficient, to be “valid.” (See the above discussion regarding section 9789.40.3 in relation to the necessity of making the parallel presumption rebuttable.)

The proposed regulation section 9789.40.6, subdivision (e) provides that dispensing, compounding and sterility fees are not payable for a compounded drug dispensed by a physician. The Administrative Director has determined that the professional dispensing fee which would be payable to a pharmacy under the Medi-Cal system is not applicable where a physician dispenses a compounded drug to his or her workers’ compensation patient. The Medi-Cal payment system does not pay for physicians to dispense pharmaceuticals, and therefore does not pay a dispensing fee to a physician. The dispensing fees calculated by Mercer for Medi-Cal are based on services and costs of dispensing by pharmacies, not physicians. Physicians will dispense drugs to their patients as part of an office visit, and will be reimbursed for an evaluation and management code, which includes time spent counseling the patient (such as advising on medication usage), and documenting the patient record. Many of the tasks involved in dispensing a drug to a patient are already included in the physician’s reimbursement. In addition, the Administrative Director has determined that an additional fee in the form of a “dispensing fee” is not warranted in light of the legislature’s express intent: “…the Legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs…” The Labor Code section 5307.1 subdivision (e)(2) cap on physician-dispensed compounded drugs of “300 percent of documented paid costs, but in no case more than twenty dollars ($20) above documented paid costs,” makes it clear that the legislature did not intend to allow a physician to be paid a dispensing fee.

The proposed regulation, subdivision (f), states that a compounded drug that is “essentially a copy of a commercially available product” as defined in federal law and regulation is not reimbursable. The discussion above relating to the parallel provision in section 9789.40.2, subdivision (g), is incorporated by reference here and supports the necessity for the provision barring reimbursement for a compounded drug that is “essentially a copy of a commercially available product.”

## Section 9789.111. Effective Date of Fee Schedule Provisions.

The proposal includes amendments to the OMFS section that sets forth a compilation of the effective dates of various portions of the OMFS. Revision is proposed to update the range of codes that constitute the physician services regulation to include section 9789.19.1. This is necessary as a “clean up” to a previous physician fee schedule rulemaking which adopted section 9789.19.1 (relating to anesthesia conversion factor) effective January 1, 2019, but which inadvertently omitted amending this section.

The proposal also adds a new provision stating that additional OMFS regulations for pharmaceuticals (sections 9789.40.1 – 9789.40.6) are effective for services rendered on or after the effective date [Month Day, 2024]. The amendment is necessary for consistency between this regulation which provides an overview of the OMFS effective dates and the new pharmaceutical fee schedule sections.

# TECHNICAL, THEORETICAL, OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS RELIED UPON

The Administrative Director relies on the following documents in proposing the regulations. They are available for public review and comment in the rulemaking file.

A Multistate Perspective on Physician Dispensing, 2011-2014, Workers’ Compensation Research Institute, Wang et al., July 2017

Are Physician Dispensing Reforms Sustainable? Workers’ Compensation Research Institute, Wang et al., January 2015

[Assembly Bill 378 (Statutes 2011, Chapter 545)](http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201120120AB378)

[Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf), US Dept. of Health and Human Services, January 2018

[Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf)

[Guidance for Industry](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf), US Dept. of Health and Human Services, January 2018

Current Trends in Compound Drug Utilization and Cost in the California Workers’ Compensation System, California Workers’ Compensation Research Institute, Swedlow and Auen, February 2013

[Department of Health Care Services Issue Paper – Proposed Pharmacy Reimbursement Changes to Comply with CMS’ Covered Outpatient Drug Final Rule (42CFR Part 447 Part II)](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_Selected_Alt.pdf), January 18, 2016

Department of Health Care Services Medi-Cal News Flash: Pharmacy Fee-For-Service Reimbursement Changes Begin February 23, 2019, January 28, 2019

[Department of Health Care Services Medi-Cal Provider Manual General Medicine Physician Administered Drugs-NDC](https://mcweb.apps.prd.cammis.medi-cal.ca.gov/file/manual?fn=reimbursement.pdf) (physician ndc), updated pages through November 16, 2023

[Department of Health Care Services Medi-Cal Provider Manual Pharmacy – Reimbursement](https://mcweb.apps.prd.cammis.medi-cal.ca.gov/file/manual?fn=reimbursement.pdf), updated pages through November 16, 2023

[Department of Health Care Services MMIS 2024 Compound Dosage Fee Table](https://www.dir.ca.gov/dwc/pharmfeesched/table2024.pdf), posted on Division of Workers’ Compensation website

[Department of Health Care Services Notice of General Public Interest Proposed Changes to Pharmacy Reimbursement for Covered Outpatient Drugs](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/SPA_17-002_Public_Notice.pdf), March 30, 2017

[Department of Health Care Services Retroactive Claim Adjustments Pharmacy Reimbursement Project](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_RetroactiveClaimAdj.pdf), March 26, 2019

Department of Industrial Relations, Division of Workers’ Compensation Background OMFS Pharmaceutical Fee Schedule Sample Data Files for Public Comment (Word document posted on DIR/DWC rulemaking page)

