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Potential Medi-Cal Drug Expenditures Savings In the Fee-For-Service Population

For the 2002-03 fiscal year, it is expected that the Medi-Cal program will spend $3.8 billion on pharmaceuticals for its Fee for Service population. From this amount, approximately $750 million is received from CMS rebates and approximately $280 million from supplemental rebates for a net expenditure of $2.77 billion, approximately half of which is paid by the federal government.

California has long been a leader in its ability to extract significant supplemental rebates from manufacturers that offset the costs of drugs. With the expected shortfall of over $38 billion for the next fiscal year and with drug expenditures increasing significantly each year, it is imperative to review the supplemental rebate program and determine whether this program achieves optimal net savings.

The Department of Health Services' approach is a sound one and achieves the best deal for the State in therapy classes where there are no generics available, such as Angiotensin Renin Blockers (e.g. Cozaar or Diovan). Under the supplemental rebate program, the department chooses a drug in a therapy class that is both efficacious and cost-effective and negotiates a supplemental rebate for that drug. DHS then requires all other manufacturers to match that specific price for the balance of the drugs in that therapy class. If a manufacturer chooses not to participate in the supplemental rebate program, then its drug is subject to the prior authorization process, which has the effect of dramatically reducing market share of the drug.

However, in therapy classes where a generic is equally as effective as a branded product (i.e., ACE Inhibitors, Statins, NSAIDs, Antihistamines and PPIs), it is prudent for legislative policymakers to ask whether the current supplemental rebate program achieves the desired result.

This paper demonstrates that by making therapeutic substitutions of equally as efficacious drugs in just five therapy classes, ingredient cost savings of over ***$450 million*** *could be achieved. This amounts to* ***$170 million*** *more than the rebates derived from* ***all*** *drugs in the entire supplemental rebate program.*

Policymakers must decide whether California's commitment to Medi-Cal recipients is that they be provided access to every drug that is introduced into the marketplace, or that recipients should be provided with a drug(s) that achieve the desired clinical outcome.

The practice of therapeutic substitutions is being implemented by other state Medicaid agencies, Kaiser Health Plan as well as other private health plans.

Negotiating a great discount on a branded product that is not needed (due to an equally efficacious generic drug), is rarely a good deal for most states. When a branded product is first offered as a generic, there oftentimes is only one generic manufacturer and the price does not initially vary that much from the branded product. Within six months, however, when there are multiple manufacturers, generic pricing is often a mere fraction of the price of the branded product.

When the price of the generic drug reaches that point, and the department has established a MAIC (Maximum Allowable Ingredient Cost) price for that specific generic, the department should consider requiring therapeutic substitutions of that generic drug if evidence shows that it is equally as efficacious as other branded products in that particular therapy class. All other branded products in that therapy class would be subject to prior authorization unless the manufacturer matched the price of the generic.

This will result in increased costs to the prior authorization program as new protocols for approval will need to be established and prescribers will need to become familiar with which drugs require prior authorization. As DHS has always administered a cost-effective prior authorization program, the benefits of therapeutic substitution will far exceed any increased costs in the P/A program.

Listed below are several examples of therapy classes for which therapeutic substitutions are appropriate in most cases. Included where available are recommendations developed by the Oregon's Practitioner-Managed Prescription Drug Plan where evidence-based evaluations on the effectiveness of similar prescription drugs have been completed.

*Please note that the savings in the therapy classes discussed below reflect **ingredient** cost savings only. The amount of the supplemental rebate for each of these drugs is not known. The purpose of this memo is to merely show that the ingredient cost savings in just five therapy classes exceed the total amount of supplemental derived from **all** drugs.*

Statins

The branded products in this therapy class include Lipitor, Lescol, Pravachol and Zocor. Mevacor has a generic (lovastatin) but retail pharmacies are not reimbursed by Medi-Cal if they dispense the generic version of this product. These five branded products account for approximately 62,176,165 units being dispensed in calendar year 2002 at a total cost of $162,941,312.

