

WORKING P A P E R

Paying for Repackaged Drugs Under the California Workers' Compensation Official Medical Fee Schedule

BARBARA O. WYNN

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Robert T. Reville, Director RAND Institute for Civil Justice, 1776 Main Street, P.O. Box 2138 Santa Monica, CA 90407-2138. Phone: (310) 393-0411 x6786; Fax: (310) 451-6979 E-mail: Robert_Reville@rand.org Web: www.rand.org/icj/

Robert H. Brook, Director, RAND Health, 1776 Main Street, P.O. Box 2138 Santa Monica, CA 90407-2138 Phone: (310) 393-0411 x E-mail: Robert_Brook@rand.org Web: www.rand.org/icj/

PREFACE

The working paper considers potential options for establishing the maximum allowable fees for repackaged drugs that are provided to California's injured workers. These are drugs that have been purchased in bulk and repackaged into individual prescription sizes for physician office dispensing. The maximum allowable fees for most pharmaceuticals under the workers' compensation program are tied to the MediCal pharmacy fee schedule. However, repackaged drugs are not in the MediCal formulary and higher fees are allowed for repackaged drugs until the Division of Workers' Compensation (DWC) Administrative Director (AD) issues a fee schedule amount for them.

The work presented here was performed for the Commission on Health and Safety and Workers' Compensation and the Division of Workers' Compensation, California Department of Industrial Relations under Task 4 of Contract Number 40336045. It is part of a broader study that examines the cost and quality issues affecting medical care provided to injured workers in California, and assesses strategies to improve the quality and efficiency of that care. The findings for the other study tasks will be reported in separate documents.

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INTRODUCTION

ISSUE

Some physicians dispense repackaged drugs to their patients. These are drugs that FDA-approved repackagers have purchased in bulk and repackaged into individual prescription sizes for physician office dispensing. The Official Medical Fee Schedule (OMFS) for pharmaceuticals is tied to the MediCal pharmacy fee schedule. The MediCal program does not pay for physician-supplied drugs and, as a result, repackaged drugs are not in the MediCal formulary. Because there is no MediCal fee schedule amount for repackaged drugs, the higher pricing policies under the prior Official Medical Fee Schedule (OMFS) continue to apply until the Division of Workers' Compensation (DWC) Administrative Director (AD) issues a fee schedule amount for them. The issue addressed in this working paper is the appropriate maximum allowable fee for repackaged drugs.

BACKGROUND

OMFS for Pharmaceuticals

Payers commonly use the average wholesale price (AWP) as a benchmark in establishing payment amounts for drugs. The AWP is self-reported manufacturer data compiled by commercial publishers of drug pricing data, such as Thomson Medical Economics (the publisher of *Red Book*) and does not reflect actual transaction prices for drugs. Typically, a fee schedule amount is a discount off the AWP.

Until January 1, 2004, the maximum allowable fee under OMFS depended on whether a brand name or generic drug was provided. The maximum allowable fee for brand-name drugs was set at 110% of the AWP plus a \$4.00 dispensing fee. For generics, the OMFS allowed 140% of the AWP plus a \$7.50 dispensing fee. A CHSWC-commissioned study found that the allowable fees represented substantial premiums over the imposed by other states' workers' compensation systems, other regulatory systems (Medicare, Federal Workers' Compensation) and private negotiated contracts (HMOs, non-occupational insurance) (Neuhauser, et al., 2002).

Beginning January 1, 2004, SB228 (Alarcón) limited the maximum allowable fee for drugs under the workers' compensation system to the MediCal fee schedule amount. Effective

September 1, 2004, the MediCal formula bases payment on the lowest of four amounts (MediCal Pharmacy Manual, 2004):

- The Maximum Allowable Ingredient Cost (MAIC) limit established for certain multi-source drugs based on a reference product that MediCal determines to be generally equivalent in quality to those products generally used by physicians throughout the state plus a dispensing fee.¹
- The Federal Allowable Cost (FAC) limit established by the federal Medicaid program for certain multi-source drugs plus a dispensing fee.
- The Estimated Acquisition Cost (EAC) limit based on the lower of the AWP minus 17 percent or the price determined for certain drugs that are frequently purchased by California pharmacies in bulk purchase sizes plus a dispensing fee.
- The charge to the general public by the pharmacy.

