



Report to the Legislature

**SHB 1128
Brand Name Medications**

Chapter 522, Laws of 2007 Substitute Bill 1128

Section 209(17)

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Financial Impacts of Brand-Name Medications versus Generics: HRSA Report to the Legislature

EXECUTIVE SUMMARY

A legislative proviso from the 2006-07 session (SHB 1128 Sec 209 (17)) directed the Department of Social and Health Services (DSHS) to assess the potential for state savings when selecting a brand or its competing generic equivalent.

Context for understanding the study results:

Drug pricing is complicated but a few general observations about the “life cycle” of drug pricing should make the results in this report more understandable. First, pricing for all prescription drugs, whether brand or generic, can and will vary on a weekly basis. Second, the actual difference in price between any specific brand and its generic equivalent will change in direct relation to each other over time. Typically, a brand’s price begins to fall after patent protection ends and its generic equivalent is introduced to the market. During the initial six months, generally only one generic manufacturer is given exclusive rights to enter the market. After the six months of exclusivity, other generic manufacturers enter the market and head-to-head competition pushes both brand and generic prices downward.

Strong external market forces promote generic use when a brand’s patent protection ends. Generic substitution rules from private payers, lower acquisition costs, and opportunities for improved profit margin to the pharmacies, are often enough to move market share away from brand and toward the generic equivalent — often within a month of its initial introduction.

That is generally the pricing “life cycle” pattern for a brand and its generic equivalent, but there are always some exceptions. The key point is that by narrowly focusing and selecting the low cost winner based on an imprecisely timed and time-limited savings, the state must consider how its current Preferred Drug List could possibly respond at precisely the right moment, and how health providers will react to more frequent changes to the state’s choice of preferred drugs – especially when scheduled on a non-routine and unexpected basis.

Summary of findings:

- ▶ Results show the generic equivalents are almost always less expensive than the brand-name drug over time. Thus, promoting generic use appears to offer the best course for state savings over the long-run.

- ▶ While a few brands examined were less expensive than their newly marketed generic equivalents for a limited time period, the opportunity for savings with the brand was time limited.
 - ▶ Brands that did have continuing lower net costs were very few in number, had much higher initial expenditures, and only very limited net savings.
 - ▶ Market-driven pharmacy preferences—rather than a drug’s price to the Medicaid program—appear to drive general utilization. The results show that even when a brand was identified as preferred, the pharmacies took the extra steps necessary to dispense the generic.
 - ▶ The commercial insurance market also appears to drive utilization to newly introduced generics which suggests preferring use of a lower net-cost brand-name drug will only pit Medicaid against private insurers’ powerful generic preference in the market.
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BACKGROUND

SHB 1128, Sec. 209(17) Proviso

(17) The department shall conduct a study to determine the financial impact associated with continuing to cover brand name medications versus the same medication in its generic form. The study shall account for all rebates paid to the state on each product studied up until the point where the generic form is less expensive, net of federally required rebates. The department shall submit its report to the legislative fiscal committees by December 1, 2007.

In addition to the proviso, Senator Prentice instructed HRSA to include several products in the study.

Notes on the completed study

Rebate amounts used in this report are based on National Drug Code (NDC) specific Unit Rebate Amounts (URAs), as invoiced to the drug manufacturer for the calendar quarter studied. These amounts can change and subsequent corrections to the original quarterly invoices are also included in the study. However, the rebate amounts used in the study do not reflect amounts actually “paid” to the state -- instead they show amounts invoiced to the manufacturers for future payment.

Study design and report elements

- ▶ Brand-name drugs and their generic equivalents were selected from the Washington State Preferred Drug List and represent a good comparison group for brand and generic costs.¹

¹ Drug names are masked to comply with CONFIDENTIALITY PROVISIONS in SSA Section 1927(b)(3)(D)

- ▶ The analysis compared the average daily net cost of a specific brand-name drug to the average daily net cost of its generic equivalent.
- ▶ The analysis compared the aggregate (or total) net cost for a brand-name drug to the total net cost for its generic equivalent.
- ▶ The study measured time on market for a generic equivalent to reach the average daily net cost of brand.
- ▶ The study sampled retail pharmacies to estimate their acquisition cost for a brand-name drug versus their acquisition cost for its generic equivalent.