Oregon HRC *"…the subcommittee concludes by consensus that all statins in equipotent doses are effective to reduce LDL-C up to 40%. To achieve a goal of LDL-c reduction of 40-49%, there is evidence that atorvastatin (Lipitor), lovastatin (Mevacor) and simvastatin (Zocor) are effective. Only Atorvastatin (Lipitor) at doses of 40mg or higher can achieve a reduction of 50% or greater."*

Kaiser, with 8 million participants, announced recently that they have successfully moved most of their patients to lovastatin (the generic of Mevacor) enabling them to treat five patients rather than one at the same cost.

If Medi-Cal were to follow Kaiser's practice of therapeutic substitution and dispense only Lovastatin to individuals taking these five drugs, the potential ingredient cost savings would be approximately **$113 million annually**. We acknowledge that not every single patient would meet the desired clinical outcomes by utilizing only lovastatin but many patients cholesterol management needs would have the clinical outcomes at a fraction of the cost.

We can assume that Lipitor would retain 20% of market share since it is the most potent agent in lowering LDL and its use could be limited to those individuals that must reduce their LDLs by more than 50%. In addition, an assumption could be that Zocor would retain 2.5% of the market and Pravachol would retain 7.5% of market share as this drug has shown to have some cardioprotective effects that are beneficial for patients after they have had a heart attack. Under this scenario, ingredient cost savings would be reduced from $113 million to **$95 million**. It should be noted that the generic price of lovastatin of $.80 per pill will likely decrease over the next few months, resulting in additional savings to the program.

Statins	**No. of Pills**	**Cost Per Pill**	**Total Cost**
Lipitor	32,387,614	$2.37	$76,856,723
Lescol	2,752,838	$1.60	$4,420,697
Mevacor	565,417	$2.33	$1,321,360
Pravachol	12,750,999	$2.77	$35,350,353
Zocor	13,719,297	$3.27	$44,992,179
Totals	**62,176,165**		**$162,941,312**
Lovastatin	**62,176,165**	**$.80**	**$49,740,932**
Savings Possible			**$113,200,380**
Savings Likely			**$95,195,257**

ACE Inhibitors

The major branded products in this therapy class include Prinivil/Zestril, Accupril, Altace, and Lotensin (although there are additional 5-7 drugs in this

therapy class). These five branded products account for 45,913,659 units being dispensed in calendar year 2002 at a total cost of $50,841,735. Prinivil/Zestril became available generically (lisinopril) in July of 2002 and to date Medi-Cal will only reimburse retail pharmacies if they dispense the branded version of this product. If lisinopril (generics for Prinivil/Zestril) were substituted for all drugs in this therapy class, Medi-Cal could realize ingredient cost savings of approximately **$41 million** annually.

Once again, it is not likely that 100% of individuals currently taking ACE Inhibitors would take lisinopril. Up to 20% of individuals would likely stay with the branded medications. This would reduce expected ingredient cost savings from $41,199,867 to approximately **$33 million**.

The results of the Oregon Evidence-Based Review on this therapy class are pending, but there is currently evidence showing that there is little difference between the drugs in this therapy class and that the generic Prinivil/Zestril could be easily substituted in most cases.

ACE Inhibitors	**No. of Pills**	**Cost Per Pill**	**Total Cost**
Prinivil/Zestril	12,338,851	$1.17	$14,478,217
Accupril	3,373,783	$1.00	$3,364,972
Altace	7,761,866	$1.35	$10,502,521
Lotensin	22,439,159	$1.00	22,496,025
Totals	**45,913,659**	**$1.11 (average)**	**$50,841,735**
Lisinopril	**45,913,659**	**$.21**	**$9,641,868**
Savings Possible **Savings Likely**			**$41,199,867** **$32,959,893**

NSAIDs (Non-Steroidal Anti-inflammatory Drugs)

