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 9789.40 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.

- (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 <u>code</u> and <u>CPT-codes</u> <u>CPT code</u> for the vaccine. Other physician-administered drugs, biologicals and blood products shall be reported using the NDC <u>code</u> and J-codes the Healthcare Common <u>Procedure Coding System Level II code</u> (HCPCS Level II code) assigned to the product. <u>Physician-administered drugs</u>, 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 <u>CPT code or HCPCS Level II</u> 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 <u>injectable</u> 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 <u>physician fee schedule</u>. 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, 9789.40.1, 9789.40.4, 9789.40.6, or 9789.40.7 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, 9789.40.1, 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 July 1, 2025.

(a) The maximum reasonable fee for pharmaceuticals and pharmacy services rendered after January 1, 2004, and prior to July 1, 2025, is 100% of the reimbursement prescribed in the relevant Medi-Cal payment system <u>data file</u> "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. Medi-Cal rates The data file will be made available on the Division of Workers' Compensation's Official Medical Fee Schedule Internet Website

(http://www.dir.ca.gov/DWC/dwc_home_page.htm) 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) "ŧTherapeutically 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".) The Orange Book may be accessed through the Food and Drug Administration's website. website: http://www.fda.gov/cder/orange/default.htm.;
- (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 July 1, 2025.
- (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 July 1, 2025.

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 July 1, 2025.

This section is effective 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.
- (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 sections 9789.40.2 through 9789.40.7 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 Pharmaceutical Fee Data File.
- (C) For retroactive cost changes within the Pharmaceutical Fee Data File or costs used during the implementation period allowed pursuant to paragraph (a)(3)(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 Pharmaceutical Fee Data 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.

- (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 pharmacy dispensing fee pursuant to sections 9789.40.2, 9789.40.3, 9789.40.4 and 9789.40.5 based on each new Medi-Cal NPI file not later than the second calendar day after posting the Medi-Cal NPI file on the division's website.
- (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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u>
<u>Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.</u>

<u>Section 9789.40.2. Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy on or after July 1, 2025.</u>

- (a) The maximum reasonable fee payable for a legend or non-legend drug dispensed by a pharmacy 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)(1), 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 seg.
- (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".) The Orange Book may be accessed through the Food and Drug Administration's website.
- (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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u>

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

<u>Section 9789.40.3. Compounded Pharmaceuticals Dispensed By a Pharmacy on or after July 1, 2025.</u>

- (a) Except as provided in subdivisions (b)(2) and (c)(1), the maximum reasonable fee payable for a compounded drug dispensed by a pharmacy 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

<u>assignment of an NDC. The National Drug Code Directory may be accessed on</u> the FDA's website.

- (c)(1) The drug ingredient cost for a compounded drug, 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) ("lowest cost"), or (a)(2) ("no substitution cost".)
- (2) 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 9789.40.4.
- (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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u>

<u>Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.</u>

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 July 1,
2025.

The maximum allowable compounding fee, sterility fee, and professional dispensing fee payable to a pharmacy pursuant to section 9789.40.3 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:
- (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	<u>0</u>	<u>0</u>
<u>Dental</u>	000 to 9999999	<u>0</u>	<u>0</u>
<u>Enteral</u>	000 to 9999999	<u>0</u>	<u>0</u>
Infusion	000 to 9999999	0.99	0.32
<u>Inhalation</u>	000 to 9999999	<u>0</u>	<u>0</u>
Injection	000 to 9999999	0.99	0.32
<u>Intraperitoneal</u>	000 to 9999999	<u>0</u>	0.32
Irrigation	000 to 9999999	<u>0</u>	0.32
Mouth/Throat	000 to 9999999	<u>0</u>	<u>0</u>
Mucous Membrane	000 to 9999999	<u>0</u>	0.32
<u>Nasal</u>	000 to 9999999	0.81	<u>0</u>