Data for the report

Information for this report was obtained from Health and Recovery Services Administration's "HealthWatch Technologies Single Data Source" database which covered the period from July 1, 2005, through June 30, 2007 (State Fiscal Years 2006 and 2007).

- ▶ The information is displayed by calendar quarters for each state fiscal year.
- ▶ Expenditures and average daily net costs are reported for Point-of-Sale (POS) transactions only, which are limited to prescription drug claims submitted by an outpatient pharmacy.
- ▶ Net cost calculations include nationally established "Unit Rebate Amounts" (URAs) per the Omnibus Budget Reconciliation Act (OBRA 90) rebate requirements.

How average daily net cost was calculated

- Average net cost per unit = State's maximum allowable cost² less the federal URA³.
- Total Net Cost per NDC = Average net cost per unit times total units dispensed within date span.
- Average daily net cost = Total net cost per NDC divided by total days supplied.⁴

Maintaining the confidentiality of manufacturer rebates

The actuarial firm Milliman, Inc. has reviewed the summarized cost data, associated calculations and the report narrative to help assure compliance with legislative requests as well as the accuracy of the results and conclusions. However, to avoid violating Medicaid's federally-protected, pharmaceutical manufacturer rebate confidentiality rules, the specific drug names used in the study were excluded from this version of the report.

² State's maximum allowable cost in this data is the lesser of AWP-14%, Federal Upper Limit (FUL), Automated Maximum Allowable Cost (A-MAC), AWP-50%, or State Maximum Allowable Cost (S-MAC).

³ Federal unit rebate amount is the invoiced rebate amount (including subsequent quarter corrections from Centers for Medicare & Medicaid Services (CMS)).

⁴ Days Supplied is a field value in the Point of Sale system and contains the "days supplied" as reported by the dispensing pharmacy.

FINDINGS

A total of 18 pairs of drugs (i.e., a brand-name drug with its generic equivalent) were examined over eight State Fiscal Year quarters. Of the 18 brand-generic pairs examined, 15 are in therapeutic classes that are on the Washington State Preferred Drug List (PDL).

Findings for generics available throughout the 24-month study window

Cost of brand higher than cost of generic (See Graph A for an example.)

1. Within the group that had generics available throughout the study window, 10 of the 13 pairs (76.9%) produced a higher average daily net cost for brand than for the generic equivalent.

On average in this group of drug pairs:

- ▶ Generics were utilized about 4 to 1 over the brand-name drugs.
- ▶ Average daily net costs for the brand-name drugs were approximately two to three times higher than for their corresponding generics.

For the entire group of 10 pairs taken as a whole, the average daily net costs were approximately \$3 for the brand-name drugs as compared to about \$1 for the generics.

Cost of generic higher than cost of brand (See Graph B for an example.)

2. Among the 13 brand-generic pairs where a generic equivalent was available throughout the period studied, three showed generic equivalents with higher average daily net cost than their brand counterpart (pairs 1, 13, and 17).

On average, in this smaller group of drug pairs:

- ▶ Generics were dispensed to Medicaid clients roughly 9 times more often than were their brand-name equivalents.
- ▶ The average daily net cost difference was relatively small: generic equivalent costs were approximately 12% higher than for the corresponding brand-name drug.

In total for this group, the average daily net costs were approximately \$2.79 for brand-name drugs and \$3.40 for generics or a difference favoring brands of 61 cents per day, on average for all 3 pairs combined.

3. More specifically, Pair 1 in this group showed generic average daily net cost to be 22 % higher than the name-brand's average daily net cost (when averaged over the eight quarters of the study period).