Oregon HRC: *"…there is no evidence to demonstrate a significant difference in efficacy among COX-2 Inhibitors, COX-2 preferential NSAIDS and nonselective NSAIDS. By consensus the subcommittee raised concern that for patients taking aspirin the benefit of celecoxib (Celebrex) was obviated. Even though evidence may demonstrate decreased adverse gastrointestinal events of COX-2 inhibitors compared to other non-steroidal anti-inflammatory agents, limitations of studies currently available for review preclude a confident conclusion that these are clinically significant safety advantages. It is possible that better constructed studies may or may not yet demonstrate such differences. The subcommittee has concerns about cardiac adverse events of COX-2 inhibitors, but data is inconclusive at the present time to draw definitive conclusions. Better-constructed studies in the future may elucidate this issue as well.* ***As a result of this study, the Department of Human Services recommends the following drugs that can be used in this therapy class without an exception. They are Naproxen, Ibuprofen, Piroxicam, and Salsalate.***

Kaiser: *"Cox-2 inhibitors are no better than NSAIDS at relieving pain and inflammation, cause adverse renal, HTN, and CHF effects, similar to NSAIDS, have similar rates of dyspepsia and nausea as NSAIDS, and do not eliminate the risk of GI bleeding. ALL beneficial effects appear to be lost with low-dose aspirin use." Kaiser has been successful in reducing their COX-2 usage to 5% of patients needing medication in this class of drugs. This 5% includes those individuals who are at high-risk for GI bleeding.*

In Calendar Year 2002, Medi-Cal spent $135,733,648 on the COX-2 drugs, Celebrex, Vioxx and Bextra for 55,914,202 units. There are no prior authorization requirements for these drugs since manufacturers have paid a supplemental rebate. If these drugs were prescribed to only those individuals with a very high risk of GI bleeding (10%), ingredient cost savings of close to **$119 million annually** could be achieved. (There are many other NSAIDs that could be supplanted by Naproxen and Ibuprofen, but these were not included in this analysis as the COX-2's are by far the most costly in this drug class.) Assuming that 10% (a liberal assumption since Kaiser has limited their use of COX-2s to 5% of participants needing a drug in this therapy class) of people would need COX-2's due to GI concerns, estimated ingredient cost savings would be reduced from $119 million to **$107 million**.

Cox-2 Inhibitors	**No. of Pills**	**Cost Per Pill**	**Cost**
Celebrex	38,931,716	$2.01	$96,340,713
Vioxx	16,877,602	$2.31	$39,095,606
Bextra	104,884	$2.83	$297,329
Total	55,914,202	$2.42 (average)	$135,733,648
NSAIDS	**No. of Pills**	**Cost Per Pill**	**Cost**
Naproxen	55,809,318	$.46 $.30	$16,742,795
Ibuprofen		$.33 (average)	
Potential Savings			**$118,990,853**
Likely Savings			**$107,000,000**

Proton Pump Inhibitors

In 2002, Medi-Cal spent $223,133,623 for 55 million pills in this therapy class. When OTC of Prilosec becomes available in late summer of 2003, the price will likely decrease to $.75 per pill.

When this happens, other state Medicaid programs have indicated that the OTC of Prilosec will become the preferred drug for this therapy class and all other drugs will require prior authorization. Should the OTC of Prilosec be priced at $.75/pill, over $180 million in ingredient cost savings could be achieved.

Oregon HRC:..."There are no significant, demonstrable differences among the PPIs, whether treatment is for GERD, peptic ulcer, non-steroidal anti-inflammatory drug-induced ulcer, duodenal ulcer, or eradication of h. pylori bacteria.

PPIs	**No. of Pills**	**Cost Per Pill**	**Total Cost**
Prilosec	15,532,147	$4.40	$68,486,503
Prevacid	23,461,415	$4.22	$99,215,499
Nexium	4,802,557	$4.13	$19,867,092
Aciphex	4,677,623	$3.98	$18,595,064
Protonix	6,692,411	$2.53	$16,969,465
Totals	**55,166,153**		**$223,133,623**
OTC Prilosec		**$.75**	**$41,374,614**
Potential Savings			**$181,759,009**

If Medi-Cal covered Over-The-Counter Claritin and required all other antihistamines to be subjected to prior authorization ingredient cost savings between **$30-$40 million** could be achieved. Missouri has started to cover the OTC Claritin even though they don't typically cover OTCs.

