oppaga Progress Report



April 2003 Report No. 03-27

Changes to Medicaid Preferred Drug List Requirements and Competitive Bidding Pharmacy Contracts Could Save an Additional \$86.6 Million in 2003-04

at a glance

As recommended in our 2001 report, the Legislature directed the Agency for Health Care Administration to establish a mandatory preferred drug list and to negotiate supplemental rebates. During 2001-02, the agency developed procedures for and phased in a Medicaid preferred drug list. However, the agency has not implemented our recommendation to competitively bid for pharmacy services.

Based on our analysis of the 50 most expensive therapeutic categories, the preferred drug list saved Florida \$81 million in 2001-02 in combined state and federal funds. The highest percentage of savings came from drug classes containing only drugs in which manufacturers gave supplemental cash rebates. The Legislature could save an additional \$64.2 million in 2003-04 by restricting supplemental rebates to only cash rebates.

We continue to recommend that the agency competitively bid pharmacy networks, which would save an estimated \$22.4 million in 2003-04 as well as make it easier to monitor and control pharmacy error, abuse, and fraud.

Scope

In accordance with state law, this progress report informs the Legislature of actions taken by Florida's Agency for Health Care Administration (AHCA) in response to a 2001 OPPAGA review. ^{1, 2} This report assesses the extent to which the agency has taken action to address the findings and recommendations in our prior review and reports on the effectiveness of these actions.

Background

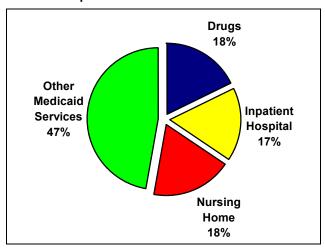
Florida's Medicaid program provides prescription drug coverage for its fee-for-service beneficiaries. ³ Medicaid covers prescription drugs as well as some over-the-counter medicines on an outpatient basis. In Fiscal Year 2002-03, prescription drug expenditures are expected to exceed \$2 billion, comprising 18% of total Medicaid spending (see Exhibit 1).

¹ Section 11.51(6), F.S.

² Justification Review: Growth in Medicaid Prescription Drug Costs Indicates Additional Prudent Purchasing Practices Are Needed, OPPAGA Report No. 01-10, February 2001.

³ Prescription drugs for eligible individuals provided by health maintenance organizations, hospitals, nursing homes, and other institutional settings are covered under those Medicaid service categories, not the prescription drug services category.

Exhibit 1
Prescription Drugs Expected to Account for 18% of Medicaid Expenditures in 2002-03



Source: Consensus Estimating Conference, March 2003.

Prior Findings

At the time of our prior report, rapid growth in spending for prescription drugs was a major factor driving projected deficits in the Medicaid budget for Fiscal Years 2000-01 and 2001-02. We noted that despite obtaining lower retail drug prices than most other state Medicaid programs, Florida's prescription drug costs per recipient were among the highest. This was largely due to doctors prescribing higher-cost drugs over lower-priced alternatives. To help control the rapid increases in the cost of Medicaid prescriptions and to promote effective drug therapies for the least cost, we recommended that the Legislature

- authorize the Agency for Health Care Administration to develop a mandatory preferred drug list, negotiate supplemental rebates, and use incentives to encourage doctors and pharmacists to comply with the preferred drug list, and
- require the agency to competitively bid contracts for Medicaid pharmacy networks.

Current Status -

Since 2000-01, the agency has made progress in slowing the growth in Medicaid expenditures for prescription drug services. Since that time, the agency has implemented major cost control initiatives that include placing monthly limits on the number of prescriptions a patient can fill, implementing a drug management program for patients who are high users of prescribed drugs, lowering drug ingredient prices, and implementing a preferred drug list. Because of these drug control initiatives, the annual growth rate in Medicaid drug costs dropped from a high of 27.8% in Fiscal Year 1999-00 to 10.3% in 2000-01 and 15.1% in 2001-02. However, we believe that additional savings can be achieved by eliminating value-added contracts and better controlling costs for drugs exempted from preferred drug list requirements.

Mandatory preferred drug list has been implemented and produced savings

The 2001 Legislature authorized the Agency for Health Care Administration to establish a mandatory preferred drug list and to negotiate supplemental rebates in addition to those required by federal law. 4 During 2001-02, the agency developed procedures for and phased in a preferred drug list. During this time, the agency negotiated supplemental rebate agreements from pharmaceutical companies, established a pharmaceutical and therapeutic (P/T) committee composed of doctors and pharmacists to recommend preferred drugs, and periodically updated the preferred drug list as negotiations and reviews of drug classes were completed. Even though all therapeutic categories had not been reviewed by the end of the year, the state realized a savings of \$81 million in combined state and federal Medicaid funds. 5 In addition, prescriber

⁴ Title XIX Section 1927 of the Social Security Act requires drug manufacturers participating in state Medicaid programs to participate in the federal Medicaid rebate program. The minimum rebate for brand name drugs must be at least 15.1% of the average manufacturer price nationwide; the minimum rebate for generic drugs must be 11% of the average manufacturer price nationwide.