The MediCal professional dispensing fee is set at \$7.25 for drugs dispensed by pharmacies. The MediCal fee schedule establishes by National Drug Code (NDC) the payment amount for each drug in its formulary.² Because MediCal does not recognize the additional costs due to repackaging drugs for dispensing from physician offices and does not have repackaged drugs in its formulary, there is no established MediCal fee schedule amount for the repackaged drugs. Under the SB 228 provisions, the prior fee schedule rules apply to repackaged drugs until the DWC AD issues a fee schedule amount for them. The Labor Code provides that the maximum allowable fee adopted by the AD for drugs that are not in the MediCal fee schedule cannot exceed 100 percent of the MediCal fees for drugs that require comparable resources.

Physician-Dispensed Drugs

In the late 1980's, there was considerable debate over whether physicians should be allowed to dispense drugs to patients. Proponents argued that dispensing drugs at point-of-service was convenient for patients, provided more confidentiality and increased patient

¹A drug product is multi-source if there are three (or more) versions of the product rated therapeutically equivalent and at least three suppliers are listed in the current editions of published national compendia.

²Each drug product has a unique NDC code that contains information on the drug labeler (manufacturer, relabeler, or repackager), the product (specific strength, dosage form, and formulation for a particular labeler) and the package size.

compliance in filling and refilling prescriptions. Opponents argued that allowing physicians to profit from dispensing medications could inappropriately influence prescribing practices and that eliminating a pharmacist review of prescriptions for errors and drug interactions might jeopardize quality of care. Several Federal Trade Commission rulings upheld the right of physicians to dispense drugs, deciding that physician dispensing maximizes consumer options in purchasing of prescription drugs and might, through increased competition among physicians and between physicians and pharmacists, lead to lower prices (Vivian, 2002).

Physician dispensing is facilitated by FDA-approved repackagers who purchase drugs in bulk and repackage them into individual prescription sizes for sale by physician offices. Many of the larger repackagers, including Allscripts, Southwood, and Physicians Total Care, also market computerized medical management systems that include inventory control, information on commonly prescribed medications for given conditions, drug interactions, conflicts with payer formularies, etc. The advent of sophisticated software to support point-of-service dispensing and aggressive marketing by repackagers has increased the percentage of physicians dispensing drugs to an estimated 7-10 percent of practices. Some systems, such as Physicians Total Care, can provide on-line connectivity to pharmacy benefit managers, facilitating pre-approval and dispensing to insured patients. Other systems, such as All Scripts, also provide on-line connectivity to pharmacies to facilitate ordering of prescriptions that are not in the physician's office formulary (Borfitz, 2001; Meosely, undated; Physicians Total Care, undated; Reece, 2002; Reece, 2005).

While the debate over physician office dispensing quieted with the FTC rulings, the issues regarding the impact that physician dispensing has on quality, utilization, cost, and patient choice and satisfaction remain. We were unable to find any recent studies systematically examining these issues generally or with respect to workers' compensation patients. Below, we discuss some of the issues within the context of workers' compensation.

Legality. Section 4024(b) of the California Business and Professions Code regulates physician dispensing of medications. The Code protects patient choice by requiring that the patient be offered a written prescription before the medication is prescribed and also be given written notice that the patient has a choice between obtaining the prescription from the dispensing physician or a pharmacy.

Workers' Compensation Benefits. The California Labor Code implicitly recognizes physician-dispensed drugs as a covered service in Section 4600.1 (dealing with generic drugs) and Section 5307.1 (dealing with the fee schedule).

Ethics. The American Medical Association Code of Ethics provides that physicians may dispense drugs within their office practices as long as there is no patient exploitation and patients have the right to a written prescription that can be filled elsewhere (AMA, 2002).

Drug Safety. Computerized medical management systems are likely to address some of the quality concerns with physician dispensing. For example, drug errors are less likely to occur since all drugs are pre-packaged and bar-coded. Information on dosage strength, contraindications and drug interactions is readily available electronically. However, the primary treating physician for an injured worker is not likely to be the patient's primary care physician unless the physician was pre-designated and may be less knowledgeable regarding the other drugs the patient is taking than the local pharmacy where the patient normally fills prescriptions. Further, the computerized checks for drug errors may not be as effective as a pharmacist review.