Compound Route of Administration Description	Metric Decimal Quantity Range	Compounding Fee	Sterility Fee
<u>Ophthalmic</u>	000 to 9999999	2.04	0.32
<u>Oral</u>	000 to 9999999	<u>0</u>	<u>0</u>
Other / Miscellaneous	000 to 9999999	<u>0</u>	<u>0</u>
<u>Otic</u>	000 to 9999999	0.81	<u>0</u>
Rectal	000 to 9999999	<u>0</u>	<u>0</u>
Sublingual	000 to 9999999	<u>0</u>	<u>0</u>
<u>Topical</u>	000 to 9999999	<u>0</u>	<u>0</u>
Transdermal	000 to 9999999	<u>0</u>	<u>0</u>
<u>Translingual</u>	000 to 9999999	<u>0</u>	<u>0</u>
<u>Urethral</u>	000 to 9999999	<u>0</u>	0.32
<u>Vaginal</u>	000 to 9999999	<u>0</u>	<u>0</u>

(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
<u>01</u>	<u>Capsule</u>	0000000	0000005	0.00
<u>01</u>	<u>Capsule</u>	0000006	0000036	1.98
<u>01</u>	<u>Capsule</u>	0000037	9999999	3.95
<u>02</u>	<u>Ointment</u>	0000001	0000179	1.64
<u>02</u>	<u>Ointment</u>	0000180	9999999	3.29
03	<u>Cream</u>	0000001	0000179	1.64

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

Compound Dosage Form	Compound Dosage Form Description	Compound Claim Quantity Low Range	Compound Claim Quantity High Range	Compounding Fee
<u>18</u>	<u>Enema</u>	0000000	9999999	0.99

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u> Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

<u>Section 9789.40.5. Miscellaneous Provisions - Pharmaceuticals Dispensed</u> <u>By a Pharmacy on or after July 1, 2025.</u>

- (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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u> Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

<u>Section 9789.40.6. Pharmaceuticals Dispensed By a Physician on or after</u> July 1, 2025.

- (a) The maximum reasonable fee payable for a legend drug dispensed by a physician is the lower of the drug's ingredient cost, calculated on a per unit basis, times the number of units dispensed, plus the dispensing fee, or the physician's usual and customary charge to patients under the physician's care, based on the date the drug is dispensed.
- (1) The drug ingredient cost means the "lowest cost" as set forth on the Pharmaceutical Fee Data File unless subdivision (a)(2) or subdivision (a)(3)(B) is applicable.
- (2) When a physician dispenses a legend brand name drug and has fulfilled the requirements in sections 9792.27.7 and 9792.27.8, the drug ingredient cost

- means the "no substitution cost" as set forth on the Pharmaceutical Fee Data File.
- (3)(A) When a physician dispenses a repackaged drug, the drug ingredient cost means the "lowest cost" for the National Drug Code of the underlying drug product from the original labeler as set forth on the Pharmaceutical Fee Data File, or
- (B) When a physician dispenses a repackaged brand name drug, and has fulfilled the requirements in sections 9792.27.7 and 9792.27.8, the drug ingredient cost means the "no substitution cost" for the National Drug Code of the underlying drug product from the original labeler as set forth on the Pharmaceutical Fee Data File, or
- (C) When a physician dispenses a repackaged drug and the National Drug Code for the underlying drug product from the original labeler is not listed in the Pharmaceutical Fee Data File, the drug ingredient cost means the "lowest cost" of the lowest priced therapeutically equivalent drug as set forth on the Pharmaceutical Fee Data File.
- (b) The maximum reasonable fee for a non-legend drug, including a non-legend repackaged 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).
- (c) "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.
- (d) For a repackaged drug, 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.
- (e) For purposes of this section:
- (1) "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".) The Orange Book may be accessed through the Food and Drug Administration's website.
- (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.

- (f) The maximum reasonable fee for any pharmacy good dispensed by a physician that does not fall within sections 9789.40.1, 9789.40.4, 9789.40.6, 9789.40.7 applicable to physicians shall be the fee determined in accordance with the formula in subdivision (b).
- (g) 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.
- (h) 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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u> Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.

<u>Section 9789.40.7. Compounded Pharmaceuticals Dispensed By a</u> Physician on or after July 1, 2025.

- (a) The maximum reasonable fee payable for a compounded drug dispensed by a physician 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), calculated based on units used in the compound, 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 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) The metric decimal quantity/units billed for each ingredient is the total amount within the compound regardless of the number of containers.
- (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 may be accessed on the FDA's website.
- (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.

<u>Authority: Sections 133, 4603.5, 5307.1 and 5307.3, Labor Code.</u>
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 July 1, 2025. Additional OMFS regulations for pharmaceuticals (Sections 9789.40.1 –9789.40.7) are effective for services rendered on or after July 1, 2025.
- (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.