⁵ See Appendix A for descriptions of the methodologies used to calculate cost savings presented in this report.

compliance with the preferred drug list has been high. ⁶

Florida's preferred drugs do not require prior authorization before being prescribed to patients. Generally, the agency places drugs on the preferred drug list only after drug manufacturers negotiate supplemental rebates and the P/T committee has reviewed the drugs for clinical effectiveness and cost. Supplemental rebates can be cash rebates or can include other program benefits that guarantee savings to the Medicaid program such as drug product donation, disease management, and prescriber counseling and education. ⁷ In addition, the agency places mental health and antiretroviral drugs on the preferred drug list because state law exempts drugs from these prior authorization requirements.

Florida can achieve additional savings by eliminating value-added contracts and seeking ways to contain costs for drugs exempted from preferred drug list requirements

In Fiscal Year 2001-02, Florida saved \$81 million in the 50 most expensive drug therapeutic categories, with the highest percentage of savings coming from drug classes composed of drugs in which all manufacturers gave supplemental cash rebates. To examine the potential for modifying the Medicaid preferred drug list to produce additional savings, we analyzed expenditures for 2001-02 in the 50 most costly therapeutic categories, constituting 79% of the total expenditures for that year. We further divided these 50 categories into four groupings.

- Managed includes medications in therapeutic categories in which drugs were placed on the preferred drug list only after manufacturers negotiated supplemental cash rebates
- Value-added includes medications in therapeutic categories in which at least one drug was placed on the preferred drug list through a value-added contract
- Exempt includes medications in therapeutic categories that are exempt by state law from prior authorization requirements
- Other includes medications in therapeutic categories that had not gone through the P/T committee process by the end of Fiscal Year 2001-02

Exhibit 2 shows that for the top 50 therapeutic categories, the Medicaid program \$81 million in 2001-02. However, the exhibit also shows that the managed group generated the greatest percentage of savings (21%). savings were due to achieving a 16% increase in the percentage of total rebates (federal and state) and a \$10 drop in the average price per prescription. In contrast, the value-added group saved less, rebated less and actually produced an increase in the average price per prescription. The value-added group generated an 11% savings, experienced a 6% increase in total rebates, and a \$1 increase in the average price per prescription.

Value-added contracts suppress cost reductions by limiting the shift in the market to drugs with lower prices or larger rebates. Negotiating cash rebates encourages manufacturers to compete to lower the unit price of their drugs through giving the state supplemental cash rebates. When reviewing therapeutic categories, the P/T committee considers clinical effectiveness as well as relative costs. During these reviews, manufacturers can compare their prices in relation to other companies. If necessary to ensure placement on the preferred drug list, companies can adjust their prices by offering the state larger supplemental cash rebates.

⁶ Although the 2001 Legislature directed the agency to use tiered dispensing fees to encourage compliance, it has not done so. According to the agency, in 2001-02, 93% of Medicaid's prescriptions were for preferred drugs and more recently, compliance was nearly 98%. While incentives are not currently needed, the agency should reconsider using them if compliance drops to some predetermined level.

⁷ The agency contracted for guaranteed savings with several manufacturers, which provide product donations and finance disease management, health literacy education, and medication error reduction programs; these agreements are referred to as value-added contracts. See Appendix B for a description of the value-added contracts.

Exhibit 2 In 2001-02, the Medicaid Preferred Drug List Saved a Net of \$81 Million in the Top 50 Most Expensive Therapeutic Categories—Managed Group Saved Relatively More

		Percentage Rebate		Average Cost of Prescription ⁴			
Preferred Drug List Groupings	Percentage of Market ¹	Before July 1, 2001 ³	Last Quarter FY 2001-02	Before July 1, 2001	Last Quarter FY 2001-02	Percentage Savings in Categories	Savings 2001-02 (in Millions)
Managed – Therapeutic categories in which drugs were placed on the preferred drug list only after manufacturers negotiated for							
supplemental cash rebates	18.6%	22.4%	38.4%	\$ 75.72	\$ 66.11	20.6%	\$50.3 M
Value-Added – Therapeutic categories in which at least one preferred drug was placed on the preferred drug list through a value-							
added contract ² Exempt – Therapeutic categories that are exempt by state law from prior authorization	39.6%	19.4%	25.3%	47.41	48.42	11.1%	57.8 M
requirements	34.8%	21.0%	21.9%	131.81	145.74	-5.4%	-24.9 M
Other - Therapeutic categories that had not gone through the P/T committee process by							
the end of 2001-02	7.1%	14.5%	14.1%	2,050.00	2,272.00	-2.4%	-2.2 M
Total	100.0%	20.2%	25.9%	\$ 72.53	\$ 74.34	6.2%	\$81.0 M

 $^{^{1}}$ Based on Fiscal Year 2001-02 expenditures for 50 most expensive therapeutic categories.

Source: OPPAGA analysis of data provided by Agency for Health Care Administration.

However, competition to lower the unit price of drugs is limited when some manufacturers do not have to pay the state supplemental cash rebates in order for their drugs to be placed on the preferred drug list. While most companies supplemental rebates, must offer cash manufacturers that have a value-added contract with the agency do not have to do so. Thus, drug companies with competing products that do not have a value-added contract may not have to significantly lower the price of their products to be considered for the preferred drug list. This is particularly true when the price for a drug from a manufacturer with a value-added contract is already among the highest. In such instances, manufacturers without value-added contracts may only have to offer cash rebates to meet minimum requirements of law. 8 The average rebate for drugs in these categories typically does not increase as it would otherwise.