Compliance. Greater patient compliance in filling and refilling prescriptions is frequently cited as a reason for physician dispensed drugs. While compliance with recommended medical treatment is an issue for workers' compensation patients, we are uncertain whether this concern should extend to drugs. The highest volume drugs are pain medications, for which over-utilization is the major concern. Presumably, workers would fill their prescriptions if they felt the need for help with their pain. Compliance and patient confidentiality may be more of an issue with prescriptions for depression and other mental health problems.

Convenience. Another commonly cited advantage of physician dispensing drugs is convenience for both the patient and the physician. Physician dispensing may be particularly convenient for workers' compensation patients, where some pharmacies are not willing to fill their prescriptions. Further, it offers a convenience for some physician practices by eliminating the need to call in prescriptions.

Financial Incentives. Repackagers market their services as an opportunity for physicians to increase their practice revenues. Physician dispensing may be particularly attractive to CA physicians with substantial workers' compensation patient volume because the OMFS fees for physician services are among the lowest in the nation. Concerns center on whether physician profits on office-dispensed drugs create an incentive for inappropriate prescribing practices. A

physician's profit depends on payer mix, the financial arrangements with the repackager, and volume. According to a 2001 article in *Medical Economics* (Borfitz, 2001), physicians using Physicians Total Care had an average margin of \$16 per prescription for workers' compensation compared to \$4.50 per script covered by managed care plans. Allscripts estimated profits to be about \$4–6 per prescription, with higher amounts common for self-pay and workers' compensation patients.

High profit margins create an incentive to over-prescribe medications, particularly those drugs that provide the greatest profit margin to the physician practice. Depending on the repackagers' financial arrangement with the physician and the payers' fee schedule, the most profitable drugs could be either particular brand names or generic drugs. If the fee schedule is a discount off AWP, as is the case with the OMFS rules for repackaged drugs, generic drugs may actually yield the highest return for the physician. This is because the difference between the physician's acquisition costs and the AWP is likely to be greater for generic drugs than brand name drugs.³

Cost. From the employer or payer perspective, drug costs are a function of the drugs that are prescribed, whether they are generic or brand name, the amount paid for a given prescription and the amount that is prescribed at one time for chronic conditions. Multiple prescriptions in small quantities that need to be refilled often are more expensive than single prescriptions in larger quantities. Understanding the cost implications of physician dispensing would require a comparative analysis of drug costs for injured workers whose physicians who typically dispense drugs from their office with those who receive pharmacy-supplied drugs. While this would require an analysis of administrative data, more limited comparisons of the maximum allowable fees under the OMS for repackaged drugs relative to comparable drugs dispensed by a pharmacy are possible without administrative data.

³A 2002 study conducted by the Office of the Inspector General for the Department of Health and Human Services found a wide range of variation in the relationship between the AWP and estimated acquisition cost (EAC) that depended on the category of drug. Pharmacies purchased single source brand name drugs at an average cost of 82.8 percent of AWP compared to multiple source drugs with federal upper limits at 27.9% of AWP (Department of Health and Human Services, 2002).

ANALYSIS OF OMFS ALLOWANCES

A California Workers' Compensation Institute (CWCI) study of pharmacy costs reported national information on the top drugs furnished to injured workers (CWCI, 2002). Using the highest volume drugs on this list, we priced what would be allowed if they were dispensed by a pharmacy using the MediCal pharmacy fee schedule. We compared this to the amount that would be allowed for repackaged drugs using the prior OMFS pharmacy fee schedule rules and *Redbook 2004* AWP prices for three large repackaging firms: Allscripts, Physicians Total Care, and Southwood. Without analysis of administrative data, we do not know the extent to which these particular repackaging firms market to physicians treating workers' compensation patients in California. The findings are for purposes of illustrating the potential differences in OMFS allowances between non-repackaged and repackaged drugs. A detailed explanation of our methodology is in Appendix A. The amount allowed under the OMFS for pharmacy-dispensed drugs is based on the MediCal fee schedule and is shown in Columns E and F. The OMFS (MediCal) allowance for a brand name drug is shown in Column E. For example, when a physician prescribing Ultram indicates only the brand name should be dispensed, the OMFS (based on MediCal) allowance is \$111.19.⁴ If the brand name is not required, the fee schedule amount will be \$37.93 based on the fee for the generic equivalent. The allowances under the OMFS for the same drugs when they are repackaged are shown in Columns G and H.

