

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

**FINAL 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.**

**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 Final Statement of Reasons is prepared to comply with the procedural requirements of Labor Code section 5307.4 for this non-APA rulemaking proceeding.

**CONSIDERATION OF RELEVANT MATTER PRESENTED**

After Notice of the Proposed Rulemaking was published pursuant to Labor Code section 5307.4, a public hearing was held on April 11, 2024, at which interested persons could participate through the submission of written data, views, and arguments, including oral presentations. Simultaneously a written comment period closing April 11, 2024, was conducted. After review of comments received, a modified proposal was issued with a 15-day written comment period closing on June 28, 2024. After review and consideration of comments received, a further modified proposal was issued with a 15-day written comment period closing on October 23, 2024. The Administrative Director has subsequently considered all of the data, views, statements, and arguments presented or submitted.

The Administrative Director of the Division of Workers' Compensation, pursuant to the authority vested in him, has adopted and amended the following sections of Division 1, Chapter 4.5, Subchapter 1, of title 8, California Code of Regulations, relating to the Physician Fee Schedule and Pharmaceutical Fee Schedule components of the Official Medical Fee Schedule:

<b>Title 8, CCR Section Amend/Adopt</b>	<b>Title of Section as Amended / Adopted</b>
<b>Section 9789.12.1</b>	Section 9789.12.1. Physician Fee Schedule: Official Medical Fee Schedule for Physician and Non-Physician Practitioner Services – For Services Rendered On or After January 1, 2014. [Amend]
<b>Section 9789.13.2</b>	Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products. [Amend]
<b>Section 9789.13.3</b>	Physician-Dispensed Drugs. [Amend]
<b>Section 9789.40</b>	Pharmacy – Pharmaceuticals Dispensed and Pharmaceutical Services Rendered Prior to [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Amend]
<b>Section 9789.40.1</b>	Pharmaceutical Fee Data File for Pharmacy and Physician Dispensed Pharmaceuticals; National Provider Identifier File for Pharmacy Dispensed Pharmaceuticals; for Products Dispensed and Services Rendered on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.2</b>	Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.3</b>	Compounded Pharmaceuticals Dispensed By a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments

Title 8, CCR Section Amend/Adopt	Title of Section as Amended / Adopted
	are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.4</b>	Compounding Fee and Sterility Fee for Pharmacy Dispensed or Physician Dispensed Compounded Drugs: Route of Administration Compounding Fee / Sterility Fee Table; Dosage Form Compounding Fee Table; Compounded Drugs Dispensed on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.5</b>	Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.6</b>	Pharmaceuticals Dispensed By a Physician on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.40.7</b>	Compounded Pharmaceuticals Dispensed By a Physician on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Adopt]
<b>Section 9789.111</b>	Effective Date of Fee Schedule Provisions. [Amend]

## UPDATE OF INITIAL STATEMENT OF REASONS AND INFORMATIVE DIGEST

The Administrative Director incorporates the Initial Statement of Reasons prepared in this matter. The purposes and rationales for the regulations as set forth in the Initial Statement of Reasons continue to apply, unless otherwise noted in the Final Statement of Reasons.

The following sections of the initially proposed regulations were modified after consideration of comments received during the 45-day written comment period and

public hearing, and comments received during the two additional 15-day public comment periods. The regulation changes beyond those set forth in the Initial Statement of Reasons are summarized below.

**THE FOLLOWING SECTIONS WERE ADOPTED OR AMENDED FOLLOWING CONSIDERATION OF PUBLIC COMMENTS IN THE 45-DAY WRITTEN COMMENT PERIOD AND PUBLIC HEARING, AND TWO 15-DAY PUBLIC COMMENT PERIODS.**

**Modifications to 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.**

Subdivision (c) which specifies that physicians shall utilize other applicable parts of the Official Medical Fee Schedule to determine maximum fees for services or goods not covered by the Physician Fee Schedule was modified to update the cross references to sections relating to physician-dispensed drugs. The purpose of the modification was to conform the citations to numbering changes in the modified text of regulation.

**Modification to Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products.**

**Subdivision (a)(4)** of this section of the Physician Fee Schedule provides that maximum reimbursement for physician *administered* drugs, biologicals, vaccines, or blood products that are not listed in the Medi-Cal Rates file will be paid in accordance with the pharmaceutical fee schedule sections applicable to physicians for *dispensed* drugs. Subdivision (a)(4) was modified to update the cross-references to sections of the pharmaceutical fee schedule applicable for physician-dispensed drugs by adding sections 9789.40.1, 9789.40.4, 9789.40.7 (to supplement the listing of sections 9789.40 and 9789.40.6) and by deleting section 9789.40.5. This modification was necessary for accuracy as the sections listed in the 1<sup>st</sup> 15-day comment period text were not complete and the inclusion of section 9789.40.5 was erroneous as it applies only to pharmacies.

**Modification to Section 9789.13.3. Physician-Dispensed Drugs.**

This section was modified to update the cross references to sections relating to physician-dispensed drugs. The citations were modified to add 9789.40.1, 9789.40.4, 9789.40.7, and to delete 9789.40.5 in order to conform to other numbering changes in the modified text of regulation.

