PROPOSED CHANGES TO PHARMACEUTICAL FEE SCHEDULE FOR DWC FORUM PUBLIC COMMENT PERIOD ENDING OCTOBER 8, 2018

Title 8, California Code of Regulations Chapter 4.5, Division of Workers' Compensation Subchapter 1 - Administrative Director – Administrative Rules Article 5.3

Section 9789.40. Pharmacy – <u>Pharmaceuticals Dispensed and Pharmaceutical</u> Services Rendered Prior to January 1, 2019.

(a) 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 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) "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".) The Orange Book may be accessed through the Food and Drug Administration's 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 January 1, 2019.

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 January 1, 2019.

- (a) The maximum reasonable fee payable for pharmaceuticals dispensed by a pharmacy on or after January 1, 2019 will be 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.
- (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 (a)(2)(B);
- (B) \$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.
- (b) The Medi-Cal pharmacy drug ingredient rates and the dispensing fee files 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.

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Section 9789.40.2 Pharmaceuticals Dispensed by a Physician on or after January 1, 2019.

- (a) The maximum reasonable fee payable for legend and non-legend drugs dispensed by a physician on or after January 1, 2019 will be the lower of the rate that is 100% of the payment allowed pursuant to the Medi-Cal pharmacy payment methodology for the drug ingredient cost or the physician's usual and customary charge to patients under the physician's care.
- (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).
- (b) A dispensing fee is not payable for a drug that is dispensed by a physician.
- (c) The Medi-Cal pharmacy 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).

<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 on or after January 1, 2019 by a Pharmacy.</u>

- (a) The maximum reasonable fees for compounded drugs dispensed by a pharmacy shall be 100% of the fees payable by Medi-Cal for compounded drugs, including drug ingredient costs, professional dispensing fee, and compounding fees if applicable. Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.
- (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); or
- (2) Where the compound is composed of bulk chemicals, the Wholesale Acquisition Cost of each active pharmaceutical ingredient.
- (2) The professional dispensing fee is:
- (A) \$10.05 for all pharmacies except those that meet the requirements of (a)(2)(B);
- (B) \$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.
- (3) The compounding fees are set forth on the Medi-Cal Compound Dosage Fee Table which is adopted and incorporated by reference.

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

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

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<u>Section 9789.40.4 Compounded Pharmaceuticals Dispensed on or after January 1, 2019 by a Physician.</u>

- (a) The maximum reasonable fees for compounded drugs dispensed by a physician shall be the lower of:
- (1) Three hundred percent (300%) of documented paid costs for the drug ingredients; or
- (2) Documented paid costs plus twenty dollars; or
- (3) The drug ingredient cost and compounding fees if applicable. The "drug ingredient cost" has the meaning set forth in section 9789.40.3 subdivision (a)(1). "Compounding fees" has the meaning set forth in section 9789.40.3, subdivision (a)(3).
- (b) Documented paid costs means the price paid by the physician for the drug, net of discounts, evidenced by documentation of the price actually paid by the physician for the drug. The physician must submit documentation to support a bill for a compounded drug. (c) A dispensing fee is not payable for a compounded drug that is dispensed by a physician.

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

<u>Section 9789.40.5 Miscellaneous Provisions - Pharmaceuticals Dispensed on or after January 1, 2019.</u>

- (a) For mail order pharmacies, the provisions of this article apply to determine maximum fees for pharmaceuticals dispensed to injured workers residing within 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) For a repackaged drug, the maximum drug ingredient fee shall not exceed the fee determined pursuant to section 9789.40.1 or 9789.40.2, 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.
- (2) 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 Wholesale Acquisition Cost of the lowest priced therapeutically equivalent drug, calculated on a per unit basis.
- (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

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Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book".) The Orange Book any be accessed through the Food and Drug Administration's website:

https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm https://www.fda.gov/drugs/informationondrugs/ucm129662.htm;

- (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.
- (f) Unless otherwise specified in this Article, for a pharmacy service or drug that is not covered by a Medi-Cal payment system, 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. Reference: Sections 4600, 4603.2 and 5307.1, Labor Code.</u>