- ▶ The low average daily net cost for the brand in this pair is due to high federal rebates, which range (over the period studied), from 56% to 86% of the up-front cost to the state. This brand-name drug showed dramatic fluctuations in unit rebate amounts over the course of the study window.
 - ▶ A check of retail pharmacy acquisition costs for this drug pair found that a commonly used strength of the brand-name cost a pharmacy more than twice as much as the generic.
 - ▶ On average, the generic was dispensed 9 to 1 over the brand in this pair.
4. Pair 13 in this group shows the generic with an average daily net cost that was 117% higher than the brand-name drug. For this pair, net costs averaged 61 cents a day for the generic versus 28 cents for the brand (averaged over the eight quarters of the study period).
- ▶ Federal Unit Rebate Amounts for the brand-name drug varied by quarter from a low of 2.3% of up-front expenditures in 1QtrSFY06 to 6.8% for all of State Fiscal Year 2007.
 - ▶ The brand-name drug in this pair also showed only a small amount of utilization with only \$60,000.00 in expenditures within the study period.
 - ▶ The spread between the relative net costs was decreasing over time and at the end of the study period the average daily net cost of the brand was 17 cents less than the generic.
 - ▶ On average the generic was utilized 10 to 1 over the brand.
5. Pair 17 showed generic average daily net cost 12% higher than the brand-name drug. Utilization of both drugs in this pair was minimal.
- ▶ Federal rebates on the brand accounted for anywhere from 31.6% to 43.01% of the difference between the brand's up-front cost and net cost.
 - ▶ Showing a similar pattern to the other pairs in this group, the generic equivalent was dispensed roughly 94% of the time within this pair over the 24-month period.

Findings for the three brand-generic pairs where the generics became available during the last half of the study window (See Graph C for an example.)

6. Among this group, generics had a greater average daily net cost than the brand-name drugs during the generics' first months on the market.
7. Within 6 months of the generics appearing on the market, their average daily net costs became roughly comparable to the average daily net cost of their corresponding brands.
8. Within 9 to 12 months, the average daily net cost of the generic equivalents in this group fell below the average daily net cost of their paired name-brand.

9. For all 3 pairs in this group, as soon as a generic was available, it rapidly gained market share. This happened before any Medicaid intervention occurred (such as cost controls or preferred drug status.)

CONCLUSIONS

1. **In the aggregate, generics provide a lower net cost to the state than their brand-name equivalents. Generics also have lower up-front cost⁵ to the state.**
 - ▶ Out of 18 brand-generic pairs examined in this study, 14 showed lower average daily net costs for the generic equivalent. (See Attachment A.)
 - ▶ Only 4 pairs showed lower average daily net costs for the brand.
 - ▶ Finally, looking closely at these 4 pairs (1, 12, 13, and 17) in order to assess how the state could take further advantage of the net cost difference, some common patterns emerge:
 - High generic utilization rates completely independent of new state interventions;
 - Generic prices falling predictably over time—within 6 months their average daily net costs became comparable to brand; and within 9 to 12 months their average daily net costs were the same or lower than the brand-name drug.
 - For Pair 13, unit costs of both brand and generic were well under \$1.00 and the relative difference between them was narrowing toward the end of the study period. Generics were utilized at a rate of 10 to 1 over the brand.
 - For Pairs 1, 12, and 17, the lower average daily net cost for brands was attributable to the high federal rebates. That is, the average daily cost before the federal rebates is actually higher for the brands than the generics. Therefore, while the ultimate cost may be lower for these brands, the long term savings requires an initial investment due to the higher up-front cost, which can take months to years to recoup from the drug manufacturers.
 - Steering utilization to the brands in this situation would result in expending more money up-front and waiting for the investment to be returned to the state months, or even years later in the form of federal rebates.⁶

⁵ Up-front cost is the initial expenditure or outlay of taxpayer money. Net costs after federal rebates are not realized until the rebates are collected.