Other therapy classes that have been evaluated by Oregon Health Resources Commission and are worth analyzing the impact of their recommendations on Medi-Cal's drug utilization data include long-acting OPIOID Analgesics for non-cancer pain, SSRIs, Triptans for Migraines, Urinary Incontinence Drugs, Skeletal Muscle Relaxants, Calcium Channel Blocks for blocking Calcium, Beta Blockers for blocking adrenaline as well as estrogen therapy drugs.

In order to accomplish therapeutic substitutions, DHS needs to develop a MAIC program (Maximum Allowable Ingredient Cost) that it does not currently have. A MAIC program would place a maximum amount that Medi-Cal will reimburse retail pharmacies for generic drugs.

The federal government has established its own program that places a maximum dollar amount that the Medicaid program will reimburse retail pharmacies on approximately 200 drugs. This program is called the FUL (Federal Upper Limit). Other states have taken it upon themselves to place a State MAIC on the drugs that presently are subject to the Federal Upper Limit, thereby further reducing the pricing of most of the drugs on the FUL.

Other states have also expanded the FUL and included an additional 200+ generic drugs. Although DHS has not implemented a MAIC program, many other states, including Delaware, Georgia, Minnesota, Missouri, Nebraska, North Carolina, North Dakota, New Mexico, Ohio, Oklahoma, South Carolina and Washington have done so - either in-house or contracting out this program to companies that have expertise in this area. Combined federal/state savings they have quoted

approximates 3-4% of total drug costs. New York is currently bidding for a consultant to set up a MAIC list.

DHS advises that there have been several factors limiting DHS from implementing a MAIC program. One factor is due to the inability of DHS to recruit pharmacists at the current salary range authorized by the Department of Personnel Administration. Another factor is that up until last year a state regulation prohibited DHS from establishing a MAIC. DHS changed the law last year, but due to the shortage of pharmacists and DHS's inability to contract this program out to the private secotr, they have been unable to implement this program. It should be noted that other states have contracted this program out to companies with expertise in this area. The advantages is doing so is that a program of this type could be operational within 90 days and the savings of 3-4% of total drug costs would be immediate.

Opponents will state that the State is trying to implement a closed formulary. This is absolutely not the case, nor would a closed formulary be good public policy. The State would merely be saying that the first prescription prescribed by a doctor should be the lower cost drug, but only if studies have shown the lower cost drug to be equally as efficacious as other drugs within a therapy class, and has no additional side effects. If that drug is not tolerated, the physician would be able to shift to another drug through the prior authorization process.

Summary

California has long been a leader in its ability to achieve the best possible price for pharmaceuticals under its Fee for Service population through its supplemental rebate program.

However, obtaining a great price on a drug that isn't needed, when there is an equally effective generic drug available, is rarely a good deal for the state. Policymakers must decide whether California's commitment to Medi-Cal recipients is that they be provided access to *every* drug that is introduced into the marketplace, or that they should be provided with a drug or drugs that achieve the desired clinical outcome.

Ingredient cost savings from utilizing generics in just *five* therapy classes (Statins, ACE Inhibitors, NSAIDs, Antihistamines, and PPIs) would approximate **$450 million**, depending upon how the program is structured. This amounts to **$170 million** more than the rebates received for all drugs from the entire supplemental rebate program.

There are various ways to implement a program of this type. California may want to have a voluntary program as Oregon has (where 30% compliance has been achieved) to a mandatory prior authorization program like Michigan's Medicaid,

where 95% compliance has been achieved. There are several degrees of adherence to prior authorization protocols as well that could be implemented.

With the State facing the prospect of reducing the eligibility level for Medi-Cal recipients, any and all efforts must be taken to achieve cost savings in the Fee for Service pharmaceutical program so that the greatest number of Medi-Cal recipients maintain their eligibility.

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