**Modification to Section 9789.40. Pharmacy – Pharmaceuticals Dispensed and Pharmaceutical Services Rendered Prior to [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

The Administrative Director determined that it was reasonable to extend the effective date of new provisions from 90 days to 180 days after the amendments are filed with the Secretary of State to allow adequate time for the affected public to adjust systems as needed for implementation. For clarity and ease of implementation, the effective date is the first of the month as specified. The heading was modified to provide that this section maintaining the current fee schedule provisions is effective for services rendered prior to the date that is the first day of the month following: 180 (rather than 90 days) after the amendments are filed with the Secretary of State, in the year 2025.

Subdivision (a) was modified to extend the effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025. In order to improve clarity of the identification of the current file posted on the DWC website, the language is modified to conform the text of the regulation to the file name as posted “NDC\_lowest\_prices\_2019-02-20” since 03/08/2019.

Subdivision (d) was modified to extend effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

Subdivision (e) was modified to improve clarity of the identification of the current file that remains in effect for services prior to the effective date. As originally proposed in the 45-day comment period, the current file was identified as “Medi-Cal data file *dated 03/08/2019.*” [Emphasis added.] However, although the file was posted on the DWC website on 03/08/2019, the title of the file itself is “NDC\_lowest\_prices\_2019-02-20”. To improve clarity and avoid confusion to the public, the identification of the current file that will remain in effect as specified in §9789.40 for services prior to the “effective date” was changed to “Medi-Cal data file “NDC\_lowest\_prices\_2019-02-20” posted 03/08/2019.” In addition, to improve the clarity of the regulation the text was modified to identify the “Table 2024” compounding fee table that is in effect currently, and which has been effective and posted on the DWC website since the year 2004.

The subdivision was also modified in light of the modification of effective date of changes from 90 days to 180 days (specifying the first day of the month following) in sections 9789.40.1 through 9789.40.7, and to indicate that this will be in the year 2025.

**Section 9789.40.1 Pharmaceutical Fee Data File for Pharmacy and Physician Dispensed Pharmaceuticals; National Provider Identifier File for Pharmacy Dispensed Pharmaceuticals; for Products Dispensed and Services Rendered on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

The proposed text of regulation was modified to add a new section 9789.40.1 to improve clarity and streamline the regulations by consolidating provisions relating

to the Pharmaceutical Fee Data File and the Medi-Cal NPI file in one section, and by including details on implementation timeframe and retroactive changes. The section specifies that it is effective for services rendered on or after the first day of the month following: 180 days after the amendments are filed with the Secretary of State.

**Subdivision (a)** defines “lowest cost” and “no substitution cost” to mean the rates set forth in the Pharmaceutical Data File, and specifies the formulas used by DWC to calculate the “lowest cost” and “no substitution cost.” These formulas were removed from other regulation sections. The modification was intended to avert any misunderstanding by the public as the calculations of “lowest cost” and “no substitution cost” are performed by the DWC; the formulas for these components are not calculated by the public. Rather the “costs” set forth in the Pharmaceutical Fee Data File are calculated by the DWC and then used in the applicable formulas set forth in the other regulation sections to determine the maximum reasonable fee. The section specifies the formula for drug ingredient “lowest cost” as the lowest of: the National Average Drug Acquisition Cost (or Wholesale Acquisition Cost plus 0% if a NADAC does not exist), the Federal Upper Limit, or Maximum Allowable Ingredient Cost. The section specifies the “no substitution cost” formula as the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) +0%, for products where the “no substitution cost” differs from the “lowest cost”.

To provide clarity on the schedule of Pharmaceutical Data File updates, the regulations specify that an updated file will be posted on a weekly basis absent extenuating circumstances. To ensure that payers will implement updates promptly the section requires that payers shall begin calculating fees based on each new file not later than the second calendar day after posting on the DWC website. In light of potential retroactive changes in the weekly update, or cost updates during the period between posting of the file and implementation, the regulation specifies that the payer shall re-adjudicate previously paid claims upon submission of a request for second review by the provider. These changes were necessary to provide clarity on the mechanism to initiate payment of retroactive changes. The regulation also improves clarity by adding details regarding the Legend Indicator column of the Pharmaceutical Fee Data File.

Subdivision (b) consolidates information regarding the National Provider Identifier (NPI) file which lists pharmacy NPIs eligible for the higher tier dispensing fee. To provide clarity on the schedule of Medi-Cal NPI file updates, the regulations specify that an updated file will be posted on a weekly basis absent extenuating circumstances. To ensure that payers will implement updates promptly the section requires that payers shall begin utilizing the updated file to calculate the dispensing fee for eligible pharmacy providers not later than the second calendar day after posting on the DWC website. In light of potential retroactive changes in the weekly update, or NPI updates during the period between posting of the file and implementation, the proposed regulation specifies that the payer shall re-adjudicate previously paid claims upon submission of a request for second review

by the provider. This is necessary to provide clarity on the mechanism to initiate payment of retroactive changes.

Authority and reference citations are added to inform the public of the authorizing statutes and the statutes that are implemented by the new section.