⁶ For example, in one pair of drugs studied, hypothetically, if all units dispensed over the study period had been brand-name and were paid at an average of Medicaid's standard payments for the brand—the "up-front"

2. Time value of money and return on investment should be considered when selecting drugs based on lowest net cost to the state.

- ▶ Federal drug rebates are invoiced once quarterly, approximately 60 days after the end of the quarter. Manufacturers then have 38 days to pay after being invoiced. However, federal rebate rules allow manufacturers to adjust rebate amounts for up to three years after the rebate period. Moreover, utilization numbers may be disputed indefinitely by manufacturers, further delaying payments.
- ▶ Choosing a lower net-cost brand purely on the basis of high federal rebates may not be fiscally or strategically advisable. Federal rebate amounts are changeable and beyond the state's control. The state must weigh the comparative return on investment, the risks involved, and the amount of time it takes to collect on the predicted rebates.

3. Utilization of generics appears to be driven by market forces outside of state influence.

- ▶ In all examined pairs, the data shows a rapid move to patient use of the generic equivalent as soon as it is available—regardless of pricing limits or introducing administrative hurdles. New generics gained utilization quickly and their use continued to increase while prices dropped.
- ▶ The state's ability to discourage use of a higher net cost generic (high net cost relative to the brand equivalent) will probably not be effective as long as the generic is available at a significantly lower acquisition cost to pharmacies. Pharmacies appear to quickly and persistently substitute their lower cost choice between brand and generic equivalents whenever possible. Market incentives to use the generic would quickly neutralize the state's effort to encourage use of the brand.
- ▶ If our utilization controls are not effective, we run the risk of the controls becoming only administrative nuisances (i.e. frequent PDL changes requiring more provider calls). In brand-versus-brand utilization with comparable acquisition costs, preferred drug status will probably do better to drive utilization to one drug over another. However, the availability of a generic at a lower acquisition cost to the pharmacies appears to drive pharmacy choice.

expenditure would have been \$7.8 million more than if all units were generic and paid at an average of the state maximum allowable prices for the generics. However, the net savings to the state in the brand scenario would only be about \$142,000. Although this example of high rebates and high up-front expenditures is the most extreme among the drug pairs, the interplay of expenditures, rebates and net savings are the same for all three pairs cited above. (See Attachment B.)

Report to the Legislative Fiscal Committees
 Budget Proviso SHB 1128, Sec. 209(17)
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Attachment A:

