# 15 Day Proposed Changes and Adoptions – Accessible Version

# Format:

The original 45 day proposal showed the additions and deletions to the codified text in strikethrough and underline format. For the 15 day proposal, this document compiles the 15 day comment period modifications of the original proposal, and sets forth the explanation of the changes between the 45 day comment period and the 15 day proposal. Each section contains the proposed modified language and/or additions following the explanation as set forth in the Notice of Modification to Text of Proposed Regulations. The sections will read as if all the changes in the 45 day proposal, as modified by the 15 day proposal, have been adopted.

For comparison, here are the links to the current codified text: section [9789.12.1](https://www.dir.ca.gov/t8/9789_12_1.html); section [9789.13.2](https://www.dir.ca.gov/t8/9789_13_2.html); section [9789.13.3](https://www.dir.ca.gov/t8/9789_13_3.html); section [9789.40](https://www.dir.ca.gov/t8/9789_40.html); and section [9789.111](https://www.dir.ca.gov/t8/9789_111.html).

# 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. [Modified Proposal]

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 is modified to update the cross references to sections relating to physician-dispensed drugs. The citations are amended to conform to numbering changes in the modified text of regulation.

**The following is the proposed modified language:**

(a) Maximum reasonable fees for physician and non-physician practitioner medical treatment provided pursuant to Labor Code section 4600, which is rendered on or after January 1, 2014, shall be no more than the amount determined by the Official Medical Fee Schedule for Physician and Non-Physician Practitioners, consisting of the regulations set forth in Sections 9789.12.1 through 9789.19.1 (“Physician Fee Schedule.”) Maximum fees for services rendered prior to January 1, 2014 shall be determined in accordance with the fee schedule in effect at the time the service was rendered. The Physician Fee Schedule shall not govern fees for services covered by a contract setting such fees as permitted by Labor Code sections 5307.1 and 5307.11.

(b) Maximum fees for services of a physician or non-physician practitioner are governed by the Physician Fee Schedule, regardless of specialty, for services performed within his or her scope of practice or license as defined by California law, except:

(1) Evaluation and management codes are to be used only by physicians (as defined by Labor Code §3209.3), as well as physician assistants and nurse practitioners who are acting within the scope of their practice and are under the direction of a supervising physician.

(2) Osteopathic Manipulation Codes (98925-98929) are to be used only by licensed Doctors of Osteopathy and Medical Doctors.

(c) Physicians and non-physician practitioners shall utilize other applicable parts of the OMFS to determine maximum fees for services or goods not covered by the Physician Fee Schedule, such as pharmaceuticals (sections 9789.40, 9789.40.1, 9789.40.4, 9789.40.6, 9789.40.7), pathology and clinical laboratory (section 9789.50) and durable medical equipment, prosthetics, orthotics, supplies (section 9789.60), except: 1) where such services or goods are bundled into the Physician Fee Schedule payment, and/or 2) as otherwise specified in the Physician Fee Schedule.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 5307.1 and 5307.11, Labor Code.

# Section 9789.13.2. Physician-Administered Drugs, Biologicals, Vaccines, Blood Products. [No 15 Day Changes – Text Sets Forth the 45 Day Proposal]

(a) Physician-administered drugs, biologicals, vaccines, or blood products are separately payable, unless bundled or packaged into the procedure code pursuant to official medical fee schedule rules.

(1) Vaccines shall be reported using the NDC code and CPT code for the vaccine. Other physician-administered drugs, biologicals and blood products shall be reported using the NDC code and the Healthcare Common Procedure Coding System Level II code (HCPCS Level II code) assigned to the product. Physician-administered drugs, biologicals and blood products that do not have an assigned HCPCS Level II code shall be reported with the NDC code and the appropriate unclassified HCPCS Level II code.

(2) The maximum reimbursement shall be determined using the “Basic Rate” for the CPT code or HCPCS Level II code contained on the Medi-Cal Rates file for the date of service.

(3) The “Basic Rate” price listed on the Medi-Cal rates page of the Medi-Cal website for each physician-administered injectable drug includes an injection administration fee of $4.46. This injection administration fee should be subtracted from the published rate because payment for the injection administration fee will be determined under the physician fee schedule. See section 9789.19 for a link to the Department of Health Care Services’ Medi-Cal rates file.

(4) For a physician-administered drug, biological, vaccine or blood product not contained in the Medi-Cal Rates file referenced in subdivision (a)(2), the maximum reimbursement is the amount prescribed in the pharmaceutical fee schedule applicable to physicians as adopted by the Division of Workers’ Compensation in sections 9789.40, 9789.40.5, or 9789.40.6 and posted on the Division website as the Pharmaceutical Fee Schedule. See section 9789.19 for a link to the Division of Workers’ Compensation Pharmaceutical Fee Schedule.

(b) The physician fee schedule shall be used to determine the maximum reimbursement for the drug administration fee.

(1) Injection services (codes 96365 through 96379) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time. Pay separately for those injection services only if no other physician fee schedule service is being paid.

(2) Pay separately for cancer chemotherapy injections (CPT codes 96401-96549) in addition to the visit furnished on the same day.

(c) Physician-administered radiopharmaceuticals. When furnished to patients in settings in which a technical component is payable, separate payments may be made for low-osmolar contrast material used during intrathecal radiologic procedures (HCPCS Q-codes Q9965-9967), pharmacologic stressing agents used in connection with nuclear medicine and cardiovascular stress testing procedures (HCPCS A-codes A4641, A4642, A9500-A9507, A9600), radionuclide used in connection nuclear medicine procedures furnished to beneficiaries in settings in which TCs are payable.

Low-osmolar contrast media is reported using HCPCS Q-codes.

(d) All claims for a physician-administered drug, biological, vaccine, or blood product must include the specific name of the drug and dosage.

(e) “Administer” means the direct application of a drug or device to the body of a patient by injection, inhalation, ingestion, or other means.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 5307.1 and 5307.11, Labor Code.

# Section 9789.13.3. Physician-Dispensed Drugs. [Modified]

This section is modified to update the cross references to sections relating to physician-dispensed drugs. The citations are amended to conform to other numbering changes in the modified text of regulation.

**The following is the proposed modified language:**

The maximum reimbursement for physician-dispensed drugs is determined pursuant to the Pharmaceutical Fee Schedule set forth in sections 9789.40, 9789.40.1, 9789.40.4, 9789.40.6, 9789.40.7 and pursuant to the provisions of Labor Code section 5307.1.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 5307.1 and 5307.11, Labor Code.

# Section 9789.40. Pharmacy – Pharmaceuticals Dispensed and Pharmaceutical Services Rendered Prior to [Month 1, 2025] [the first day of the month following: 90 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL]. [Modified]

The Administrative Director has determined that it is 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. For clarity and ease of implementation, the effective date is the first of the month as specified. The heading is 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. The heading is also modified to indicate that the date will be in the year 2025.

Subdivision (a) is 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. (See subdivision (e) for more detailed information.)

Subdivision (d) 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 (e) is 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” is 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 is 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 is 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.

**The following is the proposed modified language:**

(a) The maximum reasonable fee for pharmaceuticals and pharmacy services rendered after January 1, 2004 and 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] is 100% of the reimbursement prescribed in the relevant Medi-Cal payment system data file “NDC\_lowest\_prices\_2019-02-20” posted 03/08/2019, including the Medi-Cal professional fee for dispensing of $7.25 or $8.00 if the patient is in a skilled nursing facility or in an intermediate care facility. The data file will be made available on the Division of Workers' Compensation's [Official Medical Fee Schedule](https://www.dir.ca.gov/dwc/OMFS9904.htm) Internet Website (<https://www.dir.ca.gov/dwc/OMFS9904.htm> or successor web page) or upon request to the Administrative Director at:

DIVISION OF WORKERS' COMPENSATION  
(ATTENTION: OMFS - PHARMACY)  
P.O. BOX 420603  
SAN FRANCISCO, CA 94142.

(b) For a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum reasonable fee paid shall not exceed the drug cost portion of the fee determined in accordance with this subdivision, plus $7.25 professional fee for dispensing or $8.00 if the patient is in a skilled nursing facility or in an intermediate care facility. The maximum fee shall include only a single professional dispensing fee for dispensing for each dispensing of a drug.

(1) If the National Drug Code for the drug product as dispensed is not in the Medi-Cal database, and the National Drug Code for the underlying drug product from the original labeler appears in the Medi-Cal database, then the maximum fee shall be the drug cost portion of the reimbursement allowed pursuant to section 14105.45 of the Welfare and Institutions Code using the National Drug Code for the underlying drug product from the original labeler as it appears in the Medi-Cal database, calculated on a per unit basis, plus the professional fee allowed by subdivision (b) of this section.

(2) If the National Drug Code for the drug product as dispensed is not in the Medi-Cal database and the National Drug Code for the underlying drug product from the original labeler is not in the Medi-Cal database, then the maximum fee shall be 83 percent of the average wholesale price of the lowest priced therapeutically equivalent drug, calculated on a per unit basis, plus the professional fee allowed by subdivision (b) of this section.

(c) For purposes of this section:

(1) “Therapeutically equivalent drugs” means drugs that have been assigned the same Therapeutic Equivalent Code starting with the letter “A” in the Food and Drug Administration’s publication [“Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”.)](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book) The Orange Book may be accessed through the Food and Drug Administration’s website:

<https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book> or successor web page;

(2) “National Drug Code for the underlying drug product from the original labeler” means the National Drug Code of the drug product actually utilized by the repackager in producing the repackaged product.

(d) This section applies to pharmaceuticals dispensed and pharmaceutical services rendered prior to [Month 1, 2025] [the first day of the month following 90 180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(e) The Medi-Cal data file “NDC\_lowest\_prices\_2019-02-20” posted 03/08/2019 and the Table 2024 compounding fee/sterility fee table posted on the internet website of the Division of Workers’ Compensation will remain in effect for pharmaceuticals dispensed 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].

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified Proposal - New Section]

The proposed text of regulation is modified to add a new section 9789.40.1 to improve clarity and streamline the regulations by consolidating provisions relating to the Pharmaceutical Data File and the Medi-Cal NPI file in one section, and by including details on implementation 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 have been removed from other regulation sections. The modification is 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 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 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. 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 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.

**The following is the proposed language:**

This section is effective for 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] where applicable pursuant to sections 9789.40.2 through, 9789.40.7.

(a) The Pharmaceutical Fee Data File setting forth the Division’s calculation of “lowest cost” and “no substitution cost” drug ingredient rates based on the Medi-Cal methodology will be made available on the Division of Workers' Compensation's Official Medical Fee Schedule web page (<http://www.dir.ca.gov/dwc/OMFS9904.htm> or successor web page).

(1) The drug ingredient “lowest cost” means the rate set forth in the Pharmaceutical Fee Schedule data file, as calculated by the division based upon the lowest of:

The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%; or

The Federal Upper Limit (FUL); or

The Maximum Allowable Ingredient Cost (MAIC).

(2) The drug ingredient “no substitution cost” means the rate set forth in the Pharmaceutical Fee Schedule data file, as calculated by the division. For products where the “no substitution cost” differs from the “lowest cost”, the division has calculated the cost based upon the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) +0%.

(3) The Division of Workers’ Compensation will post an updated Pharmaceutical Fee Data File on a weekly basis absent extenuating circumstances.

(A) 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 of the Pharmaceutical Fee Data File on the division’s website.

(B) The costs for each NDC are effective for products dispensed on or after the effective date listed in the file.

(C) For retroactive cost changes within the Pharmaceutical Fee Data File or costs used during the implementation period allowed pursuant to paragraph (A), payers shall re-adjudicate previously paid claims to correct the cost used for the date a drug was dispensed upon submission of provider’s request for second review pursuant to section 9792.5.5.

(4) The status of each NDC as Legend (prescription required) is indicated in the PFS file with “Y” in the Legend Indicator field for the cost effective date of the NDC. The status of each NDC as Non-Legend (non-prescription or over-the-counter) is indicated in the PFS file with “N” in the Legend Indicator field for the cost effective date of the NDC,

(b) The Medi-Cal National Provider Identifier (NPI) file listing pharmacy NPIs eligible for the higher tier dispensing fee, and listing the effective dates of eligibility, will be made available on the Division of Workers' Compensation's Official Medical Fee Schedule web page (<http://www.dir.ca.gov/dwc/OMFS9904.htm> or successor web page).

(1) The Division of Workers’ Compensation will post an updated Medi-Cal NPI file on a weekly basis absent extenuating circumstances.

(2) A pharmacy is eligible for the higher dispensing fee for products dispensed during the effective dates listed, where the effective date period is listed as Active (“A”).

(3)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 division’s website.

(4) For retroactive NPI effective date changes within the Medi-Cal NPI file, retroactive changes of Active / Inactive status, or for NPI effective dates used during the implementation period allowed pursuant to paragraph (b)(3), payers shall re-adjudicate previously paid claims to correct the dispensing fee upon submission of provider’s request for second review pursuant to section 9792.5.5.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

This section is renumbered from section 9789.40.1 to 9789.40.2 due to the modified proposal adding a new section 9789.40.1. 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)** text is modified to extend the effective date of changes from 90 days to 180 days, and to indicate that this will be in the year 2025. A grammatical change is made to specify “a legend or non-legend drug” instead of “legend and non-legend drugs.” To improve clarity the modified text states 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 has been 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. 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” is 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. This modification streamlines the regulation and improves clarity.

**Subdivision (b)** setting forth the pharmacy dispensing fee provision is substantively unchanged. The numbering is modified from (a)(2) to subdivision (b).

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

**Subdivision (d)** relating to the Pharmaceutical Data File and NPI file is deleted since the provisions are moved and consolidated in the newly proposed section 9789.40.1.

**The following is the proposed modified language:**

(a) The maximum reasonable fee payable for a legend or non-legend drug 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] is determined in accordance with this section. The maximum allowable fee is the lower of the drug’s ingredient cost, calculated on a per unit basis, times the number of units dispensed, plus the professional dispensing fee, or the pharmacy’s usual and customary charge to the public, based on the date the drug is dispensed.

(1) The drug’s ingredient cost means the “lowest cost” as set forth on the Pharmaceutical Fee Data File, or

(2) When a prescriber indicates “Do Not Substitute”, “Dispense as Written” or words of similar meaning on a prescription for a brand name drug in compliance with the Business and Professions Code sections 4052.5, 4073, or 4073.5, and has fulfilled the requirements in section 9792.27.7, the drug ingredient cost means the “no substitution cost” as set forth on the Pharmaceutical Fee Data File.

(b) The professional dispensing fee is:

(1) $10.05 for all pharmacies except those that meet the requirements of subdivision (b)(2);

(2) $13.20 for a pharmacy whose National Provider Identifier is designated by the Medi-Cal National Provider Identifier file as eligible on the date the drug is dispensed.

(c)(1) The maximum reasonable fee for a legend or non-legend repackaged drug is the lower of:

(A) the drug ingredient cost using the National Drug Code of the underlying drug product from the original labeler as set forth in the Pharmaceutical Fee Data File, calculated on a per unit basis pursuant to subdivision (a)(1) or (a)(2) plus the professional dispensing fee, or

(B) the pharmacy’s usual and customary charge to the public.

(2) If the National Drug Code for the underlying drug product from the original labeler is not in the Pharmaceutical Fee Data File, then the maximum reasonable fee is the lower of:

(A) the drug ingredient cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis pursuant to subdivision (a), plus the professional dispensing fee, or

(B) the pharmacy’s usual and customary charge to the public.

(3) The National Drug Code of the dispensed repackaged drug and the National Drug Code of the underlying drug product shall both be identified on the bill, in accordance with the billing regulations for paper and electronic billing set forth in section 9792.5.1 et seq.

(4) For purposes of this section:

(A) “Therapeutically equivalent drugs” means drugs that have been assigned the same Therapeutic Equivalence Code starting with the letter “A” in the Food and Drug Administration's publication [“Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”.)](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book) The Orange Book may be accessed through the Food and Drug Administration's website:

https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book or successor web page;

(B) “National Drug Code for the underlying drug product from the original labeler” means the National Drug Code of the drug product actually utilized by the repackager in producing the repackaged product.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

This section is renumbered from section 9789.40.2 to 9789.40.3. 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)** text is 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.

**Subdivision (c)** is 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 composed of a finished drug product is determined pursuant to section 9789.40.2 subdivision (a)(1) or (a)(2). This is necessary for clarity and for consistency of the compounded drug fee for a finished drug product 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 medically necessary, for example for a patient that needs a liquid rather than a tablet or capsule.

**The following is the proposed modified language:**

(a) Except as provided in subdivisions (b)(2) and (c)(2), the maximum reasonable fee payable for a compounded drug 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] is the rate that is 100% of the payment allowed by the Medi-Cal payment methodology for compounded drugs, including:

(1) drug ingredient costs, and

(2) professional dispensing fee, and

(3) compounding and sterility fees if applicable.

(b)(1) Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.

(2) Notwithstanding Medi-Cal payment policy, ingredients without a valid NDC are not reimbursable.

(3) An NDC is presumed to be valid if the NDC is listed in the FDA’s National Drug Code Directory as either a finished or unfinished drug product, and does not appear on the excluded drugs database file. The presumption may be rebutted by a showing that the product is not a drug product legally eligible for assignment of an NDC. The [National Drug Code Directory](https://www.fda.gov/drugs/informationondrugs/ucm142438.htm) may be accessed on the FDA’s website: https://www.fda.gov/drugs/informationondrugs/ucm142438.htm or successor web page.

(c)(1) The “drug ingredient cost” for a compounded drug composed of finished drug product(s), calculated based on units used in the compound on the date the drug is dispensed, means the lower of the billed amount for each ingredient or the fee for each ingredient determined pursuant to section 9789.40.2, subdivision (a)(1) or (a)(2).

(2) Where the compounded drug is composed of unfinished drug product(s), the “drug ingredient cost” means the documented paid cost of each unfinished drug product, calculated based on units used in the compound, plus 10%, not to exceed the unfinished drug product’s WAC as published by the manufacturer.

(3) Where the compounded drug is composed of both finished drug product(s) and unfinished drug products(s), the “drug ingredient cost” for each ingredient is determined pursuant to (c)(1) or (c)(2) applicable to the NDC.

(4) The metric decimal quantity/units billed for each ingredient is the total amount within the compound regardless of the number of containers.

(d) The professional dispensing fee is:

(1) $10.05 for all pharmacies except those that meet the requirements of subdivision (d)(2);

(2) $13.20 for a pharmacy whose National Provider Identifier is designated by the Medi-Cal National Provider Identifier file as eligible on the date the drug is dispensed.

(e) “Compounding fees and sterility fees” means the fees determined pursuant to section 9789.40.3.

(f) “Documented paid cost” means the price paid by the pharmacy for the unfinished drug product(s), net of discounts and rebates, evidenced by documentation of the price actually paid by the pharmacy for the unfinished drug products. Documentation shall consist of invoices, proof of payment, and inventory records as applicable. The pharmacy must submit documentation of paid costs upon request by the claims administrator.

(g) A compounded drug that is essentially a copy of a commercially available product is not reimbursable. The status of a compounded drug as “essentially a copy of a commercially available drug product” is determined pursuant to applicable federal law and regulation.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

This section is renumbered from section 9789.40.3 to 9789.40.4. In order to provide adequate time for implementation, the heading is 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 is also modified to include reference to “Physician Dispensed” and to reorganize for clarity. This is necessary to inform the public of the expanded applicability of the section.

The introductory textual language is also modified to include the revised effective date. In addition, the language is modified to add reference to the regulation section 9789.40.7(a)(2) which has been revised to allow physicians to receive a dispensing fee, compounding fee, and sterility fee as applicable. The DWC has 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.) 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, are modified to include applicability to a physician. It is 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 is necessary to change the cross reference from section 9789.40.2 to 9789.40.3 to conform to numbering changes.

Language is 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 contained. 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 is 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.

**The following is the proposed modified language:**

For dates of service on or after [Month 1, 2025] [the first day of the month following: 180 days after the regulations are filed with the Secretary of State; date to be inserted by OAL], the maximum allowable compounding fee, sterility fee, and professional dispensing fee payable to a pharmacy pursuant to section 9789.40.2 or to a physician for purposes of section 9789.40.7, subdivision (a)(2), shall be determined as follows:

(a) The Compounding Fee per allowed container is the lower of the billed compounding fee amount or either:

(1) the fee designated for the compounded drug’s route of administration on the Route of Administration Compounding Fee / Sterility Fee Table set forth in subdivision (e), or, if that amount is zero,

(2) the fee designated for the compounded drug’s applicable dosage form and range of dosage metric decimal units on the Dosage Form Compounding Fee Table set forth in subdivision (f).

(b) The Sterility Fee per allowed container is the lower of the billed sterility fee amount or the fee designated in the Route of Administration Compounding / Sterility Fee Table set forth in subdivision (e). A Sterility Fee is allowed only when sterility testing is performed by the pharmacy or physician. The pharmacy or physician must maintain records of the sterility testing with the prescription.

(c) The maximum professional dispensing fee per allowed container is the dispensing fee determined pursuant to section 9789.40.3 for a pharmacy or $10.05 for a physician dispensing in accordance with Business and Professions Code section 4170.

(d) Allowed container count:

(1) The maximum billable container count per dispensed compounded prescription equals one.

(2) Notwithstanding paragraph one, up to 20 containers may be billed for the following Compound Route of Administration Descriptions:

(A) Injection

(B) Infusion.

(e) Route of Administration Compounding Fee / Sterility Fee Table

| **Compound Route of Administration Description** | **Metric Decimal Quantity Range** | **Compounding Fee** | **Sterility Fee** |
| --- | --- | --- | --- |
| Buccal | 000 to 9999999 | 0 | 0 |
| Dental | 000 to 9999999 | 0 | 0 |
| Enteral | 000 to 9999999 | 0 | 0 |
| Infusion | 000 to 9999999 | 0.99 | 0.32 |
| Inhalation | 000 to 9999999 | 0 | 0 |
| Injection | 000 to 9999999 | 0.99 | 0.32 |
| Intraperitoneal | 000 to 9999999 | 0 | 0.32 |
| Irrigation | 000 to 9999999 | 0 | 0.32 |
| Mouth/Throat | 000 to 9999999 | 0 | 0 |
| Mucous Membrane | 000 to 9999999 | 0 | 0.32 |
| Nasal | 000 to 9999999 | 0.81 | 0 |
| Ophthalmic | 000 to 9999999 | 2.04 | 0.32 |
| Oral | 000 to 9999999 | 0 | 0 |
| Other / Miscellaneous | 000 to 9999999 | 0 | 0 |
| Otic | 000 to 9999999 | 0.81 | 0 |
| Rectal | 000 to 9999999 | 0 | 0 |
| Sublingual | 000 to 9999999 | 0 | 0 |
| Topical | 000 to 9999999 | 0 | 0 |
| Transdermal | 000 to 9999999 | 0 | 0 |
| Translingual | 000 to 9999999 | 0 | 0 |
| Urethral | 000 to 9999999 | 0 | 0.32 |
| Vaginal | 000 to 9999999 | 0 | 0 |

(f) Dosage Form Compounding Fee Table

| **Compound Dosage**  **Form** | **Compound Dosage Form Description** | **Compound Claim Quantity Low Range** | **Compound Claim Quantity High Range** | **Compounding Fee** |
| --- | --- | --- | --- | --- |
| 01 | Capsule | 0000000 | 0000005 | 0.00 |
| 01 | Capsule | 0000006 | 0000036 | 1.98 |
| 01 | Capsule | 0000037 | 9999999 | 3.95 |
| 02 | Ointment | 0000001 | 0000179 | 1.64 |
| 02 | Ointment | 0000180 | 9999999 | 3.29 |
| 03 | Cream | 0000001 | 0000179 | 1.64 |
| 03 | Cream | 0000180 | 9999999 | 3.29 |
| 04 | Suppository | 0000001 | 0000023 | 3.29 |
| 04 | Suppository | 0000024 | 9999999 | 5.76 |
| 05 | Powder | 0000000 | 0000005 | 0.00 |
| 05 | Powder | 0000006 | 0000036 | 1.98 |
| 05 | Powder | 0000037 | 9999999 | 3.95 |
| 06 | Emulsion | 0000001 | 0000239 | 0.81 |
| 06 | Emulsion | 0000240 | 9999999 | 1.64 |
| 07 | Liquid | 0000000 | 9999999 | 0.99 |
| 10 | Tablet | 0000000 | 0000005 | 0.00 |
| 10 | Tablet | 000006 | 0000036 | 1.98 |
| 10 | Tablet | 0000037 | 9999999 | 3.95 |
| 11 | Solution | 0000000 | 9999999 | 0.99 |
| 12 | Suspension | 0000000 | 9999999 | 0.99 |
| 13 | Lotion | 0000001 | 0000239 | 0.81 |
| 13 | Lotion | 0000240 | 9999999 | 1.64 |
| 14 | Shampoo | 0000000 | 9999999 | 0.99 |
| 15 | Elixir | 0000000 | 9999999 | 0.99 |
| 16 | Syrup | 0000000 | 9999999 | 0.99 |
| 17 | Lozenge | 0000000 | 0000005 | 0.00 |
| 17 | Lozenge | 0000006 | 0000036 | 1.98 |
| 17 | Lozenge | 0000037 | 9999999 | 3.95 |
| 18 | Enema | 0000000 | 9999999 | 0.99 |

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

This section is renumbered from section 9789.40.4 to 9789.40.5. 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)** As originally proposed, the section specifies that the provisions of the article apply to determine maximum fees for pharmaceuticals dispensed by a mail order pharmacy to an injured worker for treatment of a California workers’ compensation injury or illness, whether the injured worker resides within the state of California or outside the state of California. The modified proposed rule provides additional detail by stating that the article applies to determine the maximum “drug ingredient cost, dispensing, compounding, and sterility” fees, etc. This modification is necessary to provide clarity on the components of the “fees” that are subject to the regulatory provisions.

Subdivision (c) is modified to correct the capitalization of the word “article” since it should be lower case.

**The following is the proposed modified language:**

(a) For a pharmaceutical dispensed through a mail order pharmacy, the provisions of this article apply to determine maximum drug ingredient cost, dispensing, compounding and sterility fees for pharmaceuticals dispensed 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 of the state of California.

(b) The cost of shipping and handling of pharmaceuticals is included in reimbursement for the drug ingredient and is not separately payable.

(c) Unless otherwise specified in this article, for a pharmacy-dispensed drug that is not set forth in the Pharmaceutical Fee Data file, and not otherwise covered by, or bundled into, a fee schedule payment for facility or physician services, the maximum reasonable drug ingredient fee shall not exceed the Wholesale Acquisition Cost applicable to the National Drug Code.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

This section is renumbered from section 9789.40.5 to 9789.40.6. 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)** text is 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 subdivision is further modified by deleting the “lowest cost” formula from subdivision (a) since it has been moved to the new section 9789.40.1. The Medi-Cal methodology has been used to create the “lowest cost” in the Pharmaceutical Fee Data File and this file is to be used for maximum fees “lowest cost” so there is uniformity. This modification streamlines the regulation and improves clarity.

**Subdivision (b)** The subdivision is modified by deleting the “no substitution cost” formula from subdivision (b) since it has been moved to the new section 9789.40.1. The Medi-Cal methodology has been used to create the “no substitution cost” in the Pharmaceutical Fee Data File and this file is to be used for maximum fees “lowest cost” so there is uniformity. This modification streamlines the regulation and improves clarity.

**Subdivision (f)** has been modified to delete the provision which stated that a dispensing fee is not payable for a drug dispensed by a physician. The modified proposal states that the maximum payable dispensing fee 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 has 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. 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. 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 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 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 (i)** which 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 modification deleting this subdivision is necessary to avoid duplication of these provisions and to streamline the regulations since the provisions have been moved to the new section 9789.40.1.

**The following is the proposed modified language:**

(a) The maximum reasonable fee payable for a legend drug 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] is the lower of the drug’s ingredient cost, calculated on a per unit basis, times the number of units dispensed, or the physician’s usual and customary charge to patients under the physician’s care, based on the date the drug is dispensed. The drug’s ingredient cost means the “lowest cost” as set forth on the Pharmaceutical Fee Data file unless subdivision (b) is applicable.

(b) When a physician dispenses a legend brand name drug and has fulfilled the requirements in sections 9792.27.7 and 9792.27.8, the maximum payment for the legend brand name drug dispensed by the physician is the lower of:

1) the “no substitution cost” as set forth on the Pharmaceutical Fee Data file, or

2) the physician’s usual and customary charge to patients under the physician’s care.

(c)(1) The maximum reasonable fee for a legend or non-legend repackaged drug dispensed by a physician is the lowest of:

(A) the drug ingredient cost for the National Drug Code of the underlying drug product from the original labeler listed in the Pharmaceutical Fee Data File, calculated on a per unit basis pursuant to subdivision (a), (b) or (d), or

(B) the physician’s usual and customary charge to patients under the physician’s care.

(2) If the National Drug Code for the underlying drug product from the original labeler is not listed in the Pharmaceutical Fee Data File, then the maximum reasonable fee is the lower of:

(A) the drug ingredient cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis pursuant to subdivision (a) or (d), or

(B) the physician’s usual and customary charge to patients under the physician’s care.

(3) The National Drug Code of the dispensed repackaged drug and the National Drug Code of the underlying drug product shall both be identified on the bill, in accordance with the billing regulations for paper and electronic billing set forth in section 9792.5.1 et seq.

(4) For purposes of this section:

(A) “Therapeutically equivalent drugs” means drugs that have been assigned the same Therapeutic Equivalence Code starting with the letter “A” in the Food and Drug Administration's publication [“Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”.)](https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book) The Orange Book may be accessed through the Food and Drug Administration's website:

<https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book> or successor web page;

(B) “National Drug Code for the underlying drug product from the original labeler” means the National Drug Code of the drug product actually utilized by the repackager in producing the repackaged product.

(d) The maximum reasonable fee for a non-legend drug dispensed by a physician, is the lower of the physician’s usual and customary charge to patients under the physician’s care or the fee as determined as follows:

The lowest of:

(1) The drug’s ingredient cost as defined in subdivision (a), plus the dispensing fee, or

(2) One hundred twenty percent of the documented paid cost to the physician, or

(3) One hundred percent of the documented paid cost to the physician plus two hundred fifty dollars ($250.00).

(e) The maximum reasonable fee for any pharmacy good dispensed by a physician that does not fall within subdivision (a), (b), (c) or section 9789.40.6 (compounded pharmaceuticals) shall be the fee determined in accordance with the formula in subdivision (d).

(f) A maximum dispensing fee of $10.05 is payable to a physician dispensing a drug to their patient in accordance with Business and Professions Code section 4170.

(g) 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.

(h) “Documented paid cost” means the price paid by the physician for the drug product(s), net of discounts and rebates, evidenced by documentation of the price actually paid by the physician for the drug products. Documentation shall consist of invoices, proof of payment, and inventory records as applicable. The physician must submit documentation of paid costs together with the bill.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# 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]. [Modified and Renumbered]

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)** text is 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 subdivision is also revised to modify the formula for determining maximum allowable fee for a physician dispensed compounded drug by including provision for “the dispending, compounding, and sterility fees” applicable pursuant to section 9789.40.4. Section 9789.40.4 as modified 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 has 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.

**Subdivision (c)** is modified by deleting the “drug ingredient cost” formula from subdivision (c)(1) since it has been moved to the new section 9789.40.1. The Medi-Cal methodology has been 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 for the drug ingredient cost for finished drug products in a compounded drug. This modification streamlines the regulation and improves clarity. In addition, by referencing the “lowest cost” and “no substitution cost” as set forth in the Pharmaceutical Fee Data File, the modification corrects an apparent oversight in the initial 45-day proposal which unintentionally omitted the “no substitution cost” for a compounded finished drug product. This revision 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 (e)**: the provision which stated that dispensing, compounding and sterility fees are not payable to a physician is deleted, 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 is 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.

**The following is the proposed modified language:**

(a) The maximum reasonable fee payable for a compounded drug 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] is the lowest of:

(1) Three hundred percent (300%) of the sum of the documented paid cost of the compounded drug ingredients, but not more than $20.00 above the sum of the documented paid cost, or

(2) The sum of the drug ingredient costs as determined pursuant to subdivision (c), plus the dispensing, compounding, and sterility fees applicable to a physician pursuant to section 9789.40.4, or

(3) The physician’s usual and customary charge for the compounded drug to patients under the physician’s care.

(b) “Documented paid cost” means the price paid by the physician for the drug ingredients, net of discounts and rebates, evidenced by documentation of the price actually paid by the physician for the drug ingredients. Documentation shall consist of invoices, proof of payment, and inventory records as applicable. The physician must submit documentation of paid costs and prospective authorization to support a bill for a compounded drug at the time of billing.

(c) For purposes of subdivision (a)(2),

(1) The “drug ingredient cost” for a compounded drug composed of finished drug product(s), calculated based on units used in the compound, on the date the compound drug is dispensed, means the lower of the billed amount for each ingredient or the drug ingredient lowest cost or no substitution cost (where requirements in sections 9792.27.7 and 9792.27.8 are fulfilled) as set forth on the Pharmaceutical Fee Data File.

(2) Where the compounded drug is composed of unfinished drug product(s), the drug ingredient cost means the means the lower of the billed amount for each ingredient or the documented paid cost of each unfinished drug product ingredient, calculated based on units used in the compound, plus 10%, not to exceed the unfinished drug product’s WAC as published by the manufacturer.

(3) Where the compounded drug is composed of both finished drug product(s) and unfinished drug products(s), the “drug ingredient cost” means the amount calculated for each ingredient pursuant to (c)(1) or (c)(2) applicable to the NDC.

(d) Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.

(1) Ingredients without a valid NDC are not reimbursable.

(2) An NDC is presumed to be valid if the NDC is listed in the FDA’s National Drug Code Directory as either a finished or unfinished drug product, and does not appear on the excluded drugs database file. The presumption may be rebutted by a showing that the product is not a drug product legally eligible for assignment of an NDC. The [National Drug Code Directory](https://www.fda.gov/drugs/informationondrugs/ucm142438.htm) may be accessed on the FDA’s website: https://www.fda.gov/drugs/informationondrugs/ucm142438.htm or successor web page.

(e) A sterility fee is only included in the calculations set forth in (a)(2) if the physician’s performance of sterile compounding is allowed by state and federal law and complies with the requirements of California Code of Regulations, Title 16, Division 17, Article 7.

(f) A compounded drug that is essentially a copy of a commercially available product is not reimbursable. The status of a compounded drug as “essentially a copy of a commercially available drug product” is determined pursuant to applicable federal law and regulation.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

# Section 9789.111. Effective Date of Fee Schedule Provisions. [Modified]

This section of the Official Medical Fee Schedule which sets forth an overview of the effective dates applicable to the various sections of the fee schedule is modified to conform to the proposed changes to the effective date set forth in the 15-day comment text of regulation.

**Subdivision (d)** which summarizes pharmaceutical fee schedule effective dates is modified 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 regulation is modified so that it continues to be effective for services rendered prior to the “effective date” in 2025. Subdivision (d) is further modified to specify 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 proposed new section 9789.40.1.

**The following is the proposed modified language:**

(a) The Resource Based Relative Value Scale (RBRVS)-based OMFS regulations for Physician Services (Sections 9789.12.1 – 9789.19) are effective for services rendered on or after January 1, 2014; section 9789.19.1 is effective for services rendered on or after January 1, 2019. The OMFS regulations for Physician Services (Sections 9789.10-9789.11) are effective for services rendered on or after July 1, 2004, but before January 1, 2014. Services rendered after January 1, 2004, but before July 1, 2004 are governed by the "emergency" regulations that were effective on January 2, 2004. The OMFS for physician services set forth in Article 5.5 (Sections 9790, et seq.), is applicable only for services rendered on or before January 1, 2004, unless otherwise specified in this Subchapter (Subchapter 1. Administrative Director – Administrative Rules).

(b) The OMFS regulations for Inpatient Services (Sections 9789.20-9789.25) are effective for inpatient hospital admissions with dates of discharge on or after July 1, 2004. Services for discharges after January 1, 2004, but before July 1, 2004 are governed by the "emergency" regulations that were effective on January 2, 2004. The OMFS for inpatient services set forth in Article 5.5 (Sections 9790, et seq.), is applicable only to bills for services with date of admission on or before December 31, 2003, unless otherwise specified in this Subchapter (Subchapter 1. Administrative Director – Administrative Rules).

(c) The OMFS regulations for Outpatient Services (Sections 9789.30-9789.39) are effective for services rendered on or after July 1, 2004. Services rendered after January 1, 2004, but before July 1, 2004 are governed by the "emergency" regulations that were effective on January 2, 2004.

(d) The OMFS regulation for pharmacy (Section 9789.40) is effective for services rendered after January 1, 2004 and 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]. Additional OMFS regulations for pharmaceuticals (Sections 9789.40.1 – 9789.40.7) are effective for 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].

(e) The OMFS regulation for Pathology and Laboratory (Section 9789.50) is effective for services rendered after January 1, 2004.

(f) The OMFS regulation for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (Section 9789.60) is effective for services rendered after January 1, 2004.

(g) The OMFS regulation for Ambulance Services (Section 9789.70) is effective for services rendered after January 1, 2004.

Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.

Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.