In addition to lowering net cost through

increased rebates, savings to the state result

² Savings include \$28.6 million in guaranteed cost savings from value-added contracts.

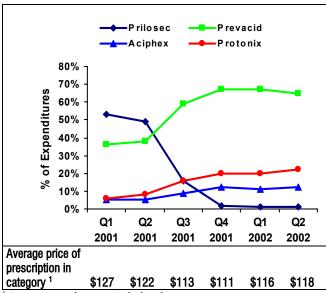
³ Third quarter Fiscal Year 2000-01 (January – March 2001).

⁴ Average cost does not include rebates.

when providers prescribe lower price drugs. Exhibit 3 demonstrates the effect on market share for drugs in a sub-class of a therapeutic category in which all manufacturers were required to give the state supplemental cash rebates to be placed on the preferred drug list. In this example, the manufacturer of Prilosec, the most expensive medication in the class, did not negotiate a supplemental cash rebate agreement with the agency. Thus, the agency did not select Prilosec as a preferred drug, requiring physicians to obtain prior authorization before they could prescribe the drug. Prilosec quickly lost market share while less expensive drugs increased their market shares driving down the average price per prescription in the category.

⁸ According to state law, except for exempt drugs, manufacturers must give the state a minimum of 25% off the average manufacturer price for products to be considered for placement on the preferred drug list; this minimum can be a combination of both federal and state supplemental rebates.

Exhibit 3 Competition Shifts Market From Higher to Lower Priced Drugs When All Companies Must Negotiate Supplemental Cash Rebates

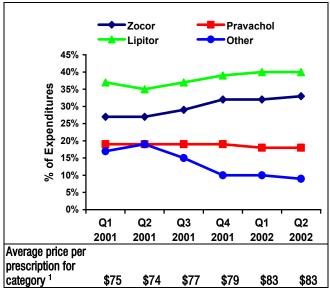


1 Average cost does not include rebates.

Source: OPPAGA analysis of Medicaid drug claims.

However, shifts in market share typically did not within therapeutic significantly categories that had at least one drug from a manufacturer that had a value-added contract with the agency. Exhibit 4 shows little change occurred in market shift and the average cost per prescription increased for a therapeutic category that included drugs manufactured by companies with a value-added contract. In fact, shifting from higher to lower cost drugs accounted for only 2% of the overall savings generated by therapeutic categories having at least one preferred drug from a company with a valueadded contract. In contrast, the shift in market share to lower priced drugs accounted for 40% of the savings generated by categories in which all drug manufacturers negotiated supplemental cash rebates.

Exhibit 4
Market Does Not Shift to Lower Priced
Preferred Drugs within Categories with at Least
One Value-Added Contract



¹ Average cost does not include rebates.

Source: OPPAGA analysis of Medicaid drug claims.

Compared to supplemental cash rebates, savings attributed to value-added contracts are less tangible and less immediate. Unlike supplemental cash rebates where manufacturers negotiate a lower price for their drugs to meet state requirements, the actual savings achieved by value-added contracts are not as concrete. The actual savings to the state under these contracts depend on:

- the value of product donations;
- contributions to implement programs provided under these contracts, like disease management; and
- recipient health care costs avoided as a result of implementing these programs which may not necessarily be the result of value-added services.

The methodologies that will be used to calculate savings due to avoiding health care costs are vague. For the most part, the value-added contracts do not fully describe the methodologies that will be used to determine savings attributable to decreased use of costly health care services such as emergency room visits and inpatient hospitalizations. In fact, one contract includes three different methodologies determining cost-savings from which oversight committee will select one. In addition, proposed methodologies do not adjust for the potential affect of other interventions on health outcomes such as changes in a patient's treatment plan, new pharmaceuticals, or services provided by other programs (e.g., Children's Medical Services).

Also, based on Florida's experience with Medicaid disease management programs, the actual cost-savings associated with value-added services will not be known for a prolonged period of time and may exceed the time-frames specified in the contracts. In a 2001 review, OPPAGA reported agency difficulty determining and reconciling cost savings of disease management programs. 9 And, when cost savings reconciliations are disputed, legal action can cause even longer delays. For example, the savings attributed to a disease management program which began in May 1999, had not been reconciled as of January 2003. In contrast, savings from supplemental cash rebates are determined by a clear-cut calculation and are primarily realized on a quarterly basis.

Further, unlike supplemental cash rebates which are tied directly to specific products, the savings guaranteed by companies with value-added contracts are not. State law provides that for a product to be considered for the preferred drug list, the manufacturer must give the state a minimum of 25% off the average manufacturer price of the product. In contrast, drug companies with value-added contracts have for the most part, had all their drugs placed on the preferred drug list in exchange for the guaranteed savings. As such, the state may not realize as much as it would have with the minimally required

⁹ Medicaid Disease Management Initiative Sluggish, Cost Savings Not Determined, Design Changes Needed, OPPAGA Report No. 01-27, May 2001. discount. In contract, companies that do not have value-added contracts frequently offer more than 25% off the average manufacturer price to ensure their products are placed on the preferred drug list.