SELECTED DRUG CLASS UTILIZATION - AVERAGE NET DAILY COST
 STATE FISCAL YEAR 2006 AND 2007

DRUG			AVERAGE NET DAILY COST							
			1ST 06	2ND 06	3RD 06	4TH 06	1ST 07	2ND 07	3RD 07	4TH 07
TOTAL OF LISTED DRUGS - BRAND W/TRUE GENERIC	BRAND		\$2.14539	\$2.24373	\$2.20490	\$2.06936	\$1.97876	\$1.87366	\$2.14901	\$2.12994
	GENERIC		\$1.26303	\$1.18902	\$1.09820	\$0.99785	\$1.01591	\$1.06518	\$1.13168	\$0.96625
PAIR 1	BRAND		\$4.81125	\$6.15657	\$6.34907	\$7.22470	\$7.16356	\$7.38575	\$3.98818	\$2.77059
	GENERIC		\$6.83934	\$6.36163	\$7.31750	\$6.64684	\$7.11778	\$8.07008	\$7.18114	\$6.48619
PAIR 2	BRAND		\$1.76610	\$1.9592	\$1.4358	\$1.5493	\$1.2784	\$1.1655	\$1.2823	\$1.1910
	GENERIC		\$0.53652	\$0.5312	\$0.5008	\$0.4735	\$0.4771	\$0.4851	\$0.4865	\$0.4718
PAIR 3	BRAND		\$5.20343	\$12.4271	\$18.6866	\$16.2238	\$21.1217	\$29.4199	\$19.8362	\$2.3456
	GENERIC		\$2.89713	\$2.8401	\$2.1495	\$2.1582	\$2.1353	\$2.0462	\$2.0906	\$1.5772
PAIR 4	BRAND		\$8.14072	\$12.83010	\$9.30314	\$9.39618	\$9.08121	\$9.24146	\$7.89372	\$7.68843
	GENERIC		\$8.45237	\$5.91356	\$7.26252	\$6.85349	\$4.62807	\$3.39158	\$4.03931	\$6.63095
PAIR 5	BRAND		\$4.53397	\$5.02285	\$5.07371	\$4.62489	\$4.89195	\$5.15705	\$4.95740	\$4.84033
	GENERIC		\$1.94905	\$1.98650	\$1.84309	\$1.77285	\$0.58310	\$0.61320	\$0.64287	\$0.58796
PAIR 6	BRAND		\$2.61956	\$2.54996	\$2.56478	\$2.48414	\$2.71702	\$2.61753	\$3.04404	\$2.87932
	GENERIC		\$1.62513	\$1.78811	\$1.67147	\$1.27543	\$1.28105	\$1.28148	\$1.58871	\$1.54383
PAIR 7	BRAND		\$1.58118	\$2.01666	\$1.80511	\$1.99844	\$1.95450	\$2.22239	\$2.98803	\$2.21503
	GENERIC		\$0.39767	\$0.40547	\$0.25198	\$0.12895	\$0.12897	\$0.12880	\$0.12946	\$0.12066
PAIR 8	BRAND		\$0.42106	\$0.47152	\$0.31853	\$0.36224	\$0.42016	\$0.31927	\$0.35286	\$0.37335
	GENERIC		\$0.28631	\$0.28914	\$0.30460	\$0.31031	\$0.31467	\$0.32995	\$0.27153	\$0.23683
PAIR 9	BRAND		\$2.41280	\$2.41232	\$2.93209	\$1.73191	\$0.93709	\$0.58155	\$1.02433	\$1.52478
	GENERIC		\$0.50344	\$0.49024	\$0.43864	\$0.38924	\$0.38816	\$0.38774	\$0.38438	\$0.34395
PAIR 10	BRAND		\$1.73678	\$2.27919	\$1.91450	\$1.94608	\$3.60840	\$3.71175	\$3.08333	\$1.45278
	GENERIC		\$0.76144	\$0.73167	\$0.74547	\$0.64332	\$0.60112	\$0.60661	\$0.61215	\$0.47727
PAIR 11	BRAND		\$2.40812	\$2.47908	\$2.54138	\$2.60814	\$2.56410	\$2.07412	\$2.09258	\$1.87332
	GENERIC		\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$2.94463	\$2.42504	\$2.56361	\$0.68021
PAIR 12	BRAND		\$1.77551	\$1.88033	\$1.89270	\$1.76886	\$1.73441	\$1.86685	\$1.47818	\$1.11905
	GENERIC		\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$3.71742	\$3.45127	\$3.68484	\$3.35687
PAIR 13	BRAND		\$0.37271	\$0.36718	\$0.34057	\$0.35845	\$0.20791	\$0.21043	\$0.19994	\$0.21159
	GENERIC		\$0.78635	\$0.79076	\$0.77594	\$0.77345	\$0.45620	\$0.47901	\$0.46569	\$0.39703
PAIR 14	BRAND		\$1.96014	\$1.98018	\$1.83499	\$1.46297	\$1.10523	\$2.57276	\$1.72231	\$3.28324
	GENERIC		\$0.00000	\$0.00000	\$0.00000	\$3.10967	\$2.98835	\$2.68519	\$1.98834	\$0.38592
PAIR 15	BRAND		\$2.31286	\$2.36739	\$2.44498	\$2.42802	\$1.53343	\$2.20705	\$1.61973	\$1.63573
	GENERIC		\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$3.63429	\$3.09444	\$2.99725	\$0.93818
PAIR 16	BRAND		\$1.40483	\$1.53251	\$1.55935	\$1.54758	\$1.54716	\$1.54484	\$1.92623	\$1.17027
	GENERIC		\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$0.00000	\$1.82835	\$1.57520
PAIR 17	BRAND		\$2.16443	\$2.36375	\$2.17019	\$2.20242	\$2.12070	\$2.04285	\$3.23112	\$1.94292
	GENERIC		\$2.52617	\$2.61512	\$2.44113	\$2.47874	\$2.71830	\$2.57045	\$2.60529	\$2.57108
PAIR 18	BRAND		\$1.59667	\$2.21005	\$3.45773	\$3.88688	\$3.46950	\$4.56129	\$5.46011	\$5.33414
	GENERIC			\$0.28251	\$0.28002	\$0.27900	\$0.26231	\$0.26248	\$0.25994	\$0.26622