- To compute the OMFS allowance for a brand name repackaged drug, we multiplied the *Redbook 2004* reported AWP by 1.10 and added a \$4.00 dispensing fee. For example, if the AWP for a brand name drug were \$100.00, the amount shown in Column G would be $\$100 \times 1.10 + \4.00 , or \$115.00.
- To compute the OMFS allowance for a generic equivalent repackaged drug, we multiplied the *Redbook 2004* reported AWP by 1.40 and added a \$7.50 dispensing fee. For example, if the AWP for a generic repackaged drug were \$50.00, the amount shown in Column H would be $\$50.00 \times 1.4 + \7.50 , or \$77.50.

The three selected repackagers do not necessarily offer all high volume drugs or both the brand name and generic equivalents of a particular drug. For example, while all three offer

⁴ Ultram is also marketed by the manufacturer in 10-tablet blister packs. The allowance would be \$117.29 for 10 blister packs (100 unit doses).

Ultram, only Physicians' Total Care offers Oxycontin. When they do offer the repackaged drugs, the OMFS allowances are consistently higher for the repackaged drugs than the pharmacy dispensed drugs. The findings are for purposes of illustrating the potential differences in OMFS allowances between non-repackaged and repackaged drugs and are shown in Table 1. Without an analysis of administrative data, we do not know the extent to which physicians dispense particular repackaged drugs in California and the typical dosage and units that are prescribed at one time for injured workers.

DISCUSSION OF FINDINGS AND OPTIONS FOR CONSIDERATION

The OMFS fee schedule formula that applies to the repackaged drugs was designed to encourage dispensing of generic drugs. It reflects an assumption that the AWP for generic drugs was significantly lower than the brand name equivalent. However, the AWP prices reported by the repackagers do not appear to be related to their own acquisition costs; the differential between the brand name and generic AWP for repackaged drugs is less than expected. In a few cases, the reported AWP for the repackaged generic drug exceed the reported AWP for the brand name (which is the case for the repackaged generic equivalents for Ultram offered by Physicians' Total Care and Southwood). In other cases, the AWP for the generic is lower, but the OMFS formula for generic drugs results in higher fee schedule amounts.

The policy issue is whether repackaging offers sufficient advantage to justify a higher price than pharmacy-dispensed drugs. The operational issue, if the OMFS remains linked to the MediCal fee schedule, is who should determine the actual allowable fee for these drugs.

Below, we discuss options that the AD might consider in establishing a fee schedule amount for repackaged drugs. In doing so, we take into account two sections of the Labor Code:

§5307.1(a) specifies that the pharmacy fee schedule provisions apply to both physician-dispensed drugs and pharmacy-dispensed drugs.

§5307.1(d) provides that if a drug is not covered by the MediCal payment system, the AD shall establish a maximum fee that does not exceed 100 percent of the fees paid by MediCal for drugs that require comparable resources.

In all cases, we assume that the maximum allowable fee would not exceed the physician's usual and customary charge.

Table 1 (continued)**Comparison of MediCal Fee Schedule Amounts for Pharmacy-Dispensed Drugs as of January 2005 and OMFS Fee Schedule Amounts for Repackaged Drugs Using RedBook 2004 AWP Amounts**

A	B	C	D	OMFS for Pharmacy-dispensed Drugs (MediCal)		Current OMFS for Repackaged Drugs	
Commercial Drug Name	Ingredient	Tablet Size	Number of Units	Brand Name (\$)	Generic (\$)	Brand Name (\$)	Generic (\$)
<i>Prozac</i>	fluoxetine hydrochloride	20mg	30	117.43	14.81		
All Scripts			30				119.56
Phys Total Care			30				20.14
Southwood			30				131.82
<i>Prilosec</i>	omeprazole	20mg		101.07			
All Scripts			30				181.91
Phys Total Care			30			171.64	372.02
Southwood			30			156.28	

*Ultram is also marketed in 10-tablet blister packs by the manufacturer. The MediCal fee schedule amount would be \$117.29 for 10 blister packs (100 50mg unit doses).