Another issue of concern is that Florida may not realize *all* cost savings achieved by the value-added contracts. Three of the four value-added contracts require the agency to share a portion of any additional savings with the manufacturer if actual savings **exceed** guaranteed savings. With supplemental cash rebates, the state is not required to credit or share savings with manufacturers.

Eliminating "value-added" contracts requiring all drug companies to negotiate cash rebates for non-exempt drugs would save the state \$64.2 million in 2003-04. The Medicaid Consensus Estimating Conference projects that expenditures for prescription drugs in 2003-04 will reach \$2.17 billion. Assuming the same level of savings experienced in 2000-01, we estimate that if the current value-added contracts are renewed for another year, therapeutic categories with at least one drug from a company with a value-added contract will save \$75.3 million in 2003-04. However, if value-added contracts are eliminated, requiring all companies to negotiate supplemental cash rebates, these same categories will save \$139.5 million or an additional \$64.2 million.

further reduce prescription drug expenditures, the Legislature could consider ways to contain the cost of drugs currently exempt from preferred drug list requirements. Mental health and antiretroviral medications are exempt from prior authorization and other cost containment initiatives. There are significant costs associated with these exemptions. In Fiscal Year 2001-02, exempt medications accounted for \$456.7 million (34.8%) of the \$1.3 billion spent on the top 50 most expensive drug categories. In fact, in that year, one group of mental health medications (atypical antipsychotics) was the single largest expense in the Medicaid prescription drug program (\$157 million). Because expenditures for exempt medications represent such a significant percentage of Medicaid drug costs, the Legislature may wish to consider ways to contain their costs.

For example, the Legislature could require manufacturers of exempt medications negotiate supplemental cash rebates to be included on the preferred drug list. Like other medications currently on the preferred drug list, patients would have full access to all mental health and antiretroviral medications, but physicians would need to obtain prior authorization before dispensing mental health and antiretroviral medications not on the preferred drug list. In the end, the physician would still ultimately decide which medications to provide. While it is difficult to predict the full impact of this action, requiring supplemental cash rebates for mental health and antiretroviral medications should slow the rate of increase in expenditures in these therapeutic categories.

alternative approach to requiring An manufacturers to negotiate supplemental cash rebates would be for the Legislature to require the agency to implement a strategy called "step therapy" for one or more of the currently exempt categories of mental health and antiretroviral Step therapy requires that physicians prescribe less expensive medications first and gradually move to more expensive medications if the patient does not stabilize or improve. 10 Under this approach, current Medicaid recipients would be grandfathered in and would not have to change medications. In addition, physicians would be able to override an established step strategy by obtaining prior authorization to prescribe a more expensive drug as a first medication. According to the agency, the state could save up to \$8 million annually by implementing a step therapy strategy for atypical antipsychotics, one of the mental health therapeutic classes. 11

The agency has not implemented our prior recommendation to competitively bid contracts for Medicaid pharmacy networks; doing so could save up to \$22.4 million in 2003-04

Our 2001 report recommended that the agency competitively bid contracts for Medicaid pharmacy services. Since that time, even though the agency in its response to our report indicated support for this recommendation, it has not taken action to competitively bid pharmacy networks. Agency officials have given two reasons for not moving forward to implement this recommendation: a concern that limiting the number of pharmacies could affect access in some areas of the state; and that the Legislature, through the appropriations process, has not directed the agency to do so.

However, the agency has statutory authority to competitively bid pharmacy networks even without proviso language. ¹² While reducing the number of pharmacies available to serve Medicaid recipients could potentially affect access to Medicaid pharmacies in some parts of the state, the agency can take steps to ensure access in these areas. For example, the agency could bid regional contracts requiring a specified number of participating pharmacies.

We continue to believe the agency should implement competitive bidding of Medicaid pharmacy services. Limiting the Medicaid pharmacy network would allow the agency to take advantage of increased purchasing power to negotiate lower prescription costs. In addition, limiting the Medicaid pharmacy network would improve the agency's ability to monitor pharmacies and better control pharmacy error, abuse, and fraud.

In our prior report, we noted that three state Medicaid programs paid lower drug ingredient costs than Florida and that nearly half of the programs paid lower dispensing fees. By limiting the Medicaid pharmacy network through competitive bidding, the agency could take advantage of increased purchasing power to negotiate lower ingredient prices and/or dispensing fees. We estimate the agency could save \$14.9 million in 2003-04 if it successfully

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¹⁰ Step therapy considers costs as well as both clinical efficacy and potential side effects and only groups similar medications in the therapy regimen. The most expensive medications could only be used if all other treatments failed.

¹¹ Medicaid Prescribed Drugs Cost Containment Options, Presented to House Subcommittee on Health Appropriations, Agency for Health Care Administration, March 14, 2003.

¹² Section 409.912(38)(a)4., F.S.

negotiated lowering current drug ingredient pricing from average wholesale price -13.25% to -15%. ¹³ The agency could save an additional \$7.5 million if negotiations lower the current \$4.23 dispensing fee to \$4.