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Attachment B:
 SELECTED DRUG EXPENDITURES - FEDERAL REBATES
 STATE FISCAL YEARS 2006-2007

		PAIR 1		PAIR 13		PAIR 17		PAIR 12
1ST QTR 2006								
	COST	\$211,898.66		\$15,153.70		\$6,050.19		\$174,146.62
	REBATE	\$128,774.64		\$352.20		\$2,272.16		\$82,858.96
	%	60.77%		2.32%		37.56%		47.58%
2ND QTR 2006								
	COST	\$192,780.47		\$15,224.22		\$7,508.61		\$174,553.60
	REBATE	\$108,410.83		\$372.99		\$2,648.73		\$81,603.00
	%	56.24%		2.45%		35.28%		46.75%
3RD QTR 2006								
	COST	\$86,238.97		\$4,974.76		\$3,063.43		\$73,240.47
	REBATE	\$52,734.95		\$154.70		\$1,201.41		\$37,534.62
	%	61.15%		3.11%		39.22%		51.25%
4TH QTR 2006								
	COST	\$78,053.72		\$5,962.93		\$4,449.79		\$69,864.58
	REBATE	\$44,480.53		\$265.44		\$1,507.36		\$38,711.48
	%	56.99%		4.45%		33.87%		55.41%
TOTAL SFY 2006								
	COST	\$568,971.82		\$41,315.61		\$21,072.02		\$491,805.27
	REBATE	\$334,400.95		\$1,145.33		\$7,629.66		\$240,708.06
	%	58.77%		2.77%		36.21%		48.94%
1ST QTR SFY 2007								
	COST	\$72,497.52		\$3,527.05		\$4,459.24		\$43,700.74
	REBATE	\$43,083.96		\$275.13		\$1,579.33		\$24,719.27
	%	59.43%		7.80%		35.42%		56.56%
2ND QTR SFY 2007								
	COST	\$74,391.32		\$3,851.60		\$2,873.25		\$15,775.21
	REBATE	\$44,323.96		\$311.96		\$908.03		\$8,376.89
	%	59.58%		8.10%		31.60%		53.10%
3RD QTR SFY 2007								
	COST	\$65,845.30		\$3,841.04		\$2,798.15		\$7,849.71
	REBATE	\$50,594.50		\$296.55		\$0.00		\$4,522.31
	%	76.84%		7.72%		0.00%		57.61%
4TH QTR SFY 2007								
	COST	\$52,845.26		\$8,611.23		\$2,686.30		\$3,563.76
	REBATE	\$45,323.12		\$464.54		\$1,155.28		\$2,129.15
	%	85.77%		5.39%		43.01%		59.74%
TOTAL SFY 2007								
	COST	\$265,579.40		\$19,830.92		\$12,816.94		\$70,889.42
	REBATE	\$183,325.54		\$1,348.18		\$3,642.64		\$39,747.62
	%	69.03%		6.80%		28.42%		56.07%



