STATE OF CALIFORNIA

**DEPARTMENT OF INDUSTRIAL RELATIONS**

**Division of Workers’ Compensation**

### NOTICE OF MODIFICATION TO TEXT OF PROPOSED REGULATIONS

### 2nd 15-Day Comment Period

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

**TITLE 8, CALIFORNIA CODE OF REGULATIONS**

**Section 9789.12.1 et seq.**

**NOTICE IS HEREBY GIVEN** that the Administrative Director of the Division of Workers’ Compensation, pursuant to the authority vested in him by Labor Code sections 59, 133, 4603.5, 5307.1 and 5307.3 proposes additional modifications of the text of the following proposed amendments to title 8, California Code of Regulations, Article 5.3 of Division 1, Chapter 4.5, Subchapter 1, which were the subject of a regulatory hearing and comment period which closed on April 11, 2024, and a 15-day written comment period which closed June 28, 2024.

## MODIFICATIONS TO PROPOSED REGULATORY ACTION

| **Title 8, CCR**  **Section to Amend/Adopt** | **Title of Section as Set Forth in Modified Proposal for 2nd 15-day Comment Period** |
| --- | --- |
| Section 9789.12.1  Amend  [No 2nd 15-day modification] | 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. |
| Section 9789.13.2  Amend | Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products. |
| Section 9789.13.3  Amend  [No 2nd 15-day modification] | Physician-Dispensed Drugs. |
| Section 9789.40  Amend  [No 2nd 15-day modification] | 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]. |
| Section 9789.40.1  Adopt | 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]. |
| Section 9789.40.2  Adopt | 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]. |
| Section 9789.40.3  Adopt | 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]. |
| Section 9789.40.4  Adopt | 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]. |
| Section 9789.40.5  Adopt | 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]. |
| Section 9789.40.6  Adopt | 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]. |
| Section 9789.40.7  Adopt | 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]. |
| Section 9789.111  Amend  [No 2nd 15-day modification] | Effective Date of Fee Schedule Provisions. |

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

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

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

This Notice of Modification to Text of Proposed Regulations – 2nd 15-Day Comment Period is prepared to comply with the procedural requirements of Labor Code Section 5307.4 and for the convenience of the regulated public in analyzing and commenting on this non-APA rulemaking proceeding.

**WRITTEN COMMENT PERIOD**

Any interested person, or his or her authorized representative, may submit written comments relevant to the modified proposed regulatory action to the Department of Industrial Relations, Division of Workers’ Compensation. The written comment period closes at 11:59 pm **on October 23, 2024.**

Please limit your comments to the modifications to the text, and the documents added to the rulemaking file (Sample Pharmaceutical Fee Data File, Sample Medi-Cal National Provider Identifier File and Background Document.) All written comments received by the close of the comment period, which pertain to the modifications to the text or documents added to the rulemaking file will be reviewed, summarized and responded to, in the Final Statement of Reasons as part of the compilation of the rulemaking file.

Submit written comments concerning the proposed regulations and the modified sample Pharmaceutical Fee Data File prior to the close of the public comment period to:

Maureen Gray

Regulations Coordinator

Department of Industrial Relations

Division of Workers’ Compensation

1515 Clay Street, 18th Floor

Oakland, CA 94612

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

Submit written comments prior to the close of the public comment period at 11:59 p.m. on October 23, 2024**.**

**AVAILABILITY OF TEXT OF REGULATIONS AND RULEMAKING FILE**

Inquiries concerning this proposed action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed modifications to amendments to the regulations, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file may be requested in writing at the same address.

The contact person is:

Maureen Gray

Regulations Coordinator

Department of Industrial Relations

Division of Workers’ Compensation

1515 Clay Street, 18th Floor

Oakland, CA 94612

The entire rulemaking file is available for public review during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers’ Compensation. The Division is located at 1515 Clay Street, 18th Floor, Oakland, California. Please contact the Division’s regulations coordinator, Ms. Maureen Gray, at (510) 286-7100 to arrange to inspect the rulemaking file.

##### BACKUP CONTACT PERSON

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

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

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

**NOTICE OF ADDITION OF DOCUMENT TO THE RULEMAKING FILE, RELIED UPON IN PROPOSING THE MODIFIED REGULATIONS**

An updated sample Pharmaceutical Fee Data File, updated Medi-Cal National Provider Identifier File and background document are added to the rulemaking file and are available for public inspection and comment during the 2nd 15-day Comment Period. The sample Pharmaceutical Fee Data File is modified to include unfinished bulk pharmaceutical ingredients used in compounded drugs as explained below regarding the modified regulatory text. The Pharmaceutical Fee Data File and Medi-Cal National Provider Identifier File utilize updated Medi-Cal data. The following documents are added to the rulemaking file:

* 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”

## FORMAT OF TEXT / PROPOSED MODIFICATIONS

Plain text is current codified language

Blue text indicates a hyperlink is provided in the text.

**Proposed Text Noticed for 45-day Comment Period (Ended 4/11/2024):**

Additions to codified language are shown in single underline (additions) and single strikeout (~~deletions~~).

**Proposed Text of Regulation Noticed for First 15-Day Comment Period on Modified Text (Ended 6/28/2024):**

Proposed 15-day changes are shown in double underline for additions (added text) and double strikeout for deletions (deleted text).

**Proposed Text of Regulation Noticed for Second 15-Day Comment Period on Modified Text (Ending 10/23/2024):**

Proposed 2nd 15-day comment period changes are shown in single bold underline for additions (**added text**) and single bold strikeout for deletions (**~~deleted text~~**).

## SUMMARY OF MODIFICATIONS TO PROPOSED REGULATIONS

**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**.

There are no proposed modifications for the 2nd 15-day comment period.

**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) is 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 is necessary for accuracy as the sections listed in the 1st 15-day comment period text were not complete and the inclusion of section 9789.40.5 was erroneous as it applies only to pharmacies.

**Section 9789.13.3. Physician-Dispensed Drugs**:

There are no proposed modifications for the 2nd 15-day comment period.

**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]**:

There are no proposed modifications for the 2nd 15-day comment period.

**Sections 9789.40.1, 9789.40.2, 9789.40.3, 9789.40.4, 9789.40.6, 9789.40.7:**

To streamline the regulation, the effective date of each new regulation section is deleted from the regulatory text of sections 9789.40.1 through 9789.40.7, but remains in the text of section 9789.40.111, subdivision (d) which summarizes the effective dates for the pharmaceutical fee regulations. In addition, the heading of each new section will retain the effective date. These changes will improve the readability of the text while retaining the necessary effective date which is “[Month 1, 2025] [the first day of the month following: 180 days after the amendments are filed with the Secretary of State.]”

Minor grammatical, punctuation and capitalization corrections are made where needed in sections 9789.40.1 through 9789.40.7.

**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].**

**Subdivision (a)(3)(A)** requires that payers shall begin calculating fees “pursuant to section 9789.40.2” based on each new Pharmaceutical Fee Data File not later than the second calendar day after posting on the DWC website. The text is modified to update the cross references to state “pursuant to sections 9789.40.2 through 9789.40.7” instead of “pursuant to section 9789.40.2.” This expansion to the range of codes is necessary for accuracy as the Pharmaceutical Fee Schedule Data File is used in the formulas beyond section 9789.40.2. This is necessary for clarity, accuracy, and to correct an inadvertent omission in the 1st 15-day comment proposed text.

**Subdivision (a)(3)(B)** is modified to enhance clarity by inserting the phrase “Pharmaceutical Fee Data File” in place of “file”.

**Subdivision (a)(3)(C)** is modified to enhance clarity by more specifically identifying the paragraph referencing “implementation period allowed pursuant paragraph (a)(3)(A)” instead of “implementation period allowed pursuant paragraph (A).”

**Subdivision (a)(4)** is modified to delete reference to “PFS file” and insert “Pharmaceutical Fee Data File” for consistency with the nomenclature used to identify the data file.

**Subdivision (b)(3)** states that payers shall begin calculating the maximum reasonable fee pursuant to 9789.40.2 based on each new file not later than the second calendar day after posting the Medi-Cal NPI file on the DWC website. The proposed text is modified to add the words “pharmacy dispensing fee” and “Medi-Cal NPI”, and to add additional cross reference sections, to state that “Payers shall begin calculating the maximum reasonable pharmacy dispensing fee pursuant to sections 9789.40.2, 9789.40.3, 9789.40.4, and 9789.40.5 based on each new Medi-Cal NPI file not later than the second calendar day after posting the Medi-Cal NPI file on the division’s website.” It is necessary to add the words “pharmacy dispensing fee” to add additional clarity because only pharmacies are listed on the NPI file. The list of codes is expanded because the Medi-Cal NPI File is used in the formulas applicable to pharmacies beyond section 9789.40.2. The modifications to (b)(3) are necessary for clarity, accuracy, and to correct an inadvertent omission of the cross-referenced sections in the 1st 15-day comment proposed text.

**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]**:

**Subdivision (c)** sets forth the formula for a pharmacy dispensed repackaged drug utilizing the NDC of the underlying drug product as set forth in the Pharmaceutical Fee Data File. 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). The text of subparagraph (c)(2)(A) is 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 is necessary 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.

**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]**:

**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 is modified to reference subdivision (c)(1) instead of subdivision (c)(2), which is 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 proposal is modified.

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 proposed subdivision is 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 is eliminated.

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 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 modified proposal 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 will streamline the billing and payment process.

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

**Subdivision (e)** “Compounding and sterility fees” definition cross-reference is modified from section 9789.40.3 to section 9789.40.4. This is necessary to make a correction to the cross-reference which was inadvertently overlooked when a new section 9789.40.1 was added in the 1st 15-day comment period modified text, resulting in the renumbering of section 9789.40.3.

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

**Subdivision (g)** is 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]:**

In the introductory sentence of this section there is cross-reference to the sections that govern the maximum allowable compounding fee, sterility fees, and professional dispensing fee payable to a pharmacy or to a physician, respectively. The cross-reference to the pharmacy section is modified from section 9789.40.2 to section 9789.40.3. This is necessary to make a correction to the cross-reference which was inadvertently overlooked when a new section 9789.40.1 was added in the 1st 15-day comment period modified text.

**Subdivision (a)** is 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.

**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]**:

There are no proposed modifications for the 2nd 15-day comment period, except for a capitalization correction in subdivision (c).

**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]**:

**Subdivision (a)** is modified and reorganized to provide greater clarity on the formula for physician-dispensed legend drugs, including the dispensing fee. 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)100% of documented paid cost, 100% of document paid cost plus $250.)

The introductory sentence is 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.” 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 reorganize and streamline the provisions so that the formula does not need to be repeated for the variations in scenarios. Clarity is 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) is deleted due to the reorganization of the provisions. Subparagraphs (c)(1) and (c)(2) are 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 is deleted because the provisions are 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” is deleted because the provisions are moved to a new subdivision (e).

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

**Subdivision (c)** which defines “documented paid cost” is identical to the previous subdivision (h) which is 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 has been moved from the previous subdivision (c)(3); it does not make a substantive change. Moving the provision to its own subdivision is 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 has been moved from the previous subdivision (c)(4); it does not make a substantive change.

**Subdivision (f)** (the previous 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 is 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 language deletes the phrase “subdivision (a), (b), (c)” and adds reference to include sections 9789.40.1, 9789.40.4, 9789.40.6, and 9789.40.7. The proposal 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)**: (previously subdivision (f)) is renumbered as (g); there is no substantive modification.

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

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

**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]**:

**Subdivision (a)** sets forth the basic formula for a physician dispensed compounded drug, lowest of: (a)(1) 300% of documented paid cost but not more than $20 above documented paid cost, (a)(2) the fee schedule “lowest amount” or “no substitution” amount as listed on the Pharmaceutical Fee Data File for each ingredient plus compounding, sterility, and dispensing fee, or (a)(3) physician’s usual and customary charge. The text is 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 proposed, 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 streamlines the regulatory text as the concept does not need to be repeated in subdivision (c); the move does 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).) 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 proposal is modified to eliminate 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 composed of finished drug product(s) is modified to delete the phrase “calculated based on units used in the compound, on the date the compound drug is dispensed.” The provision “calculated based on units used in the compound” is moved to subdivision (a) for clarity.

**Subdivision (c), subparagraphs (c)(2) and (c)(3)** as previously proposed are deleted because the formula will no longer 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 modified proposal 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 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 is 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) is added 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.”

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

There are no proposed modifications for the 2nd 15-day comment period. The regulations would go into effect on “[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].”

-End of Notice of Modification to Text of Proposed Regulations-