**Section 9789.40.2. Pharmaceuticals Dispensed and Pharmaceutical Services Rendered by a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

This section was renumbered from section 9789.40.1 to 9789.40.2 due to the addition of a new section 9789.40.1. The heading was modified to extend effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

**Subdivision (a)** text was modified to make a grammatical change to specify “a legend or non-legend drug” instead of “legend and non-legend drugs.” To improve clarity the text was modified to state that the maximum reasonable fee payable for a legend or non-legend drug “is determined in accordance with this section” instead of “is the rate that is 100% of the payment allowed pursuant to the Medi-Cal payment methodology.” The Medi-Cal methodology was used to create the “lowest cost” and “no substitution cost” in the Pharmaceutical Fee Data File and this file is to be used for maximum fees so there is uniformity. Therefore, it was necessary for clarity to specify that the drug ingredient cost is the “lowest cost” as set forth on the Pharmaceutical Fee Data File (unless no substitution criteria were met.) The “lowest cost” formula is deleted from subdivision (a) since it has been moved to the new section 9789.40.1. The rule related to the “no substitution cost” was moved from subdivision (b) (which is deleted) to subdivision (a), and the formula is deleted as it is set forth in the new section 9789.40.1. The changes to the original language were adopted to streamline the regulation and improve clarity.

**Subdivision (b)** as originally proposed was deleted (as described above). Subdivision (b) as adopted sets forth the original dispensing fees based on the Medi-Cal two-tier dispensing fee rates and was renumbered to (a)(2) to conform to the reorganization of the section. Substantively, the two-tier dispensing fee structure is unchanged, and is required to conform to the provisions of Labor Code section 5307.1(a), which specifies in pertinent part that for the pharmaceutical fee schedule “all fees shall be in accordance with the fee-related structure and rules of the relevant ... Medi-Cal payment system.”

**Subdivision (c)(1)(A)** renumbers reference to “subdivision (a) or (b)” to “subdivision (a)(1) or (a)(2)” to conform to the renumbering within the section.

**Subdivision (c)(2)(A)** was modified for clarity regarding the formula for a pharmacy dispensed repackaged drug. If the underlying drug product is not in the Pharmaceutical Fee Data File, the regulation sets the maximum drug ingredient

cost as the lowest priced therapeutically equivalent drug calculated pursuant to subdivision (a)(1). The text of subparagraph (c)(2)(A) was modified to specify that where the underlying NDC is not in the file the maximum drug ingredient cost is the lowest priced therapeutically equivalent drug calculated pursuant to “subdivision (a)(1)” rather than “subdivision (a).” It was necessary to modify the original proposal in order to specify the subdivision subparagraph (a)(1) which is the “lowest cost” to avoid an erroneous interpretation that the “no substitution cost” in subparagraph (a)(2) would be applicable. In the rare circumstance that the underlying drug product is not in the Pharmaceutical Fee Data File, the appropriate maximum is the “lowest cost” therapeutically equivalent drug which does appear in the file as this would most closely align with what Medi-Cal would pay for a drug that uses comparable resources.

**Subdivision (d)** relating to the Pharmaceutical Data File and NPI file was deleted for clarity and to avoid duplication since the provisions were moved and consolidated in the newly proposed section 9789.40.1.

**Section 9789.40.3. Compounded Pharmaceuticals Dispensed By a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].**

This section was renumbered from section 9789.40.2 to 9789.40.3. The heading was modified to extend effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

**Subdivision (a)** states that the maximum fee for a pharmacy dispensed compounded drug is 100% of payment allowed by Medi-Cal payment methodology for compounded drugs, except as provided in specified subdivisions. The language was modified to reference subdivision (c)(1) instead of subdivision (c)(2), which was necessary due to the modifications and reorganization of the section. The listing of (c)(1) as an “exception” to Medi-Cal is needed because Medi-Cal does not pay for compounded drugs using bulk active pharmaceutical ingredients; 100% of the Medi-Cal allowed amount would be zero. Since workers’ compensation does pay for bulk active pharmaceutical ingredients in a compounded drug, (c)(1) which sets forth the formula for the maximum drug ingredient cost, without distinguishing the status of the product as finished or unfinished, is listed as an exception.

**Subdivision (c)** which defines the drug ingredient cost for a compounded drug dispensed by a pharmacy initially proposed to adopt different formulas for a finished drug product (subdivision (c)(1)) and an unfinished drug product (subdivision (c)(2).) Upon evaluation of comments received relating to the complexity of distinguishing finished and unfinished drug products, and in light of the Labor Code statutory provisions, the adopted regulation was modified from the original proposal.



In the original proposed text, the drug ingredient cost for a finished drug product was determined according to the formula for non-compounded drugs, i.e. lowest cost, or no substitution cost if applicable to a brand name product. For an unfinished drug product used in a compound, the formula was based upon the documented paid cost of the unfinished drug product plus 10%. The adopted subdivision (c) was modified to provide that the drug ingredient cost means the “lowest cost” or “no substitution cost” for each drug product NDC pursuant to section 9789.40.2, subdivision (a)(1) (“lowest cost”) or subdivision (a)(2) (“no substitution cost”). The distinction between finished drug product and unfinished drug product was eliminated.

This adopted regulation will result in the finished drug products being priced at the lowest cost, or no substitution cost for a brand name drug where the applicable prerequisites are met, and will result in the unfinished drug products being priced at the “lowest cost” as the brand name concept will not apply. Upon review of comments received and reevaluation of the issues, DWC determined that the adopted provisions will align most closely with the Medi-Cal drug ingredient fee methodology for dispensed drugs (lowest of: NADAC or WAC +0% if NADAC does not exist, FUL, MAIC.) Labor Code section 5307.1, subdivision (d) states in relevant 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.” Although Medi-Cal does not pay for dispensed compounded drugs utilizing *bulk active pharmaceutical ingredients*, it does pay for compounded drugs utilizing finished FDA-approved drugs and does pay for a limited number of bulk drug products that are not active pharmaceutical ingredients, for example excipients (such as flavoring agents, sterile water, etc.) used in the compound. The adopted regulation which will result in use of the “lowest cost” formula for the unfinished compound drug ingredient products not covered by Medi-Cal most closely aligns with what Medi-Cal would pay for drugs that use comparable resources. In addition, utilizing the same formula for the finished and unfinished compounded drug ingredients will streamline the billing and payment process.

The Pharmaceutical Fee Data File structure is modified to add the NDCs of unfinished drug bulk pharmaceutical ingredients, which provides fees in alignment with the structure of the regulation. A sample revised Pharmaceutical Fee Data File was included in the rulemaking file and was available for public comment.

**Subdivision (c)** was also modified to delete the “lowest cost” formula since it has been moved to the new section 9789.40.1. Instead, the section provides that the “drug ingredient cost” for a compounded drug is determined pursuant to section 9789.40.2 subdivision (a)(1) (“lowest cost”) or (a)(2) (“no substitution cost.”) This was adopted for clarity and for consistency of the compounded drug fee with the usual rule applicable to a simple prescription, i.e. (a)(1) lowest cost, or (a)(2) no

substitution cost if the Dispense as Written provisions are met. Where the brand name drug is medically necessary as documented by the prescriber, a compounded version should be available where there is a medical requirement, for example for a patient that needs a liquid rather than a tablet or capsule.

**Subdivision (e)** “Compounding and sterility fees” definition cross-reference was modified from section 9789.40.3 to section 9789.40.4. This was necessary to make a correction to the cross-reference which was inadvertently overlooked when a new section 9789.40.1 was added, resulting in the renumbering of section 9789.40.3.

**Subdivision (f)** which defined “documented paid cost” was deleted as it is no longer used in this section.

**Subdivision (g)** was redesignated as (f) due to the deletion of the prior (f).

**Section 9789.40.4. Compounding Fee and Sterility Fee for Pharmacy Dispensed or Physician Dispensed Compounded Drugs: Route of Administration Compounding Fee / Sterility Fee Table; Dosage Form Compounding Fee Table; Compounded Drugs Dispensed on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

This section was renumbered from section 9789.40.3 to 9789.40.4. In order to provide adequate time for implementation, the heading was modified to extend the effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025. The heading was also modified to include reference to “Physician Dispensed” and to reorganize for clarity. As set forth below, upon review of comments submitted and reevaluation it was determined appropriate to reinstate the physician dispensing fee, and the compounding and sterility fee. The adopted regulation was modified from the original proposal as necessary to inform the public of the expanded applicability of the section.

**Subdivision (a)** was modified by deletion of the word “either” to improve clarity and avoid ambiguity. The word “either” may erroneously disrupt the logical relation between (1) the Route of Administration Compounding Fee / Sterility Fee Table and (2) the Dosage Form Compounding Fee Table.

In addition, the language was modified to add reference to the regulation section 9789.40.7(a)(2) which was revised to allow physicians to receive a dispensing fee, compounding fee, and sterility fee as applicable. The DWC considered the contention that physician dispensed medications warrant a dispensing fee. Medi-Cal does not pay a physician to dispense medications, and therefore also does not pay physicians a dispensing fee. Changes made to Labor Code section 5307.1 indicate that the legislature was concerned about inappropriate dispensing by physicians and created additional rules to govern reimbursement

for physician dispensed medication, such as the cap of “300% of documented paid cost, not to exceed \$20 above documented paid cost” in subdivision (e)(2). DWC has considered the advantages and disadvantages of physician dispensing / compounding / sterility fees in light of the Business and Professions Code section 4170 that allows a physician to dispense to their own patient for a condition they are treating if the specified requirements are met. Labor Code section 5307.1, subdivisions (e)(7) and (e)(8) provide the DWC Administrative Director with additional authority to adopt fee schedule rules specific to physician dispensing. Given this authority, and controls on inappropriate prescribing that address potential abuse (e.g. utilization review, prospective authorization formulary rule, etc.), and potential increased medication access for injured workers, the DWC has determined that dispensing, compounding and sterility fees should be considered in calculating the maximum allowed fee for physician dispensed compounded drugs.

**Subdivision (b):** the provisions stating that a Sterility Fee is only allowed when sterility testing is performed, and requiring records of the sterility testing to be maintained, was modified to include applicability to a physician. It was necessary to expand the language by including reference to “physician” in order to coordinate with the revisions to section 9789.40.7 governing the formula for calculation of fees for physician compounding.

**Subdivision (c)** provisions are expanded to encompass both pharmacies and physicians, specifying that the maximum pharmacy dispensing fee per allowed container is determined in accordance with section 9789.40.3 for pharmacies. It was necessary to change the cross reference from section 9789.40.2 to 9789.40.3 to conform to numbering changes.