We continue to recommend that the agency competitively bid contracts for Medicaid pharmacy networks. To address the issue of potential pharmacy access problems in some parts of the state, the contracts could be bid on a regional basis. As an alternative, the state could take steps to achieve the same level of cost savings through legislation. For example, the Legislature could change current statute to require reimbursement to pharmacies be set as average wholesale price less 15%. ¹⁴ The Legislature could also identify changes in pharmacy reimbursement for ingredient cost and/or dispensing fees in appropriations proviso language.

Agency Response-

In accordance with the provisions of s. 11.513, *Florida Statutes*, a draft of our report was submitted to the Secretary of the Agency for Health Care Administration for her review and response. The Secretary's written response is reprinted herein (see Appendix C, pages 12-15).

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¹³ This would affect only those drugs in which the "lowest price" is the one derived by using average wholesale price minus a discount of 15%.

¹⁴ Section 409.912(38)(a)2., F.S., currently sets reimbursement at average wholesale price less 13.25%.

Methods Used to Calculate Cost Savings

Preferred drug list cost savings in Fiscal Year 2001-02 (Exhibit 2)

To estimate the fiscal impact of the preferred drug list for Fiscal Year 2001-02, we analyzed Medicaid prescription drug expenditures and rebates for the top 50 most expensive therapeutic categories. These therapeutic categories comprised 79% of expenditures in Fiscal Year 2001-02. Table A-1 illustrates cost savings calculations for a class of medications. We calculated the average expenditure per claim within each of the top 50 therapeutic categories including all cash rebates. Using the third quarter of Fiscal Year 2000-01 as our baseline quarter, we calculated the difference in expenditures per claim from the baseline quarter for each quarter in Fiscal Year 2001-02. To estimate quarterly cost savings, we multiplied the change in average cost per claim by the number of claims for each quarter. The total cost savings for Fiscal Year 2001-02 was the sum of the four quarterly cost savings for the top 50 therapeutic categories, including the guaranteed savings from the value-added contracts, \$28.6 million, which we added as a lump sum cash rebate.

Table A-1
Example of Cost Savings Calculation for a Class of Medications¹

Baseline	Net Expenditures Per Claim ²	Difference From Baseline	Number of Claims	Cost Savings (Difference x Claims)
Third Quarter FY 2000-01	\$158			
First Quarter FY 2001-02	160	\$(2)	169,878	\$ (339,756)
Second Quarter FY 2001-02	145	13	181,767	2,362,971
Third Quarter FY 2001-02	147	11	180,811	1,988,921
Fourth Quarter FY 2001-02	150	8	188,993	1,511,944

¹ The data are hypothetical and for illustrative purposes only.

Source: OPPAGA.

To compare the fiscal impacts of the different ways the agency selected preferred drugs, we classified all expenditures and rebates into four groups. The *Managed Group* included medications in therapeutic categories in which all preferred drugs were considered for and subsequently placed on the preferred drug list only after manufacturers negotiated supplemental cash rebates. The *Value Added Group* included medications in therapeutic categories in which at least one preferred drug was placed on the preferred drug list through a value-added contract. The *Exempt Group* included the medications that are exempt by statute from prior authorization requirements. The *Other Group* included those medications that had not gone through the P/T committee process by the end of Fiscal Year 2001-02.

Projected cost savings in Fiscal Year 2003-04 from eliminating value-added contracts

We projected that the state could save \$64.2 million in Fiscal Year 2003-04 if value-added contracts were eliminated. Using the results of our cost savings analysis, we assumed that eliminating value-added contracts and instead, requiring all manufacturers to negotiate cash rebates to have their drugs considered for the preferred drug list would generate a

²Net expenditures per claim included federal and state rebates

20.62% savings (the savings achieved by the managed category) while renewing the value-added contracts would generate an 11.13% savings. To project savings, we multiplied the percentage of savings under these two conditions by the estimated expenditures for Fiscal Year 2003-04 for the therapeutic categories currently containing value-added preferred drugs. We then subtracted these results to yield the projected cost savings for eliminating value-added contracts (see Table A-2).

Table A-2
Projecting Cost Savings to Fiscal Year 2003-04 Expenditures

	FY 2003-04 (millions)
Projected total pharmacy expenditures	\$2,173.1
2. Projected expenditures in 50 most expensive therapeutic categories (78.71% of line 1)	1,710.4
3. Projected expenditures for categories with value added drugs (39.55% of line 2)	676.5
4. Projected savings without value added contracts (20.62% of line 3)	139.5
5. Projected savings with value added contracts (11.13% of line 3)	75.3
6. Projected additional savings from eliminating value added contracts (line 4 minus line 5)	64.2

Source: OPPAGA.

Fiscal Year 2003-04 projected cost savings for competitively bidding contracts for Medicaid pharmacy networks

We projected the state could save \$22.4 million in Fiscal Year 2003-04 through competitively bidding contracts for Medicaid pharmacy networks. Currently the state reimburses pharmacies for covered medications using a \$4.23 dispensing fee plus the lowest of the following drug ingredient costs.

