



## California Workers' Compensation Institute

1111 Broadway Suite 2350, Oakland, California 94607 • Tel: (510) 251-9470 • Fax: (510) 251-9485

June 12, 2006

### DELIVERED VIA E-MAIL

Maureen Gray, Regulations Coordinator  
Department of Industrial Relations  
Division of Workers' Compensation  
Post Office Box 420603  
San Francisco, CA 94142

RE: Fees for Drugs and Pharmacy Services

Dear Ms. Gray:

These Forum comments on draft regulations regarding maximum reasonable fees for drugs and pharmacy services are presented on behalf of the California Workers' Compensation Institute members. Recommended modifications to the draft are indicated by underline and ~~strikethrough~~.

Fee schedule loopholes lead to "cottage industries." This was the case for ambulatory surgery center facility fees and it is now the case for repackaged drugs. In AB 228 the Legislature required a pharmacy fee schedule that would reimburse drug products and services at Medi-Cal rates. But an unexpected loophole emerged because Medi-Cal does not determine reimbursement under repackager's National Drug Codes (NDCs) since it does not pay for repackaged drugs. CWCI supports modifying the Pharmacy Section of the Official Medical Fee Schedule to eliminate the loophole for repackaged drugs and other drugs and pharmacy services not covered by Medi-Cal. According to the plain language and intent of the statute, maximum fees for pharmacy services and drugs may not exceed 100% of Medi-Cal fees for comparable drugs and services, regardless of whether they are furnished by a pharmacy or a practitioner (Labor Code section 5307.1(a) and (d)).

Our understanding is this draft regulation is attempting to close the loophole which allows a drug dispensed by a physician to be reimbursed at a different level than the same drug dispensed by a pharmacy. Our members support that goal; however we question whether the language in the draft regulation has accomplished the objective. We offer some refinements to help achieve the goal.

When the Medi-Cal fee schedule does not determine a fee under the NDC of the dispensed drug, we recommend that reimbursement is determined in the following order of priority:

1. Determine Medi-Cal fee from dispensed NDC
2. Determine Medi-Cal fee from NDC of original labeler
3. Determine Medi-Cal fee from NDC of therapeutic/pharmaceutical equivalent
4. Calculate Medi-Cal AWP formula using therapeutic/pharmaceutical equivalent's AWP and add Medi-Cal dispensing fee
5. Calculate Medi-Cal AWP formula using dispensed drug's AWP and add Medi-Cal dispensing fee

To apply the schedule, bills for drugs and pharmacy services must be required to include the dispensed NDC, and bills for repackaged drugs must also include the NDC of the underlying drug product from the company that originally labeled the product.

To forestall disputes over whether or not the Medi-Cal dispensing fee must be paid twice, the language should be modified so that it is clear that a single dispensing fee is required.

We have heard a concern that not all NDCs of original labelers appear in the Medi-Cal database. It has been suggested this may be especially true of larger quantity ("barrel quantity") NDCs. Since repackagers order from labelers in large quantities, we recommend looking into this issue to verify that the original labelers' high-quantity NDCs appear in the database. If they do not, a solution would be to modify the pharmaceutical calculator to operate off the first nine digits of the NDC. The last two digits indicate the NDC quantity but do not change the reimbursement for the drug dispensed and are therefore not needed to calculate the allowance. The system could be modified to verify an NDC's first nine digits instead of the usual eleven, then to apply the unit price as before. This would enable the system to accurately calculate the product allowance regardless of the NDC quantity.

**9789.40**

### **Recommendation**

*(a) The maximum reasonable fee for a pharmacy services or drug rendered after January 1, 2004 is 100% of the fee prescribed in the relevant Medi-Cal payment system. Reimbursement for a pharmacy service or drug not covered by the relevant Medi-Cal payment system shall not exceed 100% of the fee paid by Medi-Cal for a comparable drug or service. 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](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*

### **Discussion**

We recommended modifications that expressly state the requirements for pharmacy services or drugs not covered by the Medi-Cal payment system as specified in Labor Code sections 5307.1(a) and (d). These modifications are necessary to help prevent additional loopholes that may otherwise arise.

## Recommendation

*(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 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 an intermediate care facility.~~*

## Discussion

We recommend removing the language that adds a dispensing fee and replacing it with language in sub-paragraphs to cover those instances where the dispensing fee is not already addressed by the Medi-Cal methodology. Without this change, the regulation could be interpreted to allow two dispensing fees: the one specified here and the one that is already part of the section 14105.45 Medi-Cal allowance.

