# DRAFT PHAMARMEUTICAL FEE SCHEDULE CHANGES FOR PUBLIC COMMENT ON DWC FORUM - CLOSING JULY 3, 2020

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## Title 8, California Code of RegulationsChapter 4.5, Division of Workers’ CompensationSubchapter 1 - Administrative Director – Administrative RulesArticle 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.

1. 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 5307.11.
2. 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:
3. 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.
4. Osteopathic Manipulation Codes (98925-98929) are to be used only by licensed Doctors of Osteopathy and Medical Doctors.
5. 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, 9789.40.4, 9789.40.5), 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.

1. Physician-administered drugs, biologicals, vaccines, or blood products are separately payable.
2. Vaccines shall be reported using the NDC and CPT-codes for the vaccine. Other physician-administered drugs, biological and blood products shall be reported using the NDC and ~~J-codes~~ HCPCS Level II code assigned to the product.
3. The maximum reimbursement shall be determined using the “Basic Rate” for the HCPCS 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 Medi-Cal pharmacy rate has been ~~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). Pursuant to the Medi-Cal State Plan Amendment 17-002, the Medi-Cal pharmacy drug ingredient cost is modified to be defined as the lower of (1) National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) if a NADAC price does not exist, (2) Federal Upper Limit (FUL), or (3) the Maximum Allowable Ingredient Cost (MAIC). The modified drug ingredient cost will be implemented for workers’ compensation prospectively as set forth in sections 9789.40.4 and 9789.40.5 for pharmaceutical products dispensed on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].
4. The “Basic Rate” price listed on the Medi-Cal rates page of the Medi-Cal website for each physician-administered 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.
5. 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, 9789.40.4, or 9789.40.5 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.
6. The physician fee schedule shall be used to determine the maximum reimbursement for the drug administration fee.
7. 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.
8. Pay separately for cancer chemotherapy injections (CPT codes 96401-96549) in addition to the visit furnished on the same day.
9. 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.

1. All claims for a physician-administered drug, biological, vaccine, or blood product must include the specific name of the drug and dosage.
2. “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, 9789.40.4, 9789.40.5 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 XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. The maximum reasonable fee for pharmaceuticals and pharmacy services rendered after January 1, 2004 is 100% of the reimbursement prescribed in the relevant Medi-Cal payment system, including the Medi-Cal professional fee for dispensing. Medi-Cal rates 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 upon request to the Administrative Director at:

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

1. 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.
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 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.
3. 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.
4. For purposes of this section:
5. “~~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;

1. “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.
2. The changes made to this Section in February, 2007, shall be applicable to all pharmaceuticals dispensed or provided on or after March 1, 2007.
3. This section applies to pharmaceuticals dispensed and pharmaceutical services rendered prior to XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].
4. Notwithstanding other provisions of law, the last Medi-Cal data file utilizing the Average Wholesale Price methodology received and posted on the internet website by the Division of Workers’ Compensation will remain in effect for pharmaceuticals dispensed prior to XXX XX, 2020 [60 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 XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. The maximum reasonable fee payable for pharmaceuticals dispensed by a pharmacy on or after XXX XX, 2020 [60 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. Payment for legend and non-legend drugs dispensed by a pharmacy is the lower of the drug’s ingredient cost plus the professional dispensing fee, or the pharmacy’s usual and customary charge to the public.
2. The drug’s ingredient cost means the lowest of:
3. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
4. The Federal Upper Limit (FUL), or
5. The Maximum Allowable Ingredient Cost (MAIC).
6. The professional dispensing fee is:
7. $10.05 for all pharmacies except those that meet the requirements of subdivision (a)(2)(B);
8. $13.20 for a pharmacy that is designated by National Provider Identifier to receive this fee in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed.
9. 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, payment for legend and non-legend drugs dispensed by a pharmacy is the lower of: (1) 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.
10. For a repackaged drug, the maximum drug ingredient cost shall not exceed the fee determined pursuant to subdivision (a), or the fee as determined in accordance with this subdivision if applicable.
11. If the National Drug Code for a repackaged 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 drug ingredient cost shall be determined 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 pursuant to subdivision (a).
12. If the National Drug Code for a repackaged 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 drug ingredient cost shall not exceed the drug ingredient cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis pursuant to subdivision (a).
13. 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.
14. For purposes of this section:
15. “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;

1. “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.
2. The data file setting forth the “lowest cost” and “no substitution cost” Medi-Cal pharmacy drug ingredient rates, and the dispensing fee 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).