Department of Industrial Relations, Division of Workers’ Compensation Sample National Provider Identifier (NPI) Data File: “SAMPLE for public comment npi\_run20240220” (posted on DIR/DWC rulemaking page)

Department of Industrial Relations, Division of Workers’ Compensation Sample Pharmaceutical Fee Schedule Data File: “SAMPLE for public comment pfs\_run20240220” (posted on DIR/DWC rulemaking page)

Differences in Outcomes for Injured Workers Receiving Physician-Dispensed Repackaged Drugs in the California Workers’ Compensation System, CWCI, Swedlow et al., February 2013

Physician Dispensing of Higher-Priced New Drug Strengths and Formulation, Workers’ Compensation Research Institute, Wang et al., April 2016

[Professional Dispensing Fee and Actual Acquisition Cost Analysis for Medi-Cal – Pharmacy Survey Report](https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP_Merc_Rpt_170127.pdf), Mercer, January 4, 2017

[Questionable Billing for Compounded Topical Drugs in Medicare Part D, U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Office of Inspector General, OEI-02-16-00440](https://oig.hhs.gov/oei/reports/oei-02-16-00440.asp), August 2018

[Replacing Average Wholesale Price: Medicaid Drug Payment Policy, Dept. of Health & Human Services, Office of the Inspector General, OEI-03-00060](https://oig.hhs.gov/oei/reports/oei-03-11-00060.asp), July 2011

The Impact of Physician Dispensing on Opioid Use, Workers’ Compensation Research Institute, Thumula, December 2014

The Prevalence and Costs of Physician-Dispensed Drugs, Workers’ Compensation Research Institute, Wang et al., September 2013

Topical Analgesic Use in Workers’ Compensation, WCRI, Thumula and Liu, August 2021

[U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, Letter of August 25, 2017 Approving State Plan Amendment (SPA) 17-002, Prescribed Drugs, and Attached Transmittal and Notice of Approval of State Plan Material [Form CMS-179]](https://www.dhcs.ca.gov/formsandpubs/laws/Documents/17-002ApvOct.pdf)

# 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 proposed pharmaceutical fee schedule would impact medical providers, pharmacies, pharmacy benefit managers, payers (insurers and self-insured employers), and entities that provide medical billing services. There will be both costs and savings for the regulated public.

System participants may incur one-time up-front costs to adjust their billing and payment systems from the current payment structure to the revised payment structure. In relation to provisions of the regulations that benchmark maximum fees using the Medi-Cal formula of “lowest of NADAC (or WAC + 0% if NADAC does not exist), FUL, or MAIC”, the Administrative Director has structured the Pharmaceutical Fee Data File for posting to mirror the current structure to the extent feasible, by providing the “lowest cost” and “no substitution” cost. The NADAC/FUL/MAIC calculation is embedded in the “lowest cost”. Maintaining the same basic data file structure should ease the programming tasks.

In regard to the professional dispensing fee for pharmacy-dispensed drugs, there will be some programming costs because of the transition from the current dispensing fee model to the Medi-Cal two-tier dispensing fee model. However, this is not expected to be a difficult transition. The determination of the appropriate tier is based upon the National Provider Identifier (NPI) of the pharmacy dispensing the drug, which is a required data element on the paper pharmacy billing form and on the electronic billing format. The Administrative Director will post the Medi-Cal dispensing fee files which set forth the NPIs of the pharmacies that are certified as Medi-Cal eligible for the higher dispensing fee. There will be some modest programming time to adapt to this model.

The aggregate expenditure for “drug ingredient costs” in workers’ compensation is expected to decline as the revised Medi-Cal payment benchmark based primarily on NADAC will produce more modest payments than the current benchmark based upon AWP minus 17%. The savings on pharmacy-dispensed drugs will be partially offset by the increase in the pharmacy professional dispensing fee. The pharmacy professional dispensing fee will rise substantially, from the current $7.25 (or $8.00 for a nursing home patient) to $10.05, or $13.20 for those pharmacies eligible for the Medi-Cal higher tier. This change will produce increased overall costs for pharmacy dispensing fees.

The regulation provisions regarding physician-dispensed pharmaceuticals will likely produce an overall reduction in pharmaceutical payments to physicians. For FDA approved legend drug products, and repackaged drug products, this is due to the Medi-Cal NADAC benchmark which replaces the AWP-17% in the Medi-Cal formula. For compounded drugs, the regulation reinforces the existing statutory provision capping physician-dispensed drugs at 300% of documented paid cost but not more than $20.00 above documented paid costs. The system wide economic impact of disallowing a dispensing fee for physician-dispensed drugs is hard to predict. Some of the physician-dispensed drugs may instead be pharmacy-dispensed. To the extent that elimination of the dispensing fee discourages inappropriate dispensing, there may be a financial savings to the system, and improved patient safety. (See above discussion regarding a Workers’ Compensation Research Institute study raising concerns that some dispensing of opioids and other drugs by physicians may be inappropriately influenced by financial incentives.)

# CONSIDERATION OF ALTERNATIVES TO THE PROPOSED REGULATIONS

The Administrative Director has not identified any more effective alternative, or any equally effective and less burdensome alternative to the regulation at this time. The public is invited to submit such alternatives during the public comment process.