Language was added to provide that the maximum physician professional dispensing fee for a physician dispensing in accordance with Business and Professions Code section 4170 is \$10.05 per allowed container. It is necessary for clarity to set forth the \$10.05 fee applicable to physicians since this is the default Medi-Cal dispensing fee except for a pharmacy whose NPI is listed on the Medi-Cal NPI file applicable to the date of service. It is necessary to include cross reference to the Business and Professions Code as this alerts physician dispensers to legal constraints on dispensing medications.

In order to avoid confusion, it was necessary to add the word “maximum” to improve clarity as the fee schedule sets maximum fees, not a guaranteed amount. For example, for both pharmacies and physicians, fees are the lower of the billed amount or the amount calculated pursuant to the fee schedule rules. For physician compounded drugs there is a special cap under Labor Code section 5307.1, subdivision (e), of 300% of documented paid cost, but not more than \$20.00 above documented paid cost.

**Section 9789.40.5. Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

This section was renumbered from section 9789.40.4 to 9789.40.5. In order to provide adequate time for implementation, the heading was modified to extend effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

**Subdivision (a)** As originally proposed, the section specified that the provisions of the article apply to determine maximum fees for pharmaceuticals dispensed by a mail order pharmacy to an injured worker for treatment of a California workers' compensation injury or illness, whether the injured worker resides within the state of California or outside the state of California. The adopted rule provides additional detail by stating that the article applies to determine the maximum "drug ingredient cost, dispensing, compounding, and sterility" fees. This modification was necessary to provide clarity on the components of the "fees" that are subject to the regulatory provisions.

**Section 9789.40.6. Pharmaceuticals Dispensed By a Physician on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

This section was renumbered from section 9789.40.5 to 9789.40.6. In order to provide adequate time for implementation, the heading was modified to extend effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

**Subdivision (a)** was modified and reorganized from the original proposal to provide greater clarity on the formula for physician-dispensed legend drugs, including the dispensing fee. For legend drugs, the adopted regulation deletes the "lowest cost" formula from subdivision (a) since it has been moved to the new section 9789.40.1. For clarity, the formula for the non-legend drugs is deleted from this subdivision and moved to a new subdivision (b). This enhances clarity because pursuant to Labor Code section 5307.1, subdivision (e)(5), a physician-dispensed non-legend drug is subject to additional caps beyond the fee schedule ((e) not to exceed: 100% of documented paid cost, 100% of document paid cost plus \$250.)

The introductory sentence was modified to set forth the basic formula for legend drugs: lower of: the drug ingredient cost times number of units dispensed plus dispensing fee, or the physician's usual and customary charge to patient's under the physician's care. The sub-paragraphs, (a)(1), (a)(2), (a)(3) provide the definitions of drug ingredient cost that are used in the formula set forth in the introductory sentence. Subparagraph (a)(1) specifies drug ingredient cost is the "lowest cost" unless (a)(2) or (a)(3) is applicable. Subparagraph (a)(2)

(renumbered, was previously subdivision (b)) specifies that for a legend brand name drug, where the physician has fulfilled the formulary regulation requirements regarding medical necessity and authorization, the drug ingredient cost is the “no substitution cost.” The “no substitution cost” formula (originally in Subparagraph (a)(3) specifies the drug ingredient cost for a repackaged drug: (a)(3)(A) “lowest cost” for the NDC of the underlying drug product; (a)(3)(B) “no substitution cost” for the NDC of the underlying drug product for a legend brand name drug where the physician has fulfilled the formulary regulation requirements regarding medical necessity and authorization; (a)(3)(C) the “lowest cost” of the lowest priced therapeutically equivalent drug where the repackaged drug’s underlying NDC is not set forth on the Pharmaceutical Fee Data File.

These modifications reorganized and streamlined the provisions so that the formula does not need to be repeated for the variations in scenarios. Clarity was improved by structuring the subdivision so that the basic formula applies to all scenarios, only the meaning of “drug ingredient cost” changes as set forth in each of the subparagraphs. The previous subdivision (c) was deleted due to the reorganization of the provisions. Subparagraphs (c)(1) and (c)(2) were deleted because the provisions relating to legend repackaged drugs have been incorporated into subdivision (a) and the provisions relating to non-legend repackaged drugs have been moved to new subdivision (b). Subdivision (c)(3), setting forth the requirement to identify the NDC of the dispensed repackaged drug and the NDC of the underlying drug product on the bill in accordance with paper and electronic billing requirements was deleted because the provisions were moved to a new subdivision (d). Subdivision (c)(4) setting forth definitions of “therapeutically equivalent drugs” and “National Drug Code for the underlying drug product from the original labeler” was deleted because the provisions were moved to a new subdivision (e).

**Subdivision (b)** setting forth the formula for the maximum reasonable fee for a non-legend drug was renumbered (was previously subdivision (d)) and was modified to include non-legend repackaged drugs.

**Subdivision (c)** which defines “documented paid cost” is identical to the previous subdivision (h) which was deleted. Moving the provision to the new subdivision (c) improves clarity as the term “documented paid cost” is utilized in the two preceding subdivisions.

