



# Medicaid Budget Document

*State Fiscal Year  
2008*

*Office of Vermont Health Access*



# *Office of Vermont Health Access*



## **Mission Statement**

To assist beneficiaries in accessing clinically appropriate health services.

To administer Vermont's public health insurance system efficiently and effectively.

To collaborate with other healthcare system entities in bringing evidence-based practices to Vermont Medicaid beneficiaries.

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**Section 1: Contact Information**Address

312 Hurricane Lane, Suite 201  
Williston, Vermont 05495

Phone

802-879-5900

Fax

802-879-5919

Website

[www.ovha.vermont.gov](http://www.ovha.vermont.gov)

Director

Joshua Slen

Email: [joshua.slen@ahs.state.vt.us](mailto:joshua.slen@ahs.state.vt.us)

Deputy Directors

Ann Rugg

Email: [ann.rugg@ahs.state.vt.us](mailto:ann.rugg@ahs.state.vt.us)

Nancy Clermont

Email: [nancy.clermont@ahs.state.vt.us](mailto:nancy.clermont@ahs.state.vt.us)

Medical Director

Scott Strenio

Email: [scott.strenio@ahs.state.vt.us](mailto:scott.strenio@ahs.state.vt.us)

Associate Medical Director

Erin Cody-Reisfeld

Email: [erin.cody-reisfeld@ahs.state.vt.us](mailto:erin.cody-reisfeld@ahs.state.vt.us)

Legislative Liaison

Stephanie Beck

Email: [stephanie.beck@ahs.state.vt.us](mailto:stephanie.beck@ahs.state.vt.us)

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## Section 2: Fast Facts

- 1) The Governor's Recommend for SFY '08 is:
  - \$749,342,679
  - 141,354 covered lives (excluding Healthy Vermonters) (61,871 children) in Vermont's publicly funded health insurance programs
  - 109 Employees ~ see Appendix 1 for Organizational Chart
- 2) State of Vermont's largest single programmatic expenditure
  - Programs for Adults ~ Traditional Medicaid Program (i.e., Dual Eligibles; Aged, Blind, or Disabled and/or Medically Needy; General Adults), Vermont Health Access Program (VHAP), and Catamount Health
  - Programs for Children ~ Traditional Medicaid (i.e., Blind or Disabled and/or Medically Needy; General Children) and the Dr. Dynasaur Program (i.e., State Children's Health Insurance Program; Underinsured Children)
  - Pharmacy Programs ~ Pharmacy Program; Medicare Part D Wrap Program, Discount Program
- 3) Largest insurer in Vermont
  - a) 1st ~ Dollars spent
  - b) 2nd ~ Number of covered lives
- 4) Pays some or all of the health care costs for 25% of Vermont's population
- 5) 9,911 enrolled providers
- 6) 9.1 million claims processed annually, 93% received electronically
- 7) 99.5% of all claims are processed within 30 days, with the average time from claim receipt to provider payment of nine days
- 8) Member services averages close to 23,000 calls a month, about 1,300 a day; all calls are picked up by the automatic attendant within 25 seconds and answered by a live person within 2 minutes 95% of the time
- 9) The health care industry is a nearly \$4 billion dollar industry in Vermont ~ the (OVHA) Medicaid represents fully 18.7% of the spending in that system

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### Section 3: Program Descriptions

The following are descriptions of the health care program populations by Global Commitment enrollment category with fiscal history information and tables that include the caseload and expenditure information by SFY, including the Governor's Recommend for SFY '08.

#### **Programs for Adults**

The OVHA's three health care programs for adults are: 1) the Traditional Medicaid Program; 2) the Vermont Health Access Program (VHAP); and 3) the Catamount Health Program. These programs are described below.

#### *Traditional Medicaid Program*

The adult *Traditional Medicaid Program* population includes Vermonters who are eligible under the Medicaid rules in Title XIX of the Social Security Act. There are no premiums associated with the *Traditional Medicaid Program*. In addition, this population includes the Breast and Cervical Cancer Treatment (BCCT) group population for women under age 65 who have been diagnosed with breast or cervical cancer through the national screening program, are uninsured, and otherwise ineligible for Medicaid.

The Global Commitment enrollment categories pertinent to the *Traditional Medicaid Program* are: 1) Dual Eligibles; 2) Aged, Blind, or Disabled/Medically Needy; and 3) General Adults. Each of the *Traditional Medicaid Program* enrollment categories is describe below.

- 1) The *Dual Eligibles* enrollment category includes those adult Vermonters who are eligible for both Medicare and Medicaid, and are categorized as aged, blind, or disabled (ABD). This population is blind, disabled, or at least 65 years of age, and below the Vermont Medicaid protected income level (PIL). Please note this excludes buy-in and clawback.

#### *Dual Eligibles*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	8,961	68,407,653
SFY '06 Actual	8,881	30,976,189
SFY '07 Appropriated	8,042	33,121,058
SFY '07 Budget Adjustment	8,507	30,522,727
<b>SFY '08 Gov. Rec.</b>	<b>8,354</b>	<b>33,631,874</b>

The *Aged, Blind, or Disabled (ABD) and/or Medically Needy* enrollment category includes Vermonters, age 18 and older, categorized as aged, blind, or disabled but not eligible for Medicare. Generally, this category includes Supplemental Security Income cash assistance recipients, the working disabled, hospice patients, Breast

and Cervical Cancer Treatment (BCCT) group participants, or Medicaid/Qualified Medicare Beneficiaries (QMB), and medically needy Vermonters [i.e., eligible because their income is greater than the cash assistance level but less than the Medicaid protected income level (PIL)]. Medically needy adults may be aged, blind, or disabled or they may be the parents/caretaker relatives of minor children.

*Aged, Blind, or Disabled (ABD) and/or Medically Needy Adults*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	14,261	86,965,332
SFY '06 Actual	15,481	91,739,541
SFY '07 Appropriated	15,491	93,854,422
SFY '07 Budget Adjustment	15,417	94,524,993
<b>SFY '08 Gov. Rec.</b>	<b>15,725</b>	<b>104,226,457</b>

Long-Term Care participants are a subset of the *Aged, Blind or Disabled (ABD) and/or Medically Needy* enrollment category, and includes Vermonters in nursing homes, home-based settings under home and community based services (HCBS) waiver programs, and enhanced residential care (ERC) settings. They participate in a new waiver (i.e., Choices for Care) managed by the Department of Disabilities, Aging, and Independent Living, in conjunction with the OVHA and the Department for Children and Families (DCF). The purpose of the waiver is to equalize the entitlement to both home and community based services with nursing home services for all those eligible.

*Long Term Care Waiver and/or Medically Needy*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	3,429	140,171,168
SFY '06 Actual	3,698	154,787,921
SFY '07 Appropriated	4,147	169,093,003
SFY '07 Budget Adjustment	4,147	164,558,229
<b>SFY '08 Gov. Rec.</b>	<b>4,723</b>	<b>184,315,222</b>

- 2) The *General Adults* enrollment category includes Vermonters who are categorized as parents/caretaker relatives of minor children including cash assistance recipients and those receiving transitional Medicaid after the receipt of cash assistance.

*General Adults*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	7,826	28,074,607
SFY '06 Actual	7,601	25,426,874
SFY '07 Appropriated	7,952	30,441,192
SFY '07 Budget Adjustment	7,715	30,659,015
<b>SFY '08 Gov. Rec.</b>	<b>7,921</b>	<b>32,810,105</b>

### Vermont Health Access Program (VHAP)

The *Vermont Health Access Program (VHAP)* enrollment category was designed as part of the original 1115 waiver to Title XIX of the Social Security Act to provide health care coverage for adults who would otherwise be underinsured or uninsured. This population includes Vermonters who are age 18 and over with incomes up to 150% of the FPL or who are parents/caretaker relatives with incomes up to 185% of the FPL. In SFY'08 this population includes individuals who are eligible under Employer Sponsored Insurance (ESI). There are premiums associated with *VHAP* and co-payments are required for some services.

<i>VHAP</i>		
SFY	Caseload	Expenditures
SFY '05 Actual	24,456	73,431,832
SFY '06 Actual	22,525	77,321,380
SFY '07 Appropriated	23,995	79,053,489
SFY '07 Budget Adjustment	23,276	79,032,744
<b>SFY '08 Gov. Rec.</b>	<b>24,789</b>	<b>89,397,564</b>

### *Catamount Health*

In fiscal year 2007, a new healthcare initiative was adopted with the purpose of reducing the total number of uninsured in Vermont. Through such, a new insurance benefit package will be offered to citizens who do not currently have access to a health plan. State assistance will be provided to people who fall at or beneath 300% of the federal poverty level.

<b>Catamount Health</b>		
Year	Caseload	Expenditures
SFY '05 Actuals	-	\$ -
SFY '06 Actuals	-	\$ -
SFY '07 Estimates	-	\$ -
SFY '08 Requested	2,755	\$ 11,657,566

### **Programs for Children**

The OVHA's two health care programs for children are: 1) the Traditional Medicaid Program, and 2) the Dr. Dynasaur Program. Both programs are described below.

#### *Traditional Medicaid Program*

The children *Traditional Medicaid Program* population includes Vermonters who are eligible under the Medicaid rules in Title XIX of the Social Security Act. There are no premiums associated with the *Traditional Medicaid Program*.

The Global Commitment enrollment categories pertinent to the *Traditional Medicaid Program* are: 1) Blind or Disabled/Medically Needy, and 2) General Children. Both categories are described below.

- 1) The *Blind or Disabled (BD) and/or Medically Needy* enrollment category includes those Vermonters, under age 21, categorized as blind or disabled. Generally, this category includes Supplemental Security Income cash assistance recipients, hospice patients, those eligible under the “Katie Beckett” rules, and medically needy Vermonters [i.e., eligible because their income is greater than the cash assistance level but less than the Medicaid protected income level (PIL)]. Medically needy children may or may not be blind or disabled.

*Blind or Disabled and/or Medically Needy Children*

SFY	Caseload	Expenditures
SFY '05 Actual	3,011	27,666,388
SFY '06 Actual	3,167	24,434,952
SFY '07 Appropriated	3,377	25,023,869
SFY '07 Budget Adjustment	3,277	25,202,928
<b>SFY '08 Gov. Rec.</b>	<b>3,371</b>	<b>27,999,838</b>

- 2) The *General Children* enrollment category includes Vermonters who are categorized as those eligible for cash assistance including Reach Up (Title IV) and foster care payments (Title IV-E), those receiving transitional Medicaid after the receipt of cash assistance, and Medicaid related Dr. Dynasaur. This population is under the age of 21 and below the Medicaid protected income level (PIL).

*General Children*

SFY	Caseload	Expenditures
SFY '05 Actual	54,135	98,393,401
SFY '06 Actual	52,845	95,671,279
SFY '07 Appropriated	52,839	106,897,131
SFY '07 Budget Adjustment	53,010	107,662,036
<b>SFY '08 Gov. Rec.</b>	<b>52,910</b>	<b>117,125,689</b>

*Dr. Dynasaur*

The *Dr. Dynasaur Program* population includes Vermonters who are under age 18 and ineligible for the (children) *Traditional Medicaid Program* with family incomes up to 300% of the FPL. There are premiums associated with the *Dr. Dynasaur Program*.

The Global Commitment enrollment categories pertinent to the *Dr. Dynasaur Program* are: 1) the State Children’s Health Insurance Program (SCHIP), and 2) Underinsured Children. Both *Dr. Dynasaur* enrollment categories are described below:

- 1) The *State Children’s Health Insurance Program (SCHIP)* enrollment category includes Vermonters who are uninsured, up to age 18, up to 300% of the FPL,

and eligible under the SCHIP eligibility rules in Title XXI of the Social Security Act.

*SCHIP*

SFY	Caseload	Expenditures
SFY '05 Actual	3,147	4,045,623
SFY '06 Actual	3,092	4,901,663
SFY '07 Appropriated	3,395	4,940,365
SFY '07 Budget Adjustment	3,131	4,618,038
<b>SFY '08 Gov. Rec.</b>	<b>4,070</b>	<b>6,127,843</b>

- 2) The *Underinsured Children* enrollment category was designed as part of the original 1115 waiver to Title XIX of the Social Security Act to provide health care coverage for children who would otherwise be underinsured. This covers children up to age 18 and up to 300% FPL.

*Underinsured Children*

SFY	Caseload	Expenditures
SFY '05 Actual	1,661	1,196,600
SFY '06 Actual	1,284	821,382
SFY '07 Appropriated	1,941	1,808,922
SFY '07 Budget Adjustment	1,169	1,278,959
<b>SFY '08 Gov. Rec.</b>	<b>1,520</b>	<b>1,860,768</b>

**Pharmacy Only Benefits**

The OVHA's three pharmacy programs are: 1) Pharmacy Program; 2) a Medicare Part D Wrap Program; and 3) Discount Program. The benefits are described below.

1) *Pharmacy Program*

- a. *VHAP-Pharmacy*, part of the 1115 waiver to Title XIX of the Social Security Act, covers medications for Vermonters up to 150% of the FPL who are at least age 65 or receive federal disability payments and are ineligible for Medicare. Vermonters enrolled in *VHAP-Pharmacy* pay only the *VHAP-Pharmacy premium* and have no co-payments or deductibles.
- b. *VScript* covers maintenance drugs for Vermonters up to 175% of the FPL who are at least age 65 or receive federal disability payments and are ineligible for Medicare. Vermonters enrolled in *VScript* pay a premium and have no co-payment or deductible.
- c. *VScript Expanded* covers only maintenance drugs where the manufacturers have agreed to pay Vermont a rebate. *VScript Expanded* is for Vermonters up to 225% who are at least age 65 or receive federal disability payments and are ineligible for Medicare. Vermonters enrolled in *VScript Expanded* pay a premium and have no co-payment or deductible.

*Pharmacy Program*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	13,802	31,336,048
SFY '06 Actual (Jul '05 – Dec '05)	13,443	16,620,453
SFY '06 Actual (Jan '06 – Jun '06)	163	182,438
SFY '07 Appropriated	400	753,812
SFY '07 Budget Adjustment	80	228,756
<b>SFY '08 Gov. Rec.</b>	<b>92</b>	<b>270,301</b>

2) *Medicare Part D Wrap Program*

*VPharm* was established by Act 71 of the 2005 Vermont Legislature in response to implementation of the Medicare Part D drug coverage. Part D is now the primary payer for any beneficiary who is eligible for Medicare. *VPharm* provides secondary coverage for Vermonters who are eligible for Medicare, have income at or below 225% FPL, and are not eligible for Medicaid. Vermonters enrolled in *VPharm* pay *VPharm* premiums. *VPharm* covers Medicare Prescription Drug Plan (PDP) premiums and cost-sharing not paid by the federal low-income subsidy, as well as coverage of certain drugs in drug classes excluded by Part D.

- a) *VPharm*1 includes those with income up to 150% FPL. *VPharm*1 covers cost-sharing for drugs used for both acute and maintenance purposes and all Medicaid drugs in drug classes excluded by Part D.
- b) *VPharm*2 includes those with income up to 175% FPL. *VPharm*2 covers cost-sharing for drugs used for maintenance purposes and maintenance drugs in drug classes excluded by Part D.
- c) *VPharm*3 includes those with income up to 225% FPL. *VPharm*3 covers cost-sharing for *VScript* Expanded covered drugs used for maintenance purposes and *VScript* Expanded maintenance drugs in drug classes excluded by Part D.

*Medicare Part D Wrap Program*

<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	-	-
SFY '06 Actual (Jul '05 – Dec '05)	-	-
SFY '06 Actual (Jan '06 – Jun '06)	13,366	8,866,070
SFY '07 Appropriated	13,960	12,076,997
SFY '07 Budget Adjustment	12,961	8,002,761
<b>SFY '08 Gov. Rec.</b>	<b>14,906</b>	<b>9,643,076</b>

3) *Discount Program*

The *Healthy Vermonters Program* includes Vermonters who are at least age 65 or those receiving federal disability benefits up to 400% of the FPL and all others up to 300% of the FPL. The *Healthy Vermonters Program* provides a discount to Vermonters by making it possible to obtain prescriptions at the Medicaid rate.

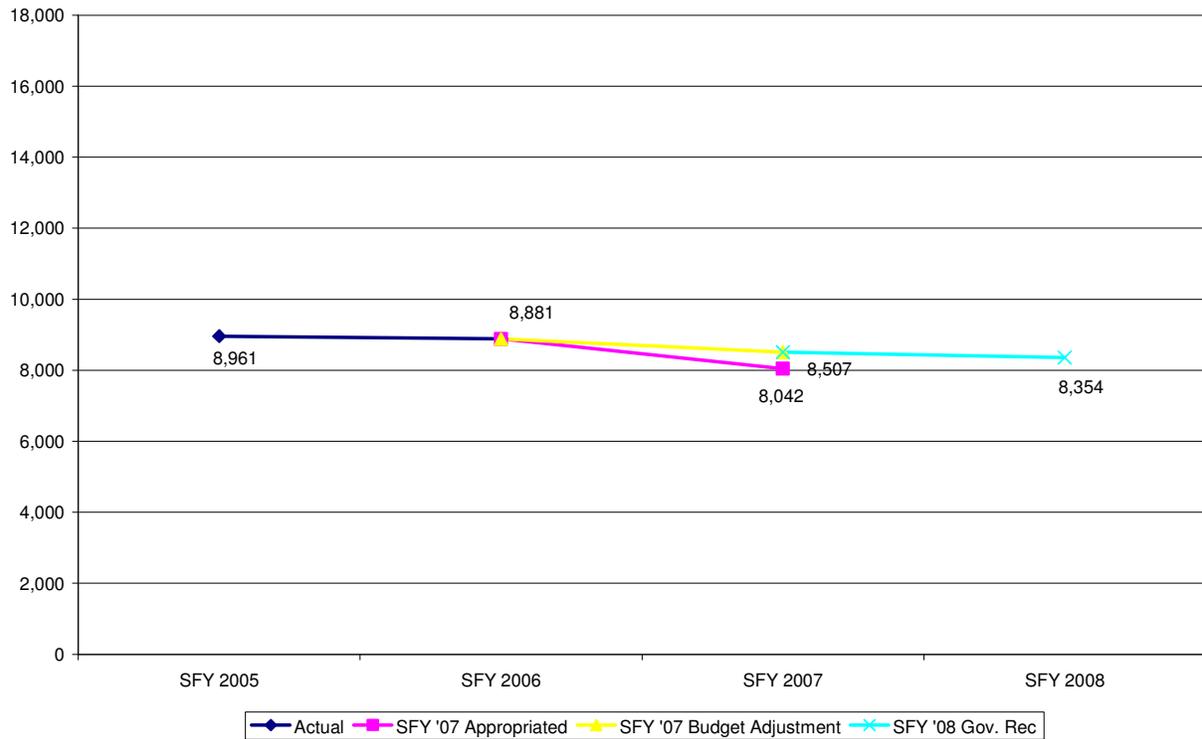
Medicare beneficiaries may use the *Healthy Vermonters Program* for drug classes that are excluded from Medicare Part D and not covered by their Medicare Prescription Drug Plan (PDP).

*Healthy Vermonters*

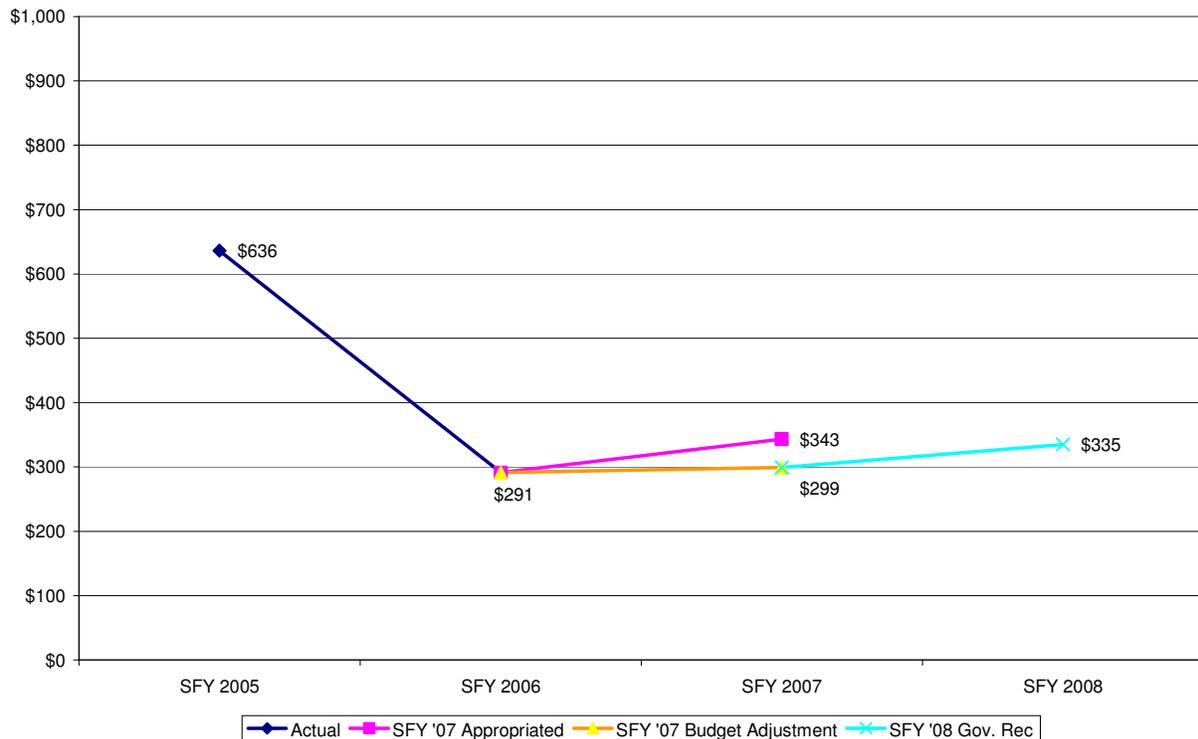
<b>SFY</b>	<b>Caseload</b>	<b>Expenditures</b>
SFY '05 Actual	13,255	0
SFY '06 Actual	13,707	0
SFY '07 Appropriated	13,733	0
SFY '07 Budget Adjustment	13,733	0
<b>SFY '08 Gov. Rec.</b>	<b>8,841</b>	<b>0</b>

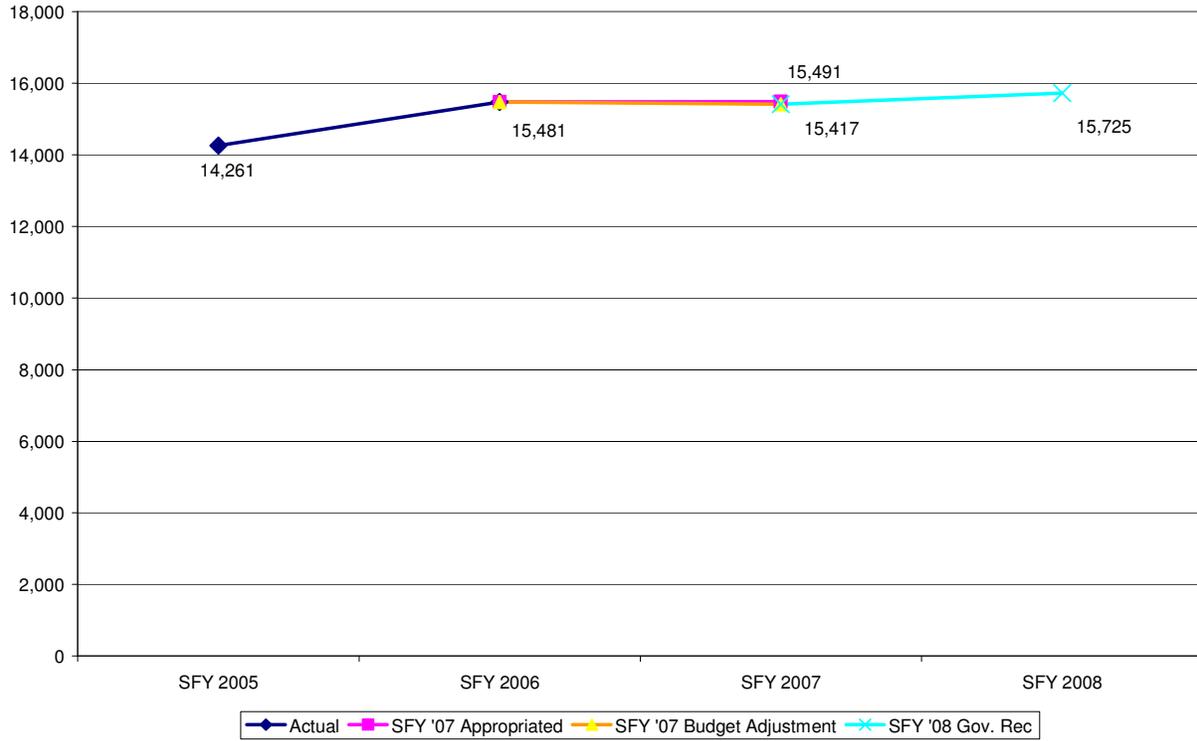
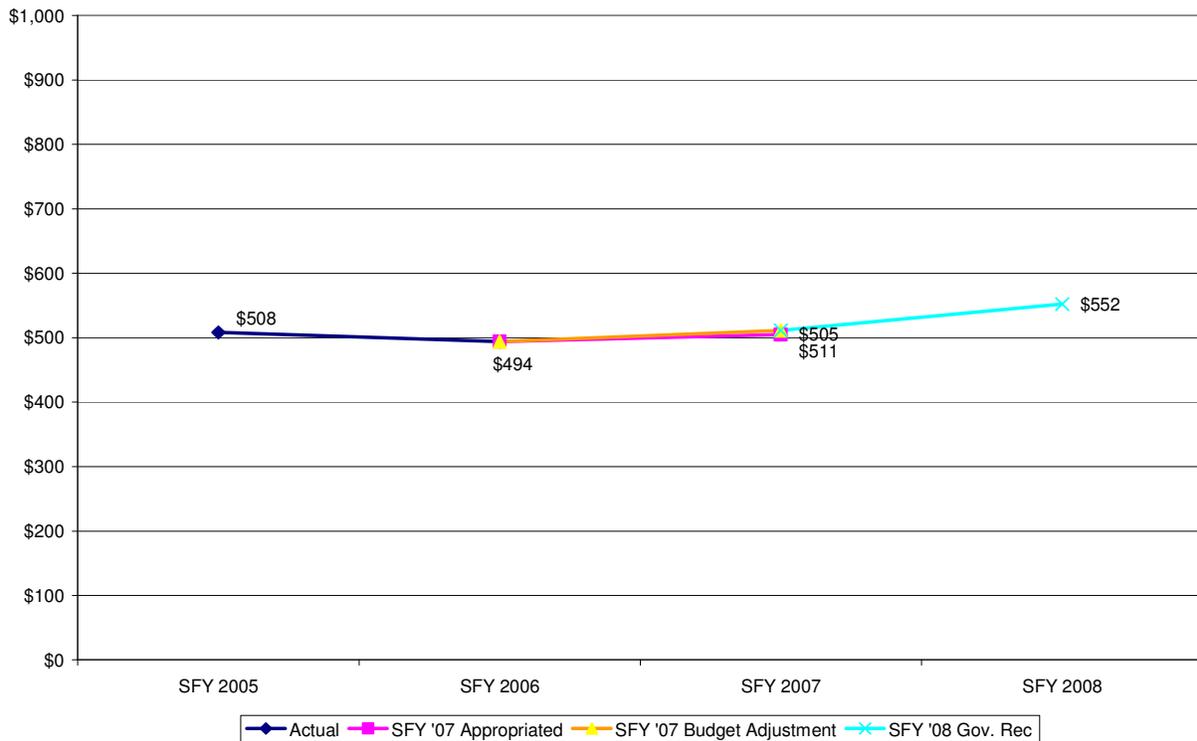
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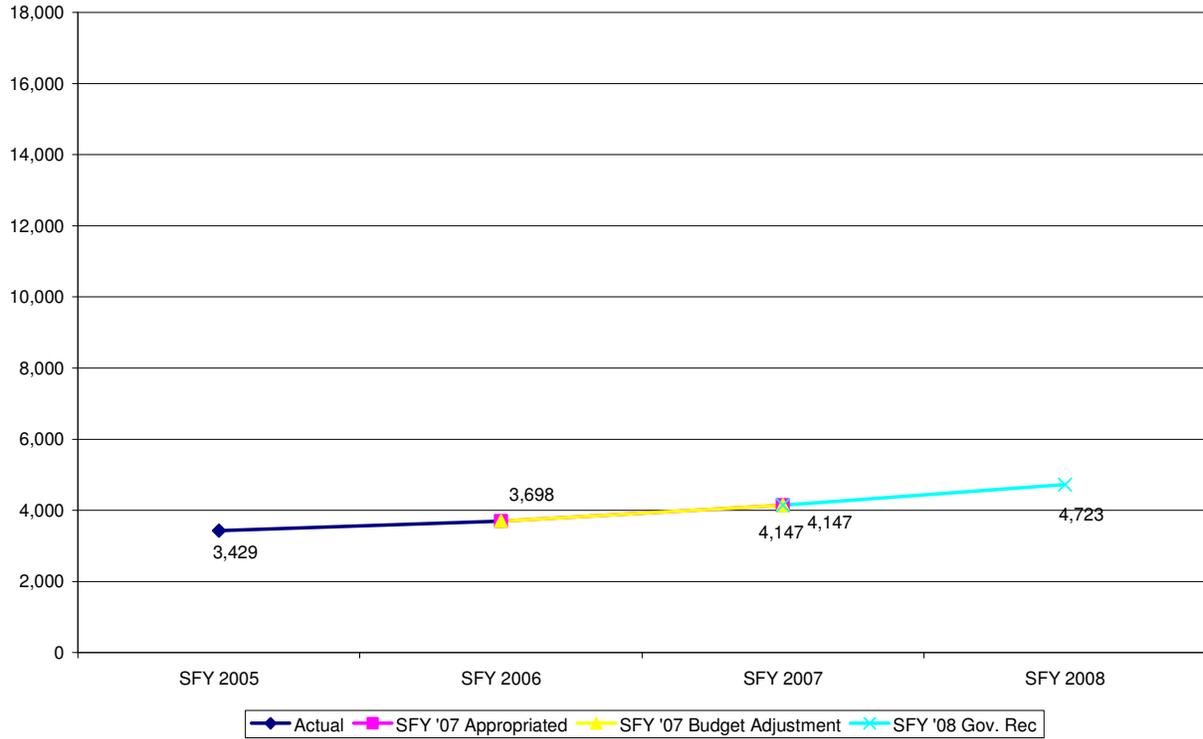
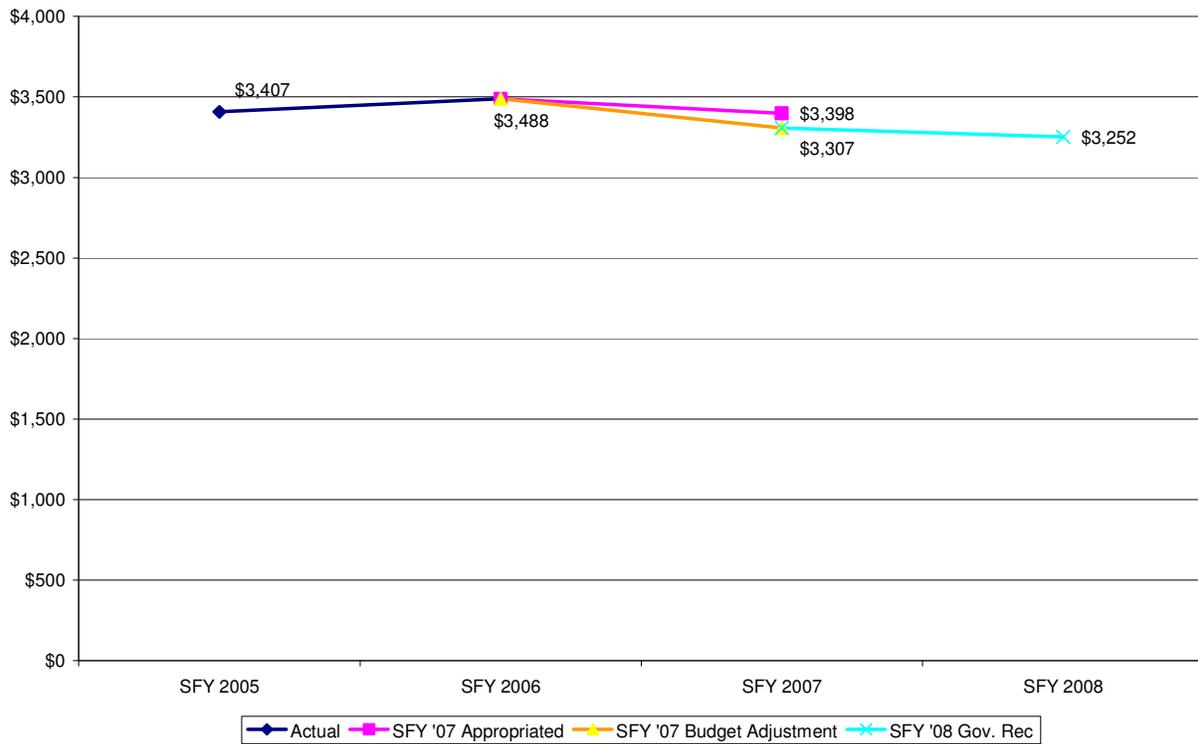
### Dual Eligibles Enrollment

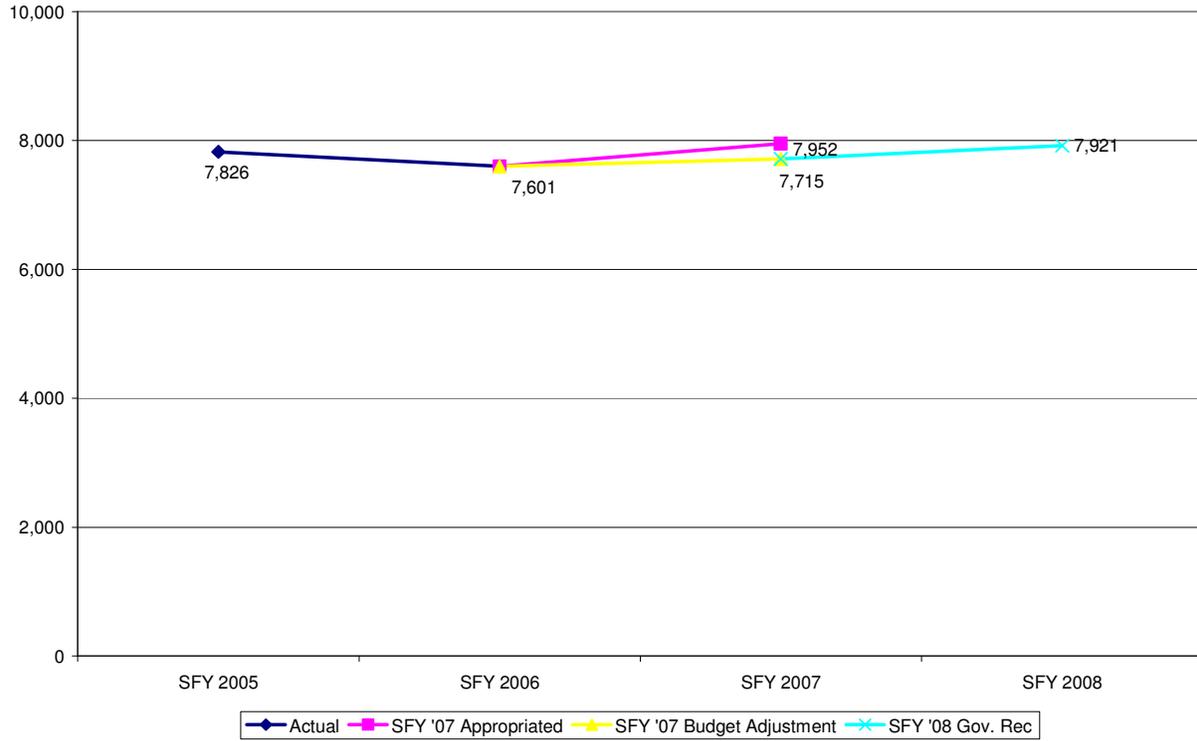
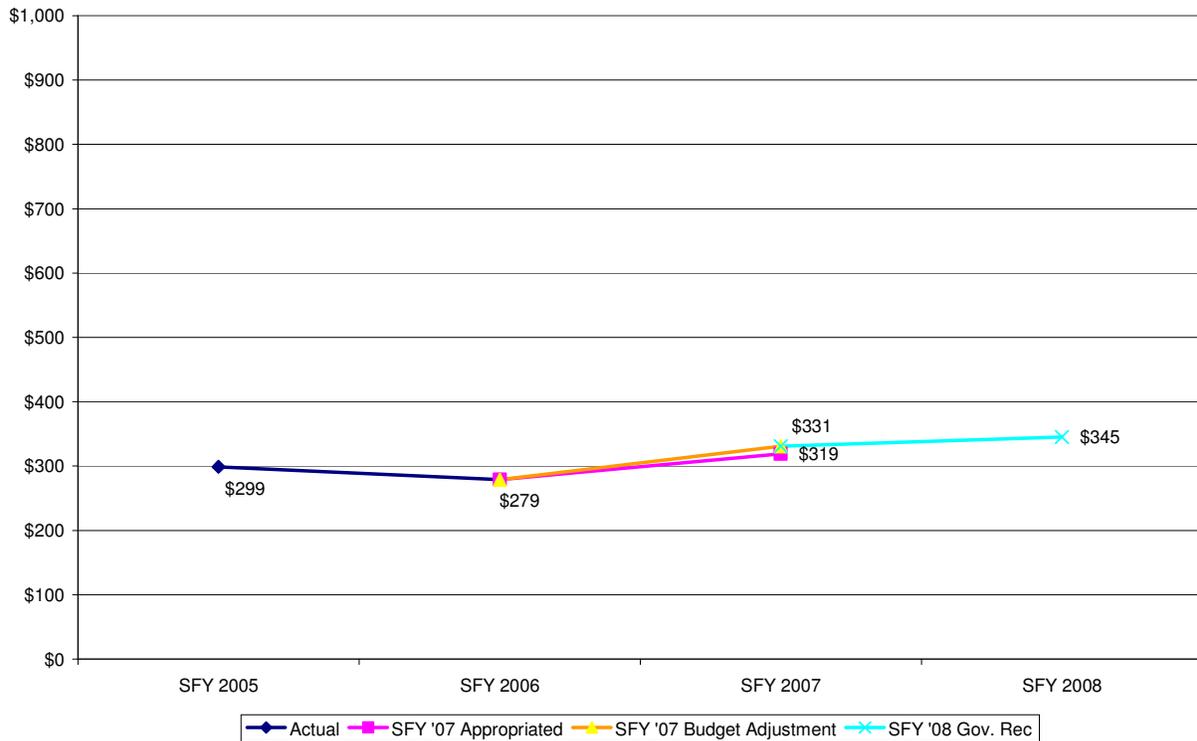


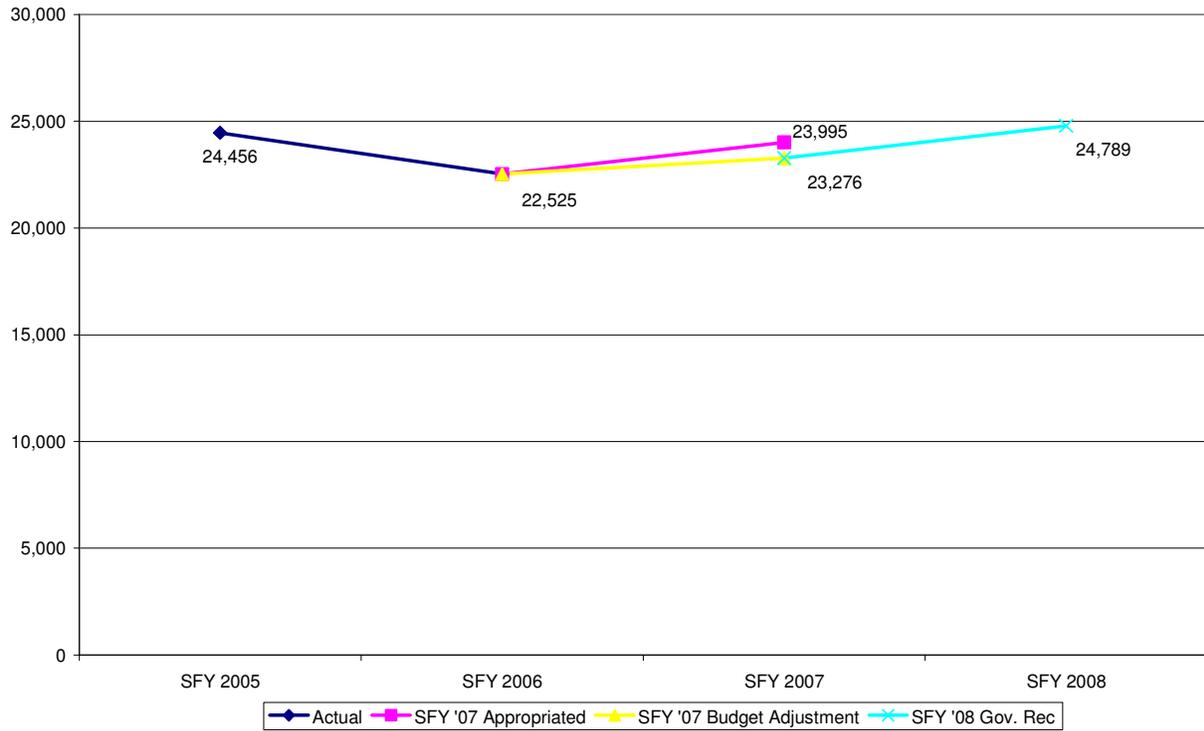
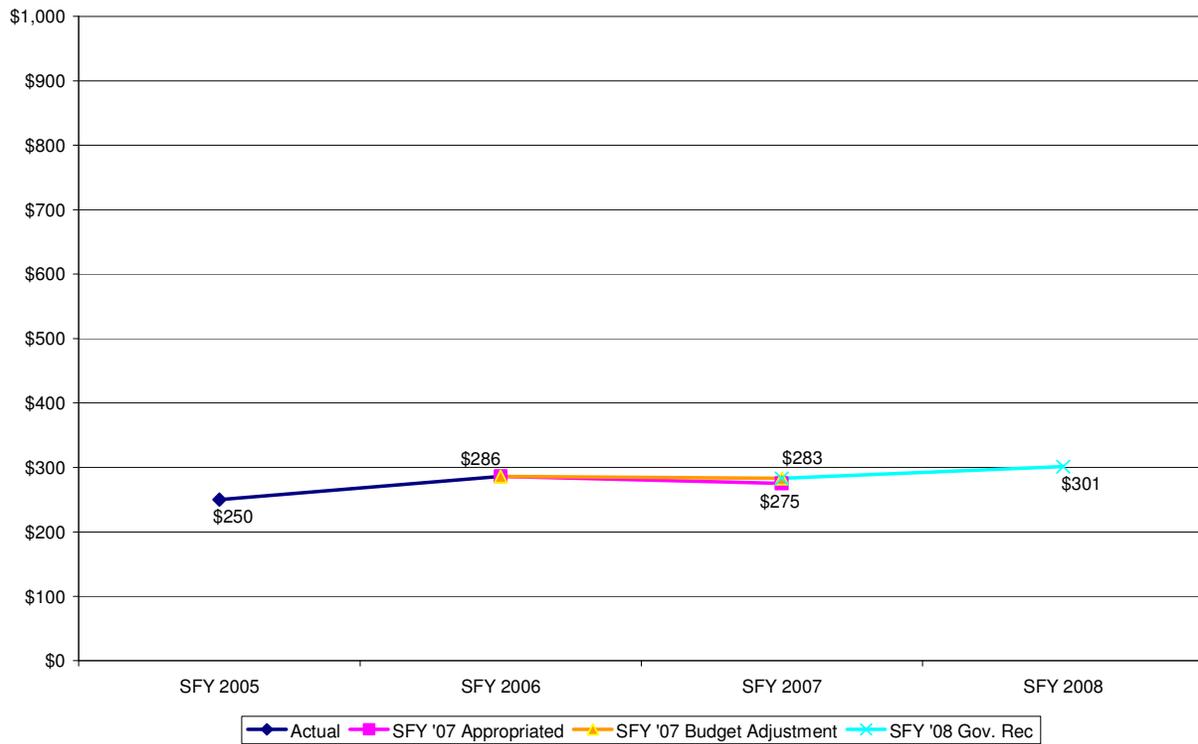
### Dual Eligibles PMPM

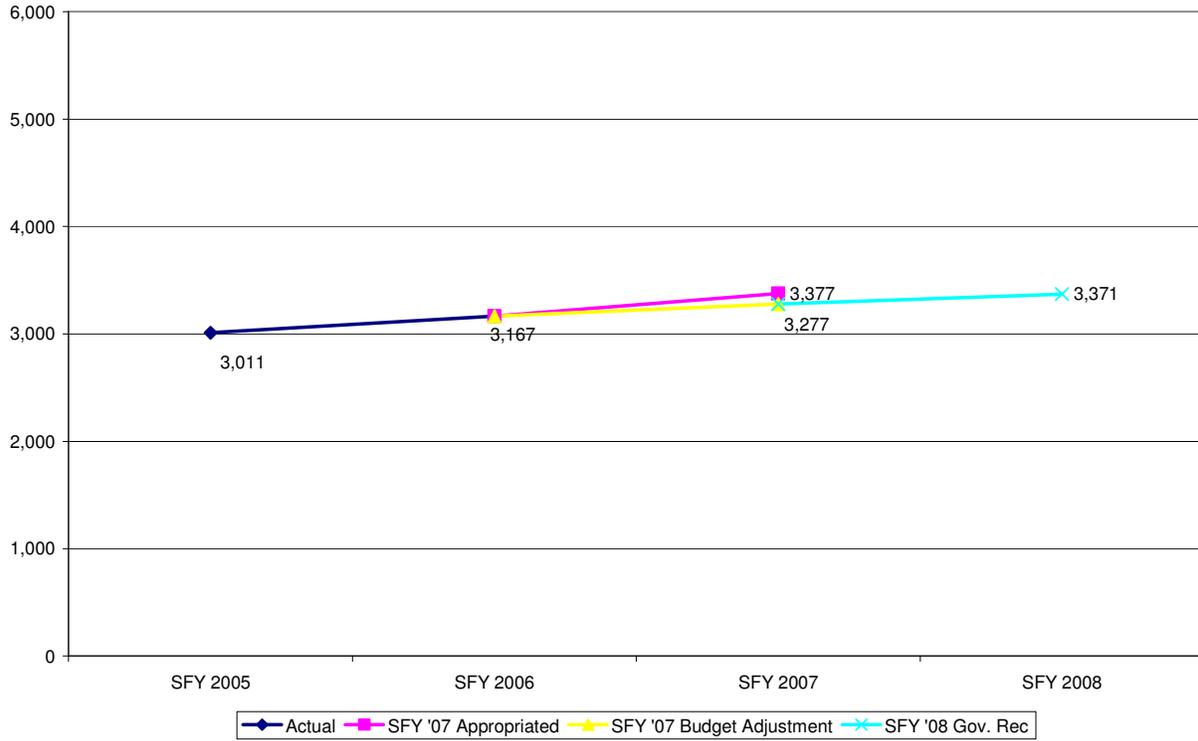
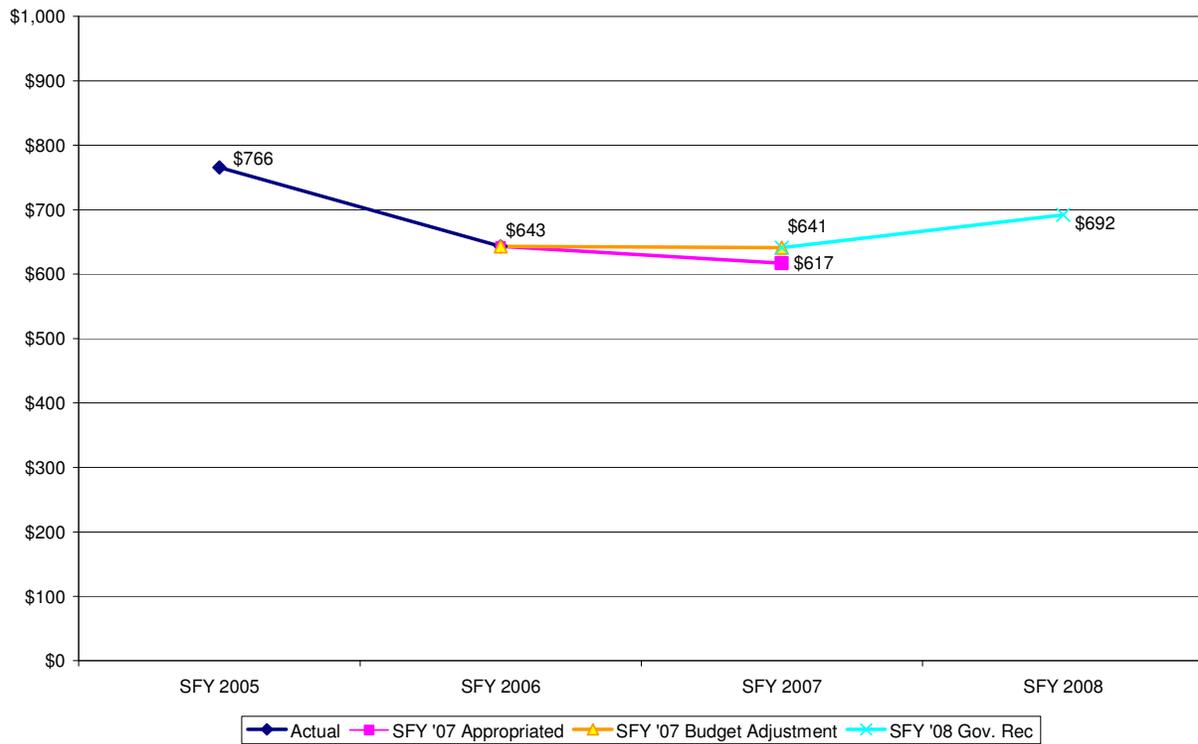


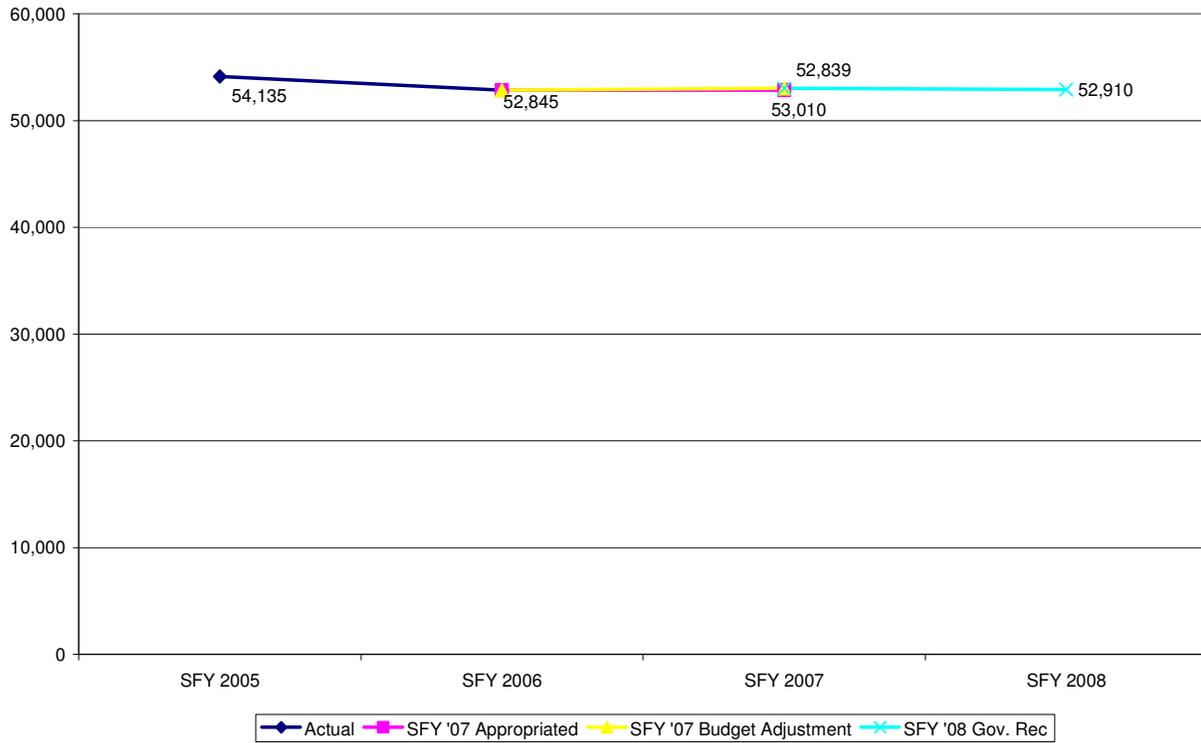
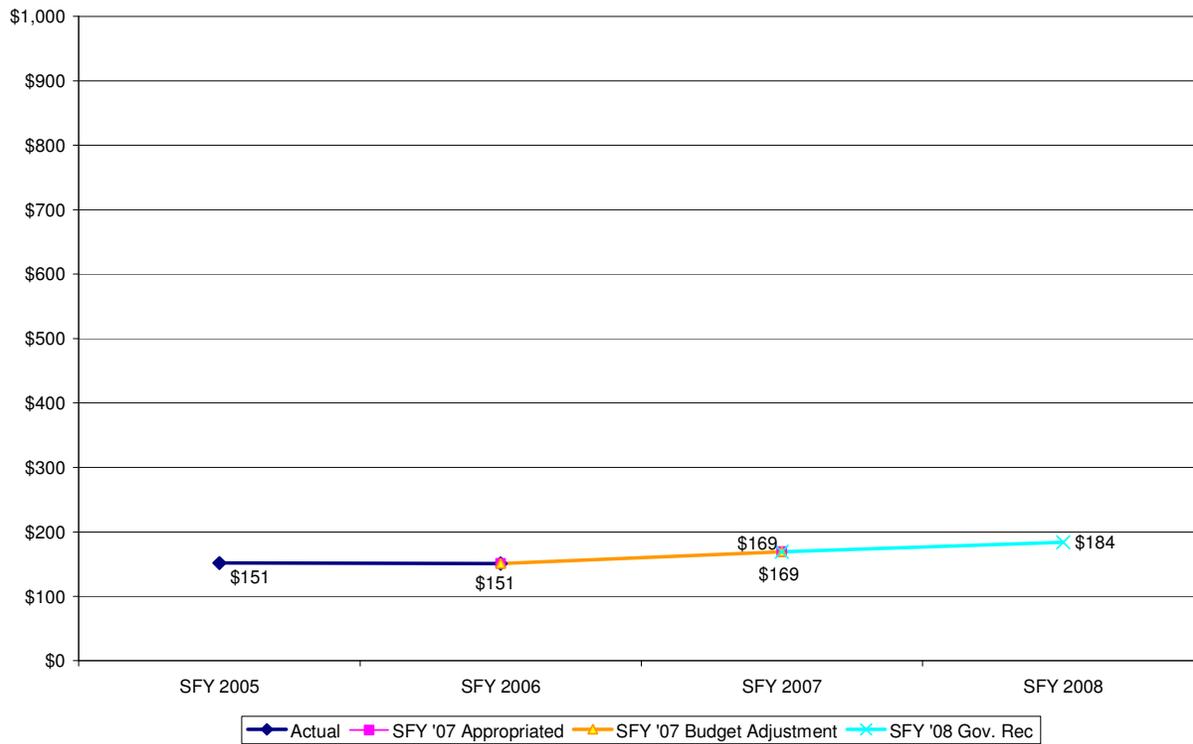
**Aged, Blind or Disabled (ABD) and/or Medically Needy Adults Enrollment**

**Aged, Blind, or Disabled and/or Medically Needy Adults PMPM**


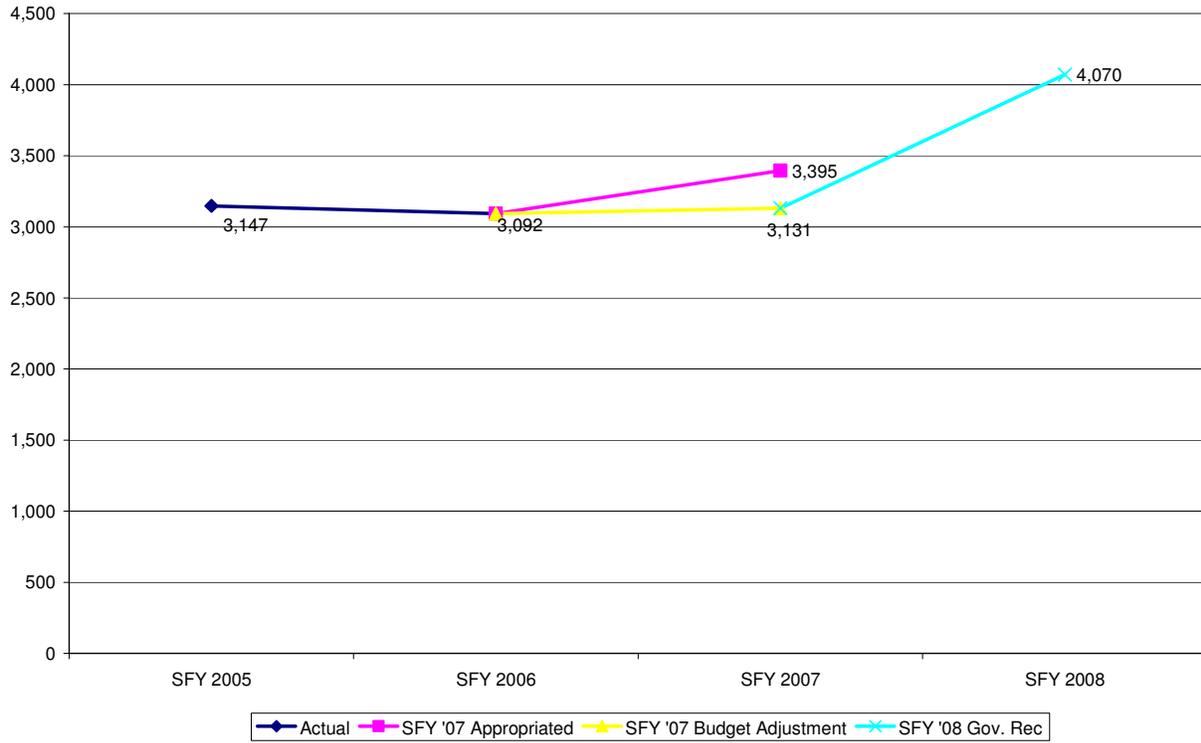
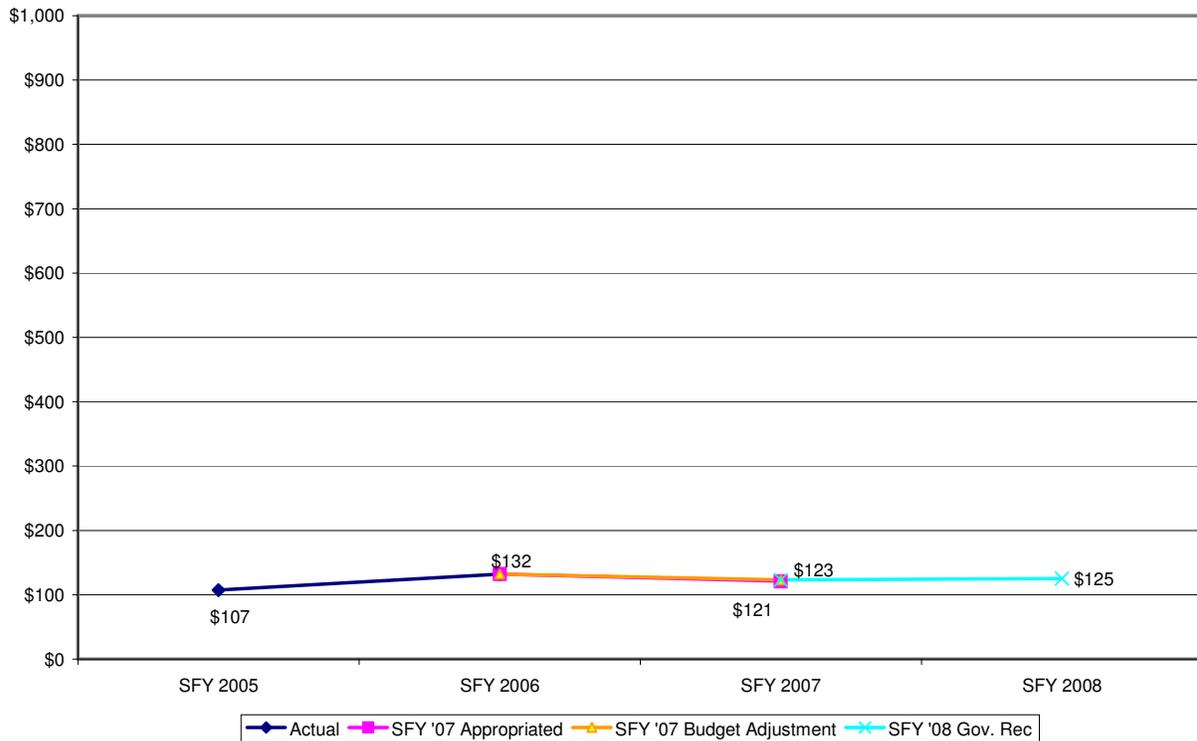
**Long Term Care Waiver and/or Medically Needy Enrollment**

**Long Term Care Waiver and/or Medically Needy PMPM**


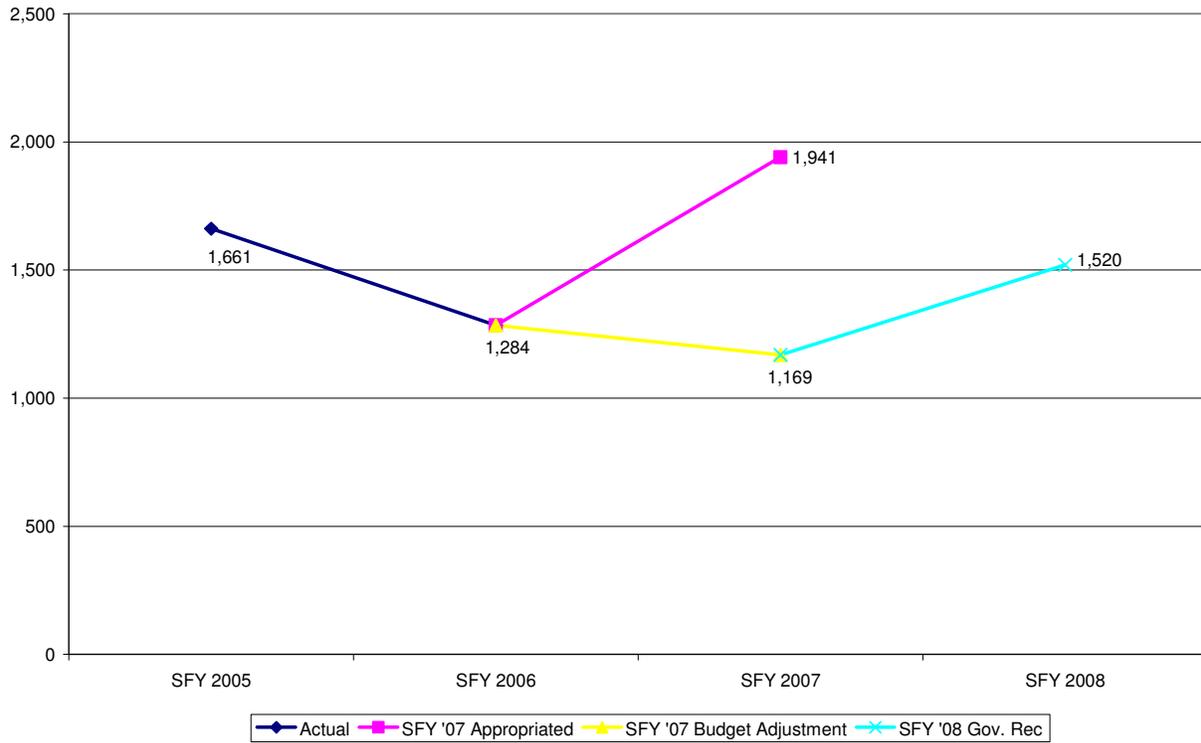
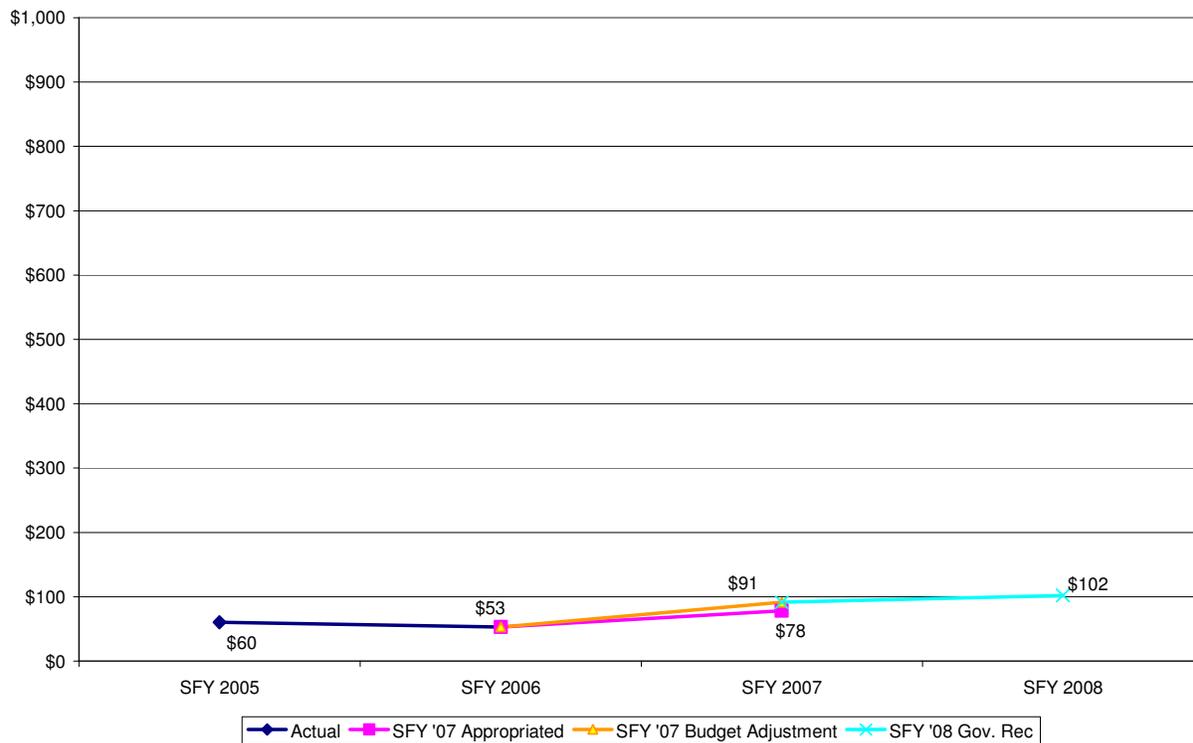
**General Adults Enrollment**

**General Adults PMPM**


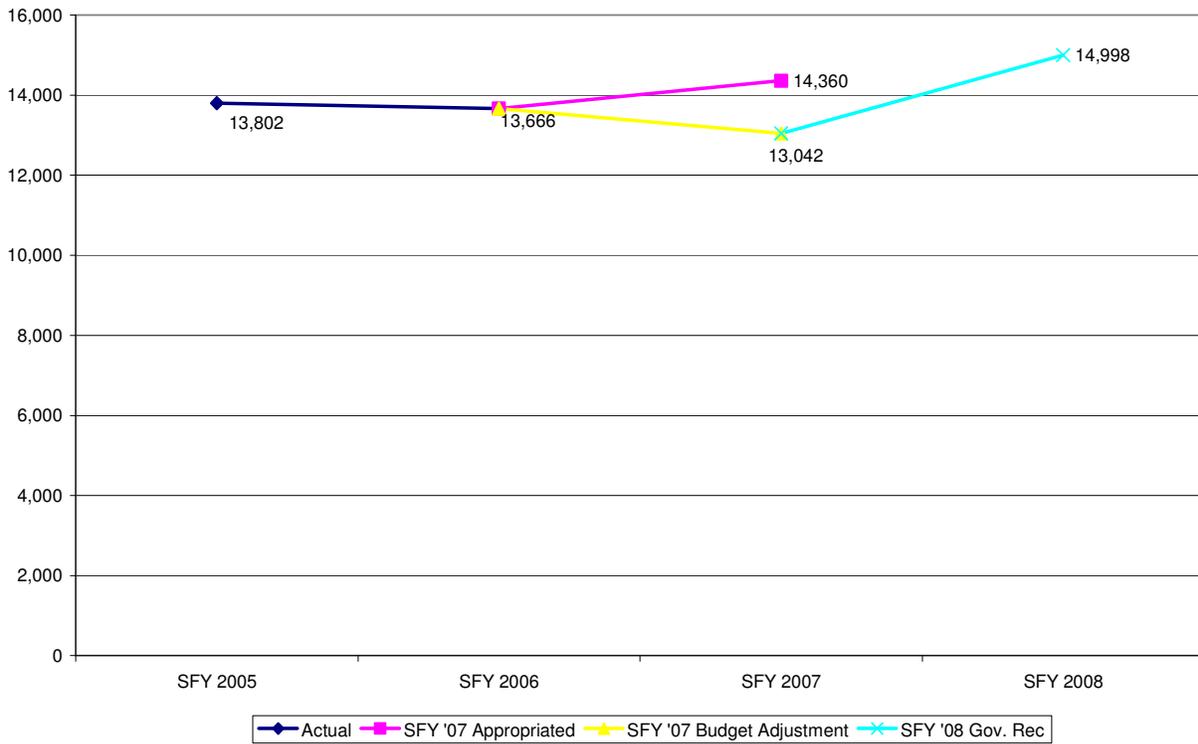
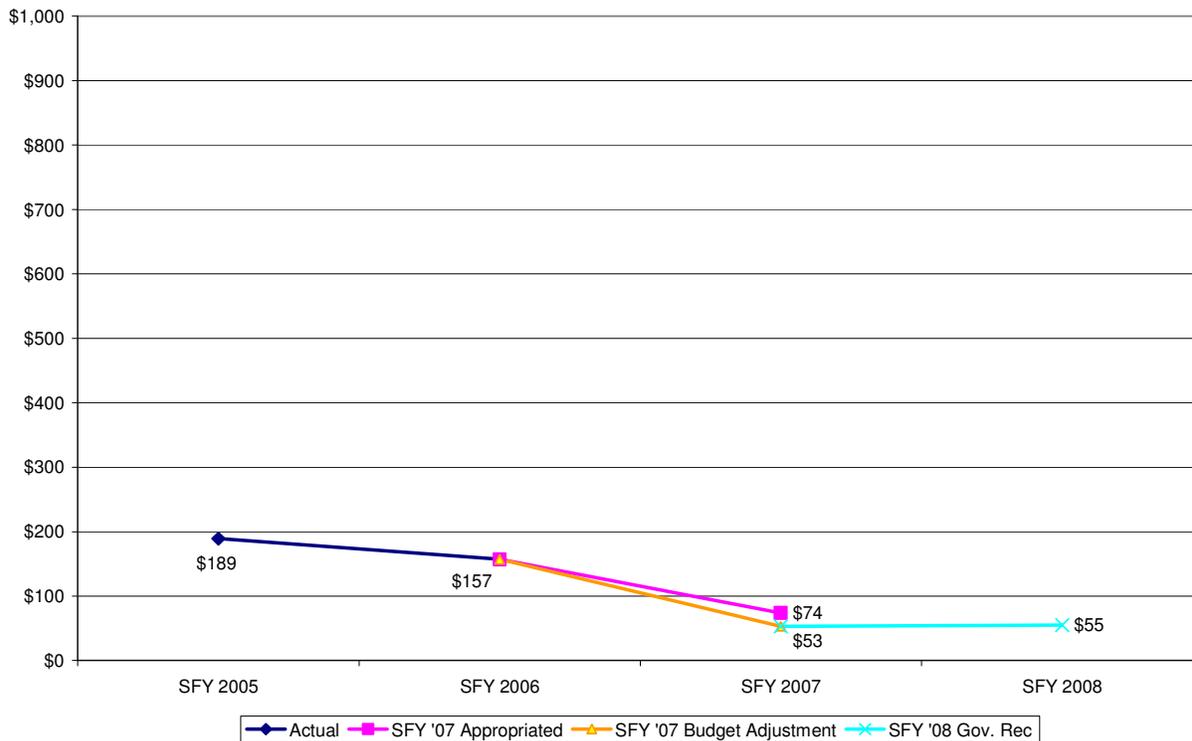
**VHAP Enrollment**

**VHAP PMPM**


**Blind or Disabled and/or Medically Needy Children Enrollment**

**Blind or Disabled and/or Medically Needy Children PMPM**


**General Children Enrollment**

**General Children PMPM**


**SCHIP Enrollment**

**SCHIP PMPM**


**Underinsured Children Enrollment**

**Underinsured Children PMPM**


**Pharmacy Program Enrollment**

**Pharmacy Program PMPM**


## Section 4: Catamount Health and Employer-Sponsored Insurance (ESI) Premium Assistance Programs

### **Fast Facts:**

- Catamount Health & ESI Premium Assistance Programs available October 1, 2007.
- Request for Proposals (RFP) for a firm to develop and implement a Comprehensive Outreach & Enrollment Strategy issued February 2, 2007.

### **Catamount Health**

Act 191, the new health care reform legislation, creates a new private insurance product called Catamount Health. Catamount Health is designed to be

comprehensive and affordable enough to attract many of Vermont's 60,000 uninsured residents to purchase it. Catamount Health plans will be available to uninsured Vermonters beginning October 1, 2007, through two or more of Vermont's largest insurance companies.

### **Employer-Sponsored Insurance (ESI) Premium Assistance**

Uninsured Vermonters with income under 300% of the Federal Poverty Level (FPL) may be eligible for assistance in paying their Employer-Sponsored Insurance (ESI) premiums beginning October 1, 2007. Applications for assistance will be made through the Department for Children and Families (DCF), Economic Services Division (ESD).

A Benefit Programs Specialist screens for Vermont Health Access Plan (VHAP) eligibility when ESD receives an application. If the applicant is eligible for VHAP and has an ESI plan available, the OVHA's Coordination of Benefits (COB) unit performs a test to determine whether it is more cost-effective to the State to enroll the applicant in VHAP or provide premium assistance for the ESI plan. Depending on the result, the applicant will be required to enroll in either VHAP or ESI. If the applicant is required to enroll in ESI, VHAP will "wrap around" the ESI plan so coverage and cost will be the same as VHAP.

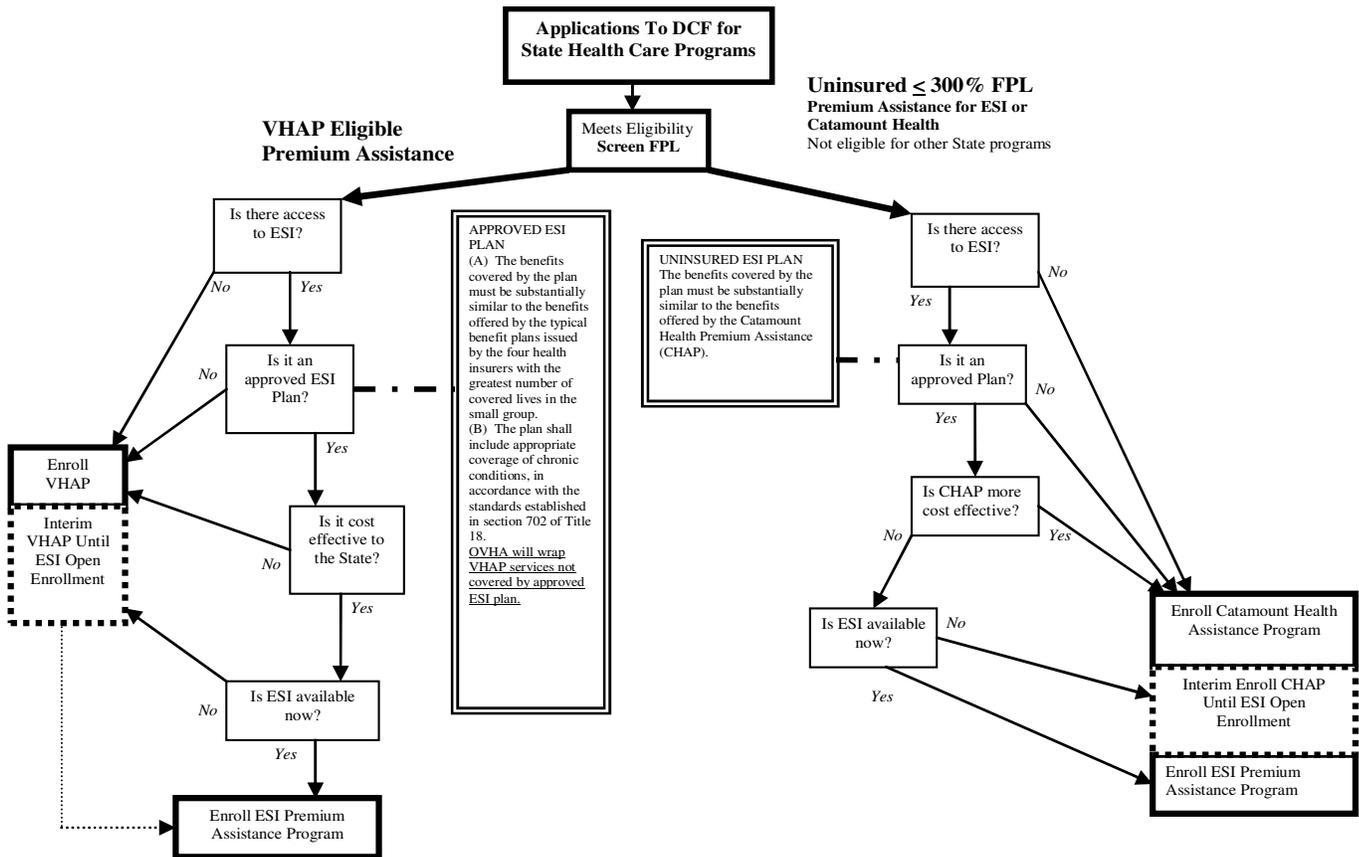
If an uninsured applicant applies for assistance and is over income for VHAP, but under 300% FPL, the OVHA's COB unit will perform a cost-effectiveness test between the ESI plan and Catamount Health. If the ESI plan with premium assistance is more cost-effective than premium assistance with the Catamount Health plan, the applicant will be required to enroll in ESI. For applicants who are not eligible for VHAP, there will be no VHAP "wrap around," but they will receive assistance with any cost-sharing associated with treatment of chronic conditions.

### **Catamount Health Premium Assistance Program**

If the cost-effectiveness test between ESI and Catamount Health determines that Catamount Health with premium assistance is more cost-effective to the State of Vermont than ESI, the applicant will be required to enroll in a Catamount Health plan, with assistance in paying the premiums, in order to receive any assistance from the

State of Vermont. Uninsured applicants who are under 300% FPL and who do not have an ESI plan available will be eligible for Catamount Health premium assistance.

Below is a diagram that illustrates the relationship between VHAP, VHAP/ESI, and Catamount Health premium assistance.



The OVHA and the DCF/ESD formed a work group in June 2006 for the planning and implementation of the ESI and Catamount Health premium assistance programs. Representatives from the Department of Banking, Insurance, Securities, and Health Care Administration (BISHCA), The Agency of Human Services (AHS), Maximus (Member Services Unit), Electronic Data Systems (Medicaid Management Information System), and Policy Studies, Inc. (system development) have participated in the work group as needed.

On September 11, 2006 the OVHA submitted a request to the Centers for Medicare and Medicaid Services (CMS) to amend the Global Commitment to Health waiver. This amendment would add the premium assistance programs to the waiver and expand eligibility up to 300% FPL.

An analysis of a recently-conducted survey of VHAP beneficiaries yielded an estimate that an ESI premium assistance program could produce gross savings and cost avoidance of \$12-\$13 million after administrative and development costs for the three-year period from SFY '08 through SFY '10. The State share of those savings and avoided costs would be approximately \$4.9-\$5.4 million.

The lower cost of ESI premium assistance would allow the State to provide assistance to more uninsured Vermonters. In addition to saving money, insuring the uninsured by maximizing their enrollment in ESI plans would bolster the commercial market on which most Vermonters depend for their health care coverage. Although other states' experience shows that premium assistance programs are challenging to administer, the resulting savings more than offset the administrative costs.

The OVHA submitted a report on ESI premium assistance to the Health Access Oversight and Joint Fiscal Committees on November 22, 2006.

### ***Impact of Premium Assistance Programs and additional VHAP Cases on Administrative Costs***

Although the ESI premium assistance program will save money, it is a very complex program that will be challenging and costly to administer, primarily due to the cost-effectiveness test and the extensive data collection needed to perform it. A conservative estimate is that an additional eight positions will be needed to collect data on the ESI plans available to new and existing VHAP and ESI beneficiaries, perform the cost-effectiveness test, and issue monthly premium assistance payments. Another 10 positions for DCF/ESD are necessary to determine eligibility for new applicants, including the increased number of VHAP beneficiaries due to lower premiums and the aggressive outreach campaign required by Act 191.

The employer database developed by the Office of Child Support (OCS) will be modified to contain details on ESI plans offered by employers across the State. The OVHA anticipates outsourcing the annual maintenance of this database, since ESI plan information and cost-effectiveness must be re-evaluated during each employer's open enrollment period.

### ***Outreach***

The OVHA issued a Request for Proposals (RFP) February 2, 2007 to procure services to develop and implement a comprehensive outreach and enrollment strategy for the uninsured, using a unified marketing campaign with specialized messages for specific populations and broader audiences as established by Vermont's Health Care Reform legislation.

The RFP can be accessed at:

<http://www.vermontbusinessregistry.com/BidPreview.aspx?BidID=4421>

The AHS has formed an Outreach and Enrollment Workgroup to work with the bidder selected in response to this RFP. The Workgroup consists of representation from the AHS Central Office, the OVHA, the Vermont Department of Health (VDH) and the Department for Children and Families (DCF). The Workgroup meets with the Director of Health Care Reform Implementation on a regular basis and is charged with coordinating the AHS outreach and enrollment activities pertinent to Vermont's Health Care Reform.

### **Premium Assistance Case Examples**

#### *Example 1 VHAP/ESI*

Sam Norton submits a VHAP/premium assistance application form through the mail to the Health Access Eligibility Unit (HAEU) in the Department for Children and Families' Economic Services Division (ESD). An eligibility specialist in HAEU screens the application to determine whether other information or verification is needed to process the application. The specialist finds Sam's application to be complete and enters the information into ACCESS, the eligibility automated system. ACCESS determines that Sam has income below 150% of the poverty level, and that he meets the definition of "uninsured." ACCESS also determines that Sam's income exceeds the part-time threshold and generates a Plan Information Request Letter (PIRL) to Sam, asking that he have his employer complete it. The PIRL will collect information on whether the employer offers an ESI plan to employees, whether Sam is eligible to enroll, how much Sam's share of the premium would be, and other information about covered services and cost-sharing. The PIRL asks Sam to return the form to the OVHA's Coordination of Benefits (COB) unit within a specified number of days. In the meantime, Sam is enrolled in VHAP and asked to pay a VHAP premium of \$33 (based on his income, which is between 100% and 150% of FPL) for his first month of VHAP coverage.

While ESI confirmation is in process, Sam will receive full VHAP coverage.

Cost-effective test example:	
Employer pays 80% of \$450:	\$360
Sam pays 20% of \$450:	\$90
VHAP PMPM for age/gender:	\$350

Sam returns the PIRL within the timeframe specified (if Sam did not return the form, a reminder letter would be sent). COB reviews the form for completeness and calls the employer if any addition information is needed. COB enters

the information into the ACCESS system. ACCESS stores the information on Sam's record, and also in an employer database that stores plan information for each employer. ACCESS compares the cost of Sam's ESI plan against the average VHAP claims for his age/gender cohort. In Sam's case, his employer offers a plan with a premium of \$450 per month; the employer pays 80% of the premium, so Sam's share is \$90 per month. The deductible under the plan is \$250 with an out-of-pocket maximum of \$500. The per-member-per-month (PMPM) for Sam's age/gender cohort is \$350 per month. ACCESS determines that Sam's ESI plan is cost-effective, and generates a letter to Sam asking him to enroll in his plan and return a form to COB indicating when coverage will begin.

Sam enrolls in his ESI plan and returns the form to COB. Sam will now pay the full \$90 share of his premium to his employer through payroll deduction. Monthly premium assistance payments will be generated directly to Sam from the MMIS. Sam has a bank account, so his premium assistance payments will be made by direct deposit. As a VHAP beneficiary, Sam has a monthly obligation to contribute \$33 toward the cost of his coverage. His premium assistance payment will be the cost of Sam's share of the ESI premium (\$90) minus his contribution (\$33), or \$57 per month.

Premium Assistance Calculation:	
Sam's share of ESI premium	\$90
Minus Sam's contribution	\$-33
Sam's monthly premium assistance	\$57

Sam will continue to receive \$57 per month, unless there is a change in his income or he becomes ineligible for VHAP for another reason (e.g., Sam moves to another state). VHAP will provide wraparound coverage so that

Sam will receive the same coverage under his ESI plan as he would under VHAP, and at a cost that does not exceed his VHAP cost obligation.

On a monthly basis the MMIS will send a transaction to Sam's ESI insurance carrier to verify that Sam is still enrolled in his plan. Sam's eligibility for VHAP and the cost-effectiveness of his ESI plan will be reviewed annually by HAEU (eligibility) and the OVHA's COB (cost-effectiveness) Unit.

### *Example 2*

#### *ESI/Catamount Health Premium Assistance*

Martha Stein applies for premium assistance on the VHAP/premium assistance application form, which she sends to HAEU. The HAEU eligibility specialist enters the information from the application form into the ACCESS. ACCESS screens Martha for VHAP eligibility, determines that she meets the definition of "uninsured," but finds she has earned income of 230% FPL, which is above the VHAP maximum of 150%. ACCESS determines that Martha has earned income above the part-time threshold, and so generates a Plan Information Request Letter (PIRL) to Martha, asking her to have her employer complete the form. Martha returns the PIRL to the OVHA's COB Unit. COB enters the information into the ACCESS system, and ACCESS determines that Martha's ESI plan is cost-effective.

Although Martha's employer offers an ESI plan, Martha can't enroll until the next open enrollment period, which is six months from now. ACCESS

State pays full premium to Catamount Health	\$362
Martha pays her share to state	\$110

generates a letter to Martha informing her that she will be required to enroll in the ESI plan at the next open enrollment period, but in the meantime, she may enroll in Catamount Health Premium Assistance (CHAP) if she chooses to do so. Information about the Catamount Health plans will be sent to her to help her make a decision on which plan to choose. Martha decides to enroll in the MVP plan, and she returns a form to COB that contains an enrollment date. A notice is sent to Martha informing her that she will begin receiving premium assistance.

CHAP beneficiaries are required to pay their premium shares to the state, and the state pays the full premium to the insurance carrier. At Martha's income level she is required to pay \$110 per month toward the cost of her Catamount Health premium of \$362. Martha will receive monthly bills from ACCESS of \$110, which she must pay to continue to receive premium assistance. The same premium payment system will be used for Catamount Health as is used for VHAP/Dr. Dynasaur premium payments. Martha may choose to mail a check to the state's lockbox or may choose automatic withdrawal as her means of payment. She may also pay cash at various locations around the state. As long as Martha continues paying her share of the premium, the state will pay her CHAP premium directly to MVP. The MMIS will issue payments to the two Catamount Health carriers by EFT; the payments will include premiums for all CHAP beneficiaries enrolled in each plan.

At least 30 days before the open enrollment period for Martha's ESI plan, Martha will be sent a PIRL advising her that COB must review the cost-effectiveness of her ESI plan. Martha will return the PIRL to COB. COB will determine whether her employer will be

Premium assistance calculation:	
Martha's share of premium assistance	\$135
Minus Martha's contribution	\$-110
Martha's premium assistance	\$25

changing plans, modifying coverage or cost for the coming year. If so, ACCESS will do a new cost-effectiveness determination. If the ESI plan is cost-effective, Martha will receive a letter asking that she enroll in the

ESI plan. Once Martha is enrolled, her CHAP eligibility will terminate and she will receive monthly premium assistance through check or direct deposit. In Martha's case, her employer pays 70% of a \$450 premium, so Martha's share is \$135 per month. Her premium assistance payment is \$135 minus her \$110 contribution, or \$25 per month. As an ESI premium assistance beneficiary, Martha will receive wraparound coverage for any cost-sharing associated with the treatment of chronic conditions. Martha's eligibility for premium assistance and the cost-effectiveness of her ESI plan will be reviewed annually.

The following three pages include consensus balance sheets for the Catamount fund as follows:

1. Total Costs for all Initiatives Reducing the Number of Uninsured in Vermont
2. Catamount Expansion Only
3. Medicaid Only – Increased Enrollment

## Total Costs for all Initiatives Reducing the Number of Uninsured in Vermont

Office of Vermont Health Access  
New Healthcare Initiative (Catamount, ESI, & Medicaid) ~ Balance Sheet  
Revised Balance Sheet ~ Total Costs for All Initiatives Reducing the Number of Uninsured in Vermont  
Friday, February 23, 2007

	# Est. Uninsured	TAKE-UP RATES	SFY '07	SFY '08	SFY '09	SFY '10
<b>ENROLLMENT DETAIL</b>						
* Adults Ineligible for Catamount	2,179	0.00%	-	-	-	-
Catamount Health ~ No Premium Assistance	9,754	8.00%	-	312	780	3,381
Catamount Health ~ Premium Assistance	13,329	53.10%	-	2,831	7,078	7,078
Catamount Eligible Employer-Sponsored Insurance	3,332	13.30%	-	142	443	443
* Employer-Sponsored Insurance ~ VHAP Enrollees Converting to ESI	n/a	n/a	-	350	1,068	1,068
* Employer-Sponsored Insurance ~ New Enrollees VHAP Eligible		0.67%	-	39	89	156
* New VHAP Enrollees Due to Reduced Premiums & Outreach	13,379	12.64%	-	1,314	1,690	2,961
* New VHAP Enrollees - <50% FPL	7,989	10.00%	-	160	799	799
New Catamount Enrollees Due to Crowd Out	-	0.00%	-	-	500	2,000
* Traditional Medicaid Enrollees	4,514	10.00%	-	90	451	451
* Children (excluded from Catamount estimates at this time)	6,580	21.50%	-	1,100	1,415	1,415
<b>TOTAL NEW ENROLLEES COVERED</b>	<b>61,056</b>	<b>23.44%</b>		<b>6,338</b>	<b>14,313</b>	<b>19,752</b>
<b>PER-MEMBER PER-MONTH STATE EXPENDITURES</b>						
Catamount Health Per-Member Per-Month				\$ 361.52	\$ 362.85	\$ 363.36
Catamount Eligible Employer-Sponsored Insurance Per Member Per Month				\$ 109.50	\$ 116.96	\$ 124.92
* VHAP Eligible Employer-Sponsored Insurance Per-Member Per-Month				\$ 119.79	\$ 127.95	\$ 136.66
* Medicaid ~ VHAP Per-Member Per-Month				\$ 327.51	\$ 349.81	\$ 373.64
* General Adult Per-Member Per-Month				\$ 345.18	\$ 368.69	\$ 393.79
* General Child Per-Member Per-Month				\$ 184.47	\$ 197.03	\$ 210.45
<b>TOTAL PROGRAM EXPENDITURES</b>						
Catamount Health				12,281,414	30,817,255	30,860,569
Catamount Eligible Employer-Sponsored Insurance				186,751	621,999	664,358
* VHAP Eligible Employer-Sponsored Insurance ~ Conversion Savings				(1,655,869)	(4,948,216)	(5,285,190)
* VHAP Eligible Employer-Sponsored Insurance ~ New				55,671	136,603	255,608
* VHAP (new)				5,166,061	7,096,049	13,278,005
* New VHAP Enrollees < 50% FPL				627,955	3,353,591	3,581,971
Catamount Health Due to Crowd Out				-	2,177,100	8,720,640
* Traditional Medicaid Enrollees				373,954	1,997,102	2,133,105
* Children				-	909,693	1,137,467
<b>Subtotal New Program Spending</b>				<b>17,035,937</b>	<b>42,161,176</b>	<b>55,346,533</b>
Catamount and ESI Administrative Costs				991,112	3,703,910	2,545,523
<b>TOTAL GROSS PROGRAM SPENDING</b>				<b>991,112</b>	<b>20,739,847</b>	<b>57,631,218</b>
<b>TOTAL STATE PROGRAM SPENDING</b>				<b>408,140</b>	<b>8,501,263</b>	<b>17,981,035</b>
<b>TOTAL OTHER EXPENDITURES</b>						
Immunizations Program				-	4,000,000	4,200,000
VT Dept. of Labor Admin Costs Assoc. With Employer Assess.				246,357	394,072	401,292
Marketing and Outreach				3,034,333	1,316,167	500,000
Blueprint				-	2,762,567	3,038,824
Individual Market Investment				-	3,750,000	4,125,000
Medicaid Reimbursement				-	-	-
* Hospitals ~ Incr (H.861)				-	-	2,100,000
Hospitals ~ Incr (Policy Change)				-	2,000,000	2,000,000
Physicians ~ Incr (Policy Change)				-	2,000,000	2,000,000
<b>TOTAL OTHER SPENDING</b>				<b>3,280,690</b>	<b>16,222,806</b>	<b>18,365,116</b>
<b>TOTAL STATE OTHER SPENDING</b>				<b>1,495,895</b>	<b>13,085,736</b>	<b>14,419,636</b>
<b>TOTAL ALL STATE SPENDING</b>				<b>1,904,035</b>	<b>21,586,999</b>	<b>32,400,671</b>
<b>TOTAL REVENUES</b>						
Catamount Health Premiums				-	3,205,684	8,014,410
Catamount Eligible Employer-Sponsored Insurance Premiums				-	175,228	546,409
VHAP Eligible Employer-Sponsored Insurance Premiums				-	15,560	35,746
VHAP Premiums (new)				-	528,113	679,160
Medicaid ~ Premium Reduction (existing)				-	(670,601)	(2,046,293)
Catamount Health Premiums Due to Crowd Out				-	-	566,182
<b>Subtotal Premiums</b>				<b>-</b>	<b>3,253,984</b>	<b>7,795,614</b>
Federal Share of Premiums				-	(1,920,176)	(4,660,218)
<b>TOTAL STATE PREMIUM SHARE</b>				<b>-</b>	<b>1,333,808</b>	<b>3,135,396</b>
Cigarette Tax Increase (\$.60 / \$.80) ~ 17.5%				9,439,500	9,083,000	9,594,500
Floor Stock				1,200,000	-	500,000
Employer Assessment				2,000,000	8,300,000	10,600,000
<b>TOTAL OTHER REVENUE</b>				<b>12,639,500</b>	<b>17,383,000</b>	<b>20,694,500</b>
<b>TOTAL STATE REVENUE</b>				<b>-</b>	<b>12,639,500</b>	<b>18,716,808</b>
State-Only Balance				10,735,465	(2,870,191)	(8,570,775)
Carryforward				-	10,735,465	7,865,274
<b>(DEFICIT)/SURPLUS</b>				<b>-</b>	<b>10,735,465</b>	<b>7,865,274</b>

\* Denotes Medicaid Only Increases

**Catamount Expansion Only**

**Office of Vermont Health Access**  
 New Healthcare Initiative (Catamount, ESI, & Medicaid) ~ Balance Sheet  
**Revised Balance Sheet - Catamount Expansion Only**  
 Friday, February 23, 2007

	# Est. Uninsured	TAKE-UP RATES	SFY '07	SFY '08	SFY '09	SFY '10
<b>ENROLLMENT DETAIL</b>						
Catamount Health ~ No Premium Assistance	9,754	8.00%		312	780	3,381
Catamount Health ~ Premium Assistance	13,329	53.10%		2,831	7,078	7,078
Catamount Eligible Employer-Sponsored Insurance	3,332	13.30%		142	443	443
New Catamount Enrollees Due to Crowd Out					500	2,000
<b>TOTAL NEW ENROLLEES COVERED</b>	<b>26,415</b>	<b>33.32%</b>		<b>3,285</b>	<b>8,801</b>	<b>12,902</b>
<b>PER-MEMBER PER-MONTH STATE EXPENDITURES</b>						
Catamount Health Per-Member Per-Month				\$ 361.52	\$ 362.85	\$ 363.36
Catamount Eligible Employer-Sponsored Insurance Per Member Per Month				\$ 109.50	\$ 116.96	\$ 124.92
<b>TOTAL PROGRAM EXPENDITURES</b>						
Catamount Health				12,281,414	30,817,255	30,860,569
Catamount Eligible Employer-Sponsored Insurance				186,751	621,999	664,358
Catamount Health Due to Crowd Out				-	2,177,100	8,720,640
<b>Subtotal New Program Spending</b>				<b>12,468,165</b>	<b>33,616,354</b>	<b>40,245,567</b>
Catamount and ESI Administrative Costs			991,112	3,703,910	2,545,523	2,284,685
<b>TOTAL GROSS PROGRAM SPENDING</b>			<b>991,112</b>	<b>16,172,075</b>	<b>36,161,877</b>	<b>42,530,252</b>
<b>TOTAL STATE PROGRAM SPENDING</b>			<b>408,140</b>	<b>6,628,933</b>	<b>14,544,307</b>	<b>17,105,667</b>
<b>TOTAL OTHER EXPENDITURES</b>						
Immunizations Program			-	4,000,000	4,200,000	4,300,000
VT Dept. of Labor Admin Costs Assoc. With Employer Assess.			246,357	394,072	401,292	421,357
Marketing and Outreach			3,034,333	1,316,167	500,000	500,000
Blueprint			-	2,762,567	3,038,824	3,342,706
Individual Market Investment			-	3,750,000	4,125,000	4,537,500
Medicaid Reimbursement						
Hospitals ~ Incr (Policy Change)			-	2,000,000	2,000,000	2,000,000
Physicians ~ Incr (Policy Change)			-	2,000,000	2,000,000	2,000,000
<b>TOTAL OTHER SPENDING</b>			<b>3,280,690</b>	<b>16,222,806</b>	<b>16,265,116</b>	<b>17,101,563</b>
<b>TOTAL STATE OTHER SPENDING</b>			<b>1,495,895</b>	<b>13,085,736</b>	<b>13,575,016</b>	<b>14,411,463</b>
<b>TOTAL ALL STATE SPENDING</b>			<b>1,904,035</b>	<b>19,714,669</b>	<b>28,119,323</b>	<b>31,517,130</b>
<b>TOTAL REVENUES</b>						
Catamount Health Premiums				3,205,684	8,014,410	8,014,410
Catamount Eligible Employer-Sponsored Insurance Premiums				175,228	546,409	546,409
Catamount Health Premiums Due to Crowd Out				-	566,182	2,264,728
<b>Subtotal Premiums</b>				<b>3,380,912</b>	<b>9,127,000</b>	<b>10,825,546</b>
Federal Share of Premiums			-	(1,995,076)	(5,456,121)	(6,471,512)
<b>TOTAL STATE PREMIUM SHARE</b>				<b>1,385,836</b>	<b>3,670,880</b>	<b>4,354,035</b>
Cigarette Tax Increase (\$.60 / \$.80)			9,439,500	9,083,000	9,594,500	9,238,000
Floor Stock			1,200,000	-	500,000	-
Employer Assessment			2,000,000	8,300,000	10,600,000	13,100,000
<b>TOTAL OTHER REVENUE</b>			<b>12,639,500</b>	<b>17,383,000</b>	<b>20,694,500</b>	<b>22,338,000</b>
<b>TOTAL STATE REVENUE</b>			<b>-</b>	<b>12,639,500</b>	<b>18,768,836</b>	<b>24,365,380</b>
State-Only Balance			10,735,465	(945,833)	(3,753,943)	(4,825,095)
Carryforward			-	10,735,465	9,789,632	6,035,688
<b>(DEFICIT)/SURPLUS</b>			<b>-</b>	<b>10,735,465</b>	<b>9,789,632</b>	<b>6,035,688</b>

## Medicaid Only – Increased Enrollment

**Office of Vermont Health Access**  
 New Healthcare Initiative (Catamount, ESI, & Medicaid) ~ Balance Sheet  
**Revised Balance Sheet - Medicaid Only Increased Enrollment**  
 Friday, February 23, 2007

	# Est. Uninsured	TAKE-UP RATES	SFY '07	SFY '08	SFY '09	SFY '10
<b>ENROLLMENT DETAIL</b>						
Adults Ineligible for Catamount	2,179			-	-	-
Employer-Sponsored Insurance ~ VHAP Enrollees Converting to ESI	n/a	n/a		350	1,068	1,068
Employer-Sponsored Insurance ~ New Enrollees VHAP Eligible		0.67%		39	89	156
New VHAP Enrollees Due to Reduced Premiums & Outreach	13,379	12.64%		1,314	1,690	2,961
New VHAP Enrollees - <50% FPL	7,989	10.00%		160	799	799
Traditional Medicaid Enrollees	4,514	10.00%		90	451	451
Children (excluded from Catamount estimates at this time)	6,580	21.50%		1,100	1,415	1,415
<b>TOTAL NEW ENROLLEES COVERED</b>	<b>34,641</b>	<b>15.91%</b>		<b>3,053</b>	<b>5,512</b>	<b>6,850</b>
<b>PER-MEMBER PER-MONTH STATE EXPENDITURES</b>						
VHAP Eligible Employer-Sponsored Insurance Per-Member Per-Month				\$ 119.79	\$ 127.95	\$ 136.66
Medicaid ~ VHAP Per-Member Per-Month				\$ 327.51	\$ 349.81	\$ 373.64
General Adult Per-Member Per-Month				\$ 345.18	\$ 368.69	\$ 393.79
General Child Per-Member Per-Month				\$ 184.47	\$ 197.03	\$ 210.45
<b>TOTAL PROGRAM EXPENDITURES</b>						
VHAP Eligible Employer-Sponsored Insurance ~ Conversion Savings				(1,655,869)	(4,948,216)	(5,285,190)
VHAP Eligible Employer-Sponsored Insurance ~ New				55,671	136,603	255,608
VHAP (new)				5,166,061	7,096,049	13,278,005
New VHAP Enrollees < 50% FPL				627,955	3,353,591	3,581,971
Traditional Medicaid Enrollees				373,954	1,997,102	2,133,105
Children				-	909,693	1,137,467
<b>TOTAL GROSS PROGRAM SPENDING</b>				<b>-</b>	<b>4,567,772</b>	<b>8,544,822</b>
<b>TOTAL STATE PROGRAM SPENDING</b>				<b>-</b>	<b>1,872,330</b>	<b>3,436,728</b>
<b>TOTAL OTHER EXPENDITURES</b>						
Medicaid Reimbursement						
Hospitals ~ Incr (H.961)				-	2,100,000	4,300,000
<b>TOTAL OTHER SPENDING</b>				<b>-</b>	<b>2,100,000</b>	<b>4,300,000</b>
<b>TOTAL STATE OTHER SPENDING</b>				<b>-</b>	<b>844,620</b>	<b>1,729,460</b>
<b>TOTAL ALL STATE SPENDING</b>				<b>-</b>	<b>1,872,330</b>	<b>4,281,348</b>
<b>TOTAL REVENUES</b>						
VHAP Eligible Employer-Sponsored Insurance Premiums				15,560	35,746	62,622
VHAP Premiums (new)				528,113	679,160	1,189,807
Medicaid ~ Premium Reduction (existing)				(670,601)	(2,046,293)	(2,046,293)
<b>Subtotal Premiums</b>				<b>(126,928)</b>	<b>(1,331,387)</b>	<b>(793,863)</b>
Federal Share of Premiums				74,900	795,903	474,572
<b>TOTAL STATE PREMIUM SHARE</b>				<b>(52,028)</b>	<b>(535,484)</b>	<b>(319,292)</b>
<b>TOTAL STATE REVENUE</b>				<b>-</b>	<b>(52,028)</b>	<b>(319,292)</b>
State-Only Balance				-	(1,924,358)	(8,122,361)
Carryforward				-	-	(1,924,358)
<b>(DEFICIT)/SURPLUS</b>				<b>-</b>	<b>(1,924,358)</b>	<b>(6,741,189)</b>

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## Section 5: Clinical Initiatives

### ***Buprenorphine***

***Mission:***

To increase access to effective treatment for opiate dependency.

***Goal***

The OVHA, in cooperation with the Vermont Department of Health Alcohol & Drug Abuse Program, the

Department of Corrections, and the commercial insurers, aims to increase access for patients to Buprenorphine services, increase the number of physicians in Vermont licensed to prescribe Buprenorphine and to support practices caring for the opiate dependent population.

### ***The Budget***

The OVHA was appropriated \$500,000 in one-time funds by the legislature to operationalize the Buprenorphine initiative. The current plan for the use of these funds, established in a collaborative manner between ADAP and the OVHA, is a capitated program that increases reimbursement in a step-wise manner depending on the number of patients treated by a physician. Many physicians limit the number of opiate dependent patients because of the challenging nature of caring for this population (ie. missed appointments, diversion, time spent by office staff). The end result is that most practices see far fewer patients than they could.

Capitated Payment Methodology:

Level	Complexity Assessment	Rated Capitation Payment			
III.	Induction	\$348.97	+	<b>BONUS</b>	=
II.	Stabilization/Transfer	\$236.32			
I.	Maintenance Only	\$101.28			

**Final Capitated Rate (depends on the number of patients per level per provider)**

ADAP was appropriated \$350,000 by the legislature for technical assistance and training of MDs in the use of Buprenorphine. \$25,000 of the total amount has been allocated to cover the expense of obtaining a waiver to prescribe Buprenorphine. The remainder of the funds have been allocated to Howard Mental Health and the Office Based Medication Assisted Therapy, this program is called Coordination of Office Based Medication Assisted Therapy (COB-MAT) which will be providing Case Management services.

The implementation of this program commenced in June 2006 when Howard Mental Health won the RFP bid to act on behalf of the OVHA and VDH/ADAP at the local level. To date, Howard Mental Health has hired and established the roles and responsibilities

of the Care Coordinators, and the Care Coordinators have started working with Buprenorphine providers as of January 2007. The OVHA has also commenced the provider outreach process and has its first tentative agreement with Berlin Family Health, pending final approval, to participate in the capitated payment plan. Further meetings with other practices across the State have been scheduled. Finally, the Department of Corrections (DOC) has agreed to participate with their population, and final procedures and protocols are being vetted within the DOC.

## How Can ADAP, OVHA & the Howard Center Help?

### *Incentives and Support!!*

#### VDH/ADAP

##### ToolKit:

- Vermont Buprenorphine Practice Guidelines
- Related office procedures
- Informational materials for patients and their families
- Screening tools
- Examples of patient contracts
- Additional resources and current literature.

#### OVHA

- Enhanced Reimbursement for Best Practices
- Piloting outreach to DOC population
- Surveillance & Utilization Review based on claims data
- Provider outreach
- Legislative Reporting

#### Howard Center

- Collaborative effort of Howard Center, Clara Martin Center, Northeast Kingdom for Human Services and United Counseling of Bennington County
- Staff support: training and supervision of Regional Care Coordinators
- Data Collection, Reporting and Evaluation of pilot program.

## Outcome Measures

Benchmarks used to judge effectiveness of program:

- 50% increase in physician access
- Successful piloting of 25 DOC patients
- Decreased buprenorphine diversion
- Increased compliance with Vermont's Buprenorphine Best Practices Guidelines
- Decreased utilization of medical resources emergency room
- Increased number and specialty of licensed Buprenorphine prescribers
- Increased number of patients in active treatment
- Increased number of patients per prescribing physician
- Decreased rates of incarceration/reincarceration for Buprenorphine patients
- Increased retention in treatment
- Increased compliance with medication and plan of care
- Reduction in overall expenses for Medicaid beneficiaries being treated for opiate addiction.

## Care Coordination Program

**Mission:**

- Identify and assist the most complex Medicaid beneficiaries in accessing clinically appropriate health care services;
- Coordinate the efficient delivery of health care to this population by attempting to remove barriers, bridge gaps, and avoid duplication of services; and
- Educate, encourage and empower this population to eventually self-manage their chronic conditions.

The OVHA's Care Coordination Program (CCP), in conjunction with the Chronic Care Management Program (CCMP), exemplifies the Chronic Care Model in action. The CCP and CCMP are the vanguard of a system redesign to improve the health outcomes of Medicaid beneficiaries.

**Goal**

Utilizing the flexibility granted by the Global Commitment to Health Waiver, the OVHA is committed to partnering with primary care providers, hospitals, Agency of Human Services (AHS) departments, and community agencies to address the need for enhanced coordination of services in a climate of increasingly complex health care needs and scarce resources.

The CCP facilitates the beneficiary-provider relationship by offering services that assist providers in tending to the intricate medical and social needs of beneficiaries without increasing the administrative burden. The CCP supports providers by providing intensive case management to the beneficiary between visits to enable the plan of care to be successful. Ultimately, the CCP aims to improve health outcomes, decrease inappropriate utilization of services, and increase appropriate utilization of services.

**Method**

The CCP focuses on Medicaid's highest utilizers with chronic conditions, approximately 1,200 beneficiaries statewide annually.

The CCP is based upon the desire for Vermonters to help other Vermonters. As supported by the Chronic Care Model, the CCP emphasizes evidence-based, planned, integrated and collaborative care for Medicaid beneficiaries who exhibit high-prevalence chronic disease states, high-expense utilization, high medication utilization, and/or high emergency room (ER) and inpatient utilization.

**Implementation**

Medicaid beneficiaries who will most benefit from the CCP are selected based upon criteria identified through claims data and in collaboration with their primary care provider. Regionally-based Care Coordination teams [one Registered Nurse (RN) and one social worker] work with the beneficiary, their provider(s), community based organizations, and State entities to devise a tailored care plan through assessment of

current treatments, services, and resources. Care Coordination teams access resources from many avenues, especially Vermont Blueprint for Health-related activities, to enable the beneficiary to obtain better self-management skills and empower the beneficiary to promote their own health and well-being.

During calendar year 2006, the OVHA hired and deployed a Field Director, an Associate Medical Director, three RNs and three social workers.

As of January 2007, Care Coordination teams are deployed in Caledonia County, Washington County and Chittenden County. During the period from January – March 2007, seven RNs and five social workers will be hired: two RNs will be hired to serve as Northern and Southern Regional Field Coordinators; a second RN will be deployed in Chittenden County; there will be an RN and two social workers for Franklin/Grand Isle/Lamoille Counties; there will be an RN and a social worker for Rutland/Addison Counties; and there will be Care Coordination teams deployed to Bennington/Windham/Windsor Counties.

The Caledonia County Care Coordination team will expand to cover Orleans and Essex Counties and the Washington County team will expand to cover Orange County.

The Agency of Human Services (AHS) reorganization recognized the need for coordination of services at the community level. As such, Care Coordination teams are located at the local district offices to provide a unique and critical aspect of the AHS support network and to establish relationships with primary care providers that are focused on health outcomes. Care Coordination teams are informed about local and statewide quality improvement initiatives and are able to assist providers to access these initiatives. The result of locally-based Care Coordination teams is the opportunity to collaborate creatively to address the unique needs of an individual beneficiary. To-date, this collaboration has been very rewarding for both beneficiaries and the OVHA.

The CCP has begun to make significant contributions towards achieving the goals of the Vermont Blueprint for Health by addressing the unique characteristics of the most complex Medicaid beneficiaries and the challenges those with chronic conditions face in participating fully within the Blueprint. Many beneficiaries need additional support to become the "...informed, activated patient" that the model describes. Care Coordination teams provide additional support by facilitating the implementation of the essential components of disease management programs, as identified by Dr. Kenneth Thorpe, such as team-based care, cross-consortium coordination, patient education, outreach and care management. Because Care Coordination teams are locally-based, they are able to implement these components within the context of the beneficiary's community, taking into account what is available and acceptable to the beneficiary and their primary care provider.

## ***Current Participating Providers, Agencies and Stakeholders***

As of January 2007, the participating providers, agencies and stakeholders include:

- 1) Barre Health Center
- 2) Berlin Health and Rehabilitation
- 3) Central Vermont Community Partnership
- 4) Central Vermont Hospital (CVH)
- 5) Central Vermont Physician Practice Corp. (CVPPC)
- 6) Central Vermont Substance Abuse Services
- 7) Community Health Center of Burlington
- 8) Corner Medical
- 9) Department for Children and Families (DCF) - field service districts
- 10) Department of Disabilities, Aging and Independent Living (DAIL)
- 11) Evergreen Family Health
- 12) Fletcher Allen Health Care (FAHC)
- 13) Health Center of Plainfield
- 14) Howard Center for Human Services
- 15) Northeast Kingdom Human Services (NEKHS)
- 16) Northeastern Vermont Area Health Education Center (NEVAHEC)
- 17) Northeastern Vermont Regional Hospital (NVRH)
- 18) Northern Counties Health Care (NCHC)
- 19) Planned Parenthood of Northern New England
- 20) Professional Nurses
- 21) Vermont Association of Hospitals & Health Systems (VAHHS)
- 22) Vermont Department of Health offices in St. Johnsbury, Barre, and Burlington
- 23) Visiting Nurse's Association (VNA)
- 24) Vocational Rehabilitation Services
- 25) Washington County Mental Health
- 26) Wellness on Wheels
- 27) Winooski Family Health

## ***Integration with the Chronic Care Management Program (CCMP)***

The OVHA's Chronic Care Management Program (CCMP) is designed to address the needs of Medicaid beneficiaries with more moderate needs on a continuum extending downward from the CCP population. Beneficiaries will be transitioned into the CCMP from the CCP when they are no longer in need of such intensive case management. It is anticipated that there will be fluidity between the CCP and CCMP as beneficiaries move up and down the health needs continuum and transition between the CCP and CCMP.

Population selection and monitoring assistance for both the CCP and CCMP will be done by the Center for Health Policy and Research at the University of Massachusetts Medical School contracted under the CCMP.

### **Provider Payments As Part Of CCP**

A segment of the operating costs for the CCP are set aside for reimbursing participating providers. A strategy has been developed to reimburse the providers with an enhanced capitated payment rate of \$15 per month for a CCP patient. To emphasize the importance of developing a plan of care with the primary care provider, the OVHA will also reimburse the provider \$50 for meeting with Care Coordination teams when one of their patients is enrolled in the CCP. Providers will also be reimbursed \$50 for a “discharge” meeting to emphasize the importance of a smooth transition when a participant leaves the CCP.

The combination of incentive payments for meetings and an enhanced case management fee, \$10 more than the PC Plus case management fee, provides primary care providers with an attractive incentive for participation in the CCP.

### **Achievements To-Date**

- 1) Almost 300 beneficiaries have received Care Coordination services.
- 2) Caledonia County, Washington County and Chittenden County teams are actively enrolling beneficiaries.
- 3) A consultant pharmacist has been hired to assist the Care Coordination teams with medication questions.
- 4) Two social workers have been identified for Franklin and Lamoille Counties.
- 5) Care Coordination teams have attended numerous trainings, including *Bridges out of Poverty* and *Foundations*.
- 6) Community and local outreach has been successful and well received.
- 7) Hospital outreach has been successful and well received in all three counties.
- 8) Claims data has been refined and organized for maximum use.
- 9) A Care Coordination Orientation Manual and Program Manual has been drafted.
- 10) Standard Care Coordination methodology has been established.
- 11) The OVHA’s Information Technology (IT) Unit has developed a case management system for tracking Care Coordination Program participants.
- 12) Intermediary and final outcomes have been established.
- 13) Meetings with Blueprint staff have occurred to enhance alignment and consistency.
- 14) A reimbursement strategy has been devised to encourage providers to participate in the Care Coordination Program.
- 15) Multiple AHS departments and OVHA units have collaborated to ensure the successful implementation of the Care Coordination Program.

## Chronic Care Management Program

**Mission:**

- Identify and assist Medicaid beneficiaries with chronic health conditions in accessing clinically appropriate health care information and services;
- Coordinate the efficient delivery of health care to this population by attempting to remove barriers, bridge gaps, and avoid duplication of services; and
- Educate, encourage and empower this population to appropriately self-manage their chronic conditions.

The OVHA's commitment to a Chronic Care Management Program (CCMP) is supported by legislation (Act 191) which specifically authorizes a CCMP.

**Goal**

The purpose of the CCMP is to improve health outcomes and reduce costs for Medicaid beneficiaries with chronic health conditions.

Approximately 116,000 beneficiaries are potentially eligible for the CCMP. Medicaid beneficiaries specifically targeted for enrollment in the CCMP are not dually-eligible and have at least one chronic condition including, but not limited to: arthritis, asthma, chronic obstructive pulmonary disease (COPD), chronic renal failure, congestive heart failure, depression, diabetes, hyperlipidemia, hypertension, ischemic heart disease, or low back pain. There are approximately 25,000 beneficiaries with at least one of the above-cited diagnoses.

**Method**

A Request for Proposals (RFP) was issued on October 5, 2006 for Intervention Services (IVS) and Health Risk Assessment Administration (HRA), with a projected program start date of July, 2007.

The IVS vendor will minimally do the following:

- 1) Perform risk stratification to pro-actively identify the specific intervention populations from within the overall target population.
- 2) Generate and distribute mailings to all eligible beneficiaries with disease-specific, self-care information which complies with established State disease-specific best practice standards (as promoted by the Blueprint to Health) when available.
- 3) Maintain a call center to provide incoming and outgoing nurse telephone contact with both patients and providers during both business hours and limited extended hours. The call center will be staffed by licensed nurses minimally holding an LPN certification, providing evidence-based clinical advice and counseling.
- 4) Provide face-to-face interventions for high acuity patients, with the goal of eliminating barriers to optimal self-management of chronic health conditions.

- 5) Conduct provider outreach and education reaching all statewide Medicaid providers. The content will include current guidelines for prevention and treatment of chronic diseases in support of the Chronic Care Model.

In the implementation of the CCMP interventions, the IVS vendor will apply Blueprint chronic illness management standards to program design as the standards become available. Additionally, the IVS vendor will partner with the OVHA in periodic “Plan Do Study Act” (PDSA) cycles to ensure continuous quality improvement efforts in the on-going CCMP.

The HRA vendor will administer a generic health risk assessment to all beneficiaries with a chronic condition. The HRA will be administered in an impartial manner in electronic, paper, telephonic, or face-to-face format. The results of the HRA will be provided to the IVS vendor in order to assist in their risk stratification and care plan development, as well as to the individual beneficiary’s primary care provider.

### ***Implementation***

The OVHA is utilizing an “evidence-based” procurement process in order to choose the most effective IVS vendor possible. Bidder proposals include promised program outcomes, which are based upon their past program evaluations. In this process, those evaluation methodologies are analyzed for validity and relevance to the current proposal, enabling the OVHA to more confidently assess that aspect of the proposals.

The OVHA has contracted with the University of Massachusetts Medical School Center for Health Policy and Research (CHPR) to independently conduct on-going assessments to estimate the degree to which interventions provided in the programs are effective. In partnership with the IVS vendor, CHPR will monitor intervention process metrics, program activities, and clinical health outcomes.

### ***Integration with the Care Coordination Program (CCP)***

A number of program processes will be shared between CCMP and CCP, including:

**Selection:** CHPR will be selecting eligible program participants for both CCP and CCMP, to ensure that beneficiaries in need of services are selected for program participation in a consistent manner.

**Data System:** The CCMP IVS vendor will be employing a data collection and management system which will enable CCP as well as CCMP program staff to securely collect and store relevant patient-level information. The system will incorporate Medicaid claims data, including point-of-sale pharmacy claims and will be compatible with the Blueprint for Health Chronic Care Information System.

**Clinical Best-Practice Guidelines:** Taking the lead from the Blueprint for Health, CCP and CCMP promote consistent disease-specific best-practice guidelines.

Health Risk Assessments: Beneficiaries targeted for participation in both CCP and CCMP will be asked to complete the same HRA and will be provided assistance if needed. The HRA data will flow to CCP and CCMP program staff to assist in population stratification and care plan development, to primary care providers to inform their medical decisions, and to CHPR for program monitoring and evaluation purposes.

Direct Service Collaboration: Beneficiaries will be moving between programs when appropriate, therefore front-line program staff will have regular contact in their day-to-day work in order to facilitate those transitions.

Outcomes Measurement: CHPR will be conducting consistent ongoing program monitoring and evaluation for both CCP and CCMP, utilizing the same measurements, methodology, and reporting for both.

### ***Achievements To-Date***

- 1) August, 2006: RFP for Consulting Services for CCP and CCMP Program Selection and Monitoring released
- 2) September, 2006: Health Care Reform Commission of the Vermont Legislature approves CCMP IVS and HRA Services RFP
- 3) October, 2006: CCMP IVS/HRA RFP released
- 4) January, 2007: 8 IVS and 8 HRA proposals received from a total of 9 bidders

January, 2007: Contract finalized with University of Massachusetts Medical School Center for Health Policy and Research for CCP and CCMP Program Selection and Monitoring Services.

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## Section 6: Citizenship

In the Deficit Reduction Act (DRA) passed in February of 2006, Congress mandated a new verification requirement for Medicaid applicants and beneficiaries. The law requires

**Fast Facts:**

- Member Services staffs a Citizenship and Identity Help Line.
- Data matching supports documentation requirements.

most U.S. citizens who apply for or receive Medicaid to present documentary evidence of their citizenship status and identity. Medicaid applicants and beneficiaries who also receive Social Security Income (SSI), Social Security Disability Insurance (SSDI), or Medicare are exempt from the requirement

because they had to prove citizenship and identity when they applied for those federal programs. Children in foster care or receiving Title IV-E Adoption Assistance are also exempt. Non-citizens are already subject to a similar documentation requirement.

In an effort to minimize the burden of this new requirement, the Economic Services Division (ESD) of the Department for Children and Families (DCF) attempts to obtain the needed documentation through data matching. When that is not feasible, individuals need to obtain the documents themselves.

To ensure that individuals have the information and assistance they need to successfully comply with the new requirements, the OVHA expanded the capacity of its Member Services contractor, MAXIMUS, to staff a Citizenship and Identity Help Line through its existing toll-free number. Help Line staff is specially trained to respond to a full range of inquiries and requests:

- 1) Answer general questions regarding the verification requirements.
- 2) Explain the types and tiers of documents.
- 3) Help to identify the documents that may be relied upon to satisfy the requirements.
- 4) Advise as to the process for obtaining needed documentation (*e.g.*, the required elements of an application for a state-issued identification card).
- 5) Provide contact information for other state vital record centers.
- 6) Problem-solve with callers who are having difficulty getting or bringing in documents.
- 7) Make referrals to local agencies for additional assistance (*e.g.*, CAP agencies, AAA, etc.).
- 8) Offer direct assistance to callers who are unable to independently satisfy the requirements and who lack the assistance of family, friends, or local agencies.
- 9) Enter extension requests.
- 10) Facilitate financial assistance requests.
- 11) Submit additional data matching requests.

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## Section 7: The Dental Dozen

### **Fast Facts:**

- Ensure Oral Health Exams for School-age Children
- Increase Dental Reimbursement Rates
- Reimburse Primary Care Physicians for Oral Health Risk Assessments
- Place Dental Hygienists in Each of the 12 District Health Offices
- Selection/Assignment of a Dental Home for Children
- Enhance Outreach
- Codes for Missed Appointments/Late Cancellations
- Automation of the Medicaid Cap Information for Adult Benefits
- Loan Repayment Program
- Scholarships
- Technology Grants
- Supplemental Payment Program

### **Overview**

According to the Surgeon General, “a silent epidemic of oral disease is affecting our most vulnerable citizens—poor children, the elderly, and many members of racial and ethnic minority groups.” In Vermont, several indicators (i.e., coverage of oral health services, dentist participation in the Medicaid program, oral health status indicators, and utilization rates by Medicaid beneficiaries) exceed national averages. However, there remains room for improvement.

While the U.S. population overall has seen an improvement in oral health,

this trend has not been evident among lower-income individuals who continue to have high rates of dental diseases<sup>1</sup>. This trend is also true in Vermont where Medicaid beneficiaries and individuals without dental insurance face numerous barriers to access.

Many Vermonters face challenges in receiving appropriate oral health care due to the limited number of practicing professionals, the affordability of services, and a lack of emphasis on the importance of oral health care.

Challenges frequently are more acute for low-income Vermonters, including those Vermonters participating in the state’s Medicaid program. Absent material changes in program policies and priorities, current problems will get worse.

47% of eligible Medicaid beneficiaries accessed dental services in SFY '05.

The Dental Dozen are 12 targeted initiatives to improve oral health for all Vermonters, establish the framework to remedy existing delivery system issues and proactively confront future challenges. The Dental Dozen are:

- Initiative #1: Ensure Oral Health Exams for School-age Children
- Initiative #2: Increase Dental Reimbursement Rates
- Initiative #3: Reimburse Primary Care Physicians for Oral Health Risk Assessments
- Initiative #4: Place Dental Hygienists in Each of the 12 District Health Offices
- Initiative #5: Selection/Assignment of a Dental Home for Children
- Initiative #6: Enhance Outreach
- Initiative #7: Codes for Missed Appointments/Late Cancellations
- Initiative #8: Automation of the Medicaid Cap Information for Adult Benefits

<sup>1</sup> GAO Study. “Oral Health: Dental Disease is a Chronic Problem Among Low-Income Populations.” (Jan, 2000).

Initiative #9: Loan Repayment Program  
Initiative #10: Scholarships  
Initiative #11: Technology Grants  
Initiative #12: Supplemental Payment Program

The Dental Dozen are based on the goals and strategies outlined in the **Vermont Oral Health Plan (2005)** and the survey results outlined in the **Vermont Oral Health Initiative Dental Survey Report (December, 2005)**.

The Dental Dozen provides for a statewide commitment and promotes a cultural transformation by reinforcing the importance of oral health. The Dental Dozen recognizes oral health as a fundamental component of overall health and moves toward creating parity between oral health and other health care services. The Dental Dozen combine to support the following goals:

- Increase the supply of practitioners providing dental care
- Increase supply of providers serving Medicaid beneficiaries
- Increase access to dental care for Medicaid beneficiaries
- Promote preventive oral health care
- Make dental care more affordable
- Reduce missed appointments and appointments not canceled at least 48 hours ahead of time by Medicaid beneficiaries

While this section includes descriptions of the initiatives, additional refinement is essential. Continual analysis and evaluation of the Dental Dozen in relation to the oral health care delivery system is recommended to ensure that the goals are achieved.

Implementation of the initiatives requires a coordinated effort between many different entities, including but not limit to the following:

- Office of Vermont Health Access (OVHA)
- Vermont Department of Health (VDH)
- Department for Children & Families (DCF)
- Department of Education (DOE)
- Vermont State Dental Society (VSDS)
- Vermont Dental Hygiene Association (VDHA)
- Vermont Dental Assistants Association (VDAA)
- Vermont Chapter of American Association of Pediatrics (AAP)
- Area Health Education Centers (AHEC)

Once a determination is made as to the prioritization of Dental Dozen for implementation, a comprehensive work plan will be developed with detailed description, implementation tasks and a schedule for implementation. The start date for each initiative is:

7/1/2007

- Initiative #6: Enhance Outreach
- Initiative #9: Loan Repayment Program
- Initiative #10: Scholarships
- Initiative #11: Technology Grants
- Initiative #12: Supplemental Payment Program

1/1/2008

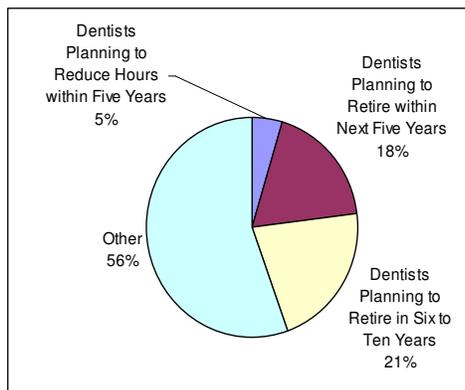
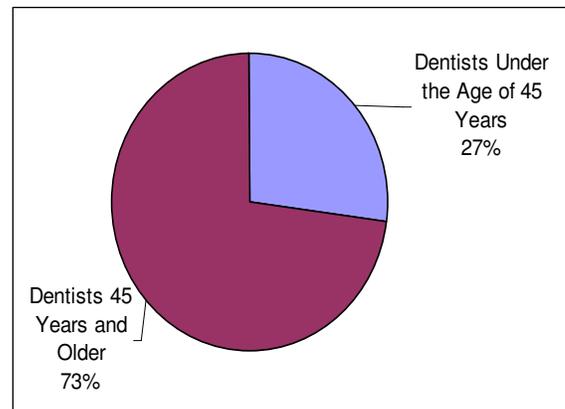
- Initiative #2: Increase Dental Reimbursement Rates
- Initiative #3: Reimburse Primary Care Physicians for Oral Health Risk Assessments
- Initiative #4: Place Dental Hygienists in Each of the 12 District Health Offices
- Initiative #5: Selection/Assignment of a Dental Home for Children
- Initiative #7: Codes for Missed Appointments/Late Cancellations
- Initiative #8: Automation of the Medicaid Cap Information for Adult Benefits

7/1/2008

- Initiative #1: Ensure Oral Health Exams for School-age Children

### Access

Vermont must confront issues of access to dental care for Medicaid beneficiaries. Based on the 2005 Vermont Dental Survey (conducted summer 2005), 90% of Vermont dental practices were accepting new non-Medicaid enrolled patients, while only 61% of Vermont dental practices were accepting new Medicaid-enrolled patients<sup>2</sup>. In SFY '05, 55% of Medicaid-eligible children and 33% of Medicaid-eligible adults accessed dental services, with overall Medicaid population utilization of approximately 47%<sup>3</sup>.



Access to dental care becomes more problematic as the number of practicing dentists declines. In Vermont, there are currently 352 practicing dentists. Seventy-nine percent, or 278, are primary care dentists. More than 57% of practicing dentists are age 50 years or over; 40% are 55 years old or older<sup>4</sup>.

In Vermont, 18% of dentists plan on retiring in the next five years<sup>5</sup>; an additional 21% plan to retire within the next six to ten years. Currently, there are

<sup>2</sup> 2005 Vermont Dental Survey

<sup>3</sup> Medicaid Child & Adult Dental Utilization by State Fiscal Year, Medicaid Claims Analysis

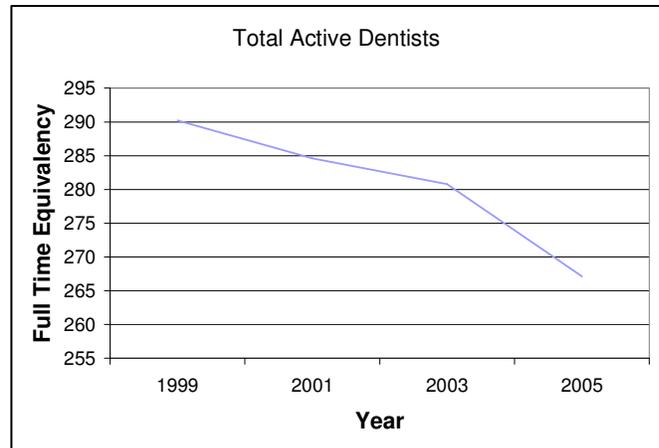
<sup>4</sup> 2005 Vermont Dental Survey

<sup>5</sup> Ibid

not enough new dentists entering practice in Vermont to replace those who will be retiring. Of the 9 pediatric dentists in the state, 7 are 52 years old or older<sup>6</sup>.

Current access issues will be exacerbated as the number of dentists practicing in the State declines over the next few years.

In 2003, there were 367 active dentists compared to 352 reported in the 2005 Vermont Dental Survey – a 4% net loss of dentists. Compounding the problem of fewer dentists, there has been a decrease in the average number of clinical hours per week per dentist<sup>7</sup>. As a result, the number of full time equivalent dentists is declining.



As of summer 2005, the wait for an appointment (irrespective of payor) for a new dental patient is 3.2 weeks and 2.9 weeks for a current patient<sup>8</sup>. In 2003, the wait period for a new patient was 3.1 weeks and 2.5 weeks for a current patient<sup>9</sup>.

Along with the decline in available dental care, the prevalence of oral health issues is increasingly focused among a small group of Vermonters. Eighty-two percent of decay was found in 23% of all school-aged children, between first and third grades. Within this subset, the decay was more prevalent in children in lower income level families<sup>10</sup>.

### *Chronic Care Management Program*

The OVHA has issued a Request for Proposals (RFP) for two types of services (i.e., Intervention Services and Health Risk Assessment Administration) to administer the OVHA's Chronic Care Management Program. As a primary component of overall health, oral health will be considered in the vendor activities, and in the evaluation and health management of Medicaid beneficiaries who participate in the Chronic Care Management Program.

### *Care Coordination Program*

The OVHA's Care Coordination Program targets the top 1-2% of Medicaid beneficiaries with the most complex health care issues. As a primary component of overall health, oral health will be addressed as part of the evaluation and health management of Medicaid beneficiaries who participate in the Care Coordination Program.

<sup>6</sup> Oral Health Care for the 21<sup>st</sup> Century: Investing in Kids

<sup>7</sup> 2005 Vermont Dental Survey

<sup>8</sup> 2005 Vermont Dental Survey

<sup>9</sup> 2003 Vermont Dental Survey

<sup>10</sup> Vermont Oral Health Plan 2005

### *Dental Dozen Summary Descriptions*

A brief summary of the Dental Dozen is included below. An analysis of each initiative is provided later in this section.

- 1) Ensure Oral Health Exams for School-age Children – reinforce the importance of oral health exams for school-age children; the premise is to encourage appropriate preventive care and reduce utilization of more costly dental procedures.
- 2) Increase Dental Reimbursement Rates – increase Vermont Medicaid reimbursement rates to the same levels as New Hampshire Medicaid rates; the premise is to attract new dentists as Medicaid providers and encourage dentists to see more Medicaid-enrolled patients.
- 3) Reimburse Primary Care Physicians for Oral Health Risk Assessments – Vermont Medicaid will reimburse Primary Care Providers for performing oral Health Risk Assessments (HRAs) to promote preventive care and increase access for children from 0-3.
- 4) Place Dental Hygienists in all 12 District Health Offices-Dental hygienists will be placed in the 12 district health offices.
- 5) Selection/Assignment of a Dental Home for Children – selecting/assigning a primary dentist to each child allows for the same type of continuity of care as assigning a primary care physician for health improvement.
- 6) Enhance Outreach – perform outreach activities that create awareness and understanding of the Dental Dozen, and support implementation and operation of the initiatives.
- 7) Codes for Missed Appointments / Late Cancellations – implementation of codes for missed appointments/late cancellations
- 8) Automation of the Medicaid Cap Information for Adult Benefits - automation of the cap information for adult benefits.
- 9) Loan Repayment Program – Vermont recruitment and retention program; encourages new dentists to locate to Vermont.
- 10) Scholarships – encourage new dentists and hygienists to practice in Vermont and work with Medicaid beneficiaries; engage dentists to support children enrolled in Medicaid in adherence of a preventive oral health regimen.
- 11) Technology Grants – encourage dentists to adopt the electronic claims submission process for shortened turnaround time on claims processing.

- 12) Supplemental Payment Program – provides incentives for accepting Medicaid beneficiaries and recognizes practitioners serving high volumes of Medicaid beneficiaries for their efforts.

It is important to note that the Dental Dozen build on one another to form a comprehensive approach for improving oral health in the State. For example, raising reimbursement rates and scholarships help attract and retain Medicaid dental providers. Also, when a school-aged child is required to go for an exam, a dental home would already have established a source of care.

**Impact of Initiatives on Cited Goals**

<b>INITIATIVE</b>	<b>Increase Supply of Practitioners Providing Dental Care</b>	<b>Increase Supply of Providers serving Medicaid Beneficiaries</b>	<b>Increase Access to Dental Care for Medicaid beneficiaries</b>	<b>Promote Preventive Oral Health Care</b>	<b>Make Dental Care More Affordable</b>	<b>Reduce Missed Appointments/ Late Cancellations</b>
Ensure Oral Health Exams for School-age Children				✓		
Increase Dental Reimbursement Rates		✓	✓		✓	
Reimburse Primary Care Physicians for Oral Health Risk Assessments			✓	✓		
Place Dental Hygienists in Each of the 12 District Health Offices		✓	✓	✓	✓	
Selection/ Assignment of a Dental Home for Children			✓	✓		
Enhance Outreach	✓	✓	✓	✓		✓
New Codes for Missed Appointments / Late Cancellations		✓	✓			✓
Automate Adult Dental Cap System		✓	✓			
Loan Repayment Program	✓	✓	✓			
Scholarships	✓	✓	✓			
Technology Grants		✓	✓		✓	
Supplemental Payment Program		✓	✓			

### *Investment & Medicaid Funding*

The estimated investment for each initiative for SFY '08, SFY '09, and SFY '10 is depicted in the following table. The table depicts the initiative, the total program investment and the breakout between the federal and state shares. Each initiative is shown with the amount needed for SFY08, and then additional money needed for the following fiscal years. At the bottom, the first line shows the total “new” money that is needed each year. Because Vermont’s Medicaid program provides coverage for more than 40% of Vermont’s children and Vermont’s Global Commitment to Health Demonstration Waiver provides the State with additional flexibility to invest in the

Vermont health care system, an estimated 59% of the estimated first-year investment will be supported by Federal Medicaid dollars.

Investment Summary						
Initiative #	Initiative Description	Start Date	New Money SFY08	New Money SFY09	New Money SFY10	SFY08-SFY10 Total Money
1	Ensure Oral Health Exams for Children	7/1/2008	\$0	\$735,147	\$54,649	\$1,524,943
2	Increase Dental Reimbursement Rates	1/1/2008	\$637,862	\$1,412,441	\$2,250,851	\$6,989,316
3	Reimburse PCP for Oral HRA	1/1/2008	\$40,000	\$40,000	\$0	\$200,000
4	Dental Hygienist Placement	1/1/2008	\$58,000	\$58,000	\$0	\$290,000
5	Selection/Assignment of a Dental Home for Children	1/1/2008	\$0	\$0	\$0	\$0
6	Enhance Outreach	7/1/2007	\$0	\$0	\$0	\$0
7	Codes for Late/Missed Appointments	1/1/2008	\$0	\$0	\$0	\$0
8	Automation of Adult Cap	1/1/2008	\$0	\$0	\$0	\$0
9	Loan Repayment Program	7/1/2007	\$20,000	\$0	\$0	\$60,000
10	Scholarships	7/1/2007	\$20,000	\$0	\$0	\$60,000
11	Technology Grants	7/1/2007	\$20,000	\$0	\$0	\$60,000
12	Supplemental Payment Program	7/1/2007	\$20,000	\$0	\$0	\$60,000
<b>Projected Savings from Preventable Dental Expenditures</b>			<b>-\$543,436</b>	<b>-\$1,167,667</b>	<b>-\$1,254,468</b>	<b>-\$2,965,571</b>
<b>New Annual Investment</b>			<b>\$272,425</b>	<b>\$1,077,921</b>	<b>\$1,051,031</b>	
State Share			\$111,694	\$441,947	\$430,923	
Federal Share			\$160,731	\$635,973	\$620,109	
<b>Total Annual Cost</b>			<b>\$272,425</b>	<b>\$1,350,346</b>	<b>\$2,401,377</b>	<b>\$4,024,149</b>
Cumulative State Share			\$111,694	\$553,642	\$984,565	\$1,649,901
Cumulative Federal Share			\$160,731	\$796,704	\$1,416,813	\$2,374,248

Since Federal Matching Rates are not available for SFY09 or 10, the SFY08 was used.

The estimated investment for each initiative was derived from Medicaid claims data in conjunction with utilization increase assumptions. Additional details regarding development of the estimates is provided as part of the analysis of each initiative, found later in this section.

### Information Technology Investment

As depicted in the following table *Information Technology Investment Summary*, initiatives #5, 7, & 8 require a financial investment in addition to the investment depicted in the *Investment Summary* because implementation of the initiative(s) require changes to either the ACCESS eligibility system or the Medicaid Management Information System (MMIS).

Information Technology (IT) Investment Summary						
Initiative #	Initiative Description	Start Date	SFY2008		SFY2009	
			State Share	Federal Share	State Share	Federal Share
5	Selection/Assignment of a Dental Home for Children	1/1/2008	\$92,250	\$132,750	\$92,250	\$132,750
7	Codes for Missed Appointments/Late Cancellations	1/1/2008	\$10,250	\$14,750	\$10,250	\$14,750
8	Automation of the Medicaid Cap Information for Adult Benefits	1/1/2008	\$10,250	\$14,750	\$10,250	\$14,750
<b>Total</b>			<b>\$112,750</b>	<b>\$162,250</b>	<b>\$112,750</b>	<b>\$162,250</b>

## Savings

To determine the savings projections shown in the *Investment Summary*, the following methodology was utilized. The 2007 Medicaid dental budget of approximately \$17 million dollars was inflated by the first year rate increase, and then inflated for both SFY '09 and SFY '10. It was then projected that 30% of those expenditures were preventable. However, since these initiatives are designed for long-term oral health care improvement, it was estimated that costs would be reduced by 5% (\$543,436) for SFY '08, 10% (\$1,167,667) for SFY '09 and 10% (\$1,254,468) for SFY '10.

The same formulas were used to inflate outpatient hospital costs over the three year period. However, it was projected that savings for these expenditures would be reduced by 20% for SFY '08, and 40% for SFY '09 and SFY '10.

### *Aggregate Cap for the Global Commitment to Health Demonstration Waiver*

Year	Expenditure
1st year	\$272,425.00
2nd year	\$1,350,346.00
3rd year	\$2,401,377.00
4th year*	\$642,368.35
<b>Total</b>	<b>\$4,666,516.35</b>

\*Since the cap will end in Sept. 2010, only a quarter of the year's Plan expenditures will impact the cap

The State of Vermont entered into an agreement (Global Commitment to Health Waiver) with the Federal Government that caps the amount of Federal reimbursement dollars for Medicaid, but allows for additional flexibility at the State level. The Waiver went into effect on October 1, 2005, and will end on September 30, 2010. A majority of the funding for the Dental Dozen will impact the cap. To project the aggregate impact, 7% yearly inflation is assumed. In addition, tiered implementation figures for the reimbursement rate increases are added to the second- and third-year figures.

### ***Initiative #1: Ensure Oral Health Exams for School-age Children***

Under this initiative, the Vermont Department of Health, the Office of Vermont Health Access, and the Department of Education would collaborate to implement tools that encourage parents and school systems to reinforce the importance of oral health exams and preventive care for school-age children.

Examples of tools:

- Inclusion or highlighting of oral health exams as a part of school enrollment
- Tie-in to the Dental Home Program for Medicaid enrolled children
- Checkpoint (second and sixth grade) data collection and analysis
- Leverage existing Tooth Tutor Program

It has been determined that new adult teeth (i.e., back molars) often come in during the second and sixth grade years. These teeth are at risk for tooth decay, and this is the best time for dentists to apply sealants to help prevent future cavities.

In addition, the initiative could be combined with outreach activities to emphasize the importance of oral health to all Vermonters.

## Analysis

If additional emphasis was placed on oral health exams for children receiving Medicaid benefits (targeted at second and sixth grades) there would be an increase in utilization with an associated increase in costs. To determine Medicaid program costs, an analysis was performed based on current Medicaid eligible children for the two age groups (7 & 11) who receive services but who do not receive dental health services. It was then assumed that 90% of those not receiving dental care would access dental care if targeted.

Using Medicaid claims data, an average visit cost for each age group was calculated. As a point of reference, a vast majority of visits include the periodic oral exam, a fluoride treatment, and teeth cleaning. The visits also include x-ray services. If utilization increased to the assumed 90% at the two grade levels, the investment would total \$735,146 per year. The chart below depicts the investment by age group (reflecting the proposed rate increase for the first year).

<u>Age/Grade</u>	<u>Eligible</u>	<u>Recipients</u>	<u>Eligible, not receiving dental care</u>	<u>90% of Non-Participants</u>	<u>Cost Per Visit</u>	<u>Cost</u>
7 (second grade)	6624	2391	4233	3810	\$90.91	\$346,341.36
11 (sixth grade)	7093	2341	4752	4277	\$90.91	\$388,805.61
					<b>Total</b>	<b>\$735,146.97</b>

## The Illinois Experience

The State of Illinois enacted a program requiring dental exams for all children entering kindergarten, second and sixth grades. Exams were required for children entering the respective grades during the 2005-2006 school-year. Exams were to be completed by May 15<sup>th</sup> or proof of appointment for an exam 60 days after. Any exam completed within 18 months prior to the May 15<sup>th</sup> deadline also counted. The only penalty for not completing the mandatory exam allows the school to withhold the child's report card. However, Illinois provides a waiver if one of the following conditions is met:

- Child is enrolled in the free and reduced lunch program and is ineligible for public insurance (waiver 1 in table)
- Child does not have any type of dental insurance, and there are no low-cost dental clinics in the community that will see the child (waiver 2 in table)
- Child is enrolled in free and reduced lunch program and is not covered by private or public dental insurance (waiver 3 in table)
- Child is enrolled in Medicaid/KidCare, but is unable to find a dentist or dental clinic in the community that is able to see the child and will accept Medicaid/KidCare (waiver 4 in table)

### Initial Illinois Results

Overall, Illinois has experienced a relatively high level of compliance, with students from all schools complying at 80.30% (public school children complied at 78.76% and private school children complied at 90.57%). One limitation when drawing conclusions from the success or lack of success of the program was that the report from the Illinois State Board of Education did not include data from the Chicago Public School system, the largest public school district in Illinois. One notable trend is that compliance gradually decreases at each successive grade level. While not as pronounced for private-school students, the decrease is significant for public school children.

Status for All Illinois School Students		
<u>Compliance Status</u>	<u>Number of Students</u>	<u>Percent</u>
Complete Dental Exam	311831	78.01
Approved Appointment Scheduled	4739	1.19
Religious Exemption	57	0.01
<b>Waiver</b>	<b>4387</b>	<b>1.09</b>
Waiver Type 1	651	0.16
Waiver Type 2	959	0.24
Waiver Type 3	1487	0.37
Waiver Type 4	1290	0.32
Not in Compliance	78732	19.7

Status for Public School Students		
<u>Compliance Status</u>	<u>Number of Students</u>	<u>Percent</u>
Complete Dental Exam	265542	76.43
Approved Appointment Scheduled	3796	1.09
Religious Exemption	44	0.01
<b>Waiver</b>	<b>4235</b>	<b>1.22</b>
Waiver Type 1	646	0.19
Waiver Type 2	898	0.26
Waiver Type 3	1427	0.41
Waiver Type 4	1264	0.36
Not in Compliance	73799	21.24

- Child is enrolled in the free and reduced lunch program and is ineligible for public insurance (waiver 1)
- Child does not have any type of dental insurance, and there are no low-cost dental clinics in the community that will see the child (waiver 2)
- Child is enrolled in free and reduced lunch program and is not covered by private or public dental insurance (waiver 3)
- Child is enrolled in Medicaid/KidCare, but is unable to find a dentist or dental clinic in our community that is able to see the child and will accept Medicaid/KidCare (waiver 4)

The State of Illinois has the following requirements for their exam:

<b>Oral Health Status (yes or no)</b>	<b>Treatments</b>
Dental Sealants Present	Urgent Treatment
Caries Experience / Restoration History	Restorative Care
Untreated Caries	Preventive Care
Soft Tissue Pathology	Other
Malocclusion	

### Vermont's Investment

The start date for Initiative #1 is 7/1/2008 so there is no investment for SFY '08. The investment for SFY '09 is \$735,147. As depicted in the *Investment Summary*, the \$735,147 is included in the base for SFY '10 so the new investment is \$54,649. The total investment for SFY '08 – SFY '10 is \$1,524,943.

### Initiative #2: Increase Dental Reimbursement Rates

This proposal commits to a 24% increase over three years in dental rates. Access to dental care is a nationwide problem for Medicaid beneficiaries. In Vermont during SFY '05, 55% of Medicaid-eligible children and 33% of Medicaid-eligible adults accessed dental services, with overall Medicaid utilization of approximately 47%<sup>11</sup>. Claims data indicates that 25% of Medicaid dental providers in Vermont serve 200 or more Medicaid beneficiaries annually.

One approach to address current access issues is to increase Medicaid reimbursement rates. For Vermont, one proposal has been to raise reimbursement rates to match those of the New Hampshire Medicaid program. Currently, Vermont's Medicaid reimbursement rate is approximately 60% of average New England dental fees, and 67% of the national average fee. New Hampshire pays higher rates for clinical examinations, preventive care, and most restorations. Dentists asked for higher Medicaid fee reimbursements for these services in a survey<sup>12</sup>. Dentists cite low reimbursement rates as their primary reason to not serve Medicaid-enrolled patients<sup>13</sup>.

As a further reference point, the following are three different state examples that evaluated the impact of rate increases on access to dental care.<sup>14</sup>

- Alabama** - In 2000, Alabama increased Medicaid reimbursement rates to 100% of Usual and Customary Rates (UCR), reduced prior authorization barriers, and increased outreach. Over a three-year period, there was a 7% increase in dentist participation and the number of dentists seeing a "significant" number of Medicaid-eligibles increased 39%. The number of Medicaid-insured children utilizing dental services increased 5%, from 26% to 31%. Starting in October of 2002, Alabama increased Medicaid reimbursement rates to levels close to those



The map above reflects the number of Medicaid eligible children in each county for SFY '04.

<sup>11</sup> Medicaid Child & Adult Dental Utilization by State Fiscal Year, Medicaid Claims Analysis

<sup>12</sup> Vermont Oral Health Initiative Dental Survey Report (Dec, 2005)

<sup>13</sup> US HHS Health Resource and Services Report (Dec, 2000)

<sup>14</sup> State Health Policy Leadership of the National Conference of State Legislatures Brief

of Blue Cross Blue Shield of Alabama; the increase is attributed to enrolling 140 new dentists as Medicaid providers.

- *Ohio* - After Ohio increased reimbursement rates to 75% UCR, there was only a 2% provider increase over a one-year period. There was an 11% utilization increase among Medicaid-insured children.
- *Michigan* - Michigan enrolled Medicaid-eligible children in a private insurance plan that paid dentists the same rates as private clients. The number of children receiving treatment in this program jumped 35.2% in one-year.

To compare Vermont's Medicaid reimbursement fees to those in the Northeast (NE) region (i.e., Connecticut, Massachusetts, Maine, New Hampshire & Rhode Island), 15 procedures were used to compare reimbursement rates among the individual states. The following table depicts the 15 procedures, along with Vermont's Medicaid reimbursement rate, the average fee a NE region dentist would charge for the procedure, the NE region 75% UCR fee, and the national average fee for that procedure<sup>15</sup>.

Provider participation in Medicaid would increase if Vermont's rates were raised to those of New Hampshire<sup>16</sup>. A comparison of the 2005 rates from Vermont and New Hampshire indicates that New Hampshire had a higher reimbursement rate for 20% of procedure codes. Using this data, adjusted for the increase in procedures performed based on the new rates, it was determined that increasing Vermont's reimbursement rates to those of New Hampshire's Medicaid program would increase Vermont Medicaid expenditures for dental services by 24%.

Once legislative approval and administrative regulations are developed for the increased rates, the actual implementation would occur by adjusting the rates and files in the Medicaid Management Information System (MMIS) to reflect the new reimbursement rates. However, to realize the benefit of the rate increase, Vermont would need to market the new rates to dentists.

#### *Vermont's Investment*

The start date for Initiative #2 is 1/1/2008 so the investment (\$637,862) for SFY '08 is calculated for six months. As depicted in the *Investment Summary*, the \$637,862 is included in the base for SFY '09 so the new investment for SFY '09 is \$1,412,441. The \$1,412,441 is included in the base for SFY '10 so the new investment for SFY '10 is \$2,250,851. The total investment for SFY '08 – SFY '10 is \$6,989,316.

<sup>15</sup> "Medicaid Reimbursement for New England Region-Using Marketplace Principles to Increase Access to Dental Services." *American Dental Association*. (March, 2004).

<sup>16</sup> Vermont Oral Health Initiative Dental Survey Report (Dec, 2005)

### **Initiative #3: Reimburse Primary Care Physicians for Oral Health Risk Assessments**

To help expand access and utilization, North Carolina has had success in having a child's primary care physician (PCP) administer an Oral Health Risk Assessment (HRA). *Note: while called a Health Risk Assessment, the services provided are more comprehensive, as detailed below.*

North Carolina's Medicaid program reimburses PCPs for up to six visits before a child reaches three years of age. Each visit includes:

- Oral Screening
- Oral HRA
- Fluoride Varnish Application
- Referral to a dentist when needed
- Counseling of oral health care practices

As a result of this program, North Carolina has experienced a dramatic increase in the number of children receiving preventive dental care, and an increase in the utilization of dental services. Using Medicaid claims, it has been determined that the preventive visits have prevented 264 caries-related treatment per 1,000 children through age three.<sup>17</sup>

This initiative accomplishes goals from the **Vermont Oral Health Plan (2005)** and receives support from dentists based on the findings in the **Vermont Oral Health Initiative Dental Survey Report (December, 2005)**. The **Vermont Oral Health Plan (2005)** has called for "training dental and medical providers to conduct oral health risk assessments, especially targeting subpopulations such as children ages 0-3..." It also expands upon the partnership of the medical and dental communities. A study funded by the Robert Wood Johnson Foundation found that the dental community views allowing primary care physicians to conduct dental screenings as a beneficial way for them to direct patients to more complete care in a dentist's office.

Effective January 1, 2007, two additional Medicaid codes went into affect. The first code "Topical Fluoride Varnish for Moderate to High Caries Risk Patients #D1206" and "Oral Evaluation for a Patient under Three Year of Age with Primary Caregiver #D0145<sup>18</sup>". Both of the codes could be used by PCPs performing the HRA.

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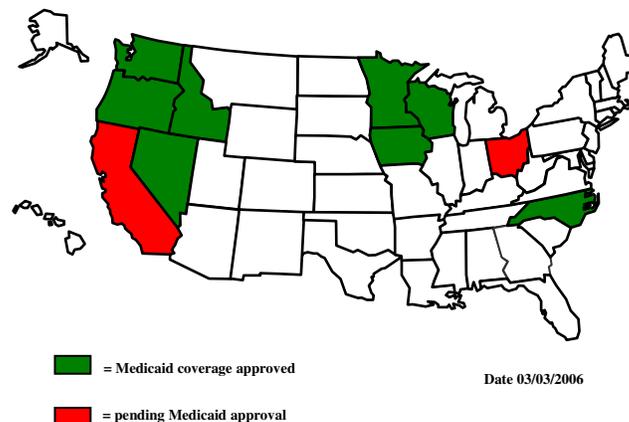
<sup>17</sup> "Primary care physicians enlisted to provide preventive dental services." R. Gary Rosier, D.D.S., M.P.H. American Academy of Pediatric News. (April, 2006).

<sup>18</sup> Defined as: "Diagnostic and preventive services performed for a child under the age of three, preferably within the first six months of the eruption of the first primary tooth, including recording the oral and physical health history, evaluation of caries susceptibility, development of an appropriate preventive oral health regimen and communication with the counseling of the child's parent, legal guardian and/or primary caregiver."

The National Guideline Clearinghouse has issued the following guidelines for HRAs.<sup>19</sup> Early childhood caries is an infectious and preventable disease that is vertically transmitted from mothers or other intimate caregivers to infants. All health care providers who serve mothers and infants should integrate parent and caregiver education into their practices that instruct on effective methods of prevention of early childhood caries.

- 1) The infectious and transmissible nature of bacteria that cause early childhood caries and methods of oral health risk assessment, anticipatory guidance, and early intervention should be included in the curriculum of all pediatric medical residency programs and postgraduate continuing medical education curricula at an appropriate time.
- 2) Every child should begin to receive oral health risk assessments by six months of age from a pediatrician or a qualified pediatric health care professional.
- 3) Pediatricians, family practitioners, and pediatric nurse practitioners and physician assistants should be trained to perform an oral health risk assessment on all children beginning by six months of age to identify known risk factors for early childhood dental caries.
- 4) Infants identified as having significant risk of caries or assessed to be within one of the risk groups listed in the original guidelines should be entered into an aggressive anticipatory guidance and intervention program provided by a dentist between 6 and 12 months of age.
- 5) Pediatricians should support the concept of the identification of a dental home as an ideal for all children in early toddler years.

The following map depicts a summary of state Medicaid programs that reimburse PCPs for Oral HRAs or are considering the addition of HRAs as a covered service.



### *Vermont's Investment*

It is estimated that 2,000 Oral Health Risk Assessments will be completed annually by Primary Care Physicians at a Medicaid-reimbursement level of \$40. The start date for

<sup>19</sup> "Oral health risk assessment timing and establishment of the dental home." Hale, K.J. *Pediatrics*. (May, 2003)

Initiative #3 is 1/1/2008 so the investment (\$40,000) for SFY '08 is calculated for six months. As depicted in the *Investment Summary*, the \$40,000 is included in the base for SFY '09 so the new investment for SFY '09 is \$40,000. The \$40,000 is included in the base for SFY '10 so the new investment for SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$200,000.

#### ***Initiative #4: Place Dental Hygienists in Each of the 12 District Health Offices***

The Vermont Department of Health sees over 16,000 children (ages 0-5) and their parents annually in District Health Office WIC clinics. These clinics could be expanded to address children's oral health needs.

Through this initiative, a half-time dental hygienist would be placed in each of the 12 district health offices. At District Health Office WIC clinics the hygienists would provide dental health education, early risk assessment, work to connect young children with a local dental practice as their "dental home" and provide therapeutic interventions such as fluoride varnish. In addition, the hygienist would be a resource for other human services' programs in connecting kids with dental homes. Adding a half-time dental hygienist to the staff would go a long way toward integrating oral health into overall health - each district office has nurses, social workers, health outreach specialists and nutritionists. Hygienists should be there as well.

This initiative meshes seamlessly with the first portion encouraging primary care physicians to incorporate oral health risk assessment and primary prevention within their practices. In each instance, children from 0-5 are being aggressively targeted for early prevention intervention. Although 12% of children under age three are seen in dental offices, they are seen in the physician's office from 10-12 times in the first three years of life. 95% of families on Medicaid also take advantage of WIC resources and are often seen in WIC offices for health information, resources and consultations. By using both resources, we are "going where the kids are" and reaching virtually 100% of all Medicaid eligible children from ages 0-5 with important oral health assessments, information and prevention intervention!

#### ***Vermont's Investment***

The start date for Initiative #4 is 1/1/2008 so the investment (\$58,000) for SFY '08 is calculated for six months. As depicted in the *Investment Summary*, the \$58,000 is included in the base for SFY '09 so the new investment for SFY '09 is \$58,000. The \$58,000 is included in the base for SFY '10 so the new investment for SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$290,000.

**Initiative #5: Selection/Assignment of a Dental Home for Children**

A Dental Home Program would establish a source of oral health care for children under the Medicaid program. *Note: a Dental Home could be expanded to include Medicaid-eligible adults or all Vermonters.*

The Vermont Oral Health Plan (2005) defines a Dental Home as “a specialized primary dental care provider who is accessible, continuous, comprehensive, coordinated, compassionate, and culturally effective.” Under this initiative, each Medicaid-enrolled child would either select or be assigned to a primary dentist who would then be responsible for this child’s dental health needs. This is similar to, and would occur at the same time as, the selection or assignment of a primary care physician – typically upon initial enrollment in Medicaid. A Dental Home program is a direct way to emphasize the importance of oral health care for new parents, and begins an early thought process that oral health and seeing a dentist is just as important as a regular physical and seeing a primary care physician.

A Dental Home Program could be expanded to include eligible Medicaid adults or all Vermonters.

The American Academy of Pediatric Dentistry (AAPD) adopted a 2001 policy calling for the creation of a dental home for all children. The AAPD found that children who see a primary dentist are more likely to receive preventive and routine oral health care, and that this type of health care reduces the likelihood of oral diseases and provides more timely treatment of disease. The AAPD recommends that all children be placed in a dental home by age one.

The Dental Home Program would likely increase access to oral health care by establishing a need for dental visits starting from an early age, and could be reinforced through outreach activities. One concern is whether Vermont has an adequate supply of dental providers to accommodate the influx of new patients; as such, implementation of the dental home needs to be done concurrently with other initiatives that strive to increase the supply of providers serving Medicaid population.

A Dental Home Program would require changes to the ACCESS system, outreach and reporting activities to measure any gaps in the supply of providers. Initiative #3 would assist in alleviating supply concerns and based on supply, additional consideration will need to be given to streamlining the scope of practice for dental assistants and hygienists.

A similar program was developed in Washington State, but also included medical, developmental, and mental health services. The program, “Kids Get Care” was based on a “services first” philosophy, where each child was seen at a community health clinic where a complete assessment was provided. Based on the needs, a case management model was then used to help eligible families secure public coverage for future visits. This model was developed after a two year effort to enroll eligible children in Medicaid and other state-supported insurance plans at a cost \$418 per newly enrolled child without any guarantee that the child received any health care services.

To facilitate the program, private sector dentists received a slightly increased reimbursement rate when working with enrolled children, and outreach activities conducted by the public health department helped families obtain necessary services, minimize missed appointments, and support dental offices in billing and other administrative areas.

After implementation of the program, one community health center reported a 109% increase in the administration of fluoride varnishes. The same clinic reported a 76% increase in patient visits for children 0-6 years old in one year. By focusing on preventive health care, Washington State expects to save money by not paying for emergency care, and these funds were used to help pay for the program. For example, if all the Medicaid-enrolled children under six years old in one county in Washington received fluoride varnishes during their “well-child visits”, the state expected to save \$0.3 million based on a 69% decrease in cavities.

### *Vermont's Investment*

The start date for Initiative #5 is 1/1/2008 so the investment (\$50,000) for SFY '08 is \$225,000 to accommodate changes to the ACCESS eligibility system. As depicted in the *Information Technology Investment Summary*, the \$225,000 is included in the base for SFY '09 so the new investment for SFY '09 is \$0. No further investment is needed for SFY '10. The total investment for SFY '08 – SFY '09 is \$450,000.

### ***Initiative #6: Enhance Outreach***

The OVHA will develop a Communications Plan that addresses all of the initiatives and includes outreach activities targeted at eligible Medicaid beneficiaries and affected enrolled dentists as well as outreach to prospective beneficiaries and prospective dentists. The Communications Plan will present a multi-faceted promotional approach that includes regular meetings/communication with VDH and the Vermont State Dental Society (VSDS), and addresses coordination of outreach activities with the DOE, DCF, and the Vermont Medical Society, as well as other health care entities.

Preliminary review indicates that the following initiatives require outreach to both Medicaid beneficiaries and dentists:

- Initiative #1: Ensure Oral Exams for School-age Children
- Initiative #3: Reimburse Primary Care Physicians for Oral Health Risk Assessments
- Initiative #5: Selection/Assignment of a Dental Home for Children
- Initiative #7: Codes for Missed Appointments / Late Cancellations
- Initiative #8: Automation of the Medicaid Cap Information for Adult Dental Benefits
- Initiative #10: Scholarships

Preliminary review indicates that the following initiatives require outreach targeted at dentists:

- Initiative #2: Increase Dental Reimbursement Rates
- Initiative #4: Place Dental Hygienists in Each of the 12 District Health Offices
- Initiative #9: Loan Repayment Program
- Initiative #11: Technology Grants
- Initiative #12: Supplemental Payment Program

Mechanisms for outreach to providers (i.e., dentists) may include the OVHA and Electronic Data Systems (EDS) provider relations staff, the EDS provider newsletter and banner pages; press releases, events, mailings, and coordination with VSIDS.

Mechanisms for outreach to beneficiaries may include press releases, events, mailings, and coordination with Maximus (member services), and the OVHA's Chronic Care Management and Care Coordination programs. The OVHA and VDH will perform outreach activities that create awareness and understanding of the Dental Dozen, and support implementation and operation of the initiatives.

#### *Vermont's Investment*

The start date for Initiative #6 is 7/1/2007. As depicted in the *Investment Summary*, the total investment for SFY '08 – SFY '10 is \$0.

#### ***Initiative #7: Codes for Missed Appointments / Late Cancellations*** ***Initiative #8: Automation of the Medicaid Cap Information for Adult Benefits***

New Hampshire (NH) instituted two codes on August 1, 2005 to track missed appointments and late cancellations by Medicaid beneficiaries. These codes do not provide for reimbursement but are used for data collection and process development. During the first year, NH recorded approximately 5,000 missed appointments and 5,000 late cancellations. This is a voluntary tracking system but it is communicated to dentists and the feedback from NH dentists has been positive.

The negative impact of missed appointments and late cancellations is three-fold: 1) the originally scheduled beneficiary does not receive care, and 2) that appointment could have gone to another beneficiary, and 3) dental office productivity and income is reduced. Missed appointments and late cancellations directly impact access for both Medicaid beneficiaries and all Vermonters because it impacts the availability of appointments. According to the Vermont Oral Health Initiative Dental Survey Report (December, 2005), "...dentists commented that missed and late appointments were of equal importance to the Medicaid fee structure."

Once the codes are implemented, they will need to be communicated to dentists. The process of reporting and following up with beneficiaries will need to be determined.

The process for dentists to access cap information will be automated.

### *Vermont's Investment*

The start date for Initiatives #7 and #8 is 1/1/2008 so the investment (\$50,000) for SFY '08 is to accommodate changes to the Medicaid Management Information System (MMIS). As depicted in the *Information Technology Investment Summary*, the \$50,000 is included in the base for SFY '09 so the new investment for SFY '09 is \$0. No further investment is needed for SFY '10. The total investment for SFY '08 – SFY '09 is \$100,000.

#### ***Initiative #9: Loan Repayment Program***

The Loan Repayment Program is administered by the Vermont Department of Health and awards up to \$160,000 annually based on the following general criteria: 1) must be a VT resident working as a dentist for at least 20 hours per week in Vermont; 2) practice site or region must have a need for dentists, or be an underserved area, as defined by the Program; 3) must meet a one-year service commitment; 4) must agree to see Medicaid-enrolled patients—# to be defined in award offer/contract letter.

### *Vermont's Investment*

The start date for Initiative #9 is 7/1/2007 so the investment for SFY '08 is \$20,000. As depicted in the *Investment Summary*, the \$20,000 is included in the base for SFY '09 - SFY '10 so the new investment for SFY '09 – SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$60,000.

#### ***Initiative #10: Scholarships***

To increase the number of dentists and hygienists who practice in the State and encourage them to provide oral health care to Medicaid beneficiaries, the investment recommendation includes \$20,000 per year for scholarships. A 2003 survey of graduating dentists found that nearly 60% indicated that loan indebtedness was a factor in planning their practice type. The State will collaborate with the Vermont State Dental Society to determine the scholarship criteria, and to administer and award the scholarships.

One scholarship option is to provide a scholarship to a student who graduated from a Vermont High School and is currently attending dental school. In return, upon graduation, the student would agree to return to Vermont to practice and agree to serve a pre-determined amount of Medicaid beneficiaries for 5 years. Currently, there are 14 Vermonters attending dental school who could be approached about their level of interest in this scholarship option.

Another scholarship option is to provide a scholarship to a student who graduated from a Vermont high school and is currently attending a dental hygienists program. In return, upon graduation, the student would agree to return to Vermont to practice and agree to serve a pre-determined amount of Medicaid beneficiaries for 5 years.

### *Vermont's Investment*

The start date for Initiative #10 is 7/1/2007 so the investment for SFY '08 is \$20,000. As depicted in the *Investment Summary*, the \$20,000 is included in the base for SFY '09 - SFY '10 so the new investment for SFY '09 – SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$60,000.

### ***Initiative #11: Technology Grants***

Dentists in Vermont are proponents of the current billing support provided by Vermont Medicaid and overwhelmingly support the continued use of American Dental Association (ADA) codes, universal billing forms, and electronic claims submission. However, only 51% of Medicaid dental claims are submitted electronically.

This initiative assists enrolled dentists serving the Medicaid population in the purchase or upgrade of electronic equipment/services to participate in the Medicaid electronic claims submission process. One area of focus is to decrease the turnaround time for claim reimbursement<sup>20</sup>. With the greater efficiency afforded by electronic claims submission, shorter turnaround times are reasonable to achieve.

The State will collaborate with the Vermont State Dental Society to determine the grant criteria, and to administer and award the grants.

### *Vermont's Investment*

The start date for Initiative #11 is 7/1/2007 so the investment for SFY '08 is \$20,000. As depicted in the *Investment Summary*, the \$20,000 is included in the base for SFY '09 - SFY '10 so the new investment for SFY '09 – SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$60,000.

### ***Initiative #12: Supplemental Payment Program***

Recently, the Vermont Legislature authorized the OVHA to distribute \$242,836 each fiscal year as supplemental payments to dentists serving a high percentage of Medicaid beneficiaries. After review, OVHA and the Vermont State Dental Society agreed that the funds should be distributed bi-annually. Each dental practice that receives greater than \$50,000 in Medicaid reimbursement is eligible for the payment. The amount a practice receives is calculated as a percentage of the Medicaid claims paid. Current estimates project that the legislation will affect approximately 30 practices, who will receive between \$1,700 and \$9,400. Such a payment would effectively increase the Medicaid reimbursement rate approximately 3%. Dental practices who receive cost-based reimbursement are ineligible for the program because their overall reimbursement is already greater based on cost.

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<sup>20</sup> Vermont Oral Health Initiative Dental Survey Report (Dec, 2005)

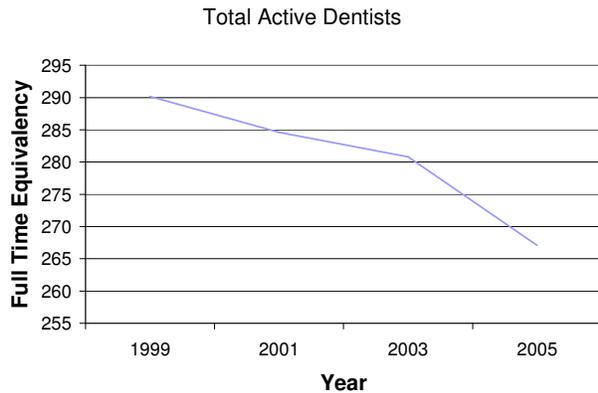
The investment in this initiative is to offer an additional incentive for dentists to enroll as Medicaid providers and for currently enrolled dentists to see more Medicaid beneficiaries.

*Vermont's Investment*

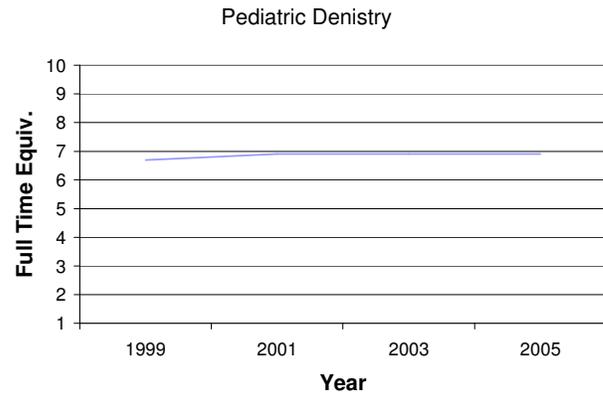
The start date for Initiative #12 is 7/1/2007 so the investment for SFY '08 is \$20,000. As depicted in the *Investment Summary*, the \$20,000 is included in the base for SFY '09 - SFY '10 so the new investment for SFY '09 – SFY '10 is \$0. The total investment for SFY '08 – SFY '10 is \$60,000.

## Vermont Dentistry Trends

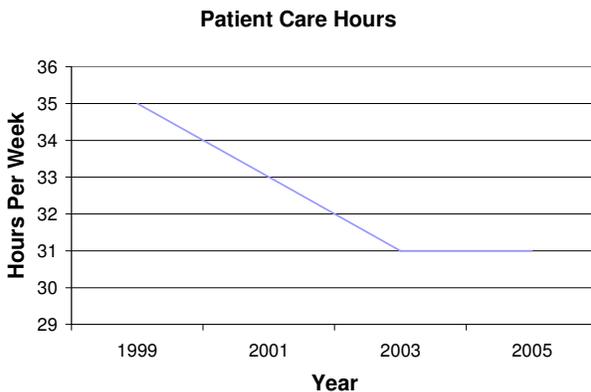
From the Vermont Department of Health 2003 and 2005 Dentist Survey



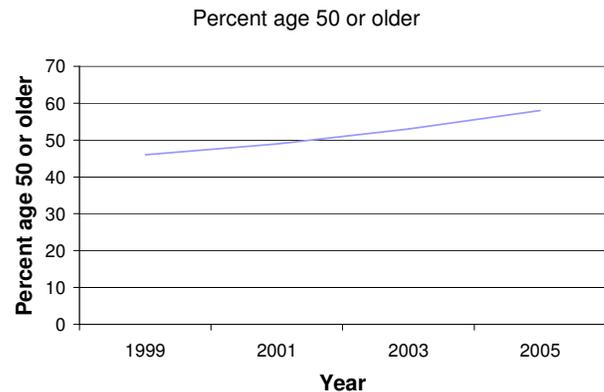
The total number of active dentists in Vermont has been declining from 1999-2005. There is no indication that the trend will not continue.



There has been a slight increase (6.7 to 6.9) in the full time equivalency of pediatric dentists.



The number of patient care hours per week has also declined.



The percentage of dentists who are over 50 years old is on the increase, indicating that younger dentists are not entering the profession.

## ***Vermont's Tooth Tutor Dental Access Program***

Vermont's Tooth Tutor Dental Access Program is an example of a dental program that encompasses several of the goals (e.g., promote preventative oral health care) of the Dental Dozen and pertains to several of the initiatives (e.g., Selection/Assignment of a Dental Home for Children).

### *Background*

Children covered by Medicaid/Dr. Dynasaur have almost double the rate of decayed, missing and filled teeth as those children covered by private insurance/cash. Approximately 50% of Vermont's children with Medicaid/Dr. Dynasaur visited a dentist in the last year. The Tooth Tutor Dental Access Program:

- Gives schools a realistic and effective approach to improving dental health through education, prevention, and by assisting children without a regular dentist to find a dental home.
- Supports school districts that consider dental health and access to care to be a priority to use EPSDT reinvestment money, grants or other sources to hire a Tooth Tutor to carry out the Tooth Tutor Dental Access Program.
- Is cost effective as most schools spend approximately \$3500.00 to fund a Tooth Tutor to work one day a week during the school year.

### *Program Components*

- Identifying the target group of children – no dentist named on the school health history or last visit over a year ago
- Assisting parents in finding a dental home for their child
- Addressing barriers to making and keeping appointments
- Visual screening offered only to those students without a dental home
- Classroom dental health education

### *School to Community Link*

The intent of the Tooth Tutor Dental Access Program is to place most of its resources toward children who do not have a dentist. The goal of this program is to promote a dental intervention program that will increase the number of children receiving oral preventive services and routine care in a dental office. The Tooth Tutor provides a link with local dental offices where children are seen

for preventive, comprehensive and continuous care. School nurses have stated that the Tooth Tutor is a partner in providing needed care to the children in their schools.

### *Data*

- In 2004/2005, children in 110 Tooth Tutor schools started the year with 79% having a dental home – this grew to 94% by June. Each year we have found that the Tooth Tutor can successfully link students with a dentist in most areas of the state if the parent desires it. Additional strategies are used to encourage parents to take advantage of the program by providing information about the program, personal phone calls and even a take home video.
- In 2006/2007 there are 123 schools participating
- Over half of the students need preventive care only – with fluoride and sealants a child may never have a cavity.

### *0-5 Program*

- All of Vermont's 7 Head Starts and 3 Early Head Starts are participating in the program.
- Many schools include their pre-school and EEE Programs in the Tooth Tutor program

University Pediatrics, a large medical practice in Burlington, has hired a dental hygienist to help train pediatricians to perform oral health risk assessments for children ages 0-3, with Medicaid as their insurance. She helps to find dental homes for those children determined to be at high or moderate risk for caries.

## Section 8: Global Commitment to Health Waiver

**Fast Facts:**

- Financial and programmatic flexibility to help maintain public health care coverage and provide for more effective services.
- To lead in exploring new ways to reduce the number of uninsured.
- Foster innovation within health care by focusing on health care outcomes.

During the fall of 2005, the State received approval from the Centers for Medicare and Medicaid Services (CMS) for a Section 1115 Medicaid Waiver known as “Global Commitment to Health Waiver”. The Waiver

allows the State to fundamentally restructure the Medicaid program and imposes a cap on the amount of federal funding available for acute care services for the Medicaid population. The State exchanged the risk of operating under a capped funding arrangement for the opportunity to use federal Medicaid funds for non-Medicaid health programs.

The goals of the Waiver include:

- 1) Financial and programmatic flexibility to help maintain public health care coverage and provide for more effective services.
- 2) To lead in exploring new ways to reduce the number of uninsured.
- 3) Foster innovation within health care by focusing on health care outcomes.

The five-year Waiver term began effective October, 2005, and allows the State to deviate from traditional federal Medicaid law and regulations in the following key ways:

- 1) Imposes a global cap on federal funds.
- 2) Establishes the OVHA as a managed care organization.
- 3) Allows the State to use federal Medicaid funds for state fiscal relief and non-Medicaid health programs.
- 4) Provides flexibility to reduce benefits, increase cost sharing, and limit enrollment for optional and expansion populations with some limits.

Within the AHS, the Waiver will allow cross-departmental initiatives to obtain the greatest value from scarce health care dollars. The flexibility of the Waiver allows the State to effectively manage public resources, provide the tools necessary to make health care programs fiscally sustainable, and improve the Vermont health care system.

Under the Global Commitment to Health Waiver, the OVHA is a Managed Care Organization (MCO), and must meet rules for Medicaid MCOs. The OVHA has intergovernmental agreements (IGAs) with the AHS and AHS departments that make them part of the MCO within the framework of the Global Commitment to Health Waiver. The State desires to use the Global Commitment to Health Waiver flexibility to integrate a Chronic Care Management Program (CCMP) into a system of care that can be used to benefit Medicaid beneficiaries, providers, and the OVHA.

An amendment to the Global Commitment to Health Waiver was submitted to the Centers for Medicare and Medicaid Services (CMS) on September 11, 2006. Reference Section 4 for amendment details.

## Section 9: Information Technology

**Fast Facts:**

- The MMIS and ACCESS systems require attention.
- OVHA participates in VITL.

The OVHA has a number of Information Technology (IT) projects that impact the SFY '08 budget request. The OVHA is planning its IT projects to align with Vermont's Health Care Reform 5-Year Plan and Vermont's Health Information

Technology Strategic Plan, as well as to meet federal and State program requirements.

### ***Medicaid Information Technology Architecture (MITA) State Self Assessment (SSA)- Medicaid Management Information System (MMIS) and Eligibility Determination System***

MITA is a Center for Medicare and Medicaid Services (CMS) initiative that establishes a vision and framework for future Medicaid Management Information Systems (MMIS) development. MITA's goal is to change the way states design, build and modify their MMIS and perform Medicaid IT investment planning.

In order to receive federal funding for MMIS procurements states must align their business goals and objectives with MITA goals and objectives and must plan MMIS procurements and enhancements within the MITA Framework. CMS is requiring each state to complete a state self assessment (SSA) for submission with a funding request. Assessment methodology is defined by CMS and entails an extensive evaluation of the current state of affairs in the "Medicaid enterprise" against Vermont's vision and MITA framework, goals and objectives. The SSA encompasses all related business processes including member eligibility and enrollment, claims processing/payment, and program integrity. The State must develop strategies for meeting its objectives in accordance with the MITA framework because CMS expects improvements in return for funding.

Two Vermont Medicaid systems currently require attention:

#### **MMIS**

The OVHA must begin a procurement cycle for its claims processing/payment system. The contract with the current fiscal agent, Electronic Data Systems (EDS), is set to expire on December 31, 2008, with extensions available through 2011. A contemporary MMIS that leverages the benefits that newer technologies afford, such as greater flexibility and responsiveness, would better serve the needs of Vermont's health care programs.

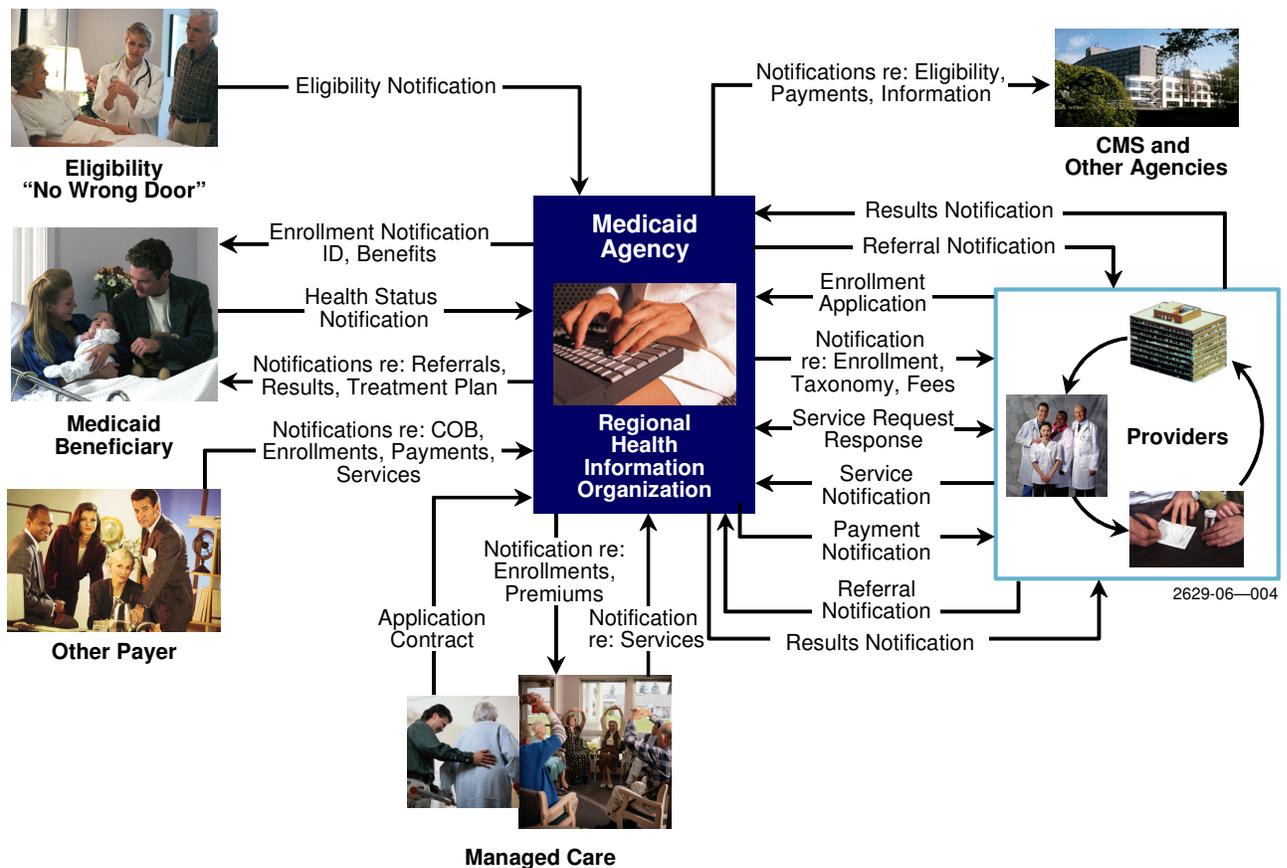
#### **ACCESS**

Coverage under Medicaid and other Vermont health care programs is authorized in the ACCESS eligibility determination system. The ACCESS system has been in operation since 1983. The OVHA is concerned about the system's ability to respond to the demands and deadlines of the current health care environment and about the cost associated with implementation of program initiatives. The constraints of this system

also hinder Vermont’s ability to realize its health care vision through enhanced consumer services, such as web based screening and enrollment.

In SFY’08, the OVHA plans to complete an SSA to chart the future claims processing system and for the future of ACCESS as it relates to health care. The OVHA envisions the creation of a “Medicaid enterprise” comprised of modern, responsive, interoperable systems which are designed to leverage the health information exchange being created by the Vermont Information Technology Leaders (VITL) and which conform to the Vermont Health Care Technology Strategic Plan. A sample vision constructed within the MITA framework is shown below.

### Sample MITA Vision



Fulfilling this vision will entail several projects over several years, but can also be considered one large project designed to reach the overarching vision. Presented as such, the general timeline is:

2/07 – 6/07	7/07 – 6/08	7/08 – 12/08	1/09 – 6/10	7/10 – 12/11	1/11 – 12/12
-Advance Planning Document (APD) Development -SSA RFP & Procurement	-SSA -Elig/Enroll Requirements & RFP	Elig/Enroll Procurement	-Elig/Enroll Development -MMIS Requirements & RFP	MMIS Procurement	MMIS Development*

\*Note: OVHA anticipates requesting from CMS and the State an additional one year extension to the existing EDS contract

Completing the SSA will require consulting support. The OVHA plans to issue an RFP for consulting support in late SFY '07 in anticipation of approval for this budget item. The project is expected to cost \$500,000 at 90% Federal Financial Participation (FFP), resulting in a SFY '08 General Fund (GF) request of \$50,000.

### ***Systems Coordination with Blueprint for Health***

The OVHA and the Vermont Department of Health (VDH) (i.e., Blueprint for Health) are collaborating programmatically to align chronic disease management initiatives. The OVHA must also coordinate system support with the Blueprint. The Blueprint has made a major investment in a health information suite of software products. The Blueprint, through its contract with VITL, has also made a major investment in the creation of an electronic master patient index. The OVHA plans to leverage those investments to serve the Medicaid population, with the goal of improving the information and case management system support available to its care managers and service providers. The OVHA is requesting \$300,000 in the SFY '08 budget to procure the required system changes.

### ***Participation in Vermont Information Technology Leaders (VITL)***

The OVHA is actively participating in VITL's initiatives to create Vermont's Health Information Technology Strategic Plan and Vermont's health information exchange infrastructure, including its medication history pilot. The OVHA expects these projects to facilitate improvements in the quality of healthcare and to help control healthcare spending by making data available to the right people at the right time. Medicaid and its beneficiaries will derive benefits from being represented as decisions are made, and from the structure that is created.

### ***Multi-payer Claims Database***

This project will make possible cross-payor analysis of health care claims, leading to better health care policy decisions that are expected to improve care and control spending. The OVHA and the Department of Banking, Insurance, Securities, and

Health Care Administration (BISHCA) have been attending meetings with Maine and New Hampshire, states that have moved ahead with similar initiatives, to benefit from lessons learned during their implementations. The OVHA must collaborate with CMS on the appropriate methodology for making VT Medicaid claims data available to the database. The project resides at BISHCA but is partially supported through a position funded by the OVHA.

### ***Audit Response***

In May 2006 the State Auditor's Office began an audit of the Medicaid program. The scope of the technical audit has been broad and deep. For example, the topics covered under the systems area "OVHA Oversight of EDS processes" included system documentation, continuity of operations/disaster recovery planning and testing, information technology security including access controls, system change management, systems development processes, systems operations, federal documents (e.g., Advance Planning Documents - APDs, Implementation Advance Planning Documents - IAPDs), data reconciliation between the MMIS and the ACCESS system, claim error status codes and resolution process, and ClaimCheck/ClaimReview software processes. Similar information was requested on the pharmacy benefit manager (PBM) contract. Agency of Human Services (AHS) responsibilities and processes, such as covered entity HIPAA security policies, were also reviewed. The OVHA and its contractors, and other AHS staff, have diligently responded to audit requests, even though the demand on available resources has been significant.

No formal report has been received as of the date of this document, but the OVHA has been informed that there will be findings. Once the auditor's report is received, the OVHA will have to determine how to respond, including quantifying the financial and staffing impact.

### ***Looking To the Future and Fitting It All Together***

A major challenge and opportunity for the OVHA is to create a comprehensive vision of Medicaid health information technology and health information exchange. Each project and technology system must be part of a cohesive system of care. The OVHA must be forward thinking, but must also proceed prudently, making good spending decisions and ensuring that its beneficiaries' health information is secure and accessed appropriately. The vision will take shape as the Vermont Health Information Technology Strategic Plan and MITA assessment are completed, and as the implementation details of the Health Care Reform Plan are fleshed out.

## Section 10: Medicare Modernization Act (MMA)

### **Fast Facts:**

- Vermont Medicaid continues to have a State wraparound program, VPharm, where Medicare supplemental coverage is comparable to previous coverage from the State in 2005.
- The State of Vermont continues to take steps to ensure that Vermonters who are having trouble accessing the federal prescription drug benefit have State assistance in resolving the issues.

### **Overview**

Vermont Medicaid is entering its second year as a secondary payer for pharmacy benefits after Medicare Part D (January 2006). The pharmacy benefit for individuals covered by Medicare and Medicaid continues in 2007 much as it was in 2006.

### **Traditional Medicaid**

*(Primarily below 100% of the FPL)*

- 1) The State's coverage is limited to excluded drug classes (benzodiazepines; barbiturates; over-the counter prescriptions; vitamins or minerals; drugs when used for anorexia, weight loss, or weight gain) for those who are enrolled in a Part D plan (or Part C with a drug component) or have creditable coverage.
- 2) No State premium is charged.
- 3) The beneficiary pays the Part D co-pays (from \$1 to \$5.35) with the exception that pregnant women and children will have co-pays paid by the State.
- 4) All other cost-sharing is covered by the federal low-income subsidy.
- 5) Drugs that are not on the plan's formulary or are denied by the plan as not medically necessary are not covered without specific approval from OVHA.
- 6) When a Part C or D plan denies a non-formulary drug or a drug the plan indicates is not medically necessary, beneficiaries may apply to OVHA for coverage of the drug after the plan's appeal process is exhausted (through the Independent Review Entity level).
- 7) The plans are required to cover all or substantially all of the drugs in the following categories: antidepressant, anticonvulsive, antipsychotic, anticancer, immunosuppressant, and HIV/AIDS.

### **Vermont's Medicaid Waiver and State Pharmacy Programs**

*(100% to 225% of the FPL)*

Vermont Medicaid continues to have a State wraparound program, VPharm, where Medicare supplemental coverage is comparable to previous coverage from the State in 2005.

Throughout 2006, beneficiaries eligible for Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), and Qualified Individual (QI) programs benefited from a resource test elimination. By virtue of eligibility for these programs, they became eligible for the full federal low-income subsidy (LIS). Based on

historical expenditures the analysis indicated that this change would be (at worst) cost-neutral for the State.

VPharm coverage highlights:

- 1) Beneficiaries must be eligible for Part A or enrolled in Part B.
- 2) Beneficiaries must be enrolled in a Part D plan (or a Part C plan with a drug component, or a Part C plan without a drug component and separately enroll in a Part D plan) and secure the limited income subsidy if it appears they might be eligible.
- 3) Beneficiaries pay premiums to the State of \$15, \$20 or \$42.
- 4) The coverage will be:
  - a) Payment of cost-sharing that is not covered by the low-income subsidy, including premiums, deductibles, co-payments, coinsurance and the coverage gap (for beneficiaries at the VScript or VScript Expanded coverage level of 150% to 225% FPL, only maintenance drugs are eligible for the cost-sharing coverage); and
  - b) Coverage of drug classes that are excluded from Part D (benzodiazepines; barbiturates; over-the counter prescriptions; vitamins or minerals; drugs when used for anorexia, weight loss, or weight gain). Some of these may have requirements or limits attached. For beneficiaries at the VScript or VScript Expanded coverage level (150% to 225% FPL), only maintenance drugs in these classes are included in the benefit.
- 5) Drugs that are not on the plan's formulary or are denied by the plan as not medically necessary will not be covered without specific approval from OVHA.
- 6) When a Part C or D plan denies a non-formulary drug or a drug the plan indicates is not medically necessary, beneficiaries may apply to OVHA for coverage of the drug after the plan's appeal process is exhausted (through the Independent Review Entity level).
- 7) The plans are required to cover all or substantially all of the drugs in the following categories: antidepressant, anticonvulsive, antipsychotic, anticancer, immunosuppressant, and HIV/AIDS.

**Healthy Vermonters Program**

*(Primarily greater than 225% of the FPL)*

Healthy Vermonters Program beneficiaries who have Medicare may obtain drugs in the Part D excluded classes (benzodiazepines; barbiturates; over-the counter prescriptions; vitamins or minerals; drugs when used for anorexia, weight loss, or weight gain) at the Medicaid cost.

**Phased-Down Contribution**

The pharmacy benefit under Medicare is conceptually a federal benefit but in the case of dual eligibles (those Medicare beneficiaries who are also eligible for Medicaid) it is funded in the same way as it is funded under Medicaid, with federal and state funding.

What in Medicaid is referred to as the state share is called the phased-down state contribution for Medicare. The states contribution design calls for states to annually pay a portion of what they would have paid in Medicaid state share in that year for the support of drug coverage of Medicare beneficiaries who are also eligible for Medicaid drug coverage. This is the concept sometimes referred to as “clawback”. Key concepts of the phased-down contribution include:

- 1) Based on Medicaid state expenditures (excluding VHAP-Pharmacy, VScript, and VScript expanded) in calendar year (CY) 2003 adjusted for inflation.
- 2) Calculated on expenditures net of drug rebate.
- 3) States retain a specified portion in support of providing other coverage to their dual eligibles.

Beginning January 1, 2007, states are expected to pay the phased-down state contribution of 88 1/3 % of the estimated CY state share of Medicaid/Medicare pharmacy expenditures net of rebate. The contribution in future years will be progressively less:

CY 2008	86.67%
CY 2009	85.00%
CY 2010	83.33%
CY 2011	81.67%
CY 2012	80.00%
CY 2013	78.33%
CY 2014	76.67%
CY 2015 and thereafter	75.00%

### ***PDP Administration***

There are many issues around the administration of existing coverage, including but not limited to providing enrollment and eligibility functionality and data transfers to Medicare; managing the medical coverage for traditional Medicaid eligibles without control of the pharmacy coverage; coordinating any State pharmacy benefits with Medicare pharmacy coverage; and educating/supporting beneficiaries/providers.

### ***PDP Selection***

A Medicare-contracted Prescription Drug Plan (PDP) provides the benefit. Every beneficiary has a choice of at least two PDP’s. Beneficiaries choose their plans annually. Some beneficiaries have special enrollment periods (SEP). For example, dual eligibles may change plans any month. VPharm, the State pharmacy program that wraps the Part D benefit, is also known as a state pharmacy assistance program (SPAP) by the federal government. In the summer of 2006, CMS determined that individuals eligible for an SPAP are allowed one SEP in 2007 in addition to their annual enrollment period (AEP) which is November 15 through December 31.

### ***PDP Drug Coverage***

Each Medicare PDP will set the coverage plan (formulary) according to Medicare guidelines.

- 1) The guidelines require mandatory Medicaid class coverage. Coverage does not include specified optional Medicaid coverage including over-the-counter and selected other products (such as: products for the treatment of weight loss/gain, barbiturates, and benzodiazepines).
- 2) Unlike Medicaid, the formulary can be closed; that is, within the Medicare defined classes, not all drugs need to be covered. The regulations specify at least two drugs to a class must be included.
- 3) The formulary may change monthly. That means that beneficiaries who choose a plan based on specific drugs may not be assured the same coverage throughout the year they are enrolled in the plan.

### ***Continuing Support for Beneficiaries***

The State of Vermont continues to take steps to ensure that Vermonters who are having trouble accessing the federal prescription drug benefit have State assistance in resolving issues. These steps include:

- 1) Additional staff at the state's member services call center, and
- 2) January 1, 2007 OVHA employees were available to answer provider questions and provide special handling for members in need of assistance in obtaining their prescriptions.

## Section 11: Program Integrity (PI)

**Fast Fact:**

PI includes the provision of medically necessary and appropriate health care services, accurate reimbursement to qualified providers of those services, efficient administration of the Medicaid Program, and the prevention of inappropriate services and reimbursement. Maintaining the integrity of the Medicaid Program is one way to contain costs without adversely impacting beneficiary services or provider reimbursement.

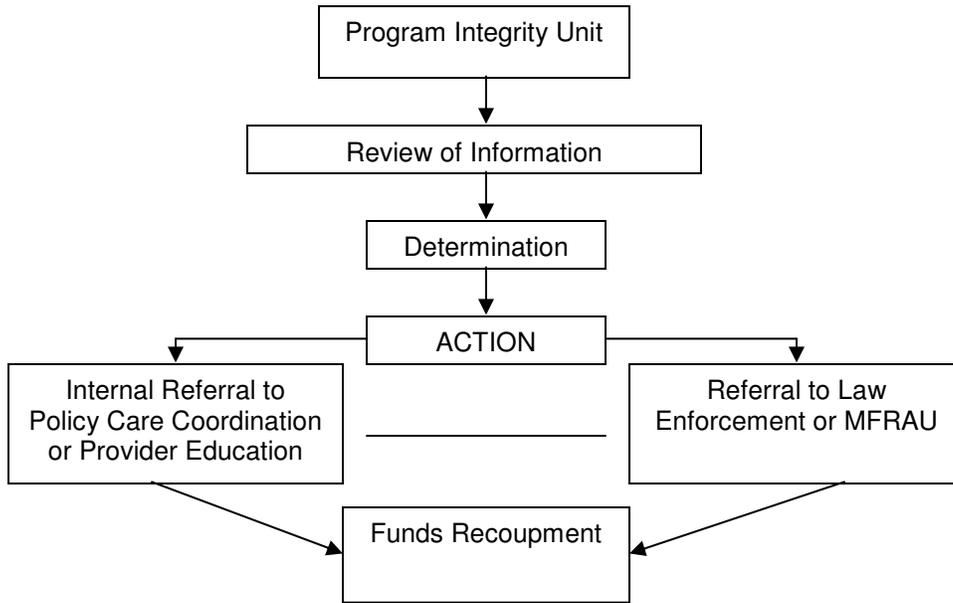
The Program Integrity (PI) Unit consists of two teams: 1) Data and 2) Surveillance & Utilization Review (SUR). PI includes; review of secure provision for appropriateness the analysis of the accuracy of reimbursement to qualified providers of those services, the allocation of resources to affect the efficient administration of the Medicaid Program, and the prevention of inappropriate services utilization. Maintaining the

integrity of the Medicaid Program is one way to contain costs without adversely impacting beneficiary services or provider reimbursement.

The Data team provides analysis of Medicaid expenditures and enrollment as well as detailed service level stratification and modeling in support of office activities. The SUR team works closely with each unit within the OVHA, other departments within the AHS and State that have services that expend Medicaid funds as well as the Medicaid Fraud and Residential Abuse Unit (MFRAU) and the Beneficiary Fraud Unit. The SUR team is primarily responsible for UR and UR from both a clinical investigator perspective. Both the data and SUR teams have been combined into one unit in recognition of the interconnectivity of the clinical UR and UR and data mining and analysis in protecting the integrity of the Medicaid system.

There are a variety of ways that fraud, waste and/or abuse can be detected. The following are a couple of examples:

- **Systematic:** The Fraud Abuse and Detection System (FADS) identifies patterns of utilization that are above or below the mean.
- **Referral:** Information that comes from a variety of sources by phone or in writing concerning potential fraud, waste and/or abuse. Referrals can be made to the PI Unit from both internal and external sources. For example, a beneficiary may contact the PI Unit because of a billing concern or an analyst may notice billing irregularities.



## Section 12: Provider Reimbursement and Taxes

### **Fast Facts:**

The SFY'08 budget proposes to increase:

Physicians	\$2,000,000
Inpatient	\$2,000,000
Home Health	\$400,000
Dental	\$637,862 (rate only)

### **Reimbursement**

In SFY'06, the OVHA was required to make reductions in the fee schedule for many providers. Effective January 1, 2007, rates for dental and Current Procedural Terminology (CPT) codes were reinstated with an increase to CPT codes.

The SFY'07 Appropriation Act directed the OVHA to link future fee increases to performance. The OVHA will align with the Blueprint for Health development with a strong focus on performance.

Currently, hospital payment methods are both out of date and provide no incentive for performance. The OVHA has contracted with Burns and Associates to develop an improved payment system for hospitals [i.e., Diagnosis Related Grouping (DRG) and Ambulatory Payment Classification (APC)]. While options are developed, the OVHA is consulting with a representative hospital work group to ensure that there is agreement on the data. The hospitals as a group and individual hospitals will have ample opportunities to recommend approach improvements prior to finalization of this baseline adjustment in payment methodology. Implementation is planned to occur during SFY '08. This change will provide a necessary foundation in preparation for future payment reforms as the Blueprint for Health develops performance criteria.

### **Taxes**

Provider taxes may be used as federal Medicaid matching funds if the tax meets specific federal requirements. One of the requirements is an upper tax rate limit of 6%. All of the implemented provider taxes in Vermont, with the exception of the pharmacy tax, are at or near the 6% limit. Effective January 2008, the Federal Government has reduced the maximum allowable Provider Tax from 6% to 5.5%. This change will have no impact on tax receipts in SFY 2008. The potential impact on SFY 2009 has yet to be determined.

There are five taxes aimed exclusively at Vermont providers that qualify under federal law as matching funds for the Medicaid program. To qualify, they must be uniformly applied to designated classes of Vermont providers and cannot exceed 5.5% of patient revenue.

The *hospital tax* applies to net patient service revenues which are taxed at 5.5%. The revenue from the hospital tax provides the general funds (GF) to support the disproportionate share hospital's (DSH) annual payments and the GF for a Vermont-only hospital rate increase.

The *nursing home tax* is a per bed tax which is calculated annually to assure that it is close to, but does not exceed, the 5.5% maximum. This revenue is used to fund nursing home Medicaid payments.

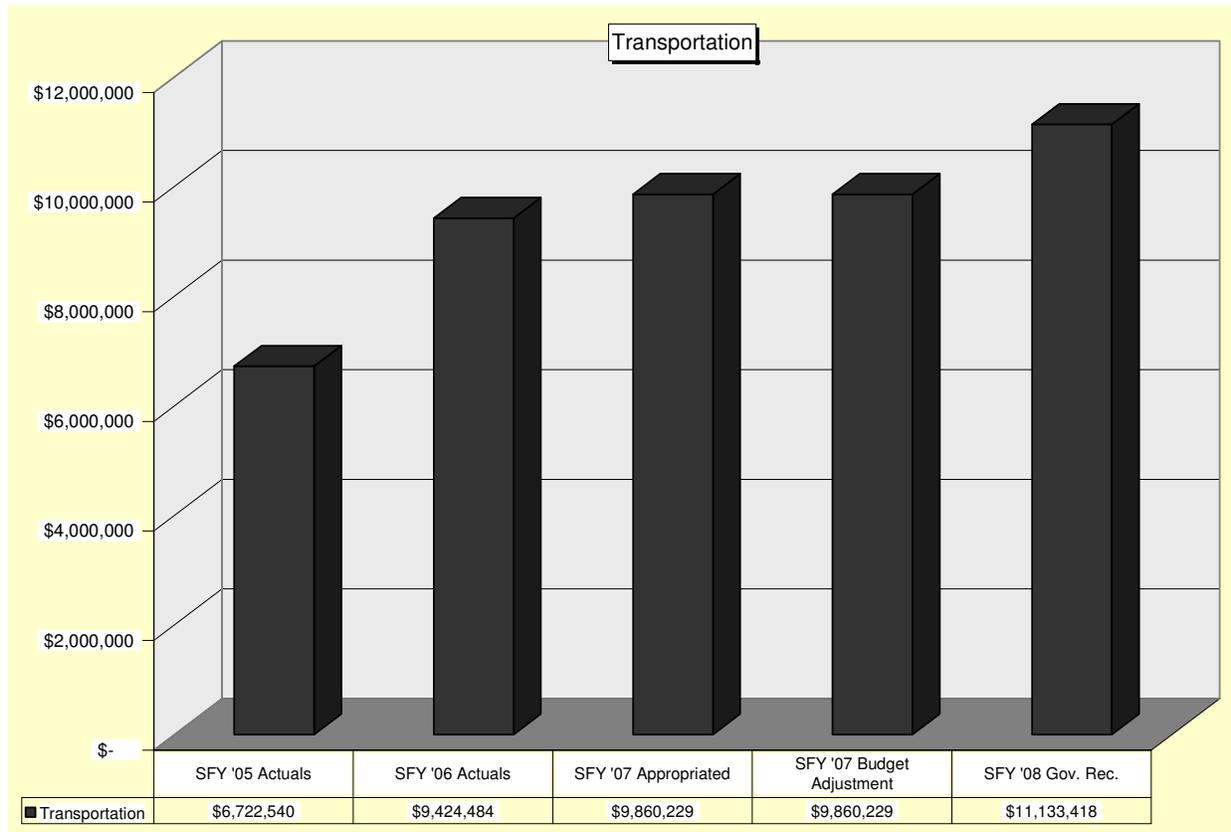
The *Intermediate Care Facility for the Mentally Retarded (ICF-MR) tax* is set at 5.5% of the audited costs for the service. There is only one ICF-MR left in Vermont and this revenue helps fund that service.

The *home health agency tax* is based on “core” service revenues excluding Medicare revenues. The current tax is close to the 5.5% maximum. The revenue from this tax continues to support past rate increases for services offered by these agencies.

The *pharmacy tax* is set at \$0.10 per prescription filled or refilled by a Vermont pharmacy. This revenue supports a portion of the dispensing fee paid for Medicaid prescriptions. For SFY '08, the State anticipates the collection of \$603,499 based on revenues collected to-date.

## Section 13: Transportation

Transportation is one of the fastest growing categories of service (COS). The expenditures associated with transportation are depicted in the following graph:



During SFY '07, the OVHA conducted extensive research and analysis into transportation which resulted in the following findings:

- 1) Increases in the mileage rate for volunteer drivers have had a significant impact on transportation costs. In SFY '06 mileage rate increases resulted in about a \$355,000 increase in expenditures. The 9% increase in the volunteer mileage rate expected in calendar year '07 (from \$0.445 to \$0.485) will increase the transportation budget on an annual basis by approximately \$254,499 based on SFY '06 volunteer miles.
- 2) Utilization has also increased. The number of total Medicaid reimbursed trips statewide has increased as follows:
  - 465,757 in SFY '04
  - 509,366 in SFY '05
  - 646,249 in SFY '06

- 3) The mix of the 646,249 trips of Medicaid financed transportation provided in SFY '06 by means of transport and expenditures is as follows:

<b>Mode</b>	<b>Percent of Trips</b>	<b>Percent of Expenditures</b>	<b>Expenditures</b>
<b>Bus</b>	38%	12.5%	\$1,058,011
<b>Volunteer</b>	26%	33.8%	\$2,854,599
<b>Taxi</b>	15%	18.7%	\$1,578,536
<b>Van</b>	14%	27.9%	\$2,357,122
<b>Hardship</b>	5%	2.7%	\$226,249
<b>Other</b>	2%	4.3%	\$362,466

- 4) Broker administrative costs have not contributed to transportation cost increases. Administrative costs have not increased significantly since FY '00.
- 5) Transportation to dialysis services is a significant cost. It is estimated that an average of 87 Vermonters are transported on a monthly basis, at an average cost of \$63,661 (per month). This represents a per trip cost of \$732. Total transportation costs to dialysis services are estimated to be \$763,932 annually.
- 6) Transportation cost to methadone clinics are estimated to be the following in the past two SFYs:
- SFY '05: \$763,583
  - SFY '06: \$889,419

Based on the findings, the OVHA is proceeding with the following changes during SFY '07 and SFY '08:

- 1) Investigate, design and consider implementation of alternative reimbursement methodologies for transportation providers.
- 2) Update and re-issue the Transportation Provider Manual to all brokers and Vermont Public Transportation Agency (VPTA). This is a document essential for proper program operation.
- 3) Implement a new bus pass procurement process in Burlington with an effective date for the new system of May 2007. (Net savings: \$162,000)
- 4) Perform a Quality Control (QC) audit based on the procedures identified in the Transportation Provider Manual and conduct audits as appropriate.
- 5) Explore Partnerships: University of Vermont (UVM) has recently received federal funding to create a Transportation Center. The Center will be conducting

research on Vermont transportation issues. Staff capacity is currently being added to the Center. One exploratory meeting has been held to discuss possible opportunities for collaboration on examining transportation issues related to Medicaid.

- 6) Transportation to methadone clinics is a significant component of transportation costs. Transportation costs are higher than necessary due to lack of capacity in certain geographic areas of the State. If an eligible beneficiary is in need of methadone treatment and there is not an available slot in the clinic that is closest geographically, transportation is provided to a clinic where a slot is available. ADAP and OVHA staff have analyzed data on the geographic location of clinic users and the actual clinic used to determine if transportation costs can be reduced by increasing clinic capacity in selective locations. The analysis indicates that transportation costs can be saved by expanding capacity in Burlington and Brattleboro, and that the expanded capacity can be met by using only a portion of the transportation savings that will result by serving patients closer to their residence. (Net savings: \$104,743)

*OVHA's Participation in Substance Abuse Program Development*

Site	Newly Added		Transportation	Savings Net of
	Slots	Annual Cost	Savings	Cost
Brattleboro	14	\$ 71,344	\$ (149,000)	\$ (77,656)
Burlington	20	\$ 124,800	\$ (151,887)	\$ (27,087)
<b>Total</b>	<b>34</b>	<b>\$ 196,144</b>	<b>\$ (300,887)</b>	<b>\$ (104,743)</b>

	Global Commitment
OVHA ~ Global Commitment Appropriation	\$ (196,144)
VDH ~ Alcohol & Drug Abuse Appropriation	\$ 196,144

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**Section 14: Highlights Impacting SFY '08 Governor's Recommend**

The OVHA's SFY '08 Governor's Recommend is comprised of a program increase of **\$65,308,014** and an administrative increase of **\$2,865,916** over SFY '07 Appropriated.

**Trends . . . . . \$23M**

Following are several categories of service with their respective dollar and percent growth rates from SFY '07 Budget Adjustment to SFY '08 Governor's Recommend:

Description of Service	\$ Chg.	% Chg.
Outpatient Hospital	\$ 6,314,296	10.00%
Physician	\$ 2,276,432	3.35%
Home Health	\$ 1,349,209	16.36%
Psychologist	\$ 2,178,864	19.70%
Transportation	\$ 1,227,233	12.45%
Medical Supplies & DME	\$ 1,283,019	15.51%
Personal Care Services	\$ 4,752,963	23.93%
Assistive Community Care Services	\$ 4,029,783	48.14%

**Long-Term Care Waiver Adjustments . . . . . \$15M**

- Increase over SFY '07 Budget Adjustment \$19,756,993 ~ 11.7%
- Increase over SFY '07 Appropriated \$15,222,219 ~ 8.8%

**Healthcare Reform Legislation . . . . . \$16M**

- Enacted to decrease the number of uninsured Vermonters
- VHAP premiums reduced by 35% resulting in anticipated enrollment increase
- Dr. Dynasaur premiums reduced by 50% resulting in anticipated enrollment increase
- Catamount Health and Employer-Sponsored Insurance programs begin October 1, 2007

	Enrollment Change	Expenditure Change
SCHIP (Uninsured Children)	675	\$ 982,689
VHAP	794	\$ 2,614,758
Catamount Health	2,973	\$ 12,468,165

**SFY '07 Rate Increases Annualized in SFY '08 . . . . . \$3.5M**

Physician	\$2,278,363
Dental	\$ 150,000
Inpatient	\$1,000,000

**New SFY '08 Additional Rate Increases/New Programmatic Support . . . . \$4.5M**

Physician	\$2,000,000
Inpatient	\$2,000,000
Home Health (Aligning Nursing Rates with LUPA ~ Low Utilization Payment Adjustment)	\$ 400,000

**Dental Dozen . . . . . \$1M**

- Ensure Oral Health Exams for Children  
(Phased Implementation – SFY '09)
  - Increase Dental Reimbursement Rates \$637,862
  - Reimburse Primary Care Physicians (PCP)  
for Oral Health Risk Assessment (HRA) \$ 40,000
  - Dental Hygienists Placement \$ 58,000
  - Selection/Assignment of a Dental Home  
for Children\*
  - Enhance Outreach  
(Managed with Existing Resources)
  - Codes for Late/Missed Appointments\*
  - Automation of Adult Cap\*
  - Loan Repayment \$ 20,000
  - Scholarships \$ 20,000
  - Technology Grants \$ 20,000
  - Supplemental Payment Program \$ 20,000
- SFY '08 Total \$815,862

\*SFY '08 IT Investment: \$275,000

**Buy-In . . . . . \$9M**

- To enroll individuals who are income eligible for Medicare Savings Programs, the OVHA eliminated the use of asset tests for Qualified Medicare Beneficiaries (QMB), Specified Low Income Medicare Beneficiaries (SLMB) and Qualified Individuals (QI)
- There are year-over-year increases in the buy-in premium assistance rate. Rate increases from \$88.50 to \$93.50 PMPM in SFY '08
- Total increase from SFY '07 appropriated to SFY '08 Gov. Rec. is \$9,228,532
- \$3.1M of the \$9.2M is full federal reimbursement

**Reduction to Disproportionate Share Hospitals (DSH) payments . . . . . (\$7M)**

In SFY '07, a decision was made to make “double DSH” payments to align DSH expenses to the MCO and federal fiscal year. In both SFY '08 and SFY '09 there will be reductions to this line item from the SFY '07 base. Funding impact: (\$7,250,289).

**Pharmacy ~ Medicare Modernization Act (MMA)**

- Medicare implemented a new pharmacy benefits program (i.e., Part D) in SFY '06
- There are significant reductions in overall pharmacy spend
- The OVHA is obligated to remit a clawback payment to the federal government resulting in a state-fund neutral net cost to Vermont

**Administration . . . . . \$3M**

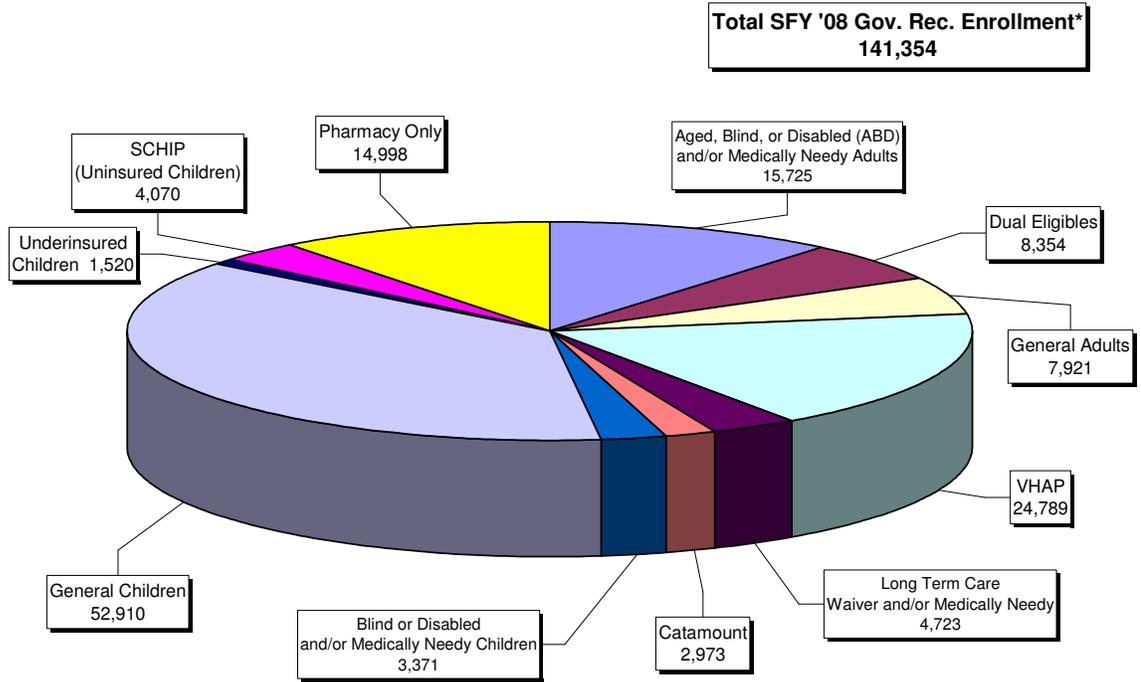
- |   |             |
|---|-------------|
| • Catamount Health implementation   | \$1,500,000 |
| • Data analysis in support of system improvements and Chronic Care Program implementation | \$ 800,000  |
| • Medicare Modernization Act (MMA) additional administrative support                      | \$ 600,000  |

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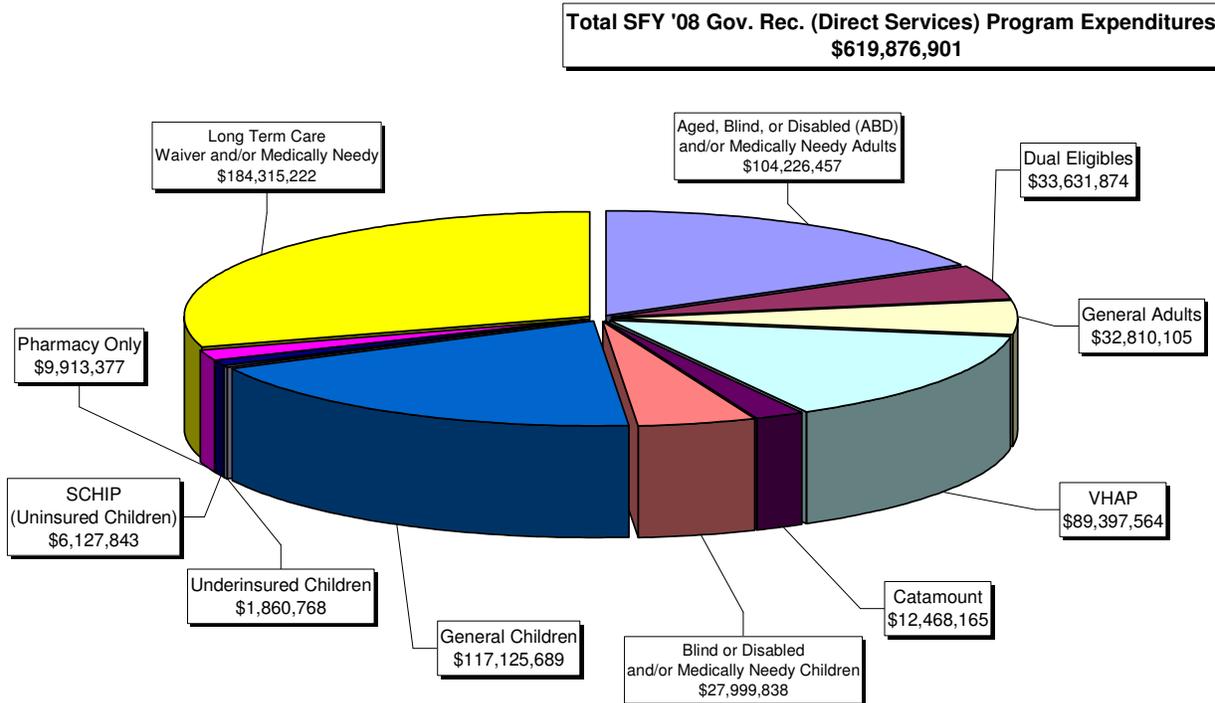


**Table 2: Cost Comparison SFY '06 through SFY '08 Governor's Recommend**

	SFY '06 Actuals				SFY '07 Appropriated				SFY '07 Budget Adjustment				SFY '08 Governor's Recommend			
	Enrollment	Expenses	PMPM		Enrollment	Expenses	PMPM		Enrollment	Expenses	PMPM		Enrollment	Expenses	PMPM	
<b>Adults</b>	15,481	91,739,541	\$ 494		15,491	\$ 93,853,422	505		15,417	\$ 94,524,993	511		15,725	104,226,457	552	
Aged, Blind, or Disabled Eligibles	8,881	30,976,189	\$ 291		8,042	\$ 33,121,058	343		8,507	\$ 30,522,727	299		8,354	33,631,874	335	
General Adults	7,601	25,426,874	\$ 279		7,952	\$ 30,441,192	319		7,715	\$ 30,659,015	331		7,921	32,810,105	345	
VHAP	22,525	77,321,380	\$ 286		23,995	\$ 79,053,489	275		23,276	\$ 79,032,744	283		24,789	89,397,564	301	
Catamount	-	-	\$ -		-	-	-		-	-	-		2,973	12,468,165	349	
<b>Subtotal Adults</b>	<b>54,488</b>	<b>225,463,983</b>	<b>\$ 345</b>		<b>55,480</b>	<b>236,469,162</b>	<b>341</b>		<b>54,914</b>	<b>234,739,479</b>	<b>356</b>		<b>59,762</b>	<b>272,534,164</b>	<b>380</b>	
<b>Children</b>																
Blind or Disabled (BI)	3,167	24,494,952	\$ 643		3,377	25,023,869	617		3,277	25,202,928	641		3,371	27,999,838	692	
General Children	52,845	95,671,279	\$ 151		52,839	106,897,131	169		53,010	107,662,036	169		52,910	117,125,689	184	
Underinsured Childre	1,284	821,382	\$ 53		1,941	1,808,922	78		1,169	1,278,959	91		1,520	1,860,768	102	
SCHIP (Uninsured C	3,092	4,901,663	\$ 132		3,395	4,940,365	121		3,131	4,618,038	123		4,070	6,127,843	125	
<b>Subtotal Children</b>	<b>60,388</b>	<b>125,829,275</b>	<b>\$ 174</b>		<b>61,552</b>	<b>138,670,287</b>	<b>188</b>		<b>60,586</b>	<b>138,761,961</b>	<b>191</b>		<b>61,871</b>	<b>153,114,138</b>	<b>206</b>	
<b>Pharmacy</b>	13,666	25,668,961	\$ 157		14,360	12,830,809	74		13,042	8,231,517	53		14,998	9,913,377	55	
Long Term Care/Waiver and	3,698	154,787,921	\$ 3,488		4,147	169,093,003	3,398		4,147	164,558,229	3,307		4,723	184,315,222	3,252	
<b>Subtotal Direct Services</b>	<b>132,240</b>	<b>531,750,140</b>	<b>\$ 335</b>		<b>135,539</b>	<b>557,063,261</b>	<b>342</b>		<b>132,690</b>	<b>546,291,185</b>	<b>343</b>		<b>141,354</b>	<b>619,876,901</b>	<b>365</b>	
<b>Miscellaneous Program</b>																
DISH		35,205,323				56,254,187				56,254,187				49,003,898		
Clawback		6,888,177				19,380,407				19,380,407				19,630,187		
Buy-in		19,598,052				18,268,507				23,289,719				27,497,039		
Legal Aid		493,820				395,906				506,142				506,142		
Rate Setting		644,746				651,491				676,983				663,065		
Misc. Pymts.		1,833,966				625,000				1,226,900				749,520		
Healthy Vermonters	13,707	-	n/a		13,733	-	n/a		8,841	-	n/a		8,841	-	n/a	
Healthy Vermonters	13,707	-	n/a		13,733	-	n/a		8,841	-	n/a		8,841	-	n/a	
<b>Total Miscellaneous Program</b>	<b>13,707</b>	<b>64,604,084</b>			<b>13,733</b>	<b>95,575,498</b>			<b>8,841</b>	<b>101,334,339</b>			<b>8,841</b>	<b>98,069,872</b>		
<b>TOTAL PROGRAM EXPENDITURES</b>	<b>132,240</b>	<b>596,354,224</b>			<b>135,539</b>	<b>652,638,759</b>			<b>132,690</b>	<b>647,625,525</b>			<b>141,354</b>	<b>717,946,773</b>		
<b>Contract</b>																
Claims Processing		8,965,554				8,633,903				12,496,853				9,133,903		
Member Services		2,120,082				2,143,223				2,974,831				3,198,772		
Pharmacy Benefits Manager		2,839,272				1,947,259				2,247,259				1,947,259		
IT for MMA & CSME		655,242				1,725,000				2,233,983				1,725,000		
Miscellaneous		4,364,822				3,366,091				5,211,331				4,415,619		
<b>Operating/Personnel Services</b>																
Quality		5,660,329				7,782,955				10,688,502				9,372,313		
Quality		-				2,931,559				1,373,198				1,603,040		
Total Administrative Expenses		24,605,302				28,529,990				37,225,957				31,395,906		
<b>TOTAL ALL EXPEND</b>	<b>132,240</b>	<b>620,959,526</b>			<b>135,539</b>	<b>681,168,749</b>			<b>132,690</b>	<b>684,651,482</b>			<b>141,354</b>	<b>749,342,679</b>		

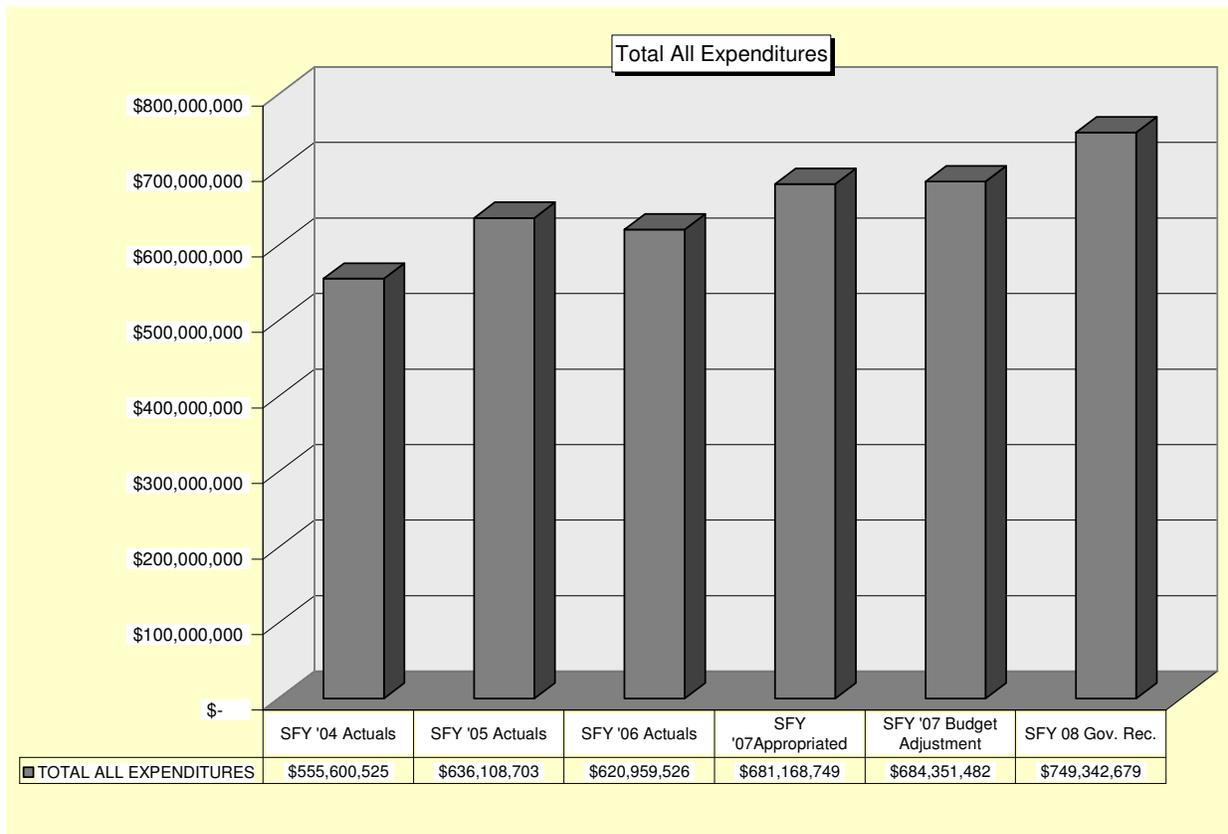
**Table 3: SFY '08 Governor's Recommend Enrollment & Program Expenditures**


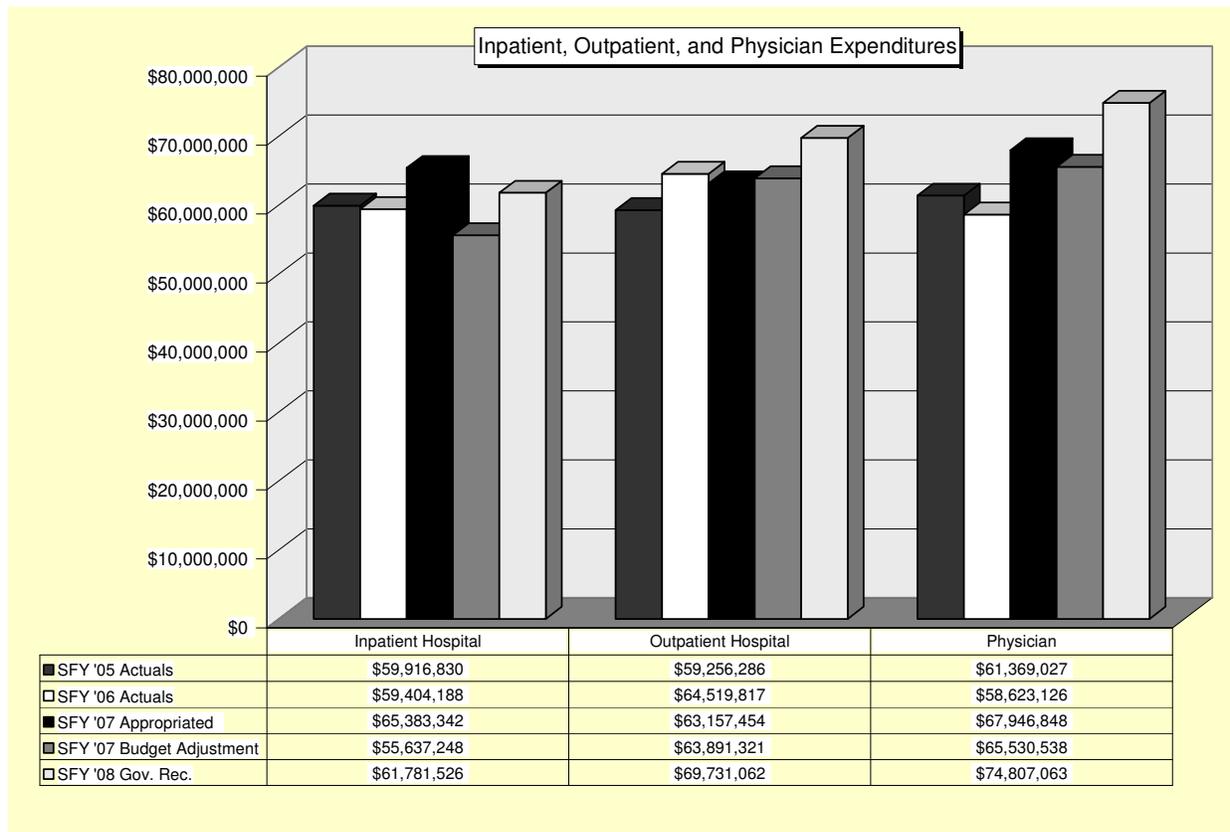
\*Healthy Vermonters excluded from caseload total as no costs are associated with this population

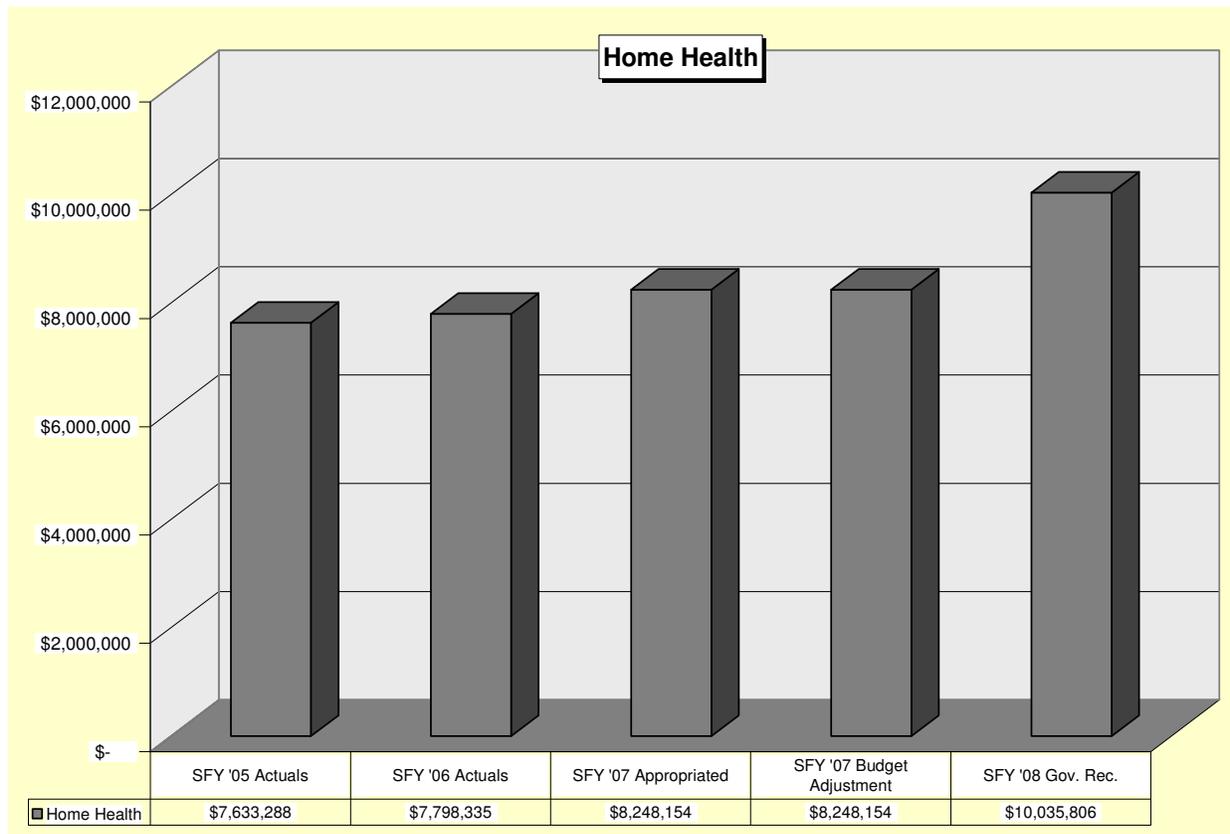


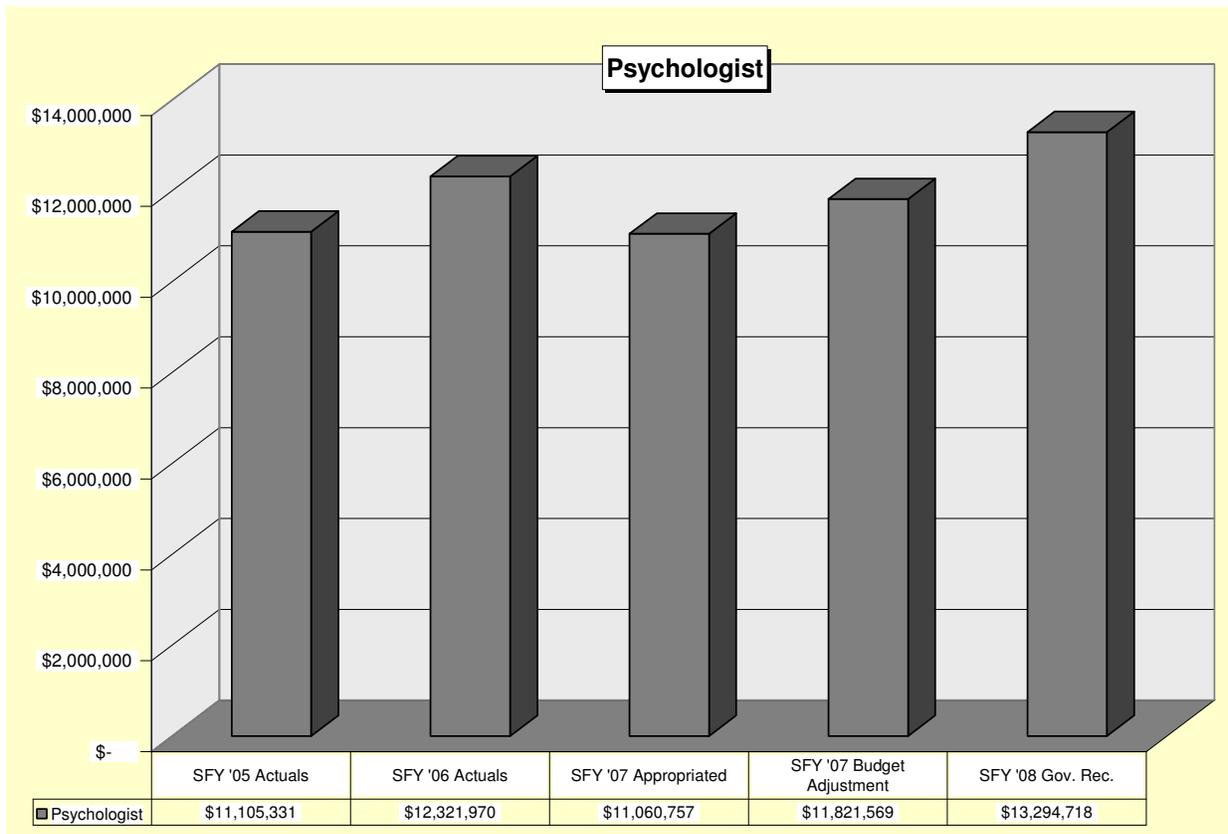
**Table 4: Enrollment History & Detail**

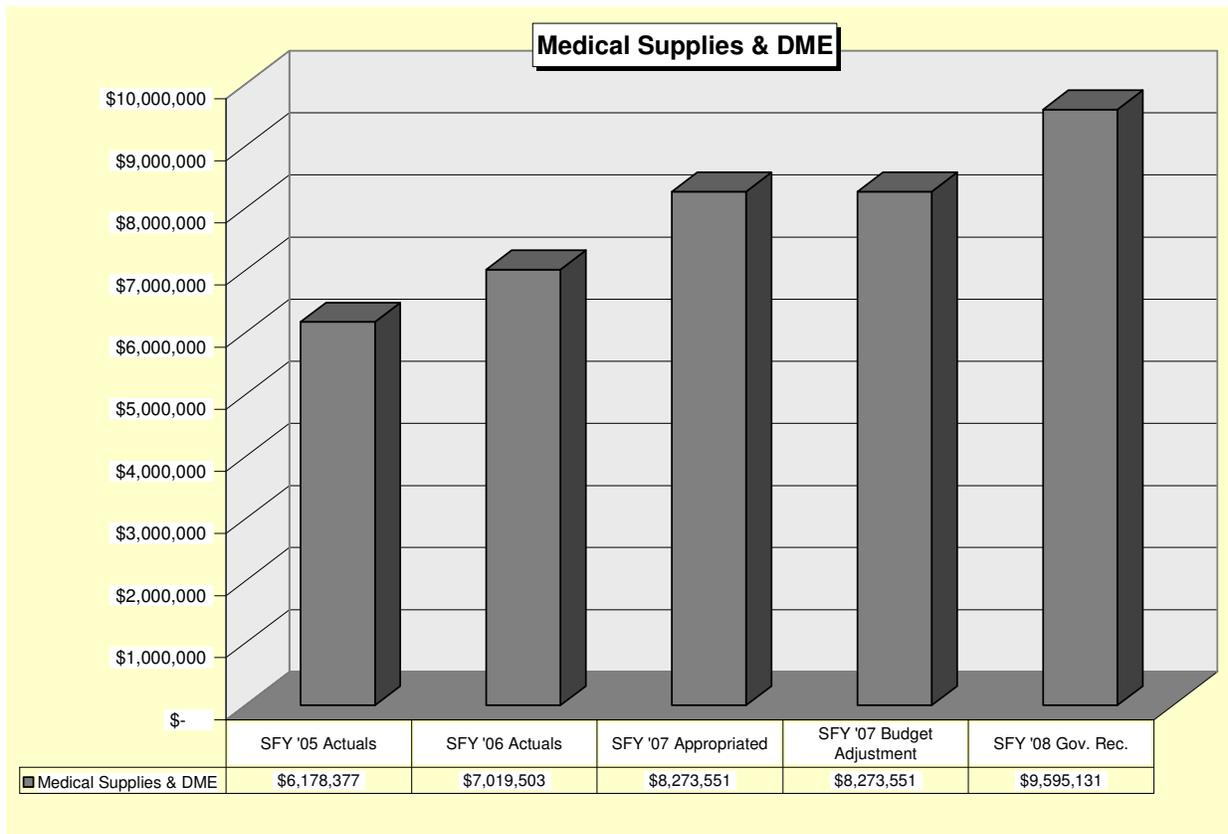
Enrollment Detail										
	SFY 05 Actuals	SFY 06 Actuals	SFY '05 Actual-SFY '06 Actual	SFY '07 Appropriated	SFY '06 Actual-SFY '07 Approp	SFY '07 Budget Adjustment	SFY '06 Actual-SFY '07 Budget Adj.	SFY '08 Governor's Recommendation	SFY '07 Approp-SFY '08 Gov Rec	
<b>Adults</b>										
Aged, Blind, or Disabled (ABD and/or Medically Needy)	14,261	15,481	8.6%	15,491	0.1%	15,417	-0.1%	15,725	1.5%	
Dual Eligibles	8,961	8,881	-0.9%	8,042	-9.4%	8,507	10.4%	8,354	3.9%	
General	7,826	7,601	-2.9%	7,952	4.6%	7,715	-4.4%	7,921	-0.4%	
VHAP	24,456	22,525	-7.9%	23,995	6.5%	23,276	-6.1%	24,789	3.3%	
Long Term Care Waiver and/or Medically Needy	3,429	3,698	7.8%	4,147	12.1%	4,147	-10.8%	4,723	13.9%	
Catamount	-	-	Nil	-	Nil	-	Nil	2,972	Nil	
<b>Subtotal Adults</b>	<b>58,934</b>	<b>58,186</b>	<b>-1.3%</b>	<b>59,627</b>	<b>2.6%</b>	<b>59,061</b>	<b>-2.4%</b>	<b>64,485</b>	<b>8.1%</b>	
<b>Children</b>										
Blind or Disabled and/or Medically Needy Children	3,011	3,167	5.2%	3,377	6.6%	3,277	-6.2%	3,371	-0.2%	
General	54,135	52,845	-2.4%	52,839	0.0%	53,010	0.0%	52,910	0.1%	
Underinsured	1,661	1,284	-22.7%	1,941	51.1%	1,169	-33.8%	1,520	-21.7%	
SCHIP	3,147	3,092	-1.8%	3,395	9.8%	3,131	-8.9%	4,070	19.9%	
<b>Subtotal Children</b>	<b>61,954</b>	<b>60,388</b>	<b>-2.5%</b>	<b>61,552</b>	<b>1.9%</b>	<b>60,586</b>	<b>-1.9%</b>	<b>61,871</b>	<b>0.5%</b>	
<b>Pharmacy Only</b>	<b>13,802</b>	<b>13,459</b>	<b>-2.5%</b>	<b>14,285</b>	<b>6.1%</b>	<b>13,004</b>	<b>-8.8%</b>	<b>14,998</b>	<b>5.0%</b>	
<b>Healthy Vermonters</b> (excluded from caseload total as no cost)	<b>13,255</b>	<b>13,707</b>	<b>3.4%</b>	<b>13,733</b>	<b>0.2%</b>	<b>8,841</b>	<b>-2.2%</b>	<b>8,841</b>	<b>-35.6%</b>	
<b>TOTAL ENROLLMENT</b>	<b>134,690</b>	<b>132,033</b>	<b>-2.0%</b>	<b>135,464</b>	<b>2.6%</b>	<b>132,651</b>	<b>-2.5%</b>	<b>141,354</b>	<b>4.3%</b>	

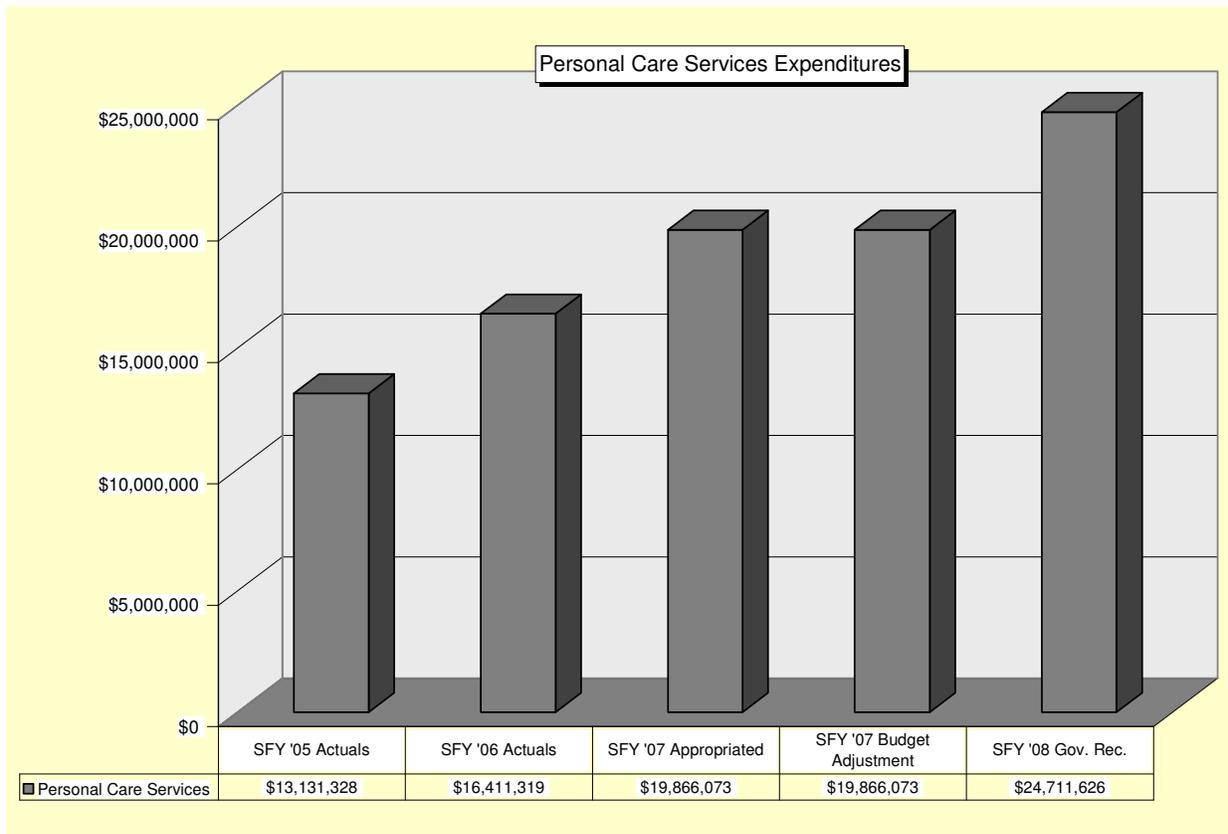
**Table 5: Total All Expenditures**


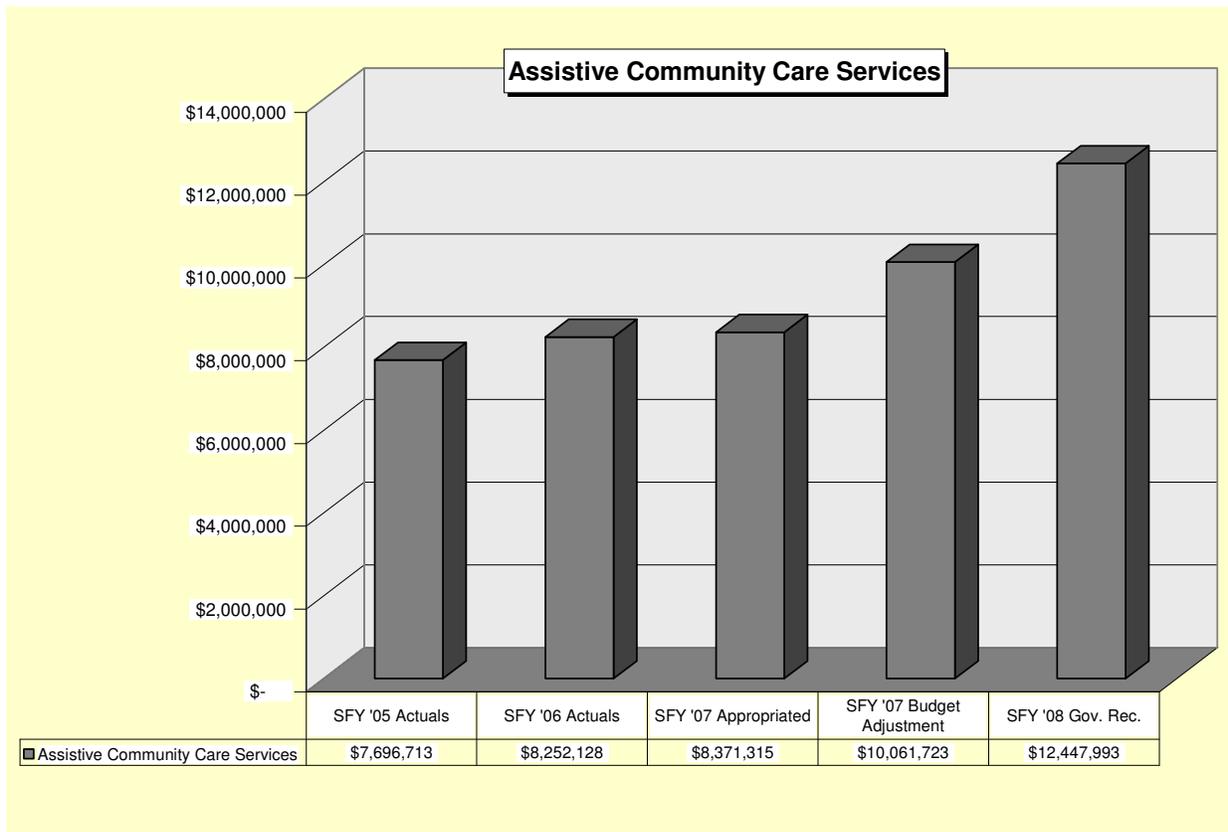
**Table 6: Inpatient Hospital, Outpatient Hospital & Physician Expenditures**


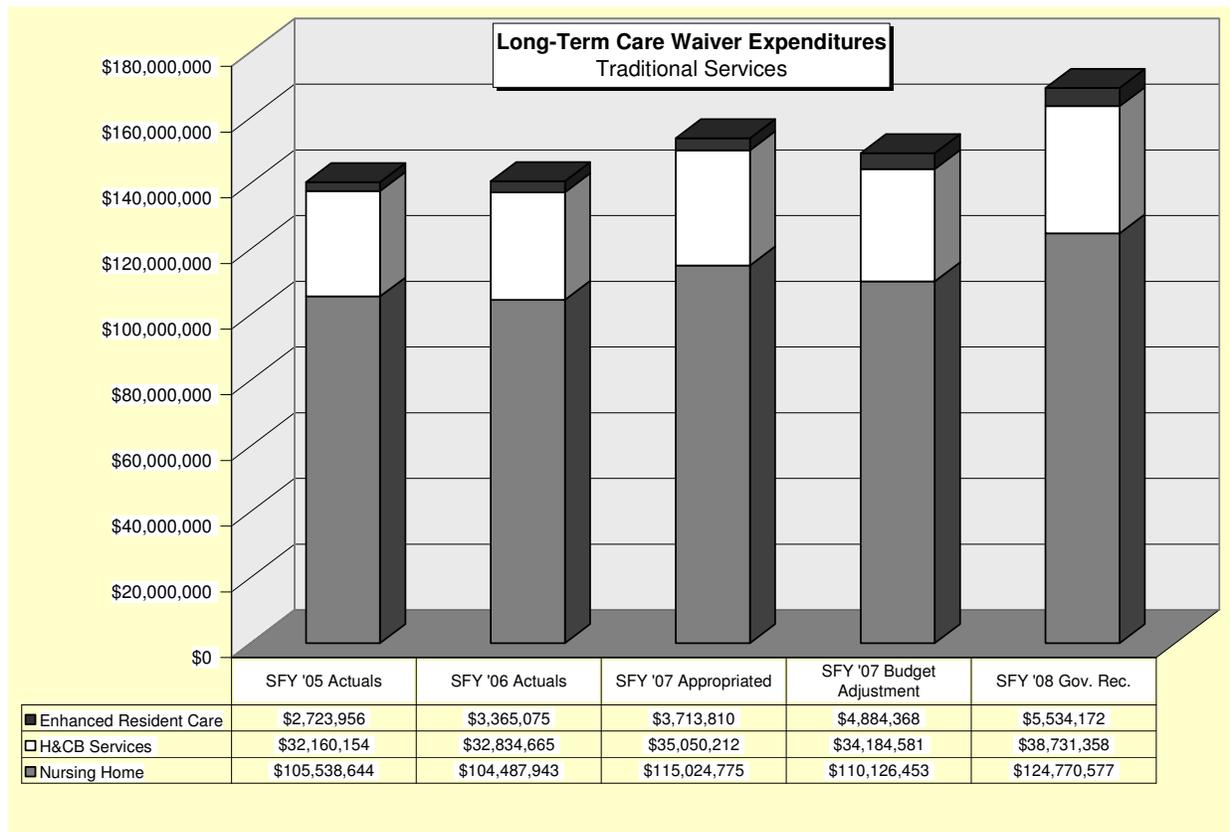
**Table 7: Home Health Expenditures**


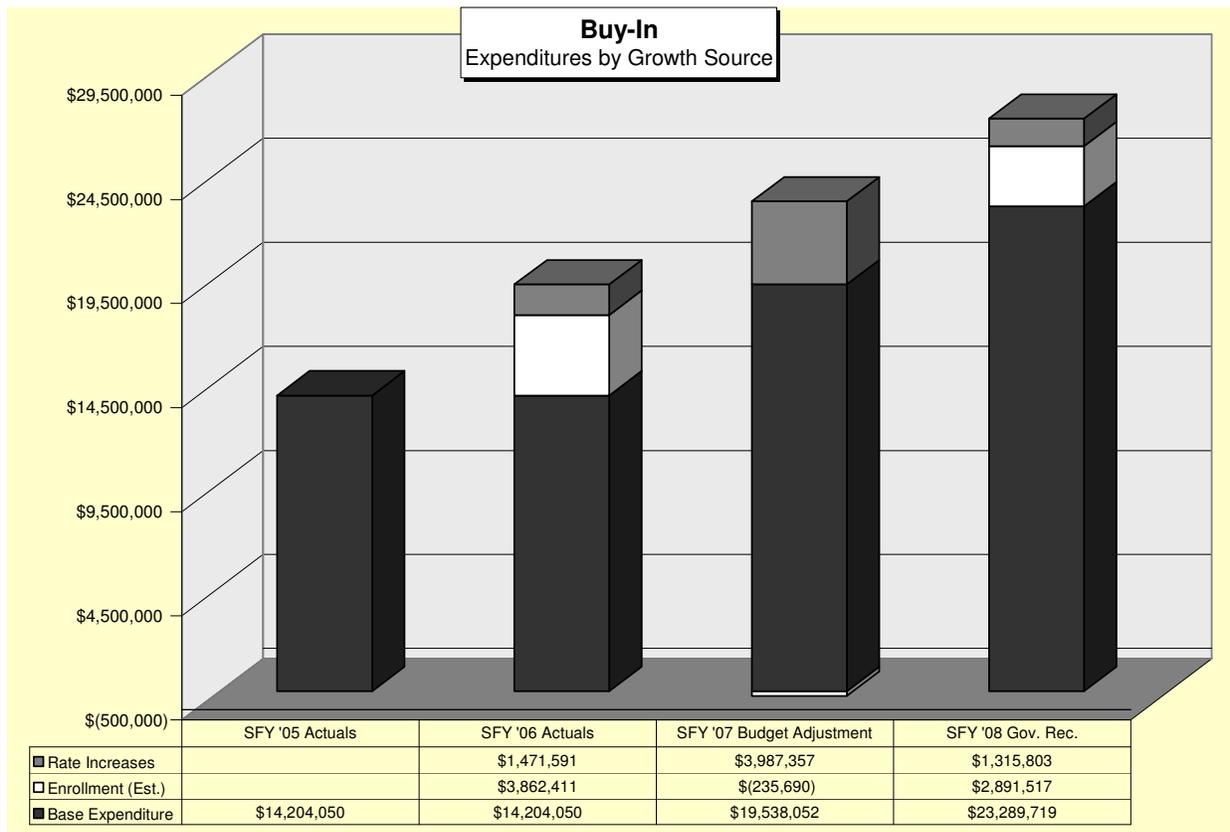
**Table 8: Psychologist Expenditures**


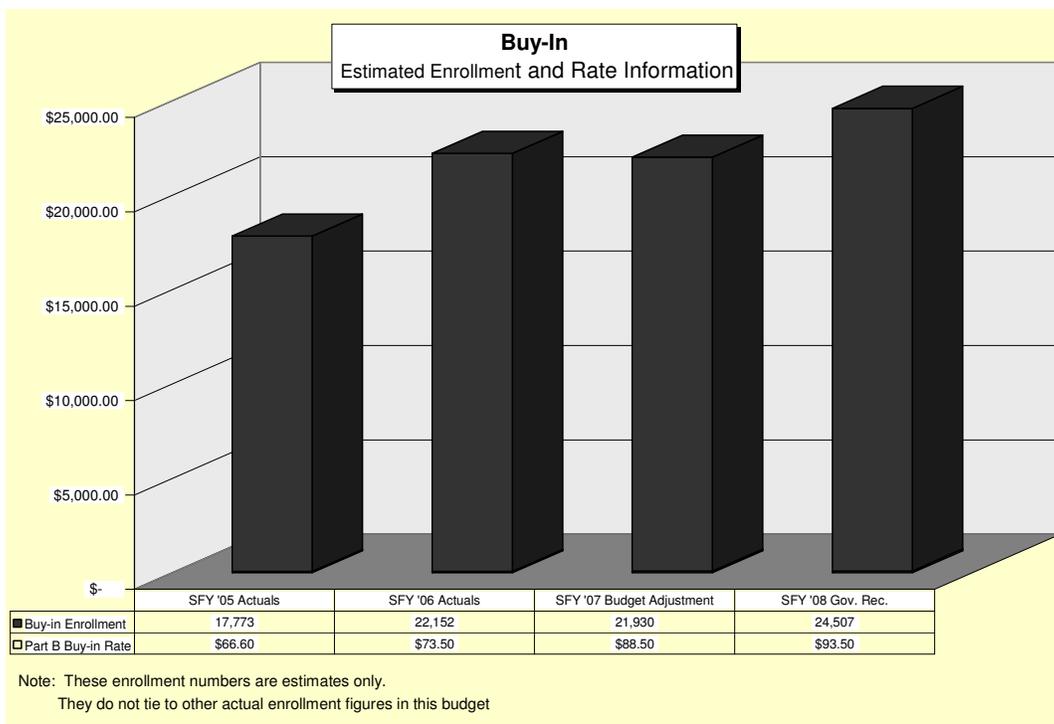
**Table 9: Medical Supplies & DME Expenditures**


**Table 10: Personal Care Services Expenditures**


**Table 11: Assistive Community Care Services Expenditures**


**Table 12: Long Term Care Waiver (Traditional Services) Expenditures**


**Table 13: Buy-In Expenditures By Growth Source**


**Table 14: Buy-In Estimated Enrollment & Rate Information**


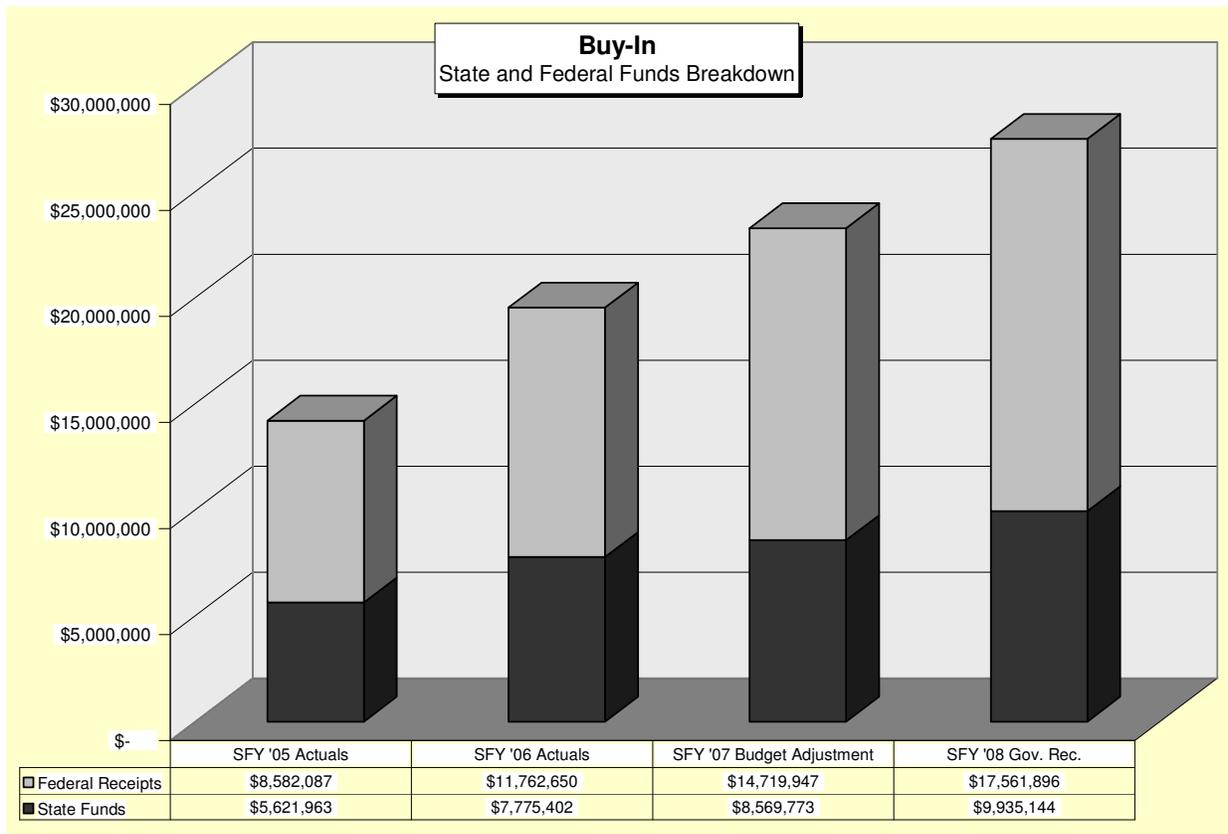
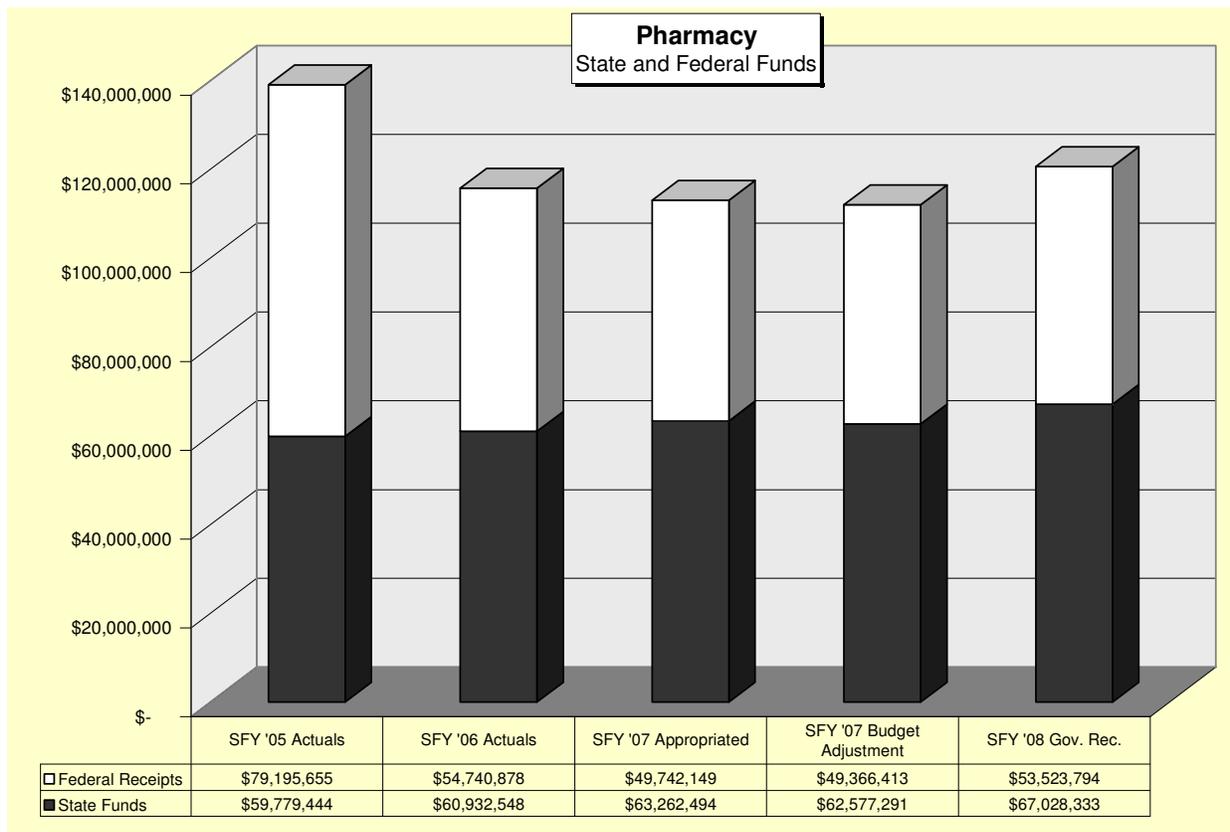
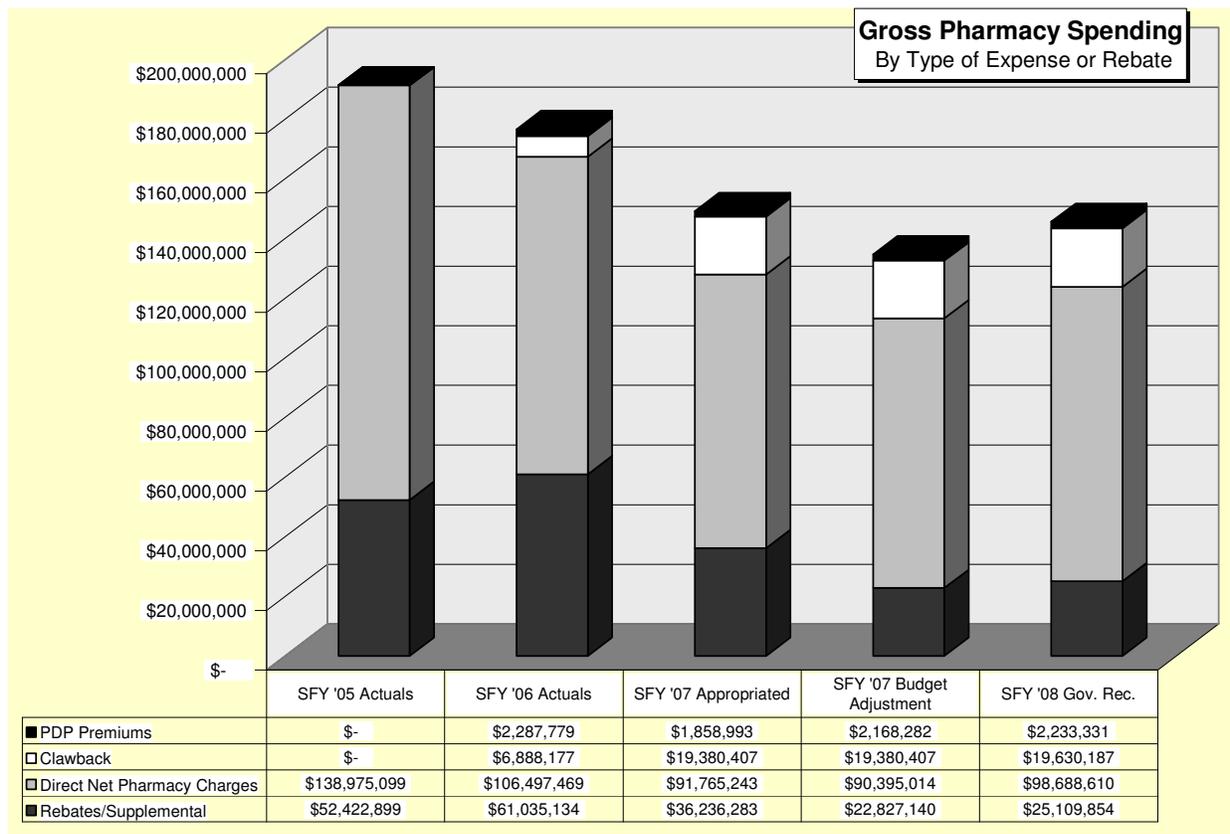
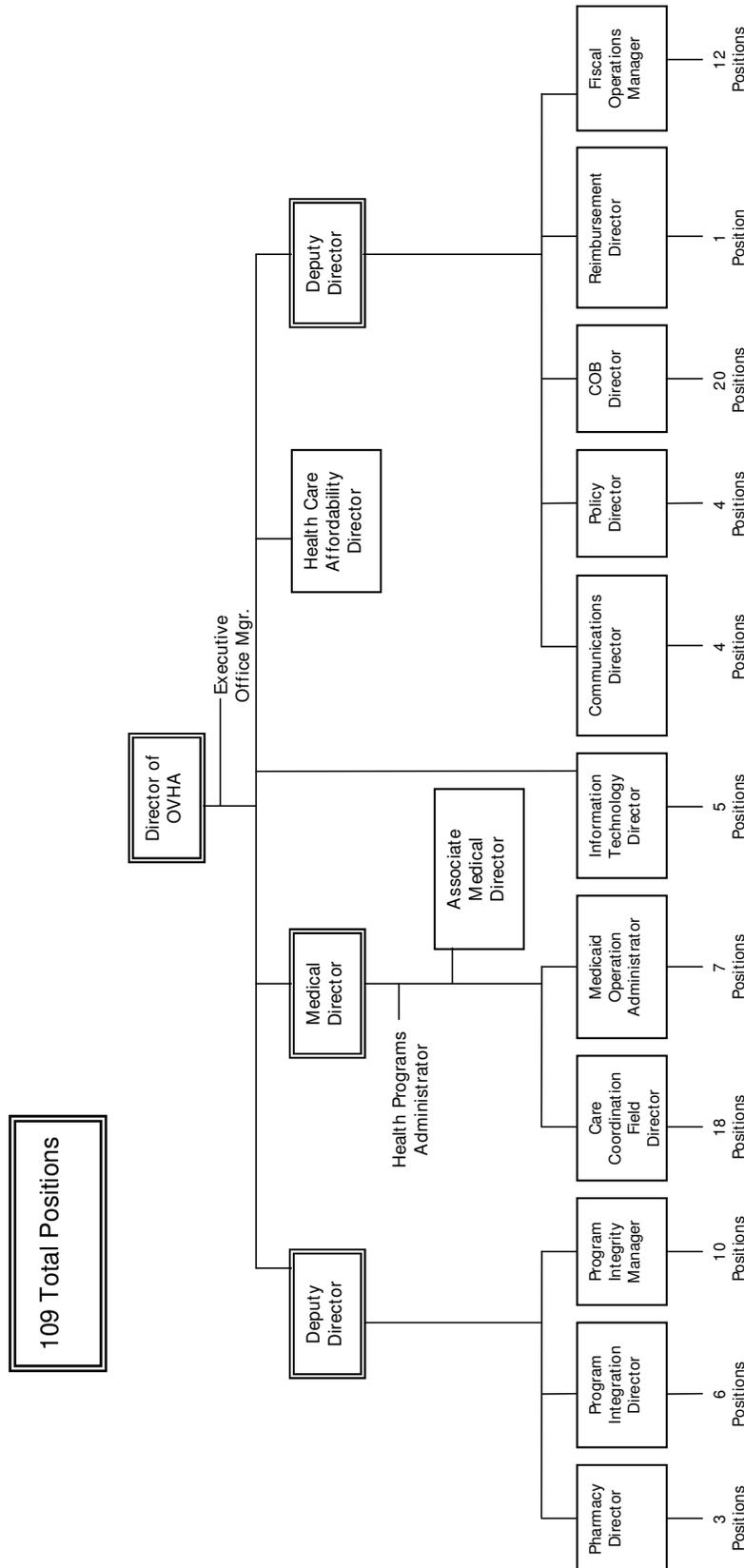
**Table 15: Buy-In State & Federal Funds Breakdown**


Table 16: Pharmacy Detail

	SFY '05 Actuals		SFY '06 Actuals		SFY '07 Appropriated		SFY '07 Budget Adjustment		SFY '08 Gov. Rec.						
	Enrollment	Costs	Enrollment	PMPM	Enrollment	Costs	Enrollment	Costs	Enrollment	Costs					
<b>PHARMACY</b>															
ABD (Adults, Duals, & Children)	29,662	\$ 95,796,688	31,227	\$ 72,863,061	194	\$ 29,257	\$ 54,590,962	\$ 155	31,947	\$ 44,509,631	\$ 118	32,173	\$ 48,103,774	\$ 125	
General (Adults & Children)	61,961	\$ 26,152,702	60,446	\$ 29,862,850	41	\$ 62,591	\$ 31,070,456	\$ 41	60,725	\$ 28,870,348	\$ 40	60,831	\$ 31,673,452	\$ 43	
VHAP (Adults)	24,456	\$ 25,370,616	22,525	\$ 28,513,911	105	\$ 23,995	\$ 28,153,796	\$ 98	23,276	\$ 27,838,291	\$ 100	24,789	\$ 29,603,848	\$ 100	
Underinsured Children	1,661	\$ 386,106	20	\$ 1,284	24	\$ 1,941	\$ 953,163	\$ 15	1,169	\$ 478,185	\$ 34	1,520	\$ 654,902	\$ 36	
SCHIP (Uninsured Children)	3,147	\$ 988,023	26	\$ 3,092	24	\$ 3,395	\$ 896,341	\$ 24	3,131	\$ 1,228,494	\$ 33	4,070	\$ 1,576,853	\$ 32	
<b>Subtotal Pharmacy in Direct Program</b>	<b>120,688</b>	<b>\$ 146,704,136</b>	<b>118,574</b>	<b>\$ 192,506,446</b>	<b>83</b>	<b>\$ 121,179</b>	<b>\$ 115,170,717</b>	<b>\$ 79</b>	<b>119,648</b>	<b>\$ 102,924,949</b>	<b>\$ 72</b>	<b>123,383</b>	<b>\$ 111,612,829</b>	<b>\$ 75</b>	
<b>Global Pharmacy</b>															
Non-Medicare			93	Incl. in t/b, below					42	\$ 150,992	\$ 300		48	\$ 178,426	\$ 310
VHAP Pharmacy prior to 1/1/06	11,187	\$ 34,793,995	8,040	\$ 13,402,363	278	\$ 8,572	\$ 2,080,436	\$ 20	7,621	\$ 367,729	\$ 4	8,764	\$ 435,168	\$ 4	
VPharm1			8,176	\$ 892,092	18										
VPharm2			2,684	\$ 4,653,443	291				2,546	\$ 1,007,569	\$ 33	2,928	\$ 1,192,385	\$ 34	
VPharm3			2,608	\$ 409,723	26				10,209	\$ 1,526,321	\$ 12	11,396	\$ 1,805,979	\$ 13	
<b>Subtotal Global Pharmacy</b>	<b>11,187</b>	<b>\$ 34,793,995</b>	<b>10,847</b>	<b>\$ 19,379,581</b>	<b>149</b>	<b>\$ 8,897</b>	<b>\$ 3,611,302</b>	<b>\$ 34</b>	<b>10,209</b>	<b>\$ 1,526,321</b>	<b>\$ 12</b>	<b>11,396</b>	<b>\$ 1,805,979</b>	<b>\$ 13</b>	
<b>State-Only Pharmacy</b>															
Non-Medicare			70						38	\$ 195,525	\$ 295		44	\$ 160,637	\$ 304
VPharm1			8,176	Incl. in t/b, below					7,621	\$ 4,209,736	\$ 46	8,764	\$ 4,981,770	\$ 47	
VPharm2			2,684	\$ -					2,546	\$ 3,210,798	\$ 105	2,928	\$ 3,799,634	\$ 108	
VScript Expanded prior to 1/1/06	2,615	\$ 7,899,867	2,719	\$ 4,720,556	289				2,794	\$ 1,214,825	\$ 36	3,214	\$ 1,437,615	\$ 37	
VPharm3			2,582	\$ 11,126,020	718				13,000	\$ 8,770,885	\$ 56	14,950	\$ 10,379,656	\$ 58	
<b>Subtotal State-Only Pharmacy</b>	<b>2,615</b>	<b>\$ 7,899,867</b>	<b>13,649</b>	<b>\$ 15,846,576</b>	<b>97</b>	<b>\$ 14,037</b>	<b>\$ 9,219,507</b>	<b>\$ 55</b>	<b>13,000</b>	<b>\$ 8,770,885</b>	<b>\$ 56</b>	<b>14,950</b>	<b>\$ 10,379,656</b>	<b>\$ 58</b>	
<b>PHARMACY BY CATEGORY OF SERVICE</b>	<b>123,503</b>	<b>\$ 191,397,998</b>	<b>132,033</b>	<b>\$ 167,532,603</b>	<b>106</b>	<b>\$ 135,464</b>	<b>\$ 128,001,526</b>	<b>\$ 79</b>	<b>132,651</b>	<b>\$ 113,222,154</b>	<b>\$ 71</b>	<b>138,381</b>	<b>\$ 123,798,464</b>	<b>\$ 75</b>	
Clawback			n/a	\$ 6,888,177	n/a		\$ 19,380,407	n/a	n/a	\$ 19,380,407	n/a	n/a	\$ 19,630,187	n/a	
PDP Premium Payments			n/a	\$ 2,287,779	n/a		\$ 1,858,993	n/a	n/a	\$ 2,168,282	n/a	n/a	\$ 2,233,331	n/a	
Drug Rebates			n/a	\$ (61,035,134)	n/a		\$ (36,236,283)	n/a	n/a	\$ (22,827,140)	n/a	n/a	\$ (25,109,854)	n/a	
<b>PHARMACY EXPENDITURES</b>	<b>134,690</b>	<b>\$ 138,975,099</b>	<b>132,033</b>	<b>\$ 115,673,425</b>	<b>73</b>	<b>\$ 135,464</b>	<b>\$ 113,004,643</b>	<b>\$ 70</b>	<b>132,651</b>	<b>\$ 111,943,704</b>	<b>\$ 70</b>	<b>138,381</b>	<b>\$ 120,592,128</b>	<b>\$ 73</b>	
Federal Receipts	134,690	\$ 79,195,655	132,033	\$ 54,740,878	35	\$ 135,464	\$ 49,742,149	\$ 31	132,651	\$ 49,366,413	\$ 31	138,381	\$ 53,523,794	\$ 32	
State Funds	134,690	\$ 59,779,444	37	\$ 132,033	38	\$ 60,932,548	\$ 63,262,494	\$ 39	132,651	\$ 62,577,291	\$ 39	138,381	\$ 67,028,333	\$ 40	
<b>PHARMACY REVENUES</b>	<b>134,690</b>	<b>\$ 138,975,099</b>	<b>86</b>	<b>\$ 132,033</b>	<b>73</b>	<b>\$ 135,464</b>	<b>\$ 113,004,643</b>	<b>\$ 70</b>	<b>132,651</b>	<b>\$ 111,943,704</b>	<b>\$ 70</b>	<b>138,381</b>	<b>\$ 120,592,128</b>	<b>\$ 73</b>	

**Table 17: Pharmacy State and Federal Funds Breakdown**


**Table 18: Pharmacy By Type of Expenses or Rebate**


**Appendix 1: Organization Chart**


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## Appendix 2: Acronyms

AAA.....Area Agency on Aging	CHPR..... Center for Health Policy and Research
AABD.....Aid to the Aged, Blind & Disabled	CIO ..... Chief Information Office
AAG.....Assistant Attorney General	CM ..... Case Management
ABAWD .....Able-Bodied Adults without Dependents	CMN..... Certification of Medical Necessity
ABD.....Aged, Blind and Disabled	CMS..... Centers for Medicare & Medicaid Services (formerly HCFA)
ACCESS.....The computer software system used by DCF and OVHA to track program eligibility information	CMSO ..... Center for Medicaid & State Operations
ACF .....Administration for Children & Families	COA.....Council on Aging
ADA .....American Dental Association	COB ..... Coordination of Benefits
ADAP.....Alcohol and Drug Abuse Programs	COPS. . . . Computer Operations and Problem Solving
ADO.....St. Albans District Office	COS ..... Categories of Service
AEP .....Annual Enrollment Period	CPH ..... Community Public Health (of the VDH)
AHCPR.....Agency for Health Care Policy & Research	CPT ..... Common Procedural Terminology
AHS .....Agency of Human Services	CRT ..... Community Rehabilitation & Treatment
AIM®. . . . Advanced Information Management system (see MMIS)	CSD.....Computer Services Division
AIRS .....Automated Information and Referral System	CSME ..... Coverage & Services Management Enhancement
ALS .....Advanced Life Support	CSR ..... Customer Service Request
AMA .....American Medical Association	CY ..... Calendar Year
AMAP .....Aids Medication Assistance Program	DAD ..... Department of Aging & Disabilities (see DAIL)
ANFC.....Aid to Needy Families with Children	DAIL.....Department of Disabilities, Aging and Independent Living
AOA.....Agency of Administration	DCF.....Department for Children and Families
APA.....Administrative Procedures Act	DDI.....Design, Development & Implementation
APC.....Ambulatory Payment Classification	DDMHS ..... Department of Developmental & Mental Health Services
APD.....Advance Planning Document	DDS.....Disability Determination Services (part of DCF)
ASD.....Administrative Services Division	DHHS ..... Department of Health & Human Services (United States)
AWP .....Average Wholesale Price	DIS.....Detailed Implementation Schedule
BAFO.....Best & Final Offer	DME.....Durable Medical Equipment
BC/BS.....Blue Cross/Blue Shield	DO.....District Office
BCCT.....Breast and Cervical Cancer Treatment Program	DOA.....Date of Application
BD .....Blind & Disabled	DOB ..... Date of Birth
BDO .....Burlington District Office	DOC..... Department of Corrections
BISHCA .....Banking, Insurance, Securities, & Health Care Administration (Department of)	DOE ..... Department of Education
BPS.....Benefits Programs Specialist	DOH..... Department of Health (see VDH)
BROC .....Bennington-Rutland Opportunity Council	DOS ..... Date of Service
CAHPS .....Consumer Assessment of Health Plans Survey	DR.....Desk Review
CAP.....Community Action Program	DR. D.....Dr. Dinosaur Program
CC .....Committed Child	DRG..... Diagnosis Related Grouping
CCMP .....Chronic Care Management Program	DSH..... Disproportionate Share Hospital
CCP .....Care Coordination Program	DSW ..... Department of Social Welfare (see PATH)
CD .....Compact Disk	DUR..... Drug Utilization Review (Board)
CF.....Crisis Fuel	EA.....Emergency Assistance
CFR .....Code of Federal Regulations	EAC ..... Estimated Acquisition Cost
CHAP .....Catamount Health Assistance Premium	EBT..... Electronic Benefit Transfer

ECS..... Electronic Claims Submission	HIPAA ..... Health Insurance Portability & Accountability Act
EDI..... Electronic Data Interchange	HRA ..... Health Risk Assessment Administration
EDS..... Electronic Data Systems Corporation	HRSA..... Health Resources and Services Administration
EFT ..... Electronic Funds Transfer	HSB..... Human Services Board
EGA..... Estimated Gestational Age	HVP..... Healthy Vermonters Program
EOMB..... Explanation of Medicare (or Medicaid) Benefits	IAPD ..... Implementation Advance Planning Document
EP..... Essential Person	IBNR ..... Incurred But Not Reported
EPSDT. . . . Early & Periodic Screening, Diagnosis & Treatment	IC ..... Individual Consideration
EQR ..... External Quality Review	ICD ..... International Classification of Diseases
ER..... Emergency Room	ICF/MR..... Intermediate Care Facility for the Mentally Retarded
ERA..... Electronic Remittance Advice	ICN ..... Internal Control Number
ERC..... Enhanced Residential Care	ICU ..... Intensive Care Unit
ESD..... Economic Services Division (of the DCF)	ID ..... Identification
ESI..... Employer Sponsored Insurance	IEP..... Individual Education Plan
ESRD ..... End Stage Renal Disease	IEVS..... Income Eligibility Verification System
EST ..... Eastern Standard Time	IGA ..... Intergovernmental Agreements
EVAH..... Enhanced VT Ad Hoc (query & reporting system)	IRS..... Internal Revenue Service
EVS..... Eligibility Verification System	IT ..... Information Technology
FA ..... Fiscal Agent	ITF ..... Integrated Test Facility
FADS..... Fraud Abuse & Detection System	IVS..... Intervention Services
FDA ..... Food & Drug Administration	JCL ..... Job Control Language
FEIN ..... Federal Employer's Identification Number	JDO ..... St. Johnsbury District Office
FFP ..... Federal Financial Participation	LAMP ..... Legal Aid Medicaid Project
FFS ..... Fee for Service	LAN..... Local Area Network
FFY..... Federal Fiscal Year	LC ..... Legislative Council
FH..... Fair Hearing	LDO ..... Brattleboro District Office
FICA..... Federal Insurance Contribution Act	LECC ..... Legally Exempt Child Care
FMAP..... Federal Medical Assistance Percentage	LIHEAP .... Low-Income Home Energy Assistance Program
FPL. . . . . Federal Poverty Level	LIS ..... Low-Income Subsidy
FUL ..... Federal Upper Limit (for pricing & payment of drug claims)	LTC..... Long-Term Care
GA..... General Assistance	LUPA ..... Low Utilization Payment Adjustment
GAO ..... General Accounting Office	MA..... Medicare Advantage – Medicare Part C in VT
GCR ..... Global Clinical Record (application of the MMIS)	MAB..... Medicaid Advisory Board
HAEU ..... Health Access Eligibility Unit	MAC..... Maximum Acquisition Cost
HATF..... Health Access Trust Fund	MAC..... Maximum Allowable Cost (refers to drug pricing)
HCBS ..... Home and Community Based Services	MARS. . . . Management & Administrative Reporting
HCFA..... Health Care Finance Administration (now CMS)	MAT ..... Medication Assisted Therapy
HCPCS ..... HCFA Common Procedure Coding System	MCO ..... Managed Care Organization
HDO..... Hartford District Office	MCP ..... Managed Care Plan
HHA..... Home Health Agency	MDB..... Medicare Database
HHS..... Health and Human Services (U.S. Department of)	MDO..... Barre District Office
HIFA..... Health Insurance Flexibility and Accountability	MEQC ..... Medicaid Eligibility Quality Control
	MFRAU ..... Medicaid Fraud & Residential Abuse Unit
	MID ..... Beneficiary Medicaid Identification Number

MIS.....Management Information System	PP&D.....Policy, Procedures and Development (Interpretive Rule Memo)
MITA.....Medicaid Information Technology Architecture	PPR.....Planning, Policy and Regulation
MMA.....Medicare Modernization Act	PRO.....Peer Review Organization
MMIS.....Medicaid Management Information System	PRWORA .. Personal Responsibility & Work Opportunity Reconciliation Act
MNF.....Medical Necessary Form	PSE.....Post-Secondary Education
MOE.....Maintenance of Effort	QC.....Quality Control
MSIS.....Medicaid Statistical Information	QI.....Qualified Individual
MSP.....Medicare Savings Programs	QIAC.....Quality Improvement Advisory Committee
MVP.....Mohawk Valley Physicians”	QMB.....Qualified Medicare Beneficiary
NCBD.....National CAHPS Benchmarking Database	QWDI.....Qualified Working Disabled Individual
NDC.....National Drug Code	RA.....Remittance Advice
NDO.....Newport District Office	RBC.....Risk Based Capital
NEKCA.....Northeast Kingdom Community Action	RBUC.....Reported But Unpaid Claims
NGA.....National Governors Association	RDO.....Rutland District Office
NPA.....Non-Public Assistance	REVS.....Recipient Eligibility Verification System
NPF.....National Provider File	RFI.....Requests for Information
NPI.....National Provider Identifier	RFP.....Requests for Proposals
OADAP.....Office of Alcohol & Drug Abuse Programs	RN.....Registered Nurse
OASDI.....Old Age, Survivors, Disability Insurance	RO.....Regional Office
OCS.....Office of Child Support	RR.....Railroad Retirement
OEO.....Office of Economic Opportunity	RU.....Reach Up program
OPS.....Operations	RVU.....Relative Value Units
OTC.....Over the Counter	SAMHSA... Substance Abuse and Mental Health Services Administration
OVHA.....Office of Vermont Health Access	SAS.....Statement on Auditing Standards
PA.....Prior Authorization or Public Assistance	SCHIP. . . .State Children’s Health Insurance Program
PACE.....Program for All-Inclusive Care for the Elderly	SDO.....Springfield District Office
PATH.....Department of Prevention, Assistance, Transition, & Health Access (now DCF)	SDX.....State Data Exchange System
PBA/PBM...Pharmacy Benefits Administrator/Pharmacy Benefits Manager	SE.....Systems Engineer
PC Plus.....VT Primary Care Plus	SEP.....Special Enrollment Periods
PC.....Personal Computer	SF.....Supplemental Fuel
PCCM.....Primary Care Case Management	SFY.....State Fiscal Year
PCP.....Primary Care Provider	SLMB.....Specified Low-Income Medicare Beneficiary
PDF.....Portable Document File	SMM.....State Medicaid Manual
PDL.....Preferred Drug List	SNF.....Skilled Nursing Facility
PDP.....Pharmacy Drug Plan	SPA.....State Plan Amendment
PDSA.....Plan Do Study Act	SPAP.....State Pharmacy Assistance Program
PEP.....Proposal Evaluation Plan or Principal Earner Parent	SRS.....Social & Rehabilitative Services (Department of)
PERM.....Payment Error Rate Measurement	SSA.....Social Security Administration
PES.....Provider Electronic Solutions	SSI.....Supplemental Security Income
PI.....Program Integrity	SSN.....Social Security Number
PIL.....Protected Income Level	SUR.....Surveillance & Utilization Review
PIRL.....Plan Information Request Letter	TAD.....Turnaround Documents
PMPM.....Per Member Per Month	TANF.....Temporary Assistance for Needy Families (Reach Up in VT)
PNMI.....Private Non-Medical Institution	TBI.....Traumatic Brain Injury
POS.....Point of Sale or Point of Service	TDO.....Bennington District Office
	TM.....Transitional Medicaid
	TPA.....Third Party Administrator

TPL..... Third Party Liability  
UC..... Unemployment Compensation  
UCR ..... Usual & Customary Rate  
UI..... Unemployment Insurance  
UIB..... Unemployment Insurance Benefits  
UM ..... Utilization Management  
UR ..... Utilization Review  
UVM ..... University of Vermont  
VA ..... Veterans Administration  
VAB..... VT Association for the Blind  
VDH..... VT Department of Health  
VDO..... Morrisville District Office  
VHAP. . . .VT Health Access Plan  
VHAP-Rx. . VT Health Access Plan Pharmacy Program  
VHAT.....VT Health Access Team  
VIP ..... VT Independence Project

VT ..... State of Vermont  
VTD.....VT Part D as Primary  
VTM..... VT Medicaid as Primary  
VUL ..... VT Upper Limit  
WAM ..... Welfare Assistance Manual  
WTW..... Welfare to Work  
YDO..... Middlebury District Office  
ZDO..... State Office/Central Office  
(Waterbury)

VISION ..... VT's Integrated Solution for  
Information and Organizational Needs  
– the statewide accounting system  
VIT.....VT Interactive Television  
VITL ..... VT Information Technology Leaders  
VLA.....VT Legal Aid  
VMS..... VT Medical Society  
VPHARM ... VT Pharmacy Program  
VPQHC .... VT Program for Quality in Health Care  
VPTA ..... Vermont Public Transportation Agency  
VR..... Vocational Rehabilitation  
VRS ..... Voice Response System  
VSA.....VT Statutes Annotated  
VScript.....VT Pharmacy Assistance Program  
VSDS ..... VT State Dental Society  
VSEA.....VT State Employees Association  
VSECU.....VT State Employees Credit Union  
VSH.....VT State Hospital  
VSHA.....VT State Housing Authority

### Appendix 3: Federal Poverty Level (FPL) Guidelines Monthly Household Income January 1, 2007 – December 31, 2007

FPL	Household Size							
	1	2	3	4	5	6	7	8
50%	\$426	\$571	\$716	\$861	\$1,006	\$1,151	\$1,296	\$1,441
75%	\$639	\$856	\$1,074	\$1,291	\$1,509	\$1,726	\$1,944	\$2,161
100%	\$851	\$1,141	\$1,431	\$1,721	\$2,011	\$2,301	\$2,591	\$2,881
120%	\$1,021	\$1,369	\$1,717	\$2,065	\$2,413	\$2,761	\$3,109	\$3,457
125%	\$1,064	\$1,427	\$1,789	\$2,152	\$2,514	\$2,877	\$3,239	\$3,602
133%	\$1,132	\$1,518	\$1,904	\$2,289	\$2,675	\$3,061	\$3,446	\$3,832
135%	\$1,149	\$1,541	\$1,932	\$2,324	\$2,715	\$3,107	\$3,498	\$3,890
150%	\$1,277	\$1,712	\$2,147	\$2,582	\$3,017	\$3,452	\$3,887	\$4,322
175%	\$1,489	\$1,997	\$2,504	\$3,012	\$3,519	\$4,027	\$4,534	\$5,042
185%	\$1,575	\$2,111	\$2,648	\$3,184	\$3,721	\$4,257	\$4,794	\$5,330
200%	\$1,702	\$2,282	\$2,862	\$3,442	\$4,022	\$4,602	\$5,182	\$5,762
225%	\$1,915	\$2,567	\$3,220	\$3,872	\$4,525	\$5,177	\$5,830	\$6,482
250%	\$2,128	\$2,853	\$3,578	\$4,303	\$5,028	\$5,753	\$6,478	\$7,203
300%	\$2,553	\$3,423	\$4,293	\$5,163	\$6,033	\$6,903	\$7,773	\$8,643
400%	\$3,404	\$4,564	\$5,724	\$6,884	\$8,044	\$9,204	\$10,364	\$11,524

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## Appendix 4: Federal Match Rates

### FEDERAL MATCH RATES FFIS as of 01-03-2007

#### Title XIX / Medicaid (program) & Title IV-E / Foster Care (program):

Federal Fiscal Year					State Fiscal Year				
FFY	From	To	Federal Share	State Share	SFY	From	To	Federal Share	State Share
1995	10/01/94	09/30/95	60.82%	39.18%	1995	7/1/1994	6/30/1995	60.50%	39.50%
1996	10/01/95	09/30/96	60.87%	39.13%	1996	7/1/1995	6/30/1996	60.86%	39.14%
1997	10/01/96	09/30/97	61.05%	38.95%	1997	7/1/1996	6/30/1997	61.01%	38.99%
1998	10/01/97	09/30/98	62.18%	37.82%	1998	7/1/1997	6/30/1998	61.90%	38.10%
1999	10/01/98	09/30/99	61.97%	38.03%	1999	7/1/1998	6/30/1999	62.02%	37.98%
2000	10/01/99	09/30/00	62.24%	37.76%	2000	7/1/1999	6/30/2000	62.17%	37.83%
2001	10/01/00	09/30/01	62.40%	37.60%	2001	7/1/2000	6/30/2001	62.36%	37.64%
2002	10/01/01	09/30/02	63.06%	36.94%	2002	7/1/2001	6/30/2002	62.90%	37.10%
2003	10/01/02	09/30/03	62.41%	37.59%	2003	7/1/2002	6/30/2003	62.57%	37.43%
fiscal relief	<b>04/01/03</b>	<b>09/30/03</b>	<b>66.01%</b>	<b>33.99%</b>	fiscal relief - Title XIX only: 63.47% 36.53%				
Per TRRA...applies only to Title XIX (excluding DSH pymts)					no adj for DSH				
2004	10/01/03	09/30/04	61.34%	38.66%	2004	7/1/2003	6/30/2004	61.61%	38.39%
fiscal relief	<b>10/01/03</b>	<b>06/30/04</b>	<b>65.36%</b>	<b>34.64%</b>	fiscal relief - Title XIX only: 65.52% 34.48%				
Per TRRA...applies only to Title XIX (excluding DSH pymts)					no adj for DSH				
2005	10/01/04	09/30/05	60.11%	39.89%	2005	7/1/2004	6/30/2005	60.42%	39.58%
2006	10/01/05	09/30/06	58.49%	41.51%	2006	7/1/2005	6/30/2006	58.90%	41.10%
2007	10/01/06	09/30/07	58.93%	41.07%	2007	7/1/2006	6/30/2007	58.82%	41.18%
2008	10/01/07	09/30/08	59.03%	40.97%	2008	7/1/2007	6/30/2008	59.01%	40.99%
2009*	10/01/08	09/30/09	60.03%	39.97%	2009	7/1/2008	6/30/2009	59.78%	40.22%
<i>2009 Is the latest estimate dated 01/03/2007</i>					<i>2009 Is the latest estimate dated 01/03/2007</i>				

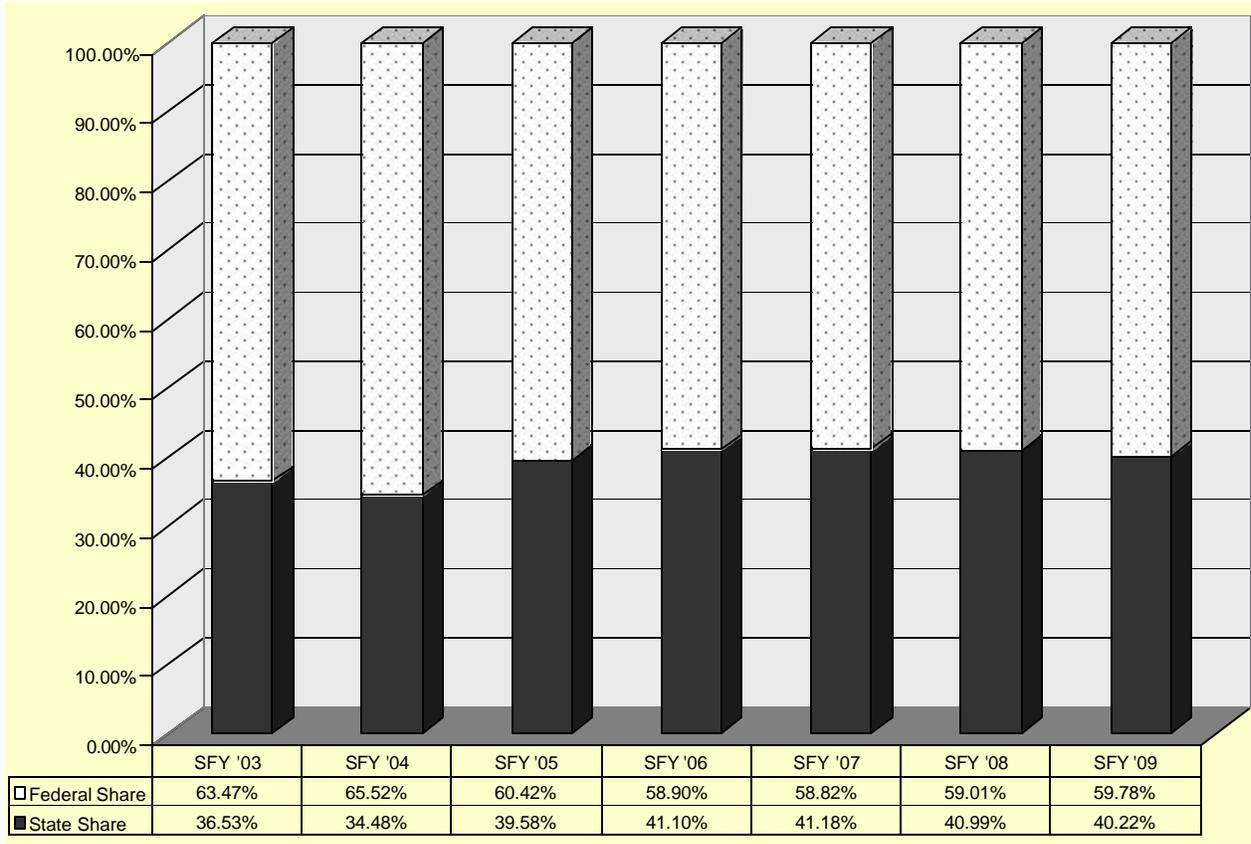
#### Title IV-D / OCSE Admin:

FFY	From	To	Regular	Enhanced	FFY	From	To	Regular	Enhanced
1975-81	7/1/1975	9/30/1981	75.00%	N/A	1996	10/1/1995	9/30/1996	66.00%	90.00%
1982	10/1/1981	9/30/1982	75.00%	90.00%	1997	10/1/1996	9/30/1997	66.00%	90.00%
1983-85	10/1/1982	9/30/1985	70.00%	90.00%	1998	10/1/1997	9/30/1998	66.00%	90.00%
1986	10/1/1985	9/30/1986	66.65%	85.69%	1999	10/1/1998	9/30/1999	66.00%	80.00%
1987	10/1/1986	9/30/1987	70.00%	90.00%	2000	10/1/1999	9/30/2000	66.00%	80.00%
1988-89	10/1/1987	9/30/1989	68.00%	90.00%	2001	10/1/2000	9/30/2001	66.00%	80.00%
1990	10/1/1989	9/30/1990	64.85%	88.43%	2002	10/1/2001	9/30/2002	66.00%	80.00%
1991	10/1/1990	9/30/1991	66.00%	90.00%	2003	10/1/2002	9/30/2003	66.00%	80.00%
1992	10/1/1991	9/30/1992	66.00%	90.00%	2004	10/1/2003	9/30/2004	66.00%	N/A
1993	10/1/1992	9/30/1993	66.00%	90.00%	2005	10/1/2004	9/30/2005	66.00%	N/A
1994	10/1/1993	9/30/1994	66.00%	90.00%	2006	10/1/2005	9/30/2006	66.00%	N/A
1995	10/1/1994	9/30/1995	66.00%	90.00%	2007	10/1/2006	9/30/2007	66.00%	
					Note: IV-D Expenses for Paternity Testing are reimbursed @ 90% ffp				

#### Title XXI / SCHIP (program & admin):

Federal Fiscal Year					State Fiscal Year				
FFY	From	To	Federal Share	State Share	SFY	From	To	Federal Share	State Share
1999	10/01/98	09/30/99	73.38%	26.62%	1999	07/01/98	06/30/99	73.38%	26.62%
2000	10/01/99	09/30/00	73.57%	26.43%	2000	07/01/99	06/30/00	73.52%	26.48%
2001	10/01/00	09/30/01	73.68%	26.32%	2001	07/01/00	06/30/01	73.65%	26.35%
2002	10/01/01	09/30/02	74.14%	25.86%	2002	07/01/01	06/30/02	74.03%	25.97%
2003	10/01/02	09/30/03	73.69%	26.31%	2003	07/01/02	06/30/03	73.80%	26.20%
2004	10/01/03	09/30/04	72.94%	27.06%	2004	07/01/03	06/30/04	73.13%	26.87%
2005	10/01/04	09/30/05	72.08%	27.92%	2005	07/01/04	06/30/05	72.30%	27.71%
2006	10/01/05	09/30/06	70.94%	29.06%	2006	07/01/05	06/30/06	71.23%	28.78%
2007	10/01/06	09/30/07	71.25%	28.75%	2007	07/01/06	06/30/07	71.17%	28.83%
2008	10/01/07	09/30/08	71.32%	28.68%	2008	07/01/07	06/30/08	71.30%	28.70%
2009*	10/01/08	09/30/09	72.02%	27.98%	2009	07/01/08	06/30/09	71.85%	28.16%
<i>2009 Is the latest estimate dated 01/03/2007</i>					<i>2009 Is the latest estimate dated 01/03/2007</i>				

### Appendix 4: Federal Match Rates (Vermont Specific)



## Memorandum

**To:** Health Access Oversight Committee  
**From:** Joshua Slen  
**Date:** August 22, 2006  
**Re:** Supplemental Payments for Dentists

---

The Legislature approved a Supplemental Dental Payment Program for implementation by October 1, 2006. The following is the pertinent legislation:

Act 215, Sec. 108 DENTAL SERVICES

(b) The office of Vermont health access shall use \$242,836 of the appropriation in Sec. 107 of this act for supplemental payments to dentists with high Medicaid patient counts. The office shall design and implement the program by October 1, 2006. These funds are in addition to the funds in subsection (a) of this section. The office shall report to the health access oversight committee in September on the parameters of the program.

As indicated by the legislation, prior to implementation, the Supplemental Dental Payment Program requires review by the HAOC. The following describes the process which resulted in a methodology that has been agreed to by the OVHA and the Vermont State Dental Society (VSDS).

### Process

For quite a few years, it has been the OVHA's standard practice to consult with both the VSDS and the Vermont Department of Health Dental Health Director prior to making any changes in dental payments. That practice continued in designing the Supplemental Dental Payment Program methodology.

Initially, the OVHA's representative met with a subcommittee of the VSDS Government Committee and VDH representatives. During the meeting, data (the data did not identify any practice by name or number) was examined and technical issues were discussed. During that meeting, the decision was made to convene the entire Government Committee to reach agreement on the methodology for structuring payments.

On August 8, 2006, a follow-up meeting occurred between the OVHA's representative, the entire VSDS Government Committee and VDH representatives. The Government Committee made its methodology recommendation to the OVHA and the OVHA agreed with that recommendation.

An overview of the methodology is described below.

## Methodology

The OVHA and the VSIDS agreed that beginning October 1, 2006 the OVHA will make two payments of \$121,418 each fiscal year, at 6-month intervals.

The funds will be distributed based on the amount paid (by both Vermont Medicaid and General Assistance) to dental practices as a percent of the practice's total for certain dates of service. For the October 1, 2006 payment, the OVHA will use paid claims (includes all dental procedure codes except Orthodontia codes) with dates of service from January 1, 2006 to June 30, 2006. For each subsequent payment, the next six-month period will be used. Dental practices receiving cost-based reimbursement are excluded because they are paid cost to deliver care and cost-based reimbursement is considerably higher than fee-for-service dentists even after the supplemental payments are made.

To conform to the legislature requirement that the supplemental payments go to "dentists with high Medicaid patient counts", the methodology facilitates the distribution of payments among dental practices that have been paid greater than \$50,000 for services to Medicaid beneficiaries during the six-month period. For example, a practice that received 10% of the claims paid to the "high count" group would receive 10% of the semi-annual amount. Current estimates indicate that about 30 practices will receive supplemental payments ranging in amount from \$1,700 to \$9,400 for the period which is the equivalent of an estimated 3% rate increase for each practice.

The dentists stressed the importance of a payment level that would be meaningful to the "high count" providers, but not so big that falling just below the cutoff would cause a significant loss of revenue. Both the OVHA and the VSIDS agree that using payments of \$50,000 or more best meets those objectives.

cc: Peter Taylor, VSIDS  
Chuck Saleen DDS, VSIDS  
Steve Arthur DDS, VDH  
James Lasaponara DDS, VDH  
File

## Memorandum

**To:** Health Access Oversight Committee  
**From:** Joshua Slen  
**Date:** November 9, 2006  
**Re:** Provider Rate Increases - Corrected

---

The Legislature approved a Medicaid Reimbursement Increase Program for implementation by January 1, 2007.

### Act 191

The following is the pertinent legislation from Act 191 (H.861):

#### Sec. 9. MEDICAID REIMBURSEMENT

(a)(1) The office of Vermont health access shall adjust Medicaid and the Vermont health access plan reimbursement to reflect the following priorities in the following order:

(A) an increase in base rates for evaluation and management procedure codes to enhance payment to a level equivalent to the 2006 rates in the Medicare program;

(B) incentives and payment restructuring for health care professionals participating in the care coordination program;

(C) an increase in base rates for current procedural terminology (CPT) codes which are significantly lower than the 2006 Medicare reimbursement levels starting with the lowest first; and

(D) an increase in dental reimbursement by, first, restoring the reductions in adult dental rates which were effective February 1, 2006 and, second, by splitting the remaining amount approximately in half to increase rates for dental services and to increase the dental cap for adults in such a manner as to offset any loss in benefit level due to the rate increases.

(2) The Medicaid reimbursement rate increases in subdivision (1) of this subsection shall be effective on January 1, 2007 for fiscal year 2007 and July 1 for fiscal years 2008 through 2010.

(b) To the extent permitted by the appropriation in Sec. 107 of H.881 of the 2005 Adj. Sess. (2006), the office of Vermont health access shall increase Medicaid reimbursements to hospitals effective January 1, 2007. In fiscal year 2008 and thereafter, the office shall increase Medicaid reimbursement rates as provided for in this subsection annually on July 1 until the federal upper limit is reached.

(c) In fiscal years subsequent to 2007, it is the intent of the general assembly that Medicaid reimbursement increases to health care professionals and hospitals under Medicaid, the Vermont health access plan, and Dr. Dynasaur should be tied to the standards and quality or performance measures developed under the Vermont blueprint for health strategic plan established in section 702 of Title 18. Prior to implementation, these standards shall be approved by the general assembly through the appropriations process.

(d) No later than October 31, 2006, the office shall report to the health access oversight committee with a plan for allocation of the appropriated amounts for fiscal year 2007 among the priorities established in subsection (a) of this section and among hospital reimbursements as provided for in subsection (b) of this section. Prior to the implementation of the reimbursement adjustments in this section, the health access oversight committee shall review and determine if the allocation among the priorities is equitable and reflects legislative intent.

**Act 215**

The following is the pertinent legislation from Act 215 (H.881):

Sec. 107. Office of Vermont health access - Medicaid program - Global Commitment

Grants	389,504,923
Source of funds	
Global Commitment fund	389,504,923

(b) In the event that H.861 of 2006 is not enacted into law, the above appropriation is reduced by \$3,428,363, and the department shall not change reimbursement rates for providers as specified in H.861, and the specified intent of Sec. 108(a) of this act is no longer required.

Sec. 108. DENTAL SERVICES

(a) It is the intent of the general assembly that effective January 1, 2007 an annualized increase of \$300,000 is made for adult dental services which shall be used to, first, restore the reductions in adult dental rates which were effective February 1, 2006 and, second, to split the remaining amount approximately in half to increase rates for dental services and to increase the dental cap for adults in such a manner as to offset any loss in benefit level due to the rate increases.

**Allocation Plan**

As cited in the legislation, rate increases were authorized for hospitals, Current Procedural Terminology (CPT) codes and dental services for implementation by January 1, 2007.

*Appropriation*

The OVHA reviewed the amounts cited in the legislation. The table below depicts the allocation based on the legislation appropriation of \$3,428,363 to fund four expenditures for six months:

	<b>6 months</b>	<b>Annual</b>
Hospitals	\$1,000,000	\$2,000,000
Dentists	\$150,000	\$300,000
Care Coordination	\$100,000	\$200,000
CPT Codes	\$2,178,363	\$4,356,726
<b>Appropriated</b>	<b>\$3,428,363</b>	

The OVHA used a full year of utilization data to forecast the cost impact of the increase, so cost impact estimates have been based on annualized amounts. The State Fiscal Year (SFY) 2008 budget will reflect the annualized amount.

### *CPT Codes*

The legislation directed the OVHA to increase the Evaluation and Management (E&M) codes to 2006 Medicare levels and use the remainder to increase other CPT codes. The OVHA refined the initial cost estimate to increase the E&M codes and concluded that the appropriation is not substantial enough to increase all E&M codes to the 2006 Medicare level. The OVHA discussed this conclusion with the Medical Society. The Medical Society and the OVHA collaborated to derive an allocation method that reflects legislative intent and increase access to primary care. The agreement between the Medical Society and the OVHA is that subsets of E&M codes for office and preventive-well visits will be increased to the 2006 Medicare level.

### *Care Coordination*

The OVHA has set aside \$100,000 to provide incentives and payment restructuring for health care professionals participating in the care coordination program.

### *Hospitals*

The Hospital Association recommended that the OVHA focus the rate increase on inpatient rates and the OVHA agreed. The OVHA estimated that the appropriation will support an inflation increase of 6.1% to the “base” rate effective January 1, 2007. This is consistent with the Medicaid State Plan payment method.

### *Dental Codes*

The legislation required restoration of the earlier 6% (\$223,309) reduction for adult services and application of the remainder (\$76,691) to both the fee schedule and the adult cap so that adults do not experience a benefit reduction caused by rate increases.

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**Memo:** Health Access Oversight Committee  
**From:** Joshua Slen, Director  
**Date:** December 1, 2006  
**Re:** Section 105 (b) Act 215 Report on Part D Implementation Expenditures

*No later than December 1, 2006, the Office of Vermont Health Access shall report to the health access oversight committee on the program and administrative costs associated with the start-up of the Medicare Modernization Act's Part D provisions. The office shall include a projection of the ongoing program and administrative costs to state operations that are attributable to the implementation and ongoing operations of the Medicare Part D prescription drug program.*

The Office of Vermont Health Access has incurred both administrative and program costs associated with the start-up of the Medicare Modernization Act's Part D. Based on the planned Part D design, initially it was anticipated that Vermont would not experience any additional administrative costs as beneficiaries transitioned from Vermont program coverage as primary to secondary to Part D. Additionally, program costs were anticipated to be wrap coverage only.

The challenges of the Part D implementation resulted in significant unplanned administrative and program costs for state fiscal year 2006. The largest costs were for providing coverage to beneficiaries in lieu of Part D coverage. Major administrative costs were information technology (IT), staff time, and staff support. IT costs were related to system changes necessary to revert to Vermont coverage as primary and pursue recovery of pharmacy costs incurred. Staff time and support were expended in support of beneficiaries and providers transitioning to the new coverage.

<b>2006 Administration</b>	
MAXIMUS member services	\$ 8,174
Health Care Ombudsmen	\$ 22,000
MedMetrics Health Partners pharmacy benefit management	\$ 246,500
Information technology/telephonic	\$ 225,491
Staff direct and related	\$ 423,996
Mailings	\$ 22,178
Other contracted and third party services	\$ 18,531
Other administrative costs	\$ 7,429
<b>Total</b>	<b>\$ 974,299</b>

Total state and federal program costs for the Part D population for SFY 2006 are as follows:

<b>2006 Program</b>	
Clawback	\$ 8,292,449
Medicaid covered Medicare non-covered drugs	\$ 1,291,775
State funded wrap benefit	\$ 11,126,020
Services subject to recovery	\$ 11,441,571
Total	\$ 32,151,815

The Office obtained a Section 402 Medicare demonstration project grant from the Centers for Medicare and Medicaid Services (CMS). This grant allows direct reimbursement for pharmacy costs for dates of service January through March 2006 for two populations:

1. Medicare eligibles with traditional Medicaid coverage or
2. Medicare/Medicaid eligibles who qualify for a Medicare low income subsidy (LIS).

In addition, the grant provides access to administrative reimbursement in support of Part D transition.

402 collections to date:

<b>2006 402 Demonstration Project Collections as of 12/1/06</b>	
Administrative	\$ 923,255
Services subject to recovery	\$ 5,003,394
Total	\$ 5,926,649

On services not fully recovered, the Office must resolve eligibility and coverage issues to pursue outstanding amounts subject to recovery. For outstanding administrative costs, CMS has indicated these are payable upon completion of the project.

For SFY 2007, anticipated additional Part D unique administrative costs include expanded member services support for beneficiaries, additional resources to assure the appropriate coordination of benefits with Part D plans, and continued IT costs in claims recovery pursuit under the 402 demonstration project as well as directly from Part D plans. The continued IT costs through our pharmacy benefit management contract is an estimate as actual costs are dependent on CMS and Part D plan requirements that have not yet been established.

<b>2007 Administration</b>	
MAXIMUS member services	\$ 411,342
Staff direct and related	\$ 184,043
MedMetrics Health Partners pharmacy benefit management	\$ 175,000
Total	\$ 770,385

Section 105 (b) Act 215 Report on Part D Implementation Expenditures

December 1, 2006

Page 3

Projected total state and federal program costs for the Part D population for SFY 2007 are as follows:

<b>2007 Program</b>	
Clawback	\$ 19,380,407
Medicaid covered Medicare non-covered drugs	\$ 1,375,328
State funded wrap benefit	\$ 8,635,359
Total	\$ 29,391,094

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LEGISLATIVE REPORT

CHIROPRACTIC REVIEW OF LITERATURE; OVHA RECOMMENDATION  
ACT 215  
Sec. 107c.

THE OFFICE OF VERMONT HEALTH ACCESS

October 31, 2006

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## **LEGISLATIVE CHARGE**

Act 215

Sec. 107c. *Review of Chiropractic Literature; OVHA Recommendation*

- (a) *The Office of Vermont Health Access shall review available literature and clinical findings related to clinical outcomes and overall treatment costs associated with chiropractic treatment. The Office shall make a recommendation to the General Assembly regarding the reinstatement of chiropractic services under the Medicaid Program during the fiscal year 2008 budget submission.*

## **BACKGROUND**

As a part of Act 71, the OVHA was mandated to design a chiropractic trial to study the clinical outcome and cost of chiropractic treatment in comparison to other treatment modalities, if federal financial participation was available. At the end of the study, the OVHA would then make a recommendation to the General Assembly regarding reinstatement of coverage for chiropractic services for adults.

As a result of collaboration with members of the Vermont Chiropractic Association (VCA), the OVHA concluded that adequate resources to conduct this type of comprehensive study within the time frame desired by the VCA were not available. An alternate proposal was to monitor the Centers for Medicaid and Medicaid Services (CMS) Demonstration Project *Expansion of Medicare Coverage for Chiropractic Services* (Sec. 651 of the Medicare Modernization Act of 2003) and consider their recommendations following their reported results and analysis.

The OVHA's memo to the Legislature, dated February 24, 2006, recommended that the CMS Demonstration Project replace the Act 71 study. Two major concerns were voiced by the chiropractic community to this recommendation: (1) relying on the outcome of the CMS Demonstration Project would unnecessarily delay the reinstatement of chiropractic coverage for Vermont's Medicaid (adult) population; and (2) the CMS Demonstration Project is limited in scope for expanding chiropractic services for neuromuscular conditions.

The current Legislative mandate for the OVHA attempts to address these concerns by reviewing the available literature and making a recommendation to the General Assembly based on this review.

## **LITERATURE REVIEW**

A focused literature review was performed by the OVHA after soliciting references from the chiropractic community, the VCA and sources cited in the CMS Demonstration Project. The literature reviewed, herein, includes original research, editorials and position papers in both full text and abstract formats. A Systematic Review by the Research Commission of the Council on Chiropractic Guidelines and Practice Parameters, *Chiropractic Best Practices*, currently in draft form, was reviewed, but was excluded from this report because of a disclaimer, 'not for distribution or for attribution' pending stakeholder comments. While the review process encompassed many more sources than cited below, it is representative of the most current literature.

**Mills MW, Henley CE, et al (2003), *The Use of Osteopathic Manipulative Treatment as Adjuvant Therapy in Children with Recurrent Acute Otitis Media*, Archives of Pediatric Adolescent Medicine 2003; 157:861-866**

This study was published in 2003 based on claims data dating back to 1999 with a total of 57 patients. There was no placebo group to account for whether patients would have improved with any perceived intervention. This is an exceptionally important factor because the parents were advised of the nature of the intervention being administered to their child and therefore introduced the potential for biased results. Thus the most the authors could conclude was that “the results of the study suggest a potential benefit” in the treatment of acute otitis media, but that a larger study was indicated.

**The Chiropractic Report 2004; Vol. 18; No. 6**

This newsletter provides an overview of the cost-effectiveness discussion in the medical/chiropractic community, drawing on past articles by Manga and Angus; Stano and Smith; Jarvis, Phillips, et al; Mosely and Cohen; as well as the large American Specialty Health Plans research study headed by Legorreta, et al from the School of Public Health at UCLA. Key statistics regarding back pain and the treatment thereof, including costs and percentage of patients who go onto long term disability, are duly noted. Concerns by payors such as whether the addition of chiropractic care will be an “add-on” cost, or rather reduce costs spent elsewhere, are also recognized as important issues in this debate.

The flaw in the estimated ‘cost-savings’, however, rests in the comparison with ‘traditional’ medical treatment which in the past ten years has undergone a complete revision. Non-surgical interventions are being recommended by the medical community in radically increased numbers, which affects any purported cost savings therein. The UCLA study was based on claims data from as far back as 1997. Many of the other studies are even older, and the first Manga work and the Jarvis study were published 13 and 15 years ago, which means the data analyzed was 2-3 years older still.

**Manga P, Angus D et al (1993), *The Effectiveness and Cost Effectiveness of Chiropractic Management of Low Back Pain*, Pran Manga and Associates, University of Ottawa, Ottawa, Ontario**

This literature review is one of the original papers documenting the enhanced cost effectiveness of chiropractic treatment for low back pain. The strength of having a health economist perform the study is ameliorated by the fact that retrospective reviews are inherently less convincing than controlled studies especially when 13+ year old data is involved.

**Manga P, Angus D et al (1998), *Enhanced Chiropractic Coverage Under OHIP as a Means of Reducing Health Outcomes and Achieving Equitable Access to Select Health Services*, Ontario Chiropractic Association, Toronto**

This study is similar in design to the one noted above except it is broader in scope and more comprehensive in its cost-effectiveness analysis. This was accomplished by trying to capture all associated costs including direct costs, costs arising from harm from treatment and compensation costs for disability. Similar concerns regarding the design and age of this study are present. Interestingly enough chiropractic services were eliminated as a covered benefit in 2004 by the Ontario Government who called chiropractic “one of the least important services” despite their own study-and Dr. Manga-a Professor of Economics-recommending otherwise.

**Legorreta AP, Metz RD, Nelson CF et al (2004), Comparative Analysis of Individuals With and Without Chiropractic Coverage, Patient Characteristics, Utilization and Costs, Arch Intern Med 164:1985-1992**

This sizeable retrospective claims study, done over 4 years, compared individuals with chiropractic coverage to those without in a California managed care plan dating back to 1997. Total annual health costs and number of x-rays, hospitalizations and MRI's were all decreased in the chiropractic group. However, as noted in the editorial cited below, there were a number of weaknesses in the study.

**Ness J, Nisly N (2004), Cracking the Problem of Back Pain: Is Chiropractic the Answer? Arch Intern Med 164:1953-1954**

Although the study above was widely recognized as one of the most substantial analysis done to date, the editors of the Archives of Internal Medicine noted “the study design does not permit the definite determination of a cause and effect relationship between access to chiropractic and a more budget-effective approach to muscular care, pointing rather to the coexistence of the two phenomena in a managed care population. Furthermore, the lack of a random element in defining the populations with and without access to chiropractic care may have partly compromised the validity of the results.” In addition, “The favorable health profile of the ‘chiropractically insured’ is of particular concern. They comprise a younger and healthier population and thus are likely to have better outcomes and fewer health expenses.” Ultimately, they conclude that “critical questions remain regarding which subsets of patients could derive the most benefit from chiropractic care and yet incur fewer health expenditures.” They caution that “extensive research in this area is warranted” and “careful scrutiny should be applied in future research”.

**Livermore GA, Stapleton DC (2005) Medicare Chiropractic Services Demonstration: Final Design Report, Cornell University Institute for Policy Research**

This paper was prepared for CMS as the basis for their Demonstration Project described below. Prepared by the Cornell University Institute for Policy Research under subcontract to the Medstat Group as recently as a year ago, it represents one of the most impressive compilations of scientific literature concerning chiropractic care. It notes at the very beginning that “previous research on the cost effectiveness of chiropractic care is inconclusive” despite acknowledging studies by the chiropractic community attesting to the contrary. The basic premise for this conclusion, as noted repeatedly above, is the presence of selection bias in many of the studies. This concern is the primary underpinning of the study design they recommended to CMS, which CMS elected to follow verbatim in rolling out their Demonstration Project in April 2005.

**DEMONSTRATION PROJECTS**

**U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program: Demonstration of Coverage of Chiropractic Services under Medicare: Notice (1/8/05)**

CMS, per sec. 651 of the Medicare Modernization Act of 2003 is conducting a Demonstration Project evaluating the feasibility and advisability of expanding coverage for scope of services that chiropractors are permitted to provide. This Demonstration Project will operate for two years and must be budget neutral. The project sites are the State of Maine; State of New Mexico; 26 Illinois Counties; Scott County in Iowa, and 17

Virginia Counties. The Demonstration Project began in April 2005 and will continue through March 31 2007.

CMS currently reimburses chiropractors for treatment limited to manual spinal manipulation to correct subluxations related to neuromuscular conditions with reasonable expectation of recovery or functional improvement. At the close of the Demonstration Project, an independent evaluation will be conducted to assess costs and other impacts of demonstration. An interim report will be submitted to Congress in spring 2008 with a final report due in late 2009. (Reference attached power point).

**U.S. Department of Health and Human Services, Health Resources and Services Administration, Elderly Back pain: Comparing Chiropractic to Medical Care (2005)**

*As abstracted from the researchers' application presentation:*

Organization Name: Palmer Chiropractic University  
Project Title: Elderly Back Pain: Comparing Chiropractic to Medical Care  
Grant Number: R18HP01423  
Project Period: 9/1/03 – 8/31/06  
FY 2005 Award Amount: \$369,572

Low back pain (LBP) in the elderly is a significant public health problem with prevalence ranging from 13-49%. Despite significant impact on elderly quality of life, there are no randomized clinical trials (RCT) examining medical and chiropractic treatment options.

We propose a prospective (RCT) of 250 elderly patients with subacute or chronic LBP. Patients will be randomized to one of three treatment conditions: 1) chiropractic care consisting of high-velocity low amplitude (HVLA) spinal adjustments (manipulation), 2) chiropractic care consisting of low-velocity variable amplitude (LVVA) spinal mobilization (flexion-distraction) and 3) standard medical care.

The study is statistically powered for two separate primary comparisons: 1) chiropractic care versus medical care and 2) HVLA manipulation versus LVVA mobilization. The two primary analyses have the potential to inform and improve medical and chiropractic clinical practice.

The Palmer Center for Chiropractic Research (PCCR) has developed a considerable infrastructure to conduct RCTs, and investigators at PCCR have significant experience conducting both clinical and biomechanical research. The PCCR is the largest and most comprehensive chiropractic research effort in the U.S., and it is well-positioned and highly experienced at medical/chiropractic collaboration. PCCR is partnering with community-based medical physicians and the Departments of Internal Medicine and Biomechanical Engineering at the University of Iowa to conduct this study.

## **RECOMMENDATION**

Reinstating chiropractic services under the Medicaid program for the adult population, as children are already covered, can be conceptually divided into three distinct groups: services provided for the treatment of back conditions; services provided for the treatment of back and neuromuscular disorders; and services provided for the treatment of conditions unrelated to back or neuromuscular conditions. Definitive literature regarding the latter is lacking, although preliminary studies offer glimpses into possible benefits in ways the medical community has heretofore dismissed. Clearly, there is literature supporting the efficacy of chiropractic care in treating back conditions, but as to the supposed cost-effectiveness there is an honest open debate, that in the minds of the medical community, as noted above, is still unresolved.

Although less studied, the efficacy of extending chiropractic services to neuromuscular conditions is noted with some of the same flaws in study design as others. The CMS Demonstration Project attempts to answer that question among others. In the meanwhile, OVHA provides for the treatment of back, neuromuscular and other conditions within chiropractors' scope of expertise through conventional medical modalities. These medical modalities have undergone an evolution toward non-surgical interventions in greater numbers and will continue to evolve as more studies are done.

However, as to how cost effective chiropractic care might be as an additional benefit in the State of Vermont remains to be determined. At this time, of greater interest to OVHA is the result of the CMS Chiropractic Demonstration Project, which is due to have preliminary results in a year. The well designed methodology being employed and the applicability to Vermont's Medicaid population will more accurately answer questions regarding clinical and cost efficacy for chiropractic services. Pending the results of the Demonstration Project (and the HSRA's Palmer College of Chiropractic Project), however, there is not enough data to support reinstatement of services at this time.

Report to  
Health Access Oversight Committee  
and  
Joint Fiscal Committee

# **Employer-Sponsored Insurance Premium Assistance**

The Office of Vermont Health Access  
Agency of Human Services

November 22, 2006

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## **Executive Summary**

An analysis of a recently-conducted survey of beneficiaries of the Vermont Health Access Plan (VHAP) yielded an estimate that an Employer-sponsored Insurance (ESI) premium assistance program could produce gross savings and cost avoidance of \$12-13 million after administrative and development costs for the three-year period of SFY08 through SFY10. The state share of those savings and avoided costs would be approximately \$4.9-5.4 million.

The lower cost of ESI premium assistance would allow the state to provide assistance to more uninsured Vermonters. In addition to saving money, insuring the uninsured by maximizing their enrollment in ESI plans would bolster the commercial market on which most Vermonters depend for their health care coverage. Although other states' experience shows that premium assistance programs are challenging to administer, the resulting savings more than offset the administrative costs.

This report recommends that the State of Vermont move forward to implement an ESI premium assistance program for the VHAP and Catamount Health populations, and analyze whether to include other populations at a future time.

*Thanks to everyone who has contributed to this report, including members of Joint Fiscal Office, Office of Vermont Health Access (OVHA), Department of Banking, Insurance, Securities and Health Care Administration (BISHCA), the Agency of Human Services' fiscal office, and the Department for Children and Families' Economic Services Division.*

## Section 1: Background

Section 13 of Act 191, An Act Relating to the Health Care Affordability for Vermonters, passed during the 2006 legislative session, requires the Agency of Human Services to submit a report to the Joint Fiscal and Health Access Oversight Committees prior to November 15, 2006, containing specific information related to the development and implementation of the ESI premium assistance program. The report must contain the following:

- A plan for additional expenditures beyond the first \$250,000 of the \$1 million appropriated in H.881 for start-up and initial administrative expenses associated with ESI planning and development,
- Results of a survey to determine whether and how many individuals currently enrolled in the Vermont Health Access Plan (VHAP) are potentially eligible for ESI premium assistance,
- The sliding-scale premium and cost-sharing assistance amounts provided under the ESI premium assistance program to individuals,
- A description and estimate of benefits offered by VHAP that are likely to be provided as supplemental benefits for the ESI premium assistance enrollees,
- A plan for covering dependent children through the premium assistance program, and
- The anticipated budgetary impact of an ESI premium assistance program for fiscal year 2008.<sup>1</sup>

The Office of Vermont Health Access (OVHA) and the Department for Children and Families' Economic Services Division (ESD) formed a work group in June 2006 for the planning and implementation of the ESI and Catamount Health premium assistance programs. Representatives from the Department of Banking, Insurance, Securities, and Health Care Administration (BIS HCA) have participated in the work group as needed, as have representatives from private firms under contract with the Agency: MAXIMUS (Member Services Unit), Electronic Data Systems (Medicaid Management Information System), and Policy Studies, Inc. (system development).

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<sup>1</sup> 33 VSA § 1974(g)(2)

## Section 2: Description of ESI Premium Assistance

### Overview

ESI premium assistance is a key feature of Vermont's health care reform plan. Because of employers' contributions to ESI premiums, the lower cost of providing ESI premium assistance (as compared to the cost of providing premium assistance to people enrolled in Catamount Health plans) will allow the state to assist more Vermonters in obtaining coverage.

### Who is eligible

There are three groups of uninsured individuals eligible for premium assistance:

- Individuals with income under 150 percent of the Federal Poverty Level (FPL) and parents under 185 percent of FPL who are eligible for VHAP and have access to ESI plans
- Individuals with income between 150 percent and 300 percent of FPL who have access to ESI plans <sup>2</sup>
- Individuals with income between 150 and 300 percent of FPL without access to ESI but who wish to enroll in Catamount Health with premium assistance.

To be eligible for premium assistance in the latter two categories, individuals must have been uninsured for at least 12 months, with some exceptions. <sup>3</sup>

Uninsured adults with income greater than 300 percent of FPL may purchase a Catamount Health plan but will receive no premium assistance.

The first two groups described above are the focus of this report.

### Benefits

For individuals who are eligible for VHAP and have access to ESI, the ESI plan must offer benefits "substantially similar to the benefits covered under the certificates of coverage offered by the typical benefit plans issued by the four health insurers with the greatest number of covered lives in the small group and association market in this state." <sup>4</sup>

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<sup>2</sup> 300 percent of FPL is \$2463 per month or \$29,556 per year; for a household with two adults, 300 percent of FPL is \$3313 per month or \$39,756 per year.

<sup>3</sup> Individuals do not have to wait 12 months for premium assistance if they lost coverage due to one of the following reasons: loss of employment; death of the principal insurance policyholder; divorce or dissolution of a civil union; no longer qualified as a dependent under the plan of a parent or caretaker relative; no longer qualifying for COBRA, VIPER, or other state continuation coverage; or a college-sponsored insurance plan became unavailable because the individual graduated, took a leave of absence, or otherwise terminated studies.

<sup>4</sup> 33 VSA § 1974(b)((2)(A)

<b>Who is Eligible</b>	<b>Type of Coverage</b>	<b>Benefits</b>
VHAP adults 0-150% FPL; or parents under 185% FPL	Employer Sponsored Insurance	The benefits covered by the plan must be substantially similar to the benefits offered by the typical benefit plans issued by the four health insurers with the greatest number of covered lives in the small group.
Uninsured Adults 151–300% FPL not eligible for any OVHA program.	Employer Sponsored Insurance	The benefits covered by the plan must be substantially similar to the benefits offered by the Catamount Health Premium Assistance.
	Catamount Health Plan	The benefits provided under Catamount Health.

In addition, OVHA will “wrap around” the ESI plan to ensure the adult receives the same benefits as would be available through VHAP. The cost of the coverage to the beneficiary under ESI will not be higher than VHAP coverage; therefore, the adult would not pay a monthly premium that is higher than the VHAP premium and would not be responsible for any cost-sharing (deductibles, co-insurance, and co-pays) above VHAP cost-sharing requirements.

For those up to 300 percent FPL who are not eligible for existing state programs, the ESI benefits must be substantially similar to the benefits offered by Catamount Health and provide appropriate coverage of chronic conditions. In addition, any cost-sharing for chronic care under ESI will be covered by the wrap-around benefit.

Those without access to ESI may enroll in Catamount Health.

#### Plan Approval & Cost Effectiveness

For OVHA to provide premium assistance it must determine the individual is enrolling in an approved health plan that is “cost-effective.” A plan is cost-effective if it is less expensive for the state to pay premium assistance and wrap-around costs for an individual in an ESI plan than to provide full coverage under the VHAP program.

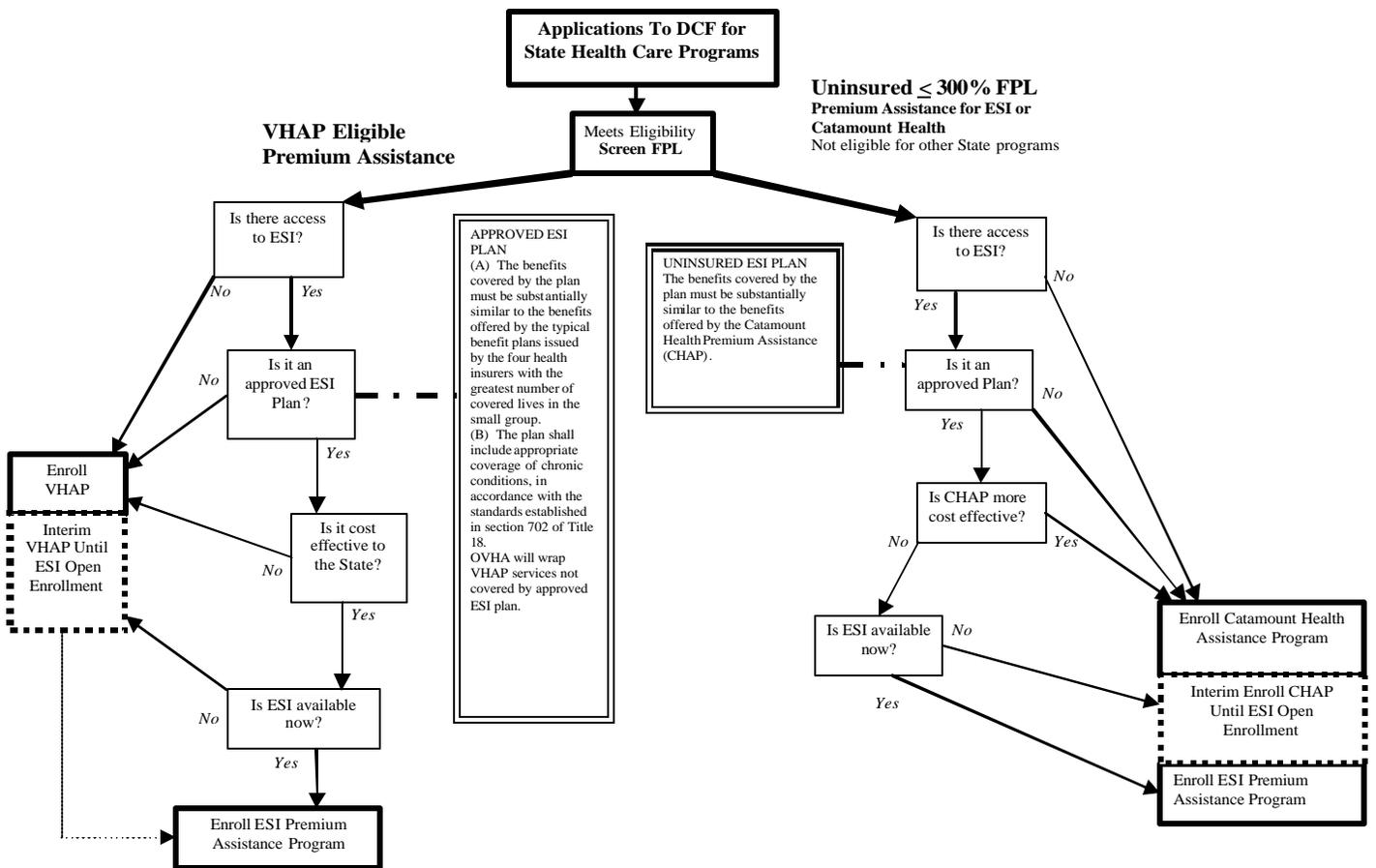
For those on VHAP, OVHA will perform a cost-effectiveness test comparing VHAP costs and ESI premium assistance costs. If a VHAP-eligible adult is required to enroll in ESI, VHAP will “wrap around” the ESI plan to ensure that the adult receives the same benefits as would be available through VHAP.

If an adult is not eligible for VHAP but is under 300 percent FPL, OVHA will perform a cost-effectiveness test comparing ESI premium assistance costs and Catamount Health premium assistance costs. If the adult receives premium

assistance in the ESI plan, the state will pay for any cost-sharing associated with the treatment of chronic conditions.

Uninsured adults with income greater than 300 percent FPL may purchase a Catamount Health plan but will receive no premium assistance.

The following flowchart shows the three groups eligible for premium assistance (VHAP/ESI, ESI, and Catamount Health), a description of the benefit, and the process flow for each group.



## **Section 3: VHAP Survey Results**

### Survey Results

The health care reform bill required the Agency of Human Services to conduct a survey to determine how many individuals currently enrolled in VHAP, including those eligible as caretakers, are potentially eligible for ESI premium assistance. In August 2006 OVHA signed an interagency agreement with BISHCA that allowed BISHCA to extend its contract with Market Decisions L.L.C. to include the VHAP survey. OVHA, BISHCA, and Department for Children and Families' Economic Services Division collaborated with Market Decisions on the content of the survey questionnaire. The survey was conducted in August and early September of 2006.

Extrapolating the results of the survey to the VHAP population as a whole, 63 percent of VHAP beneficiaries have some earned income; however, only 10 percent of VHAP beneficiaries are eligible to enroll in an ESI plan, either because their employers do not offer health insurance or because the employees do not work enough hours to qualify for their employer plans.

### Methodology for simulating cost-effectiveness test and cost savings

Those VHAP respondents who said they had access to and were eligible for ESI plans were matched against the Medicaid claims database to determine actual claims cost for the twelve months in SFY06. Actual claims costs for these VHAP beneficiaries ranged from zero to \$25,986 for the 12-month period.

An algorithm was developed to match actual claims cost for each person against estimated ESI costs using the premium, deductible, co-insurance, and out-of-pocket maximum for several product offerings, including Catamount Health and various plans from Vermont's small group and association market. Also used was a hypothetical plan with average single-person cost-sharing according to the 2006 Kaiser Family Foundation survey. This analysis determined that approximately half of VHAP beneficiaries with access to and eligible for ESI would have cost-effective ESI plans. The 1068 beneficiaries falling into this category represent five percent of the VHAP population as a whole.

For the beneficiaries for whom it would be cost-effective to enroll in ESI plans with premium assistance, the difference between their actual claims cost and the estimated cost of their ESI premium plus wrap costs (deductible and cost-sharing up to the out-of-pocket maximum) becomes the estimated cost savings. Cost savings from the sample may then be applied to the VHAP population as a whole to determine total cost savings to the program. See Section 7 for the budgetary impacts of ESI.

## Section 4: Sliding Scale Premiums and Cost-sharing Amounts

Statute requires that “the premium assistance program . . . provide a subsidy of premiums or cost-sharing amounts based on the household income of the eligible individual, with greater amounts of financial assistance provided to eligible individuals with lower household income and lesser amounts of assistance provided to eligible individuals with higher household income.”<sup>5</sup>

Since the law states that VHAP-eligible individuals enrolled in ESI should not have out-of-pocket expenditures greater than the premium and cost-sharing obligations under VHAP, the Agency is proposing to set the ESI individual contributions for VHAP-eligible ESI enrollees at the same level as VHAP premiums as of July 1, 2007.

For individuals who are not eligible for VHAP, the Agency is proposing that ESI individual contribution levels be the same as contribution levels for Catamount Health. Using the same contribution levels for both ESI and Catamount Health would ensure equity for individuals participating in premium assistance and having income above the VHAP income maximum.

Below is a chart that shows the comparison of proposed individual contributions in the VHAP, ESI, and Catamount Health premium assistance programs.

COMPARISON OF BENEFICIARY'S SHARE OF PREMIUM									
VHAP=Vermont Health Access Plan									
VHAP ESI=Premium assistance for people eligible for VHAP and enrolled in an ESI plan									
ESI=Premium assistance for people not eligible for VHAP & enrolled in an ESI plan & income <300% FPL									
CHAP=Catamount Health Assistance Program (assistance for people in Catamount Health & <300% FPL)									
		VHAP \$ <sup>1</sup>	VHAP % <sup>2</sup>	VHAP ESI \$	VHAP ESI %	ESI \$ <sup>3</sup>	ESI %	CHAP \$	CHAP %
% FPL	Monthly income								
50-75%	\$513	\$7	1.36%	\$7	1.36%				
75-100%	\$718	\$25	3.48%	\$25	3.48%				
100-150%	\$1,026	\$33	3.22%	\$33	3.22%				
150-185%	\$1,375	\$49	3.56%	\$49	3.56%	\$60	4.36%	\$60	4.36%
185-200%	\$1,580					\$60	3.80%	\$60	3.80%
200-225%	\$1,744					\$90	5.16%	\$90	5.16%
225-250%	\$1,950					\$110	5.64%	\$110	5.64%
250-275%	\$2,155					\$125	5.80%	\$125	5.80%
275-300%	\$2,360					\$135	5.72%	\$135	5.72%
<sup>1</sup> Beneficiary's share of premium									
<sup>2</sup> Beneficiary's share of premium as a percentage of income									
<sup>3</sup> Proposed beneficiary's share of ESI premium									

<sup>5</sup> VSA 33 § 1974(c)(3)

## **Section 5: Description of and Cost Estimate for the VHAP “Wrap”**

Act 191 requires the Agency of Human Services through OVHA to provide “wrap-around” benefits to beneficiaries who are enrolled in ESI and eligible for VHAP. The wrap-around, or “wrap,” ensures that any provider of a service not covered under the ESI plan, but covered under VHAP, would be reimbursed. In addition, the wrap would cover cost-sharing under the ESI plan to the extent the cost-sharing exceeds VHAP cost-sharing (the only co-pay requirement in VHAP is a \$25 emergency room fee). In essence the ESI plan becomes the primary payer, with VHAP as secondary payer.

Since the VHAP covered services package was designed to resemble closely the covered services provided by the typical private insurance plan, there will not be many service categories covered under the wrap that are not covered by the private insurance plan. The vast majority of wrap expenditures, therefore, will be charges falling under deductibles. However, after conducting a review of some of the top plans in the small group and association market, the following services covered by VHAP are not covered in some of the private plans:

- Outpatient physical therapy, occupational therapy, and speech therapy
- Skilled nursing facility (up to 30 days)
- Nurse practitioner services
- Eye exams
- Family planning services
- Mammograms
- Home health nursing
- Vasectomies/tubal ligations

### Cost estimate of the VHAP wrap

To estimate the costs of the wrap, OVHA reviewed claims from the Medicaid Management Information System (MMIS) for adults on Medicaid who are not eligible for SSI or Medicare and who have other insurance on the assumption that these adults are similar to adults on VHAP with access to ESI. For these currently eligible Medicaid adults, Medicaid is the secondary payer. This exercise, however, did not yield a large enough number of beneficiaries from which to draw sound conclusions. In addition, the types of claims represented in this small sample raised questions about whether the sample was a valid “proxy” for the VHAP working population.

Instead, an estimate of the wrap was derived from the working VHAP survey respondents who have cost-effective ESI plans by using actual claims for these

individuals over the prior fiscal year period and estimating the cost-sharing of the typical health insurance plan in the small group and association market. Using the simulation described above, the average annual wrap cost per individual would be \$28.58 per month or \$342.96 per year.<sup>6</sup> The average VHAP per-member-per-month (PMPM) cost for these individuals was \$481.27, which is higher than the PMPM of \$256.41 for the VHAP population as a whole in SFY06. This finding makes sense in that a determination of cost-effectiveness would occur more often for higher-cost beneficiaries.

Cost estimate of the ESI chronic care cost-sharing wrap

Individuals who are not eligible for VHAP but are under 300 percent FPL are eligible for premium assistance for their ESI plans. The state must also provide a wrap for any cost-sharing for treatment of chronic conditions. Since 50 percent of the actual claims for the VHAP survey respondents with cost-effective ESI plans appeared to be chronic care cost-sharing claims, that percentage was used to estimate a wrap cost of \$18.29 per month or \$219.48 per year.<sup>7</sup>

Although by looking at each claim on the VHAP survey respondents it was possible to determine which claims were likely to have been chronic care claims, it will be very difficult to automate a process that accurately makes the distinction between chronic care claims and primary acute care claims.

Premium assistance plus wrap costs

The following table summarizes the cost of providing premium assistance, including the wrap, for VHAP/ESI and non-VHAP ESI. Since this chart is offered for comparison purposes only, the beneficiary’s contribution has not been included.

<b>Category</b>	<b>Premium assistance</b>	<b>Wrap</b>	<b>Total monthly cost</b>	<b>Total annualized cost</b>
<b>VHAP/ESI</b>	\$91.21	\$28.58	\$119.79	\$1437
<b>ESI</b>	\$91.21	\$18.58	\$109.50	\$1314

<sup>6</sup> An additional \$10 per month was added to the PMPM to account for services covered by VHAP but not covered by the ESI plan, as listed in the prior section.

<sup>7</sup> \$5 per month was added for state-mandated services not covered by the ESI plan. Another \$4 per month was added should the decision be made to include ESI plans with deductibles somewhat higher than the Catamount Health deductible of \$250, in which case the state would provide a wrap down to the Catamount Health cost-sharing level.

## **Section 6: Should children be included in ESI plans?**

Act 191 requires the Agency as part of this report to develop a plan for covering dependent children through the premium assistance program. Language earlier in Section 13 states “the agency shall determine whether to include children who are eligible for Medicaid or Dr. Dynasaur in the premium assistance program at their parent’s option.”<sup>8</sup> This section of the report was to include the Agency’s decision on whether or not to include children and the justification for that decision.

In September the Agency concluded that it could not do justice to this very important analysis prior to the due date for this report. The Agency sought and received the approval of the Health Access Oversight Committee and the Health Care Reform Commission to postpone this analysis to a later date. No child will be prevented from receiving health care coverage or in any way be harmed by this postponement, since children in families below 300 percent FPL are eligible for Dr. Dynasaur, which has a richer benefit package than most ESI plans would provide.

An additional reason for this postponement is the Agency’s desire to implement premium assistance programs for adults and ensure their smooth operation before adding children. Because the implementation of premium assistance programs is a difficult challenge, and because the October 1, 2007, deadline is an ambitious deadline, the additional complexity of including children carries the risk of a delayed or flawed implementation. Since children in general are less expensive than adults to cover under state-funded programs, this is yet one more reason for not moving precipitously in this area.

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<sup>8</sup> 33 V.S.A. § 1974(a)

## **Section 7: Estimated Budgetary Impact of ESI Premium Assistance for SFY08 through SFY10 and One-time Development Costs for SFY07**

### Background

The SFY08 budgetary impact of ESI premium assistance is the cost savings of moving current VHAP beneficiaries into ESI, the costs avoided by moving new VHAP beneficiaries into ESI, and the costs avoided by new non-VHAP ESI premium assistance beneficiaries who would otherwise be enrolled in Catamount Health premium assistance at a higher cost.

The budgetary impact of the Catamount Health premium assistance beneficiaries and the anticipated increase in the number of VHAP beneficiaries without access to ESI have not been included in this report, but will be included in the new Global Commitment balance sheet and the Governor's recommended budget.

For the estimates of how many new VHAP beneficiaries will be on the rolls as a result of lower premiums and the outreach campaign, and the number of ESI premium assistance beneficiaries, the BISHCA Household Health Insurance Survey of 2005 was used to develop the base population estimates of Vermonters potentially eligible for assistance. Dr. Sherry Glied, an economist at Columbia University and a national expert on the issue of take-up rates, estimated how many of the potentially eligible Vermonters for VHAP and ESI would actually apply and enroll.

### Population estimates and take-up rates

According to the results of the BISHCA survey, there are 17,017 adult Vermonters who are eligible for VHAP but not enrolled. Dr. Glied estimated that VHAP enrollment would grow by approximately five percent<sup>9</sup> based on the premium reductions and the aggressive outreach campaign required in the legislation. This five percent gross increase would result in an additional 1316 individuals enrolling in VHAP, of which 85 would have cost-effective ESI plans.

The BISHCA survey results show that 4830 uninsured Vermonters who are over the VHAP income limit but under 300 percent FPL have access to ESI plans but have not enrolled. Dr. Glied estimates that 290 of these individuals would enroll in ESI premium assistance.

The number of people expected to enroll in non-VHAP ESI is low for several reasons. Because ESI plans are a relatively inexpensive way for people to obtain coverage, most people who have access to ESI already enroll in ESI. In fact, according to national studies, over 80 percent of employees take up their employer's ESI offer. Since Vermont's premium assistance program for ESI requires individuals to contribute toward the cost of their premiums, the difference between the total premium cost to the employee and the subsidized

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<sup>9</sup> The growth would be only three percent for the 0-50 percent FPL category, since there is no VHAP premium for this group, and so lower premiums would not attract additional applicants. The three percent growth is estimated to result from the outreach campaign.

premium cost is not great enough to entice many people to enroll. In fact, in the higher income categories, where most eligible beneficiaries are, the beneficiary's contribution is about equal to the average employee share of the ESI premium.

Based on the literature it is estimated that every 10 percent decline in employee required contributions toward insurance leads to a .05 percent increase in enrollment. This take-up estimate reflects the fact that an individual who has not already enrolled in a relatively inexpensive ESI plan is likely to be fairly healthy and have a low demand for health insurance. This group is less likely than average to apply for ESI premium assistance for what might be perceived as a small monetary gain. People who have access to ESI and do not take it up are less likely to participate in premium assistance programs than are people who have no employer offers at all.

Even though the number of people who will enroll in ESI is low, it would still be less expensive to provide premium assistance to these individuals in ESI plans than in Catamount Health plans. The average ESI premium assistance cost would be an estimated \$109.50 per month (including the chronic care cost-sharing wrap), whereas the average premium assistance for Catamount Health would be approximately \$362.

Although a higher number of people could be expected to enroll in ESI if the expected employee contribution were established at a lower level,<sup>10</sup> Dr. Glied warns that is important to be cautious about expanding these subsidies because heavily subsidizing employee premium shares for ESI could lead employers to change behavior and increase the required premium shares over time. Moreover, many people who are currently taking up employer-offered health insurance and paying the full employee share of premiums for this coverage would tend to move toward jobs where they would become eligible for subsidized premiums. The crowd-out potential of subsidizing employee premium shares at ever-increasing levels is large because such a significant portion of the potentially eligible population is already insured.

As a result of the take-up analysis, the following table summarizes the numbers of new enrollees in the various eligibility categories:

<b>Eligibility category</b>	<b>New enrollees</b>
Current VHAP to ESI	1068
New VHAP with no ESI	1231
New VHAP/ESI	85
New ESI only	290

<sup>10</sup> Dr. Glied estimates that 1687 people would enroll in ESI premium assistance if the employee contribution were decreased to one percent of income.

Estimates of Catamount Health premium assistance participation are being developed and will be included in the new Global Commitment balance sheet and the Governor's recommended budget.

Plan for SFY07 Expenditures beyond \$250,000

H.881, the 2007 appropriations bill, added \$1 million to OVHA's budget to implement ESI assistance programs within the state Medicaid program. Section 13 of Act 191 requires the submission of this report before additional expenditures beyond \$250,000 of this \$1 million appropriation may be spent. The following table estimates expenditures for planning and development for SFY07 for both ESI *and* Catamount Health premium assistance.

<b>ONE-TIME DEVELOPMENT COSTS FOR PREMIUM ASSISTANCE IN SFY07: CATAMOUNT &amp; ESI</b>		
<b>Function</b>	<b>Cost</b>	
Policy Studies, Inc. contract	\$700,000	ACCESS sys development in SFY07
Dr. Sherry Glied contract	\$11,500	Take-up rate estimates
Market Decisions contract	\$45,000	VHAP survey
Postage	\$15,000	Bulk mailing to VHAP
Rule making	\$5,400	Printing, mailing, advertising
Brochure	\$2,000	Premium assistance
Training	\$5,000	Internal staff
EDS contract costs	\$125,513	MMIS development, 50% of total cost
<b>TOTAL for SFY07</b>	<b>\$909,413</b>	

As of November 15, 2006, expenditures have been \$56,500 for the contracts with Dr. Glied and Market Decisions.

Should a decision be made to delay implementation of ESI premium assistance, the costs above would be reduced by approximately \$221,300. The remaining expenditures of \$688,113 would be necessary to proceed with development and implementation of Catamount Health premium assistance. Below is a table that estimates the marginal costs in SFY07 for the development of ESI beyond the \$56,500 that has already been spent for the two contracts described above.

<b>ONE-TIME DEVELOPMENT COSTS IN SFY07 FOR ESI</b>		
<b>Function</b>	<b>Cost</b>	
Policy Studies, Inc. contract	\$175,000	ACCESS sys development in SFY07 (ESI design)
EDS contract costs	\$31,300	MMIS development; 50% of total for ESI
Postage	\$15,000	Bulk mailing to VHAP
<b>TOTAL for SFY07</b>	<b>\$221,300</b>	

No expenditures have been included for outreach to uninsured Vermonters or to employers. Bi-State Primary Care Association has just issued a report that makes recommendations on how Vermont should outreach to uninsured Vermonters, and the Administration is pursuing grant money for these efforts.

Impact of ESI Premium Assistance to Program Budget for SFY 08-10

The following spreadsheet estimates the budgetary impact of the new enrollees in each category, including cost savings, cost avoidance, and administrative costs. Actual cost savings would occur by moving VHAP beneficiaries with cost-effective ESI plans into ESI with premium assistance. "Cost savings" means a direct reduction to current and future VHAP costs. The term "cost avoidance" is used to refer to new VHAP beneficiaries who would enroll in ESI and new non-VHAP ESI premium assistance beneficiaries. Both of these latter groups would reduce future costs, since without an ESI component, the state would have to pay the full cost of covering new VHAP beneficiaries under VHAP or, for the non-VHAP ESI group, under Catamount Health premium assistance.

	SFY '08	SFY '09	SFY '10	Total
<b>Current VHAP Enrollee</b>				
Estimated Enrollment: Current VHAP to ESI	972	1068	1068	
Estimated Cost per Enrollee (Annualized): VHAP	\$5,775	\$6,169	\$6,589	
Estimated Cost per Enrollee (Annualized): VHAP ~ ESI	\$1,437	\$1,535	\$1,640	
Annual Savings per Enrollee (Annualized):	\$4,338	\$4,633	\$4,949	
Expenditures: VHAP	\$2,019,890	\$6,587,994	\$7,036,637	
Expenditures: VHAP ~ ESI	\$502,759	\$1,639,778	\$1,751,447	
<b>Gross Savings</b>	\$1,517,132	\$4,948,216	\$5,285,190	\$11,750,538
<b>State Share Savings Estimate</b>	\$627,182	\$2,045,593	\$2,184,898	\$4,857,672
<b>New VHAP ~ ESI Enrollee</b>				
Estimated Enrollment: VHAP ~ ESI	85	85	85	
Estimated Cost per Enrollee (Annualized): VHAP	\$5,775	\$6,169	\$6,589	
Estimated Cost per Enrollee (Annualized): VHAP ~ ESI	\$1,437	\$1,535	\$1,640	
Annual Cost Avoidance per Enrollee (Annualized):	\$4,338	\$4,633	\$4,949	
Expenditures: VHAP	\$208,871	\$524,325	\$560,032	
Expenditures: VHAP ~ ESI	\$51,989	\$130,507	\$139,394	
<b>Gross Cost Avoidance</b>	\$156,882	\$393,819	\$420,638	\$971,339
<b>State Share Cost Avoidance Estimate</b>	\$64,855	\$162,805	\$173,892	\$401,551
<b>New ESI Enrollee</b>				
Estimated Enrollment: ESI	242	290	290	
Estimated Cost per Enrollee (Annualized): Catamount Health	\$4,344	\$4,640	\$4,956	
Estimated Cost per Enrollee (Annualized): ESI	\$1,314	\$1,403	\$1,499	
Annual Cost Avoidance per Enrollee (Annualized):	\$3,030	\$3,236	\$3,457	
Expenditures: Catamount	\$406,526	\$1,345,550	\$1,437,182	
Expenditures: ESI	\$122,969	\$407,010	\$434,728	
<b>Gross Cost Avoidance</b>	\$283,558	\$938,539	\$1,002,454	\$2,224,551
<b>State Share Cost Avoidance Estimate</b>	\$117,223	\$387,992	\$414,414	\$919,629
Gross Savings: VHAP	\$1,517,132	\$4,948,216	\$5,285,190	\$11,750,538
Gross Avoided Costs: VHAP ~ ESI & ESI	\$440,440	\$1,332,358	\$1,423,092	\$3,195,890
Total Gross Savings & Avoided Costs	\$1,957,571	\$6,280,575	\$6,708,282	\$14,946,428
One-time Administrative Costs	\$423,700			\$423,700
Ongoing Administrative Costs	\$428,614	\$554,298	\$570,927	\$1,553,839
<b>Total Savings/Avoided Costs Net of Administrative Costs</b>	<b>\$1,105,257</b>	<b>\$5,726,277</b>	<b>\$6,137,355</b>	<b>\$12,968,889</b>
State Share of Total Savings	\$456,913	\$2,367,243	\$2,537,182	\$5,361,339

### Impact to Administrative Budget

The marginal administrative costs of developing and maintaining the ESI assistance program are considerably lower than the total administrative costs of developing and maintaining premium assistance programs as a whole, including the Catamount Health premium assistance program.

The administrative costs included in the budget sheet on the prior page do not include the costs of developing and operating the Catamount Health premium assistance program or increased access due to lower VHAP premiums and the aggressive outreach campaign as required in Act 191. Those costs will be included in the new Global Commitment balance sheet and the Governor's recommended budget.

Total ESI development costs for SFY07 and SFY08 are estimated to be \$645,000, the bulk of which are costs for system development in ACCESS, the Agency's Medicaid eligibility system, and the MMIS operated by Electronic Data Systems (EDS). Remaining one-time costs are for work stations for additional staff, rule-making, brochure development, postage, and staff training.

Total ongoing administrative costs for ESI are estimated to be \$554,298 in SFY09 (assuming a three percent annual growth), including six additional staff at OVHA to perform cost-effectiveness tests and coordinate benefits between Medicaid and private insurance plans, a contract to do annual maintenance on the employer database, and additional EDS costs for issuing premium assistance payments to beneficiaries. Ongoing administrative costs in SFY08 are estimated to be \$428,614 because new positions will be phased in during the course of the year.

### Assumptions for budget impacts

- Premium assistance will be in operation for the second, third, and fourth quarters of SFY08.
- Current VHAP beneficiaries will be reviewed for cost-effectiveness over the second and third quarters of SFY08.
- Only 80% of current VHAP beneficiaries with cost-effective plans will be able to enroll in those plans in SFY08. Most employers have an annual open enrollment period during which current employees are able to enroll in ESI; some employers offer open enrollment twice per year. The administration is recommending legislation in the coming session that would make application for, or enrollment in, VHAP or Catamount Health premium assistance a "qualifying event" that would allow employees to enroll in ESI outside the open enrollment period; however, state law and regulations do not govern self-insured plans. Since approximately 40 percent of covered Vermonters are in self-insured plans, the 80 percent

estimate assumes that 20 percent of self-insured plans will not offer enrollment outside open enrollment periods.

- New VHAP applicants will enroll gradually over the 12-month period following the July 1, 2007, effective date of the premium reductions. New ESI applicants will enroll gradually beginning with the October 1, 2007, start date for ESI and Catamount Health premium assistance programs.
- Variable administrative costs, which are primarily staff costs, will increase gradually over the first 12 months of the program until full enrollment is reached.
- Only those administrative costs directly related to ESI implementation and ongoing administration have been used to offset ESI savings. Administrative costs necessary for Catamount Health premium assistance, with or without the ESI component, are not true ESI costs.
- In estimating cost savings, administrative barriers to enrollment have not been factored into the calculation. Administrative barriers could include employer lack of responsiveness to information requests, individuals' failure to follow through on verification requirements, and delay in enrollment in ESI due to job instability.
- Cost savings were estimated using actual claims for SFY06 for the individuals in the VHAP survey. Once the program is implemented, claims histories will not be available on new applicants, in which case an estimated PMPM will have to be used in the cost-effectiveness test. The estimated PMPM may result in less perfect predictions on individual cost-effectiveness than were obtained in the simulation completed for this report.

## **Section 8: Impact on Employers**

As requested by the Health Access Oversight Committee, a section on the impact to employers is added to this report.

Based on an average monthly premium cost of \$456.03 (derived from national statistics and a sampling of plans available in Vermont's small group and association market), and using an average employer contribution of 80 percent, the average monthly cost to employers is \$364.82 per enrolled employee.

Section 7 above estimates that a total of 1443 Vermonters would enroll in ESI plans as a result of the premium assistance program. The total annual cost to employers, therefore, is estimated to be \$6,317,223 using current premium costs. However, if these employees were not enrolled in their ESI plans, employers would be required to pay an annual assessment of \$365 per year per full-time equivalent, or \$526,695 for all 1443 employees assuming they work full time, potentially bringing total employer costs for ESI down to \$5,790,528.

According to a recent article published in *Health Affairs*, two thirds of employers surveyed either strongly agreed or somewhat agreed that “all employers should share in the cost of health insurance for employees, either by covering their own workers or by contributing to a fund to cover the uninsured.”<sup>11</sup> In addition, 95 percent of firms offering health insurance indicated that health benefits were very or somewhat important in improving employees’ health, and most employers answered that health benefits were important in recruiting and retaining qualified employees.

## **Conclusions**

Implementation of an ESI premium assistance program in Vermont would save money. Using even the most conservative estimates, approximately \$3 million gross per year would be saved in the SFY08-10 time period after accounting for one-time and ongoing administrative costs, and additional future costs of approximately \$1 million per year could be avoided. Although the challenges of operating premium assistance programs are great, other states have been operating such programs for years and report they are saving money as a result of those programs.

Because of the employer contribution to premium costs, it is generally less costly for the state to provide premium assistance to people in ESI plans than in Catamount Health plans. To the extent that premium assistance can be provided at a lower cost, and savings can be realized through enrolling VHAP beneficiaries in ESI, more people will be able to participate in premium assistance programs.

In addition, supporting people in ESI plans will benefit the commercial market.

For these reasons, Vermont should move forward with the implementation of ESI premium assistance.

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<sup>11</sup>“Employers’ Views on Incremental Measures to Expand Health Care Coverage,” by Heidi Whitmore, Sara R. Collins, Jon Gabel, and Jeremy Pickreign, *Health Affairs*, November/December 2006



**The Office of Vermont Health Access**

**Medicaid Generic Reimbursement Reductions and  
Dispensing Fee Study**

**January 2007**

**Prepared with**

**The University of Connecticut  
School of Pharmacy  
69 North Eagleville Road, Unit 3092  
Storrs, CT 06269-3092**



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## Acronyms, Definitions, and Identifications

AMP	The average prices for which manufacturers sell their products to purchasers. AMP represents the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.
APC	Advanced Pharmacy Concepts: Data subcontractor to UCSOP.
AWP	The average wholesale price as the manufacturer has reported it and made it available for use. AWP represents a suggested retail price to pharmacies that is determined through a survey of pharmaceutical wholesalers. The AWP as used in this analysis is as listed by Medi-Span corresponding to the NDC code submitted by the pharmacist for the drug product on the date of service when the prescription claim was processed by the pharmacy.
Brand	A drug designated as a single source or multisource brand product (N, M or O designation) in the Medi-Span database.
CCPA Claims	Coalition for Community Pharmacy Action The requests from pharmacies for payment for individual drugs for individual beneficiaries. These claims are submitted to insurers including OVHA acting as the insurer for Vermont's publicly funded pharmacy programs.
CMS CMS FUL	Centers for Medicare and Medicaid Services CMS federal upper limit: CMS established ceiling for cost reimbursement for generic drugs. The federal upper limit is the maximum allowable cost paid by a federal program for a drug that is manufactured and/or distributed by multiple manufacturers.
Discount	The calculated Vermont program discount applied to the AWP price of the drug, resulting in the discounted ingredient cost.
DRA	Deficit Reduction Act of 2005
FDB	First Databank, Inc.: Drug data and pricing supplier.
FUL	Federal upper limit: See CMS FUL.
Generic	A drug designated as a generic product (Y designation) in the Medi-Span database. In this context generic refers to a drug's status as a generic product.
IC	The ingredient cost to the Vermont programs. This is the amount paid by OVHA for the drug product, prior to dispensing fee and any copay.
MAC	Maximum allowable cost: See OVHA MAC.
Medi-Span	Drug data and pricing supplier.
MedMetrics	MedMetrics Health Partners: OVHA's PBA.

NACDS	National Association of Chain Drug Stores
NCPA	National Community Pharmacists Association
NCPDP	National Council for Prescription Drug Programs, Inc.
NDC	National drug code: A NDC is assigned to each drug and consists of three segments. The first segment identifies the manufacturer; the second segment is the product code which identifies the drug's strength, dosage form, and formulation; and the third segment identifies the package size and type.
OVHA	Office of Vermont Health Access
OVHA MAC	The maximum allowable cost paid for a drug that is manufactured and/or distributed by multiple manufacturers, as established by OVHA's PBA.
PBA	Pharmacy benefit administrator: OVHA's PBA is MedMetrics Health Partners (MedMetrics).
PBM	Pharmacy benefit manager
PDP	Medicare Pharmacy Drug Plan
Submitted Cost	The payment amount requested by the pharmacy. Claims that request a payment of less than the OVHA pricing methodology are paid at the submitted amount.
U&C	The report of usual and customary price as reported on an individual claim by the pharmacy. U&C includes both product costs and dispensing.
UCSOP	University of Connecticut School of Pharmacy
V.S.A.	Vermont Statutes Annotated
WAC	Wholesale acquisition cost

## Executive Summary

Section 107a of Act 215 of the Vermont General Assembly of the 2005-2006 Legislative Session (H.881) authorized a Medicaid generic reimbursement reduction and dispensing fee study.

While the focus of the text of this section is the anticipated reduction in Medicaid reimbursement for generic drugs under the federal Deficit Reduction Act of 2005 (H.R. 4241/S.1932) (DRA), the heading includes the study of dispensing fees.

Pharmacy business is both cost of dispensing and cost of products. The study here called for only the review of the cost of generic products affected by the DRA. To assure a thorough analysis, OVHA opted to include in the study all possible aspects of drug reimbursement in Vermont's publicly funded pharmacy programs. To assist in the study, the Office of Vermont Health Access (OVHA) contracted with the University of Connecticut School of Pharmacy (UCSOP).

The specific results related to Section 107a of Act 215 are:

1. The full potential impact of the DRA cannot be determined until federal rules proposed in December 2006 are finalized during 2007.
2. The average reported cost of dispensing individual prescriptions in pharmacies serving Vermont Medicaid is \$10.55.

Regarding Vermont programs' drug reimbursement the results are:

1. Vermont's current dispensing fee for in-state pharmacies is the highest dispensing fee of any New England Medicaid program for any pharmacy. That fee is also higher than the dispensing fees of New York Medicaid.
2. The price currently paid for brand drugs by OVHA programs is Average Wholesale Price reduced by 11.9% (AWP minus 11.9%). That is a higher price than paid by pharmacy benefit managers (PBMs) and commercial insurers in the Northeast where discounts against AWP are as much as 15.4%.
3. The Vermont Medicaid AWP reimbursement on brands is higher than the rates used by the other New England states and by the state of New York.
4. The Maximum Allowable Cost (MAC) discount/reimbursement structure for generics used by OVHA often pays less than the CMS Federal Upper Limit (FUL) generic reimbursement method commonly used by Medicaid programs in the region.
5. The OVHA MAC reduces payments more frequently than the current federal CMS FUL generic reimbursement model. With payments on generics based on the lesser of OVHA MAC, CMS FUL, usual and customary (U&C) charge, or AWP minus 11.9%, the frequency of use in this report's claims sample was OVHA MAC 66.3%, CMS FUL 15.7%, U&C 12.1%, and AWP pricing 5.9%. Thus the OVHA MAC is more

commonly less than the CMS FUL and, when it is, it results in lower payments on generics than the CMS FUL.

6. The DRA proposes to set the CMS FUL at 250% of the AMP. At that level, Vermont overall program costs would be less for generics assuming that the AMP rates available in July and August of 2006 are representative of the AMP rates as they will be used in calculating the CMS FUL.
7. While the use of AMP pricing logic for brand name medications is not called for under the DRA, at 250% of AMP the Vermont program reimbursement would increase on brands.
8. Wholesale Acquisition Costs (WAC) is considered a measure close to actual cost. OVHA currently pays more than WAC on brands but less than WAC on some generics.

In summary, Vermont publicly funded programs are paying:

- less than reported cost in the reimbursement for dispensing,
- more for dispensing than other Medicaid programs in New England and in the state of New York,
- more for brands than PBMs and other insurers in the Northeast region and Medicaid programs in other New England states and in New York state,
- more than WAC, a measure considered close to actual cost, on brands but less than WAC on some generics, and
- generally less than the generic reimbursement used by Medicaid programs in the region.

While at the moment Vermont programs may be paying less than the cost of dispensing, it appears that product reimbursement is greater than product cost in the most costly area of brands. Current generic reimbursement under the OVHA MAC while low compared to other regional Medicaid programs is more likely as a result to be closer to the DRA CMS FUL when calculated based on AMP at 250%. That means that generic reimbursement changes in Vermont programs as a result of the DRA may not be as dramatic as they may be in other states.

While things may change in the near future, there are many unknowns. Significant will be the evolving and final definitions and instructions under the DRA. Also significant will be potential national changes in the definition and use of other pricing options.

It is clear that changes are and will be occurring as early as calendar year 2007. However, at this juncture, it is impossible to completely identify them, much less assess the total impact on reimbursement for pharmacies or beneficiaries of Vermont's publicly funded programs. On a practical level, it would be unwise to consider changing reimbursement for dispensing costs as one aspect of the business, without knowing the effect of changes to the reimbursement for the products being dispensed.

## Project Background and Overview

The Deficit Reduction Act (DRA) proposes an important pharmacy related change to one of the common benchmarks used to calculate certain drug cost reimbursements to pharmacies. Historically, this benchmark, Average Manufacturer Price (AMP), has not been used for Medicaid reimbursement. In 2007, AMP will be used by the Centers for Medicaid and Medicare Services (CMS) in establishing the Federal Upper Limit on select generics.

The critical issue is that this change will have an impact on Medicaid generic drug reimbursement logic on a national basis. The current logic uses manufacturers' published prices to establish a ceiling or Federal Upper Limit (FUL) for cost reimbursement for generic drugs in federal programs when three or more generic equivalents are available. The DRA methodology will use AMP to establish the FUL for generic (also known as multisource) drugs when two or more equivalents are available.

AMP has been available to CMS for years. Section 1927 of the Social Security Act (the Act)<sup>1</sup> established the Medicaid drug rebate program that has been in operation since 1991. The Act specified that in order for a medication to be eligible for federal Medicaid funding, the manufacturer had to enter into a rebate agreement with CMS and pay rebates to the Medicaid program. AMP is one of the components identified for establishing unit rebates for each Medicaid covered drug. This unit rebate amount information is provided to the States who in turn determine the total rebates participating manufacturers owe by multiplying the unit rebate amount by the total number of units dispensed to their beneficiaries.

The Act requires that AMP be reported to CMS by the manufacturers on a quarterly basis. AMP is defined under section 1927(k)(1) as: "The average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts".

While AMP is specifically identified in the Act it cannot be considered definitive as an indication of the price of drugs. It is only one of a variety of price indicators. AMP cannot be assumed to be the actual cost drug wholesalers pay. It is a manufacturer reported data element that is related to the average cost drug wholesalers pay to the manufacturers to make drugs available for purchase to the "retail class of trade".

The actual method of AMP calculation has been shown to vary by manufacturer. A review and report by the Office of Inspector General dated May 2006 found requirements for determining some aspects of AMP not clear and comprehensive and identified a need to improve upon the timeliness and accuracy of reporting. It also found some manufacturers' methods of calculating AMP were

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<sup>1</sup> Section 1927 of the Social Security Act is located in Appendix 1.

inconsistent. To illustrate, the report cited the need to clarify the definition of “retail class of trade”. With this, the inclusion or exclusion of the pricing of drugs available to some such outlets can change the reported AMP. For example, while it would include retail pharmacies located in communities and available to the general population, the “retail class of trade” might also include those who may receive larger discounts on prescription medications not available to pharmacies practicing in community settings including mail order and limited service “closed shop” pharmacies; pharmacies solely serving institutions (for example, nursing homes); and pharmacy benefit managers making direct purchases and/or purchases with rebates.<sup>2</sup>

AMP does not reflect the prices paid by pharmacies to the wholesalers for the medications they stock and have available for dispensing. As a result, the DRA methodology proposes to set the FUL for pharmacy reimbursement at 250% of AMP.

AMP is not currently publicly available information. While the DRA proposes to make it public, at this time it is protected by law from disclosure. In the absence of information, pharmacies in Vermont and across the nation are concerned that the application of AMP in the calculation of FUL will result in a reduction in reimbursement for generic products.

The Office of Vermont Health Access (OVHA) administers the pharmacy benefit in Vermont’s publicly funded programs. FUL is used in establishing the reimbursement rate. Presently, OVHA reimburses based on the lesser of the following:

- the Average Wholesale Price (AWP) minus 11.9% plus the dispensing fee;
- the FUL plus the dispensing fee;
- the OVHA Maximum Allowable Cost (MAC) plus the dispensing fee; or
- the usual and customary charge (U&C) including a dispensing fee.

(At present, the dispensing fee in Vermont is \$ 4.75 for in-state pharmacies and \$3.65 for pharmacies outside the state of Vermont.)

On this basis, if the new FUL on a product proves to be less than the other pricing options there will be a reduction in the pharmacy payment.

Pharmacy concerns with the use of AMP are not limited to FUL pricing. As of July 2006, the AMP reported by manufacturers to CMS became available to state Medicaid agencies for the first time. With AMP information not readily available, some pharmacies report that they are worried that states may begin to base pharmacy reimbursements for all drugs, branded and generic, on AMP without adequately assessing the actual prices community pharmacies must pay for the medications dispensed.

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<sup>2</sup> The Report of the Office of Inspector General is located in Appendix 2.

Both professional pharmacy literature and the lay press have reported that the pharmacy reimbursement model presently in place may have resulted in State and Federal programs “overpaying” for the drug portion of prescription expenses due to what may be inflated drug costs. However, pharmacies nationally report that the dispensing fees that they receive from insurers have not increased adequately and in many cases have been decreased over time. To illustrate, the 2005 National Community Pharmacists Association (NCPA) digest reported the national average dispensing cost as \$9.24. While some insurers or Medicaid programs may pay this amount for unique drugs or unique types of dispensing, no known insurers or Medicaid programs currently pay this amount as a matter of routine.

To understand the implications of the DRA and the costs of dispensing in Vermont, Act 215 of the Vermont General Assembly of the 2005-2006 Legislative Session (H.881) authorized the following:

“Sec. 107a. MEDICAID GENERIC REIMBURSEMENT REDUCTION AND DISPENSING FEE STUDY

(a) The office of Vermont health access shall conduct an impact analysis of the Deficit Reduction Act of 2005 (H.R. 4241/S.1932) on pharmacists and the Vermont pharmacy benefits program. Specifically the office shall evaluate:

(1) The impact of the generic drugs provision on Vermont pharmacists and on program participants in Medicaid.

(2) The state’s potential direct savings due to the generic drug change.

(b) The office shall provide preliminary findings to the legislative health access oversight committee and the legislative joint fiscal committee by September 1, 2006, with a final report to be submitted to the above committees by November 15, 2006.”<sup>3</sup>

While the focus of the text of this is generic reimbursement, the section heading includes the study of dispensing fees. With pharmacy business expenses being both the cost of products and the cost of dispensing, OVHA concluded that it was necessary to study all product costs for beneficiaries enrolled in Vermont’s publicly funded pharmacy programs to the extent possible.

On August 31, 2006, the Office of Vermont Health Access (OVHA) entered into a contract with the University of Connecticut School of Pharmacy (UCSOP) to advise, assist, and perform aspects of this study. To accomplish this goal, resources of the UCSOP were augmented with the services of Advanced Pharmacy Concepts (APC) as a subcontractor. Together, this team analyzed Vermont program pharmacy claims and conducted a survey of pharmacies providing services to beneficiaries of those programs.

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<sup>3</sup> OVHA requested and the committees granted an extension to submit the final report in January 2007.

In soliciting a contractor OVHA specified the following:

**Scope of Work:**

Minimally the project related to Vermont administered pharmacy programs will include:

1. an evaluation of current reimbursement in comparison to public and private insurers;
2. an evaluation of the frequency of generic use in Vermont programs, both in terms of generic equivalents and alternatives;
3. an evaluation of branded drug pricing options;
4. an evaluation of the generic drug pricing options;
5. a comparison of current pricing to the Average Manufacturer Price (AMP) as made available by the Centers for Medicare and Medicaid Services (CMS);
6. a comparison of current pricing to any other pricing information provided by CMS;
7. an evaluation of non-standard pricing considerations including but not limited to drugs available through mail order, drugs available through specialty pharmacies, and compound drugs;
8. an evaluation of potential program savings from reduced costs for generic reimbursement;
9. the soliciting of input from pharmacies enrolled as providers in Vermont programs;
10. an evaluation of the potential business revenue losses to pharmacies from reduced generic reimbursement;
11. a comparison of cost of dispensing information as made available by pharmacies enrolled as providers in Vermont programs; and
12. an assessment of the impact of the generic price reduction on program beneficiaries' out of pocket costs.

**Significant Duties:**

- pricing and utilization data analysis involving Vermont pharmacy claims;
- pricing and utilization data analysis involving all active National Drug Codes (NDCs);
- research and analysis on pricing options and models;
- the convening and management of a provider group to assist in the information gathering of this project;
- the analysis of pharmacy business costs as made available by pharmacies;
- assisting in the resolution of differences or questions concerning data or analyses; and

- the completion of preliminary and final reports detailing the process, the description and compilation of data and analysis, and the conclusions.

## **Project Methodology**

### **Pharmacy Claims Analysis**

To conduct the assessment of pharmacy pricing options and utilization, APC obtained detailed individual pharmacy claims for coverage under Vermont's publicly funded programs. Claims were obtained in an electronic file format that included individual claim transaction records with pharmacy identification, National Drug Codes (NDCs), product quantities, and costs.

APC assessed the data file for accuracy and completeness, verifying that data fields were uniformly populated with required information according to the data dictionary provided by OVHA's pharmacy benefits administrator (PBA) and claims processing agent, MedMetrics Health Partners (MedMetrics).

APC subscribes to Medi-Span<sup>4</sup> pricing services and used these industry standard databases in the pricing and claims analysis. Medi-Span drug data files contain reference pricing information, including average wholesale price (AWP), wholesale acquisition price (WAC), and the CMS federal upper limit (CMS FUL) as reported by CMS. Using the Medi-Span file records, APC populated each claim in the OVHA transaction file with AWP, CMS FUL, and WAC prices, based on the NDC code of the claim as submitted by the pharmacy, for the date of service.

To complete the pricing assessment based on the DRA requirements, APC required Average Manufacturer Price (AMP) information. OVHA supplied this pricing information as it was provided by CMS for July and August 2006.

Because pharmaceutical prices change frequently, it was essential that the pricing comparisons be conducted during the time period that was common to all data resources.

APC received pharmacy records for 1,723,213 paid, denied, and pharmacy voided claims with a date of service between March and August 2006, the period established for the pharmacy cost of dispensing survey. Ultimately only July and August claims were used because AMP pricing data was not made available for release by CMS for dates prior to July 2006. Given this situation, analysis and comparison of pharmacy pricing was limited to claims with a date of service of July and August 2006.

Other claims were not included when conducting the pricing assessments for the following reasons:

- Only paid claims were used.

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<sup>4</sup> MediSpan is a registered trademark.

- Drug claims paid on behalf of Medicare Part D beneficiaries were eliminated because Vermont reimbursement for these is limited to each beneficiary's costs for each drug under his/her Medicare Pharmacy Drug Plan (PDP). Payments are not based on OVHA's reimbursement methodology.
- OVHA does not have a mail order contractor for its programs so no mail order claims were used.
- Compound claims were excluded from the overall drug pricing analysis because they are priced with logic different from other pharmacy claims. Since more than one product is necessary to make a compound drug, multiple products are included in a single claim and those products may be both brands and generics.
- Claims that appeared to have been billed for an abnormally low amount in comparison with AWP were eliminated because of the high likelihood that they were billed in error.

After parsing the data, APC retained a final working data set of 240,747 July and August claims upon which to proceed with a comparative analysis.

### **Pharmacy Business Cost Survey**

The UCSOP reviewed contemporary literature to gather insight and knowledge pertaining to the costs involved in prescription dispensing prior to producing a draft survey for presentation to and discussion with OVHA staff and key pharmacy stakeholders. In addition, pharmacy professional associations and other surveys performed for the purposes of measuring the cost of dispensing were queried and reviewed for a better understanding of practical methods for gathering and reporting the cost components involved in the dispensing process. A number of the documents were referenced to help with the formulation of the Vermont cost of dispensing survey including documents prepared by the Center for Pharmacoeconomic Studies at the University of Texas at Austin, the National Association of Chain Drug Stores and the National Community Pharmacists Association.<sup>5</sup> In addition, surveys and tools prepared by other states were also reviewed including documents from Texas, California and Maine.

Consideration was given to the complexity of accurately measuring costs once they were identified. In many pharmacy settings, business activities other than prescription dispensing occur. While the business as a whole may accumulate and pay for expenses as a single unit, for the purposes of this analysis, procedures were needed to measure that portion of those expenses that could be accurately attributed to the prescription dispensing activities. To illustrate, a pharmacy may have within its location a space equal in size to the prescription department dedicated to the sales of over-the-counter medications. While it is fair to calculate a way to allocate expenses such as taxes and rent based on the relative areas of the two departments, other expenses needed to be allocated

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<sup>5</sup> A sample of documents referenced is included in Appendix 3.

based on such things as the relative sales or the relative payroll expenses the two departments experienced. Methods and strategies were developed and implemented to calculate reasonable estimates to allocate expenses incurred by the whole pharmacy operation to come as close as possