Proposed Regulation Amendments and Adoptions

Format note:

Plain text is current codified language

Blue text indicates a hyperlink is provided in the text.

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

Title 8, California Code of Regulations

Division 1 Department of Industrial Relations

**Chapter 4.5, Division of Workers’ Compensation**

**Subchapter 1 - Administrative Director – Administrative Rules**

**Article 5.3**

# 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.

(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 ~~section~~ 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 (~~section 9789.~~4~~0~~ sections 9789.40, 9789.40.5, 9789.40.6), 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.

(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-codes~~ CPT code for the vaccine. Other physician-administered drugs, biologicals and blood products shall be reported using the NDC code and ~~J-codes~~ 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. ~~The Medi-Cal fee schedule reimburses drug products, vaccines and immunizations at the Medicare rate of reimbursement when established and published by the Centers for Medicare & Medicaid Services (CMS) or the Medi-Cal pharmacy rate of reimbursement when the Medicare rate is not available.~~ ~~The Medicare rate is currently defined as average sales price (ASP) plus 6 percent. The pharmacy rate is currently defined as the lower of (1) the average wholesale price (AWP) minus 17 percent; (2) the federal upper limit (FUL); or (3) the maximum allowable ingredient cost (MAIC).~~

(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 ~~RBRVS~~ 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 ~~Medi-Cal Pharmacy Fee Schedule~~ pharmaceutical fee schedule applicable to physicians as adopted by the Division of Workers’ Compensation in ~~section 9789.40~~ 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~~ 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.

The maximum reimbursement for physician-dispensed drugs is determined pursuant to the Pharmaceutical Fee Schedule set forth in ~~section 9789.40~~ sections 9789.40, 9789.40.5, 9789.40.6 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 Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(a) The maximum reasonable fee for pharmaceuticals and pharmacy services rendered after January 1, 2004 and prior to [Month Day, 2024] [90 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 updated 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. ~~Medi-Cal rates~~ 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 ~~(http://www.dir.ca.gov/DWC/dwc\_home\_page.htm~~ (<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) “~~t~~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: ~~http://www.fda.gov/cder/orange/default.htm.;~~

<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) The changes made to this Section in February, 2007, shall be applicable to all pharmaceuticals dispensed or provided on or after March 1, 2007.~~

(d) This section applies to pharmaceuticals dispensed and pharmaceutical services rendered prior to [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(e) The Medi-Cal data file dated 03/08/2019 posted on the internet website of the Division of Workers’ Compensation will remain in effect for pharmaceuticals dispensed prior to [Month Day, 2024] [90 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. Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(a) The maximum reasonable fee payable for legend and non-legend drugs dispensed by a pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL] is the rate that is 100% of the payment allowed pursuant to the Medi-Cal pharmacy payment methodology. 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 of:

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

(B) The Federal Upper Limit (FUL), or

(C) The Maximum Allowable Ingredient Cost (MAIC).

(2) The professional dispensing fee is:

(A) $10.05 for all pharmacies except those that meet the requirements of subdivision (a)(2)(B);

(B) $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.

(b) 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 maximum reasonable fee for a legend or non-legend brand name drug dispensed by a pharmacy is the lower of: (1) the “No Substitution” fee (the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%), plus the professional dispensing fee pursuant to (a)(2), or (2) the pharmacy’s usual and customary charge to the public, based 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) or (b) 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.

(d) The Pharmaceutical Fee Data File setting forth the “lowest cost” and “no substitution cost” drug ingredient rates, and the dispensing fee NPI file, will be made available on the Division of Workers' Compensation's [Official Medical Fee Schedule](http://www.dir.ca.gov/dwc/OMFS9904.htm) web pages (<http://www.dir.ca.gov/dwc/OMFS9904.htm> or successor web page).

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. Compounded Pharmaceuticals Dispensed By a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(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 Day, 2024] [90 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 as follows:

The lowest of:

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

(B) The Federal Upper Limit (FUL), or

(C) The Maximum Allowable Ingredient Cost (MAIC).

(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 9789.40.3. Compounding Fee and Sterility Fee: Route of Administration Compounding Fee / Sterility Fee Table; and Dosage Form Compounding Fee Table; Pharmacy Dispensed Compounded Drugs on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

For dates of service on or after [Month Day, 2024] [90 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 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. The pharmacy must maintain records of the sterility testing with the prescription.

(c) The professional dispensing fee per allowed container is the dispensing fee determined pursuant to section 9789.40.2.

(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 9789.40.4. Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(a) For a pharmaceutical dispensed through a mail order pharmacy, the provisions of this article apply to determine maximum 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 9789.40.5. Pharmaceuticals Dispensed By a Physician on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(a) The maximum reasonable fee payable for a legend drug dispensed by a physician on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL] 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 of:

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

2) The Federal Upper Limit (FUL), or

3) The Maximum Allowable Ingredient Cost (MAIC).

(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” fee (the NADAC of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) +0%), 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), 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 dispensing fee is not payable for a drug dispensed by a physician.

(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.

(i) The Pharmaceutical Fee Data File setting forth the “lowest cost” and “no substitution cost” drug ingredient rates 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).

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. Compounded Pharmaceuticals Dispensed By a Physician on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(a) The maximum reasonable fee payable for a compounded drug dispensed by a physician on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL] 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), 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 fee for each ingredient determined as follows:

The lowest of:

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

(B) The Federal Upper Limit (FUL), or

(C) The Maximum Allowable Ingredient Cost (MAIC).

(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) Dispensing, compounding and sterility fees are not payable for a compounded drug dispensed by a physician.

(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.

(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 Day, 2024] [90 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 – 9789.40.6) are effective for services rendered on or after [Month Day, 2024] [90 days after the amendments are filed with the Secretary of State; date to be inserted by OAL].

(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.