Option 1: Establish formula based on pre-existing OMFS formula. This option would continue the current allowances for repackaged drugs (Columns G and H). While consistent with the OMFS fee schedule requirements until the AD adopts a fee schedule amount, the option is inconsistent with the §5307.1(d) requirement that maximum allowable fees not exceed 100 percent of the fees paid by MediCal for drugs that require comparable resources.

Option 2: Establish formula based on current MediCal formula for pharmacy-dispensed drugs. This option would establish the allowance at 83% of the AWP for repackaged drugs plus the \$7.25 dispensing fee. The AWP reported for the specific NDC code would determine the maximum allowance (brand name or generic, as applicable).

On the surface, this formula appears to be consistent with §5307.1(d). However, the maximum allowance exceeds what would be payable by Medicaid for drugs requiring comparable resources in two ways:

- MediCal rules explicitly state that the additional costs of special packaging are not recognized in the fee schedule payments.
- By establishing the allowance at 83% of the AWP for the repackaged product, the formula would drop two other factors that are taken into account in establishing the MediCal fee schedule amount: the maximum allowable ingredient cost (MAIC), and the federal upper limit. The MAIC is not a common pricing factor;

however, the federal upper limit (called FAC by MediCal) is a significant pricing factor for multi-source drug products.

The potential impact that the FAC can have in determining the payment amount is seen in the difference between the MediCal brand name and generic payments for Ultram. The generic fee schedule amount, which is subject to a FAC, is 34% of the fee schedule allowance for Ultram when a physician requests that it be dispensed. In contrast, the OMFS allowance for the repackaged generic provided by Allscripts under this option would be 88% of the brand name repackaged drug. The allowable fees for repackaged generics furnished by Physicians' Total Care and Southwood would exceed the brand name amount if the amounts reported in *Redbook 2004* were used.

Option 3: Use the MediCal fee schedule allowances for pharmacy-dispensed drugs (Column E and F). This option would use the established MediCal fee schedule amounts for the same brand name, when applicable, or for the generic drug. For example, the OMFS fee schedule amount for 100 50 mg tablets of Ultram would be \$111.19 and \$37.93 if the generic equivalent were dispensed.

Arguably, this approach would be most consistent with the intent of the drafters of SB 228, who appeared to intend that the same maximum allowable fees be applicable to pharmacy-dispensed and physician-dispensed drugs and may not have recognized at the time the implications of repackaged drugs not being in the MediCal formulary. Further, the approach has the advantage of not being dependent on the AWP prices reported by a single repackager. The fee schedule would need to address situations where the particular manufacturer used by the repackager is not part of the MediCal formulary, and whether an alternative but equivalent brand name drug or generic fee schedule amount should be used. Analysis of the administrative data is needed to determine how much of an issue this would actually be.

The question is likely to arise regarding whether the MediCal fee schedule amount for pharmacy-dispensed drugs provides sufficient allowance to cover the "value added" by the convenience of providing injured workers with their medications at the site-of-service. This question cannot be answered empirically without having access to the physician acquisition costs for the drugs. However, an argument can be made that any "value added" should be covered by the dispensing fee. Moreover, in the absence of a comparative analysis of drug utilization and outcomes for injured workers when drugs are physician-dispensed compared to pharmacy-dispensed, the issue of potential inappropriate prescribing practices remains

unresolved in determining if there are offsetting factors that should be taken into consideration in determining the “value added” by physician dispensing.

Option 4: Use the MediCal fee schedule payment amounts for pharmacy-dispensed drugs minus the dispensing fee. This option would eliminate the \$7.25 dispensing fee for physician-dispensed drugs. For repackaged Ultram, for example, the allowance would be \$111.19-\$7.25, or \$103.94. The rationale would be that the fee is intended for a pharmacist consultation, and that since this is not being provided and the physician is generally being reimbursed at the same time for evaluation and management services, the dispensing fee is unnecessary and could create financial incentives for inappropriate prescribing practices.