- Average wholesale price -13.25%
- Wholesaler acquisition cost +7%
- Federal upper limit
- State maximum allowable cost
- The amount billed by the pharmacy

To project savings, we assumed the state could reduce the dispensing fee to \$4 per prescription and reduce drug ingredient costs to the lower of

- average wholesale price -15%
- wholesaler acquisition cost +7%
- federal upper limit, or
- state maximum allowable cost

To calculate the projected savings for increasing the discount off the average wholesale price from the current 13.25% to 15%, we used the Medicaid drug ingredient costs database containing prices as of February 14, 2003, applying our assumed "lower of" pricing policy to Fiscal Year 2001-02 drug utilization files, the most recent complete year of utilization information which generated a 0.69% cost savings. We then multiplied the March 2003 Medicaid consensus estimating conference projection for prescription expenditures, \$2,173.1 million, by 0.69%.

To calculate the projected savings due to reducing the dispensing fee from \$4.23 to \$4, we multiplied the consensus estimating conference projection for the number of prescriptions in Fiscal Year 2003-04 by \$0.23.

Appendix B

Value-Added Contracts

Table B-1 provides details for each of the four value-added contracts. The guaranteed savings for these contracts total around \$28.6 million for Fiscal Year 2001-02 and \$36.2 million for Fiscal Year 2002-03. However, as discussed in this report, actual cost savings are difficult to determine and may be unknown for a prolonged period of time.

Table B-1

Contract Year	Guaranteed Savings	Actual Savings Determination Date	Components	Drugs on Preferred Dru		ug List
Pfizer FY 2001-02 FY 2002-02	\$15 million 18 million	TBD by Jul 2003 TBD by Oct 2004	Disease Management for asthma, congestive heart failure, diabetes, and hypertension. Product Donation Health Literacy	Accupril Accuretic Aricept Cardura Celebrex Diflucan Dilantin Estrostep	Femhrt Geodon Glucotrol XL Lipitor Loestrin Neurontin Norvasc Procardia XL	Tikosyn Viagra Viaracept Zarontin Zithromax Zoloft Zyrtec
Bristol-Meyrs S FY 2001-02 FY 2002-03	\$6.6 million 9.7 million	TBD by Jan 2003 TBD by Jul 2004	Community-based health management programs for diabetes and behavioral health. Product donation	Avalide Avapro Bicnu Blenoxane Buspar Dividose Ceenu Cefzil Cytoguard Cytoxan Lyophilized and tablets Dovonex Droxia	Duricef Etopohos Glucophage Glucophage XR Glucovance Ifex and Mesnex Mesnex Monopril Monopril-HCT Mutamycin Mycostatin Pastilles Paraplatin Plantinol AQ	Plavix Pravachol Serzone Stadol NS Taxol Tequin Injections Teqin tablets Teslac Ultravate Vepesid Videx Videx VidesEC Vunom Zerit
GlaxoSmithKline FY 2001-02 FY 2002-03	\$6.75 million 8.10 million	On or about June 15, 2002 On or about June 15, 2003	Medication Error Reduction Demonstration Program Select Product Compliance Programs Product Donation	Advair Augmentin Avandia Bactroban Coreg Flonase Flovent	Flovent Rotadisk Requip Serevent Serevent Diskus Valtrex Zofran	
Astra-Zeneca FY 2001-02 FY 2002-03	\$215,832 353,125	No savings calculations	Area Pharmacy Management Program	Rhinocort Aqua		



JEB BUSH, GOVERNOR

RHONDA M. MEDOWS, MD, FAAFP, SECRETARY

April 4, 2003

Mr. John W. Turcotte, Director Office of Program Policy Analysis and Government Accountability 111 West Madison Street, Room 312 Claude Pepper Building Tallahassee, FL 32399-1475

Dear Mr. Turcotte:

Thank you for the opportunity to respond to the *Progress Report, Changes to Medicaid Preferred Drug List Requirements and Competitive Bidding Pharmacy Contracts Could Save an Additional* \$86.6 *Million in 2003-2004*.

Issues identified in your report and our responses are as follows:

Florida can achieve additional savings by eliminating value-added contracts and seeking ways to contain costs for drugs exempted from preferred drug list requirements.

Over the past three years, Florida Medicaid has implemented the most comprehensive and successful prescribed drug cost control program in the nation. In FY 2001 and 2002, Florida Medicaid reduced the growth in prescribed drug spending by more than \$500 million. Florida Medicaid has accomplished these cost savings by implementing a Preferred Drug List (PDL), supplemental pharmaceutical manufacturer rebates, brand-name drug restrictions, prior authorization programs for certain drugs and drug categories, a drug benefit management program, ingredient price reductions, competitive bidding of products, a mail order pharmacy program, detailing at the prescriber level, prescriber and beneficiary profiling, use of a counterfeit-proof prescription pad, pharmacy audits, and other initiatives. In FY 2002-03, Medicaid is implementing several additional drug cost control initiatives including a pharmacy home delivery program; a wireless, handheld device containing PDL, Medicaid patient drug histories, drug prescribing monographs and other features; a data warehouse; and other revenue enhancement projects.

To enhance Medicaid prescribed drug cost controls, the 2001 Florida Legislature passed legislation (SB 792) authorizing a Medicaid PDL and supplemental pharmaceutical manufacturer rebates. The Medicaid PDL and supplemental rebates were implemented in July 2001.