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 XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. Except as provided in subdivisions (b)(2) and (c)(2), 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:
2. drug ingredient costs, and
3. professional dispensing fee, and
4. compounding and sterility fees if applicable.
5. (1) Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.
6. Notwithstanding Medi-Cal payment policy, ingredients without a valid NDC are not reimbursable.
7. A “valid NDC” means an NDC that is listed in the FDA’s National Drug Code Directory as either a finished or unfinished drug product. 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 .
8. (1) The “drug ingredient cost” for a compounded drug composed of finished drug product(s), calculated based on units used in the compound, means the lowest of:
9. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
10. The Federal Upper Limit (FUL), or
11. The Maximum Allowable Ingredient Cost (MAIC).
12. 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%.
13. 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.
14. The professional dispensing fee is:
15. $10.05 for all pharmacies except those that meet the requirements of subdivision (d)(2);
16. $13.20 for a pharmacy that is designated by National Provider Identifier to receive this fee in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed.
17. “Compounding fees and sterility fees” means the fees set forth on the Medi-Cal Compound Dosage Fee Table. The table and related instructions are adopted and incorporated by reference. The table and instructions will be posted on the division’s website.
18. “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 together with the bill.
19. 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 Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. 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.
2. The cost of shipping and handling of pharmaceuticals is included in reimbursement for the drug ingredient and is not separately payable.
3. Unless otherwise specified in this Article, for a pharmacy dispensed drug that is not covered by a Medi-Cal payment system, 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 9789.40.4 Pharmaceuticals Dispensed By a Physician on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. The maximum reasonable fee payable for legend drugs dispensed by a physician on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL] is the lower of the rate that is 100% of the payment allowed pursuant to the Medi-Cal pharmacy payment methodology for the drug’s ingredient cost or the physician’s usual and customary charge to patients under the physician’s care. The drug’s ingredient cost means the lowest of:
2. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
3. The Federal Upper Limit (FUL), or
4. The Maximum Allowable Ingredient Cost (MAIC).
5. 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 legend brand name drugs dispensed by the physician is the lower of: 1) 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.
6. For a repackaged drug, the maximum drug ingredient cost shall not exceed the fee determined pursuant to subdivision (a), or the fee as determined in accordance with this subdivision if applicable.

(1) If the National Drug Code for a repackaged 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 drug ingredient fee shall be determined 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 pursuant to subdivisions (a), (b) or (d).

1. If the National Drug Code for a repackaged 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 drug ingredient fee shall not exceed the drug ingredient cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis pursuant to subdivisions (a), (b) or (d)(1)-(3).
2. 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.
3. For purposes of this section:
4. “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;

1. “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.
2. The maximum reasonable fee for a non-legend drug dispensed by a physician, or any pharmacy good dispensed by a physician that does not fall within subdivisions (a), (b), or (c), and does not fall within section 9789.40.5 (compounded pharmaceuticals), is the lowest of:
3. The drug’s ingredient cost as defined in subdivision (a), or
4. One hundred twenty percent of the documented paid cost to the physician, or
5. One hundred percent of the documented paid cost to the physician plus two hundred fifty dollars ($250.00).
6. A dispensing fee is not payable for a drug dispensed by a physician.
7. 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.
8. “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.
9. The data file setting forth the “lowest cost” and “no substitution cost” Medi-Cal 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).

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 Compounded Pharmaceuticals Dispensed By a Physician on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

1. The maximum reasonable fee payable for a compounded drug dispensed by a physician is the lower of:
2. Three hundred percent (300%) of documented paid cost of the drug ingredients, but not more than $20.00 above documented paid cost, or
3. The drug ingredient cost as determined by subdivision (c), plus the compounding and sterility fees if applicable.
4. “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.
5. For purposes of subdivision (a)(2),
6. The “drug ingredient cost” for a compounded drug composed of finished drug product(s), calculated based on units used in the compound, means the lowest of:
7. The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
8. The Federal Upper Limit (FUL), or
9. The Maximum Allowable Ingredient Cost (MAIC).
10. 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%.
11. 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.
12. (1) To receive a compounding fee pursuant to subdivision (a)(2), the dispensing physician must perform the act of compounding, pursuant to Article 4.5 (commencing with section 1735) or Article 7 (commencing with section 1751) of Division 17 of Title 16 of the California Code of Regulations, or other regulation adopted by the State Board of Pharmacy to govern the practice of compounding, or Federal law governing compounding, including title 21, United State Code, sections 353a, 353a-1, 353b.
13. “Compounding fees and sterility fees” means the fees set forth on the Medi-Cal Compound Dosage Fee Table. The table and related instructions are adopted and incorporated by reference. The table and instructions will be posted on the Division’s website.
14. Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.
15. Ingredients without a valid NDC are not reimbursable.
16. A “valid NDC” means an NDC that is listed in the FDA’s National Drug Code Directory as either a finished or unfinished drug product. 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 .
17. A dispensing fee is not payable for a compounded drug dispensed by a physician.
18. 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.

1. The Resource Based Relative Value Scale (RBRVS)-based OMFS regulations for Physician Services (Sections 9789.12.1 – ~~9789.19~~ 9789.19.1) are effective for services rendered on or after January 1, 2014. 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).
2. 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).
3. 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.
4. The OMFS regulation for pharmacy (Section 9789.40) is effective for services rendered after January 1, 2004. Additional OMFS regulations for pharmaceuticals (Sections 9789.40.1 – 9789.40.5) are effective for services rendered on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].
5. The OMFS regulation for Pathology and Laboratory (Section 9789.50) is effective for services rendered after January 1, 2004.
6. The OMFS regulation for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (Section 9789.60) is effective for services rendered after January 1, 2004.
7. 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.