Option 5: Establish a premium for physician-dispensed drugs in lieu of the dispensing fee. This option would establish a higher allowance for drugs that are physician dispensed (e.g., 90 percent of the AWP for pharmacy-dispensed drugs) in lieu of a dispensing fee. It would recognize that there is “value added” by physician dispensed drugs in terms of patient satisfaction, but would eliminate the incentives created by the dispensing fee to prescribe relatively small quantities of medications for chronic conditions. Whether there is empirical support for this option depends on the findings from a comparative analysis of drug prescribing patterns for physician-dispensed and pharmacy-dispensed drugs. The policy may be unnecessary if an analysis of administrative data shows there is no difference in the prescribing practices of physicians who dispense at point of service and physicians who write prescriptions to be filled by a pharmacy. Aggregate allowances for physician-dispensed drugs could be limited to the amount that would otherwise allowed using the MediCal fee schedule through a claims analysis or a policy-determined lower amount.

Options 3-5 are all variants off the MediCal fee schedule. Relative to Option 2, they would link maximum allowable fees to the MediCal fee schedule. In doing so, the options generate administrative savings because the burden of determining the base allowance would rest with MediCal. Under Option 2, either the payer (which is likely to lead to disputes given multiple sources for AWP prices) or DWC would need to calculate the maximum allowable fees and keep them updated on a regular basis. Another advantage of Options 3-5 over Option 2 is that they do not depend on the AWP price reported by a single repackager. The policy choice among Options 3-5 depends in large part on an assessment of the “value added” for physician-dispensed drugs. Option 3 is attractive in that it provides a “level playing field” for pharmacy-dispensed and physician-dispensed drugs. It is possible, however, that the allowances could

create inappropriate financial incentives and that a lower amount would still adequately reimburse those physicians who choose to dispense drugs at site-of-service without creating incentives for inappropriate prescribing practices. A comparative examination of drug utilization would shed some light on the extent to which there are differences in the prescribing practices of physicians who dispense drugs and those who do not.

APPENDIX A

Technical Explanation of Table 1

The list of drugs in Table 1 were identified as the top 11 drugs reported for workers compensation programs from national proprietary drug information in 2001 exclusive of Celebrex and Vioxx. The source for the drug listing was California Workers' Compensation Institute, *Pharmaceutical Cost Management in California Workers' Compensation: A Report to the Industry*, November 2002.

We used the FDA's National Drug Code (NDC) Directory to identify the active ingredients for the drug. The directory is at <http://www.fda.gov/cder/ndc/database/default.htm>. We then used *Redbook 2004* to assign an NDC number for the brand name drug and drugs repackaged by three repackagers in both the generic and brand name form: Allscripts, Physicians Total Care and Southwood. We do not know the extent to which these repackaging firms actually market to California physicians treating workers' compensation patients. Generally, we chose a medium-high dose of each drug and a prescription size offered by the repackagers to establish the NDC code. We do not know whether these are commonly prescribed drugs in typical dosage and units for workers' compensation patients. Analysis of administrative data is needed to make this determination. For multi-source drugs, we did not determine whether the particular brand name is in the MediCal formulary. The formulary includes drugs from manufacturers who have agreed to drug rebates and discounts.

We used the fee schedule calculator on the Division of Workers' Compensation Website to calculate the maximum allowable fee for each drug. The fee schedule at <http://www.dir.ca.gov/dwc/pharmfeesched/pfs.asp> was effective January 2005. We also reviewed MediCal's *Maximum Allowable Ingredient Cost (MAIC) and Federal Allowable Cost (FAC) List* that contains the maximum cost limits for certain drugs. We had downloaded this listing from the MediCal fee schedule website on February 3, 2005 (<http://files.medi-cal.ca.gov/pubsdoco/Pubsframe.asp>).

The OMFS fee schedule amount for pharmacy-dispensed drugs is based on the MediCal fee schedule amount. It is calculated as: unit cost x units + \$7.25. Where applicable, we calculated both the fee schedule payment for the brand name drug (Column E) and the generic drug (Column F). One of the top-listed drugs was a generic (acetaminophen/hydrocodone

bitartrate) and another is subject to the FAC (Darvocet (acetaminophen/ propoxyphene napsylate). We calculated the fee schedule amount for these drugs using the unit cost on the MAIC/FAC list.

We used the *RedBook 2004* AWP prices reported by the repackagers for the selected drugs (brand name and generic equivalents). We then calculated the amount that would be allowed under the current OMFS for drugs that are not in the MediCal formulary. We used the following formula:

$$\text{brand name} = \text{AWP for brand name} \times 1.10 + \$4.00$$

$$\text{generic} = \text{AWP for generic brand} \times 1.40 + \$7.50$$

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