



California Workers' Compensation Institute

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October 8, 2018

VIA E-MAIL – DWCForums@dir.ca.gov

Maureen Gray, Regulations Coordinator
Division of Workers' Compensation, Legal Unit
P.O. Box 420603
San Francisco, CA 94142

Re: Forum Comment: Pharmaceutical Fee Schedule Regulations

Dear Ms. Gray:

On behalf of its members, California Workers' Compensation Institute offers these comments on the proposed modifications to the Pharmaceutical Fee Schedule regulations. The Institute members include insurers writing 82% of California's workers' compensation premium, and self-insured employers with \$69.8B of annual payroll (31.5% of the state's total annual self-insured payroll).

Insurer members of the Institute include AIG, Alaska National Insurance Company, Allianz Global Corporate and Specialty, AmTrust North America, Berkshire Hathaway, CHUBB, CNA, CompWest Insurance Company, Crum & Forster, EMPLOYERS, Everest National Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Insurance, Republic Indemnity Company of America, Sentry Insurance, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members include Adventist Health, Albertsons/Safeway, BETA Healthcare Group, California Joint Powers Insurance Authority, California State University Risk Management Authority, Chevron Corporation, City and County of San Francisco, City of Los Angeles, City of Torrance, Contra Costa County Risk Management, Contra Costa County Schools Insurance Group, Costco Wholesale, County of Alameda, County of Los Angeles, County of San Bernardino Risk Management, County of Santa Clara Risk Management, Dignity Health, Foster Farms, Grimmway Farms, Kaiser Permanente, Marriott International, Inc., North Bay Schools Insurance Authority, Pacific Gas & Electric Company, Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group, Southern California Edison, Special District Risk Management Authority, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the proposed regulation are indicated by underline and ~~strikeout~~. Comments and discussion by the Institute are identified by *italicized text*.

The Institute recommends reconciliation with the Official Medical Fee Schedule for Physician and Non-Physician Practitioner Services. The following sections of the Physician Fee Schedule Regulations require revision to address changes in the Medicare payment calculation methodology and to include reference to the proposed subsections under §9789.40:

- §9789.13.2
- §9789.13.4
- §9789.14

Discussion:

In addition to the “Medicare rate” currently defined under § 9789.13.2 for services occurring on or after January 1, 2014, new language must be added describing the revised Medicare payment calculation for services that occur after implementation of the proposed Pharmaceutical Fee Schedule amendments.

Additionally, references to §9789.40 under §9789.13.4 and §9789.14 must be revised to include new sections and subdivisions, since amended language under subsection (d) states that §9789.40 only applies to pharmaceutical services rendered prior to January 1, 2019.

Recommendation:

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 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.

Discussion:

The Institute recommends changing “will be” to “is” for clarity.

Recommendation:

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 pharmaceuticals** dispensed by a physician on or after January 1, 2019 **will be is the lower of** 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 physician is the lower of 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.

Discussion:

The Institute recommends maintaining language that is similar to §9789.40.1 for ease of reading and clarity.

Recommendation:**Section 9789.40.3 Compounded Pharmaceuticals Dispensed on or after January 1, 2019 by a Pharmacy.**

(a) The maximum reasonable fees for compounded drugs dispensed by a pharmacy shall be is the rate that is 100% of the fees payment allowed pursuant to the payable by Medi-Cal pharmacy payment methodology 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 drug ingredient cost is the Wholesale Acquisition Cost of each active pharmaceutical ingredient.

(23) 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.

(34) The compounding fees are set forth on the Medi-Cal Compound Dosage Fee Table which is adopted and incorporated by reference.

Discussion:

The Institute recommends maintaining language that is similar to §9789.40.1 for ease of reading and clarity.

The numbering in subdivision (a) requires correction.

The Medi-Cal payment methodology is currently not limited only to “active pharmaceutical” ingredients. If the intent is to limit payment to active ingredients, then a definition of “active pharmaceutical ingredient” should be provided.

Recommendation:**Section 9789.40.4 Compounded Pharmaceuticals Dispensed on or after January 1, 2019 by a Physician.**

(a) The maximum reasonable fees for compounded drugs dispensed by a physician shall be is 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 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 prior authorization to support a bill for a compounded drug at the time of billing.
- (c) A dispensing fee is not payable for a compounded drug that is dispensed by a physician.

Discussion:

The Institute recommends changing “shall be” to “is” for consistency.

The Institute recommends additional language in 9789.40(b) to clarify and define the type of documentation necessary for payment of a physician-dispensed compounded drug, with language reflective of Section 5307.1(e)(5)(E).

PLEASE NOTE CWCI’S CONTINUED

FORUM COMMENTS

ON THE FOLLOWING PAGES.

For consideration:

Section 9789.40.5 Miscellaneous Provisions - Pharmaceuticals Dispensed on or after January 1, 2019.

(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~~ **NADAC rate for a pharmaceutically equivalent drug as defined by the standardized nomenclature for clinical drugs (RxNorm) produced by the National Library of Medicine.**

Discussion:

NADAC rates are calculated based on paid costs to more accurately reflect prices paid by retail community pharmacies acquiring prescription and over-the-counter outpatient drugs. If a particular NDC is not included in NADAC reporting, it will not be included in the NADAC database. Payment rates associated with a shared RxNorm Concept Unique Identifier (RXCU) would enable payments for pharmaceuticals produced and sold, using comparable resources to be paid in an equitable manner.

The following tables provide examples of NDC payment rates for the same drug with NADAC records, and examples of WAC values for NDCs that are not found in the current NADAC database.

NADAC price as of 10/03/18			
NDC	NDC Description	NDC Price	RXCU
00378628001	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
00378628010	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
61442010201	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
61442010210	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
61442010260	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
68001028000	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
68001028006	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
68001028008	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906
NDCs not found in NADAC database			
NDC	NDC Description	WAC	RXCU
00440639500	DICLOFENAC SOD DR 50 MG TAB	0.1434	855906
60429042110	DICLOFENAC SOD DR 50 MG TAB	0.10354	855906
60429042118	DICLOFENAC SOD DR 50 MG TAB	0.13228	855906
42291023018	DICLOFENAC SOD DR 50 MG TAB	0.15667	855906

Thank you for the opportunity to comment, and please contact us if additional information would be helpful.

Sincerely,

Stacy L. Jones
Senior Research Associate

Denise Niber
Claims and Medical Director

SLJ:DN/pm

cc: André Schoorl, DIR Acting Director
George Parisotto, DWC Administrative Director
Jackie Schauer, DWC Legal Unit
CWCI Claims Committee
CWCI Medical Care Committee
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CWCI Regular Members
CWCI Associate Members