To be considered for inclusion on the Medicaid PDL, the combined federal and state supplemental rebates for a manufacturer must equal or exceed 25 percent of spending on a manufacturer's products. As an alternative for qualifying for PDL coverage, the Legislature authorized the Agency to enter into agreements with pharmaceutical manufacturers for value-added programs (s. 409.912[37][a][7], F.S.) for programs such as "...disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments with guaranteed savings to the Medicaid program in the same year the rebate reduction is included in the General Appropriations Act."

OPPAGA Comment

OPPAGA believes the above paragraph in the agency response is somewhat misleading. While s. 409.912(38)(a)7., Florida Statutes, provides a broad definition of "supplemental rebates" to include the types of activities and investments offered by the value-added contracts, it does not specify that the savings guaranteed by these contracts can take the place of the minimum required rebates for individual drug products to be considered for placement on the preferred drug list. Rather, the law specifies that the agency negotiate supplemental rebates at no less than 10% of the average manufacturer price unless the total rebate (federal and state) equals or exceeds 25%. The law further states there is no upper limit to supplemental rebates and that agreement to pay the minimum supplemental rebate (25%) does not guarantee placement on the preferred list; it only guarantees the manufacturer that the P/T committee will consider a product for inclusion. The placement decision is to be based on clinical efficacy of a drug as well as the price of competing products minus federal and state rebates. When the agency places all products from a manufacturer on the preferred list because of a value-added contract, it cannot ensure that each product meets minimum rebate requirements; doing this also suppresses competition with other companies.

The 2001 legislation granted the Agency the authority to pioneer innovative health care initiatives with the goal of controlling prescribed drug costs while improving the health of Medicaid beneficiaries. The Agency has executed value added agreements with Pfizer, Bristol-Myers Squibb, GlaxoSmithKline and AstraZeneca. The value added agreements for the two-year period beginning July 1, 2001 and ending June 30.2003, have achieved the following:

- ❖ Manufacturer grants totaling \$24.5 million;
- ❖ Manufacturer guarantees of program savings and/or cash of \$64.7 million;
- ❖ Additional federal investments in Florida Medicaid health management programs of \$14.5 million;

OPPAGA Comment

OPPAGA believes it is important to clarify the three achievements listed above, as readers may interpret the dollar values associated with these achievements as additive and conclude that the four value-added contracts have given the state \$39 million over and above the \$64.7 million total savings guaranteed by these contracts for 2001-02 and 2002-03. This is, however, not the case. The value-added agreements stipulate that the savings guaranteed by the manufacturers *include* the amount of manufacturer grants and the amount of any federal investments. Thus, manufacturer grants and federal investments as well as the value of any product donations, serve to reduce the amount of the guaranteed savings that manufacturers have to demonstrate as due to improved outcomes and reduced service utilization.

- ❖ The Florida: A Healthy State program providing disease management and care coordination for 50.000 beneficiaries with asthma, congestive heart failure, diabetes, and hypertension. Services are provided through contracts with 10 of the states largest hospital-based health systems (Jackson Memorial Hospital/Jackson Health System (Miami); Memorial Regional Hospital/Memorial (Hollywood): Healthcare System North Broward Hospital District/Broward General Hospital (Ft. Lauderdale); Orlando Regional Medical Center/Orlando Regional Healthcare; Florida Hospital/Adventist Health System (Orlando); Tampa General Hospital; Shands at University of Florida/Shands Healthcare (Gainesville); Shands at Jacksonville/Shands Healthcare; Tallahassee Memorial Healthcare; and Sacred Heart Hospital/Sacred Heart Health System. The health systems have 60 care managers dedicated to the program. A URAC accredited call center provides 24/7 support services such as nurse triage, fulfillment, and an audio health library.
- ❖ The first Medicaid Health Literacy program in the nation, operated at 27 federally qualified health centers (FQHCs).
- ❖ A Community-Based Diabetes Health Management Program, which uses teams of health professionals and lay health workers (Promotoras) to provide culturally competent care management for minority populations with diabetes, co-morbid cardiovascular disease or a pre-diabetes condition in Miami-Dade, Broward, Pasco, Manatee, Lee, Hendry, and Charlotte counties.
- ❖ A Community-Based Behavioral Health Management Program designed to address anxiety and depression, coordinated with faith-based organizations, in Miami-Dade, Lee, Hendry and Charlotte counties,
- ❖ A Medication Error Reduction Demonstration Program (a first among the nation's Medicaid programs) to reduce medication errors in Medicaid beneficiaries; the program will target 50,000 Medicaid beneficiaries.
- ❖ An Area Pharmacy Management Program, which finances regional pharmacists who detail Medicaid participating physicians on their prescribing practices.

The health management programs financed through value added agreements have already resulted in improved health behaviors (smoking cessation, diet compliance, regular physical activity, medication compliance, use of a peak flow meter, self-foot exams, blood sugar monitoring, and weight monitoring). Substantial numbers of individuals have lost weight, reduced their blood sugars, lowered their cholesterol, suffered fewer asthma and heart failure symptoms, and reduced their blood pressure. Inpatient admissions, lengths of stay and emergency encounters are down. These health management programs are groundbreaking public-private partnerships between the state, local health systems, other providers, beneficiaries, All pharmaceutical manufacturers are meeting their and pharmaceutical manufacturers. contractual guarantees and have invested funds in addition to those required by their contracts. Unlike rebates, the value added programs not only control costs but create new programs, improve the quality of health care, invest in people and save lives. The value added agreements support the programs of Florida's safety net providers - hospital-based health systems and FOHCs. The programs reduce provider risk by ensuring earlier intervention and the proper management of diseases and lead to a healthier population with improved productivity.

OPPAGA Comment

OPPAGA recognizes that health management programs will result in improved health outcomes for some participants. However, the agency has not completed any evaluations of the value-added programs and with the exception of a document titled *Investing in People,* posted on its website on April 3, 2003, related to the Pfizer disease management program, has not made available preliminary data on clinical and behavioral health outcomes. Evaluations of these programs should consider the sustainability of behavior changes such as smoking cessation, weight loss, diet compliance, physical activity, and medication compliance. ¹⁵ Evaluations should also adjust outcomes/results of programs that target services to high-risk patients because of the tendency for post-treatment measurements to move towards the mean. ¹⁶ Further, the evaluations should control for other programs or interventions that may contribute to patients' improved health outcomes.

Your analysis assumes that all manufacturers contributing to Medicaid cost controls through value added agreements would simply convert to a supplemental rebate if that were the only option for PDL coverage of their products. An alternative, and perhaps equally likely assumption, is that the manufacturers may simply choose not to provide a rebate and depend on prior authorization to secure coverage of their products. In this event, the state would lose rebates/savings guarantees and incur additional administrative costs authorizing the coverage of high volume products. In addition, the analysis does not account for future-year savings that can be achieved through improved beneficiary health. Rebates are one-time, non-recurring savings. Finally, the OPPAGA analysis assumes that with additional manufacturers participating in supplemental rebates that all existing products would remain on the PDL and secure the same level of discounts from manufacturers currently providing rebates. Competition for product inclusion based solely on supplemental rebates may reduce the PDL portfolio of products and reduce total rebates and/or savings guarantees.

OPPAGA Comment

OPPAGA recognizes that if the Legislature eliminates value-added contracts and requires all manufacturers to negotiate supplemental *cash* rebates before products are considered for the preferred drug list, some drug manufacturers may refuse to offer these rebates and depend on physicians using prior authorization. However, past experience suggests otherwise. Agency data shows that manufacturers whose products were not selected as preferred drugs lost market share. Because these products tended to be the most expensive in a therapeutic category, the average price per prescription in the category dropped as the higher priced non-preferred drug(s) lost market share. On the whole, reducing the number of products in a category not only increased the total amount of state savings in rebates but also lowered the average price per prescription. To date, physicians have tended to prescribe from the preferred list. As long as the P/T committee recommends drugs within a therapeutic category that are low in unit cost as well as efficacious, we believe physicians will generally prescribe from the list and the state will save by having a higher volume of less expensive brand and generic prescriptions. While Florida's prior experience with its preferred drug list does not guarantee the same level of future cost savings, using actual experience to predict future savings is methodologically sound.

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¹⁵ Sustainability is particularly important because of the "Hawthorne Effect," a well documented phenomenon of research and evaluation studies that demonstrates that subjects (for disease management programs, patients) who receive extra attention will improve behaviors in the short-term. To mitigate this bias, evaluations should be designed to control for this phenomenon.

¹⁶ This is due to a statistical phenomenon called "regression to the mean" and occurs whenever subjects are selected on the basis of extreme pretest measurements. When evaluation studies do not adjust for this effect, the effect of treatments can be overstated.

Progress Report

The Agency remains committed to value added programs and will continue to carefully analyze clinical and financial data, using contracted experts, to ensure the continued success of these programs.

OPPAGA Comment

OPPAGA commends the agency's commitment to carefully analyze clinical and financial data to evaluate the success of the programs funded by the value-added contracts. However, the Legislature could maintain these programs by funding them with monies received from supplemental cash rebates. Under this scenario, the state could retain any cost savings realized by the programs and not return to the pharmaceutical companies a portion of any savings above the guaranteed savings (at least 50%).

The agency has not implemented our prior recommendation to competitively bid contracts for Medicaid pharmacy network; doing so could save up to \$22.4 million in 2003-2004.

Although authorization for competitive bidding is included the Medicaid statutes, specific proposals to limit the pharmacy network or competitively bid the network have failed to gain legislative support through the appropriations process. The Agency made proposals to limit prescribed drug costs using these tools in a special legislative session in 2001 and in the 2002 session. A proposal to reduce long term care pharmacy dispensing has been made for the 2003 session. Understanding that a competitive bid or network limitation process, if approved by the Legislature, would require additional network standards, the Agency has been acquiring information on minimum requirements from both an ease access and level of service, i.e., home delivery, asthma care, patient education services, and hours of operation.

Thank you for the opportunity to comment on your draft report. If you have any questions regarding this response, please contact Rufus Noble at 921-4897or Kathy Donald at 922-8448.

Sincerely,

/s/ Rhonda M. Medows, M.D. Secretary

RMM/kd