## Recommendation

*(b)(1) ~~If the National Drug Code reimbursement 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 manufacturer appears in the Medi-Cal database determined by Medi-Cal, then the maximum reasonable fee shall be the reimbursement, including the dispensing fee 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 manufacturer as it appears in the Medi-Cal database, calculated on a per unit basis.~~*

## Discussion

The recommended changes:

- Clarify that the maximum fee is the amount allowed by Medi-Cal, which comprises the fee for the drug and the dispensing fee
- Deletes the reference to the National Drug Code that is addressed, instead, in (b)(3)
- References the original labeler rather than the original manufacturer since the company that manufactured the drug product is not necessarily the same company as the one that originally labeled it
- Deletes “calculated on a per unit basis” since the Medi-Cal factors are already expressed on a per unit basis
- Simplifies the language and makes the meaning clearer

## Recommendation

*(b)(2) ~~If the National Drug Code reimbursement for neither the drug product as dispensed is not in the Medi-Cal database and the National Drug Code for, nor the underlying drug product from the original manufacturer labeler is not in the determined by Medi-Cal database, then the maximum reasonable fee reimbursement shall be the average wholesale price of reimbursement, including the dispensing fee, allowed pursuant to section 14105.45 of the Welfare and Institutions Code by Medi-Cal for the lowest priced therapeutically or pharmaceutically equivalent drug product covered by Medi-Cal minus 17 percent, calculated on a per unit basis. If no reimbursement for a therapeutically or pharmaceutically equivalent drug product is determined by Medi-Cal, then the reimbursement shall not exceed the lowest average wholesale price of the therapeutically or pharmaceutically equivalent drug product, minus the percentage of the average wholesale price specified in the calculation of the estimated acquisition cost of~~*

legend and non-legend drugs in section 14105.45 of the Welfare and Institutions Code, plus the dispensing fee allowed pursuant to section 14105.45 of the Welfare and Institutions Code.

### **Discussion**

Therapeutically or pharmaceutically equivalent drugs are comparable drugs. The statute requires drugs and pharmacy services not covered by Medi-Cal to be reimbursed no more than the fees paid by Medi-Cal for comparable drugs and pharmacy services (Labor Code section 5307.1(d)). Reimbursement at average wholesale price minus 17 percent (AWP – 17%) will often exceed the 100% of Medi-Cal limit. Therapeutically and pharmaceutically equivalent drugs covered by Medi-Cal must be paid, therefore, according to the Medi-Cal methodology, as the statute requires.

A drug should only be paid according to the formula in section 14105.45 of the Welfare and Institutions Code (plus the Medi-Cal dispensing fee) if no reimbursement for any therapeutically or pharmaceutically equivalent drug product is determined by Medi-Cal.

Although section 14105.45 specifies a 17 % AWP reduction, and a \$7.25 professional fee for dispensing (\$8.00 if the patient is in a skilled nursing facility or an intermediate care facility), citing the section in lieu of the percentage or dollar amount will keep the formula and dispensing fees parallel with Medi-Cal's. Without this change, the Division must modify this regulation every time that the Medi-Cal dispensing fee is changed. Those fees have changed about once a year during the past several years. I understand that in light of the well-publicized AWP abuses, Medi-Cal is now considering moving away from the use of AWP in favor of a cost-based factor.

### **Recommendation**

(b)(3) Each billing for a drug product shall include an accurate National Drug Code for the product dispensed, and if reimbursement for the dispensed drug product is not allowed by Medi-Cal, shall also include the National Drug Code for the underlying drug product from the original ~~manufacturer~~ labeler.

### **Discussion**

Without the National Drug Code of the underlying drug product from the company that originally labeled the product, there will be no way to provide reimbursement equal to that of equivalent or comparable pharmacy products allowed by Medi-Cal. The NDC codes must be supplied on the billing otherwise the reviewer will have no way of identifying the company that originally labeled the product and its NDC code.

### **Recommendation**

(c)(1) "therapeutically and pharmaceutically equivalent drugs" means are drugs that have been assigned the same Therapeutic Equivalent Code starting with the letter "A" and including "B" codes 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>;

## Discussion

Therapeutically or pharmaceutically equivalent drugs are comparable drugs. To provide equivalent payment for equivalent drugs, it is important to clarify that equivalent payment will be provided to drugs that are therapeutically and/or pharmaceutically equivalent, including drugs with codes beginning with "A" and "B" codes.

## Recommendation

*(c)(2) "National Drug Code for the underlying drug product from the original ~~manufacturer-labeler~~" means is the National Drug Code of the drug product actually utilized by the repackager in producing the repackaged product assigned to the company that originally labeled the underlying drug product, as it appears in the Medi-Cal database.*

## Discussion

The recommended language will clarify that National Drug Code for the underlying drug product is the code from the company that originally labeled the underlying drug product and not an NDC from another intermediary. Requiring the NDC from another intermediary will create yet another loophole since reimbursement may not be determined by Medi-Cal for that intermediary's NDC.

Substituting the term "labeler" for "manufacturer" throughout the regulation is necessary since a pharmaceutical company often uses one company to fabricate its products and another to label them.

I hope that these refinements will help in the effort to craft regulations that deploy the Medi-Cal payment methodology to the maximum extent possible and to all dispensers.

Thank you for your consideration. Please contact me for further clarification or if we can be of any other assistance.

Sincerely,

Brenda Ramirez  
Claims and Medical Director

BR/pm

cc: Carrie Nevans, Administrative Director  
Anne Searcy, M.D., DWC Medical Director  
Susan McKenzie, M.D.  
Jackie Schauer, DWC Counsel  
CWCI Claims Committee  
CWCI Medical Care Committee  
CWCI Associate Members