**Subdivision (d)** sets forth the requirement to include both dispensed product NDC and underlying drug product NDC on the bill for repackaged drugs, and cross references the billing regulations. The language was moved from the previous subdivision (c)(3); there was no substantive change from the original proposal. Moving the provision to its own subdivision was necessary in light of the reorganization of the regulations, which separates legend and non-legend drugs in different subdivisions.

**Subdivision (e)** sets forth the definitions of “therapeutically equivalent drugs” and “National Drug Code for the underlying drug product from the original

labeler.” The language was moved from the previous subdivision (c)(4); there was no substantive change.

**Subdivision (f)** (the originally proposed subdivision (e)) sets forth a “default” formula for physician dispensed drugs not otherwise covered by the fee schedule provisions. This subdivision implements the provisions of Labor Code section 5307.1(e)(5), which sets forth a default for physician dispensed drugs not otherwise covered:

“(5) For any pharmacy goods dispensed by a physician not subject to paragraph (2) [compounded drugs], (3) [FDA approved finished drug product], or (4) [dangerous device], the maximum reimbursement to a physician for pharmacy goods dispensed by the physician shall not exceed any of the following:

(A) The amount allowed for the pharmacy goods pursuant to the official medical fee schedule adopted by the administrative director or pursuant to paragraph (2), as applicable.

(B) One hundred twenty percent of the documented paid cost to the physician.

(C) One hundred percent of the documented paid cost to the physician plus two hundred fifty dollars (\$250).”

For clarity and accuracy, the subdivision was revised to make the default formula applicable to pharmacy goods not subject to the fee schedule by reference to all of the regulation sections that govern the fees for physician dispensed drugs, instead of the subdivisions of section 9789.40.6. Therefore, the adopted language deleted the phrase “subdivision (a), (b), (c)” and added reference to include sections 9789.40.1, 9789.40.4, 9789.40.6, and 9789.40.7. The adopted regulation modifies the reference to specify subdivision (b) (which applies to non-legend drugs) instead of subdivision (d) as the section governing the default fee, to conform to reorganization and renumbering of this section.

**Subdivision (g):** originally proposed as subdivision (f) was renumbered as (g). The adopted regulation deletes the originally proposed language stating that a dispensing fee is not payable to a physician. The adopted regulation states that the maximum dispensing fee payable to a physician dispensing a drug to their patient in accordance with Business and Professions Code section 4170 is \$10.05, which is the default fee for dispensing providers that are not on the Medi-Cal NPI file for pharmacies that are eligible for the higher tier fee.

The DWC considered comments received contending that physician dispensed medications warrant a dispensing fee. Medi-Cal does not pay a physician to dispense medications, and therefore also does not pay physicians a dispensing fee. Similarly, Business and Professions Code sections 4183 and 4193 provide that the specified clinics are not eligible for a dispensing fee under the Medi-Cal

program. Changes made to Labor Code section 5307.1 indicate that the legislature was concerned about inappropriate dispensing by physicians and created additional rules to govern reimbursement for physician dispensed medication, such as the caps set forth in subdivision (e). Research studies cited in the Initial Statement of Reasons Indicate that financial incentives may sometimes skew drug selection and physician dispensing patterns. The division is aware that physician dispensing may provide a convenience to injured workers and facilitate the early initiation of treatment. Although the employer is required by Labor Code section 5402 subdivision (c) to authorize treatment within one working day of the filing of a claim form, and must pay up to \$10,000 in treatment prior to determination of liability, these steps may cause delay in obtaining needed pharmaceuticals in some cases. Physician dispensing may increase patient compliance with treatment. DWC has considered the advantages and disadvantages of providing a dispensing fee to physicians in light of the Business and Professions Code section 4170 that allows a physician to dispense to their own patient for a condition they are treating if the specified requirements are met. Labor Code section 5307.1, subdivisions (e)(7) and (e)(8) provide the DWC Administrative Director with additional authority to adopt fee schedule rules specific to physician dispensing. Given this authority, and controls on inappropriate prescribing that address potential abuse (e.g. utilization review, prospective authorization formulary rule, etc.) the DWC has determined that on balance the considerations favor allowing a dispensing fee for physician dispensed drugs. For clarity the maximum allowable dispensing fee of \$10.05 is set forth in the regulation; this is the default Medi-Cal dispensing fee except where the entity dispensing is a pharmacy whose NPI is listed on the Medi-Cal NPI file applicable to the date of service.

**Subdivision (h):** (previously subdivision (g)) was renumbered as (h); there was no substantive modification.

The previous subdivision (h) was deleted as the definition and provisions relating to documented paid cost were moved to subdivision (c) as set forth above.

**Subdivision (i)** which originally provided that the Pharmaceutical Fee Data File setting the “lowest cost” and “no substitution cost” drug ingredient rates would be made available on the DWC website, and providing the web address, was deleted. The adopted regulation deletes this subdivision which is necessary to avoid duplication of these provisions and to streamline the regulations since the provisions were moved to section 9789.40.1.

**Section 9789.40.7. Compounded Pharmaceuticals Dispensed By a Physician on or after [Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].**

This section is renumbered from section 9789.40.6 to 9789.40.7. In order to provide adequate time for implementation, the heading is modified to extend

effective date of changes from 90 days to 180 days (specifying the first day of the month following), and to indicate that this will be in the year 2025.

**Subdivision (a)** was revised to modify the formula for determining maximum allowable fee for a physician dispensed compounded drug by including provision for “the dispensing, compounding, and sterility fees” applicable pursuant to section 9789.40.4. Section 9789.40.4 as adopted sets forth the rules for compound reimbursement (e.g. container count, dispensing fee), including the rules for applying the Route of Administration Compounding Fee / Sterility Fee Table in subdivision (e) and the Dosage Form Compounding Fee Table in subdivision (f) for both pharmacy dispensed and physician dispensed compounded drugs. DWC determined that on balance of factors, it is appropriate to allow dispensing, compounding, and sterility fees to be considered in the formula for determining the maximum fee for a physician-dispensed compounded drug. The explanation of the basis for the determination to allow dispensing, compounding, and sterility fees, set forth above in relation to sections 9789.40.4, 9789.40.6, is incorporated by reference for section 9789.40.7. It is necessary to cross reference to “the fees applicable to a physician pursuant to section 9789.40.4” in order to streamline the regulations and avoid duplication of provisions.

The adopted text was modified for clarity by moving language from subdivision (c) to subdivision (a)(2) stating that drug ingredient costs are “calculated based on units used in the compound.” The provision “on the date the compound drug is dispensed” is deleted as redundant to the provisions of section 9789.40.1 as adopted, which states that the “costs for each NDC are effective for products dispensed on or after the effective date listed in the Pharmaceutical Fee Data File.” Moving the language streamlined the regulatory text and avoided duplication as the concept does not need to be repeated in subdivision (c); the move did not make a substantive change to the formula.

**Subdivision (c)** which defines the drug ingredient cost for a compounded drug dispensed by a physician for one prong of the formula (subdivision (a)(2)) previously proposed to adopt different formulas for a compound composed of a finished drug product (subdivision (c)(1)), composed of an unfinished drug product (subdivision (c)(2)), and composed of a combination of finished and unfinished drug products (subdivision (c)(3).) The unfinished drug products were originally proposed to be priced at a maximum documented paid cost plus 10% for the subdivision (a)(2) calculation. Upon evaluation of comments received relating to the complexity of distinguishing finished and unfinished drug products, and in light of the Labor Code statutory provisions, the adopted regulation eliminated the distinction between finished drug products and unfinished drug products. The elimination of the distinction results in modification of subdivision (c)(1), and deletion of (c)(2) and (c)(3).

**Subdivision (c), subparagraph (c)(1)** definition of drug ingredient cost for compounded drug product(s) for purposes of subdivision (a)(2) was modified from the original proposal to delete the phrase “calculated based on units used in



the compound, on the date the compound drug is dispensed” because the phrase “calculated based on units used in the compound” was moved to subdivision (a) for clarity.

In subdivision (c)(1) the adopted regulation references the “lowest cost” and “no substitution cost” as set forth in the Pharmaceutical Fee Data File for purposes of the “drug ingredient cost” under the (a)(2) prong of the physician compounded drug formula. The “no substitution” language was added to correct an apparent oversight in the initial 45-day proposal which unintentionally omitted the “no substitution cost” for a compounded finished drug product. The adoption of the “no substitution cost” is necessary to ensure that a physician who has determined that a brand name finished drug product is medically necessary, and who has complied with the formulary requirements for physicians in sections 9792.7.7 and 9792.27.8, will be able to have the “no substitution” cost included in the formula for calculation of the fee for the compounded drug product as specified. This is necessary to support the injured worker’s access to appropriate medications.

**Subdivision (c), subparagraphs (c)(2) and (c)(3)** as originally proposed were deleted because the adopted formula does not distinguish the drug ingredient cost based on whether the compound is composed of finished drug products or unfinished drug products. This modification will result in the finished drug products being priced at the lowest cost, or no substitution cost for a brand name drug where the applicable prerequisites are met, and will result in the unfinished drug products being priced at the “lowest cost” as the brand name concept will not apply. This will align most closely with the Medi-Cal drug ingredient fee methodology (lowest of: NADAC or WAC +0% if NADAC does not exist, FUL, MAIC.) Labor Code section 5307.1, subdivision (d) states in relevant 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.”

Although Medi-Cal does not pay for dispensed compounded drugs utilizing bulk active pharmaceutical ingredients, it does pay for compounded drugs utilizing finished FDA-approved drugs and does pay for a limited number of bulk drug products that are not active pharmaceutical ingredients, for example excipients (such as flavoring agents, sterile water, etc.) used in the compound. The adopted regulation which uses the “lowest cost” formula for the unfinished compound drug ingredient products not covered by Medi-Cal most closely aligns with what Medi-Cal would pay for drugs that use comparable resources. In addition, utilizing the same formula for the finished and unfinished compounded drug ingredients for the subdivision (a)(2) part of the formula will streamline the billing and payment process. For physician-dispensed compounded drugs, the maximum allowable formula additionally includes a limitation of 300% of documented paid cost, not to

exceed \$20 above documented paid cost, to carry out the provisions of Labor Code section 5307.1(e)(1).

The Pharmaceutical Fee Data File structure was modified to add the unfinished bulk pharmaceutical ingredients utilized in compounded drugs and aligns with the language of the regulation.

A new subparagraph (c)(2) was added for clarity to specify that the “The metric decimal quantity/units billed for each ingredient is the total amount within the compound regardless of the number of containers.”

**Subdivision (e):** the adopted regulation did not adopt the originally proposed provision which stated that dispensing, compounding and sterility fees are not payable to a physician, because subdivision (a)(2) was modified to allow these fees where applicable pursuant to section 9789.40.4. The deletion was necessary in light of the proposed modifications to the text allowing the fees as specified. Language was added specifying that the sterility fee is only included in the physician compounded drug reimbursement calculation set forth in subdivision (a)(2) if the physician’s performance of sterile compounding is allowed by state and federal law and complies with the requirements of the specified sterile compounding regulations adopted by the California Board of Pharmacy. It is necessary for patient safety to add this provision to emphasize the legal constraints on sterile compounding performed by physicians, and to avoid any misunderstanding regarding the effect of the workers’ compensation fee regulations. The fee schedule regulations do not provide authority for sterile compounding by physicians; they set the maximum fees if independent legal authority allows sterile compounding by a physician.

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

**Subdivision (d)** which summarizes pharmaceutical fee schedule effective dates was revised from the original proposal to coordinate with the modifications to other sections which set the “effective date” of amendments as the first day of the month following: 180 days after the regulation amendments are filed with the Secretary of State. For section 9789.40, the adopted regulation provides that it continues to be effective for services rendered prior to the “effective date” in 2025. Subdivision (d) as adopted specifies that the new sections 9789.40.1 – 9789.40.7 are effective for services rendered on or after the “effective date” which is in 2025. This is necessary in light of the extension of the effective date from 90 days to 180 days after the revised regulations are filed with the Secretary of State and to include section 9789.40.7 in the range of code numbers which are added because of the new section 9789.40.1.

## **Non-substantive Modifications to the Text of Regulations Subsequent to the Close of the Second 15-Day Comment Period**

In consultation with the Office of Administrative Law, the following modifications without substantive effect were made to the text of regulations.

- The date “July 1, 2025” was substituted for the phrase “[Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]” to reflect the actual date calculated in light of the December of 2024 date the regulations are to be filed by OAL with the Secretary of State.
- Section 9789.40, subdivisions (a) and (c)(1) are modified to delete the Official Medical Fee Schedule’s web address, and the Food and Drug Administration’s Orange Book web address URL, respectively, in light of potential changes in website structure and document address.
- New sections which had proposed to include the website URL for the OMFS, the FDA’s Orange Book, and the FDA’s National Drug Code Directory are modified to omit the web address URL in light of potential changes in website structure and document address.
  - Section 9789.40.1 OMFS URL (for Pharma data file and NPI file)
  - 9789.40.2 FDA Orange Book URL
  - 9789.40.3 FDA NDC Directory URL
  - 9789.40.6 FDA Orange Book URL
  - 9789.40.7 NDC Directory URL

## **UPDATE OF MATERIAL RELIED UPON**

The following additional documents beyond those identified in the Initial Statement of Reasons were relied upon by the Administrative Director and added to rulemaking file after close of the initial 45-day comment period. They were identified in the Notice of Modification to Text of Proposed Regulations for the second 15-day comment period which closed October 23, 2024. These additional documents were available for 15-day public review and comment.

### **Additional documents relied upon by the Administrative Director and added to the rulemaking file and made available for public inspection and comment during the 15-day comment period closing October 23, 2024.**

- Pharmaceutical Fee Data File entitled: “SAMPLE for public comment pfs\_run20240911”
- Medi-Cal National Provider Identifier File entitled: “SAMPLE for public comment npi\_run20240911”
- Background document entitled: “DIR DWC Background OMFS Pharmaceutical Fee Schedule Sample Data File for 2nd 15 Day Public Comment”

The updated sample Pharmaceutical Fee Data File, updated sample Medi-Cal National Provider Identifier File and background document were added to the rulemaking file and available for public inspection and comment during the 2<sup>nd</sup> 15-day Comment Period. The sample Pharmaceutical Fee Data File was modified to include unfinished bulk pharmaceutical ingredients used in compounded drugs.

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

The Administrative Director did not rely upon additional documents beyond those identified in the Initial Statement of Reasons, aside from the three documents relied upon identified above.

## **LOCAL MANDATES DETERMINATION**

- Local Mandate: None. The proposed amendments will not impose any new mandated programs or increased service levels on any local agency or school district.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None. The proposed amendments do not apply to any local agency or school district.
- Other nondiscretionary costs/savings imposed upon local agencies: None.

## **CONSIDERATION OF ALTERNATIVES TO THE PROPOSED REGULATIONS**

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

## **SUMMARY OF COMMENTS RECEIVED AND RESPONSES THERETO CONCERNING THE REGULATIONS ADOPTED**

The oral and written comments submitted by each organization or individual are addressed in the following charts which are incorporated by reference into the Final Statement of Reasons.

The public comment periods were held as follows:

**Initial 45-day comment period on proposed regulation:**

From February 23, 2024 to April 11, 2024.

**First 15-Day Comment period on proposed regulation:**

From June 13, 2024 to June 28, 2024.

**Second 15-Day Comment period on proposed regulation:**

From October 7, 2024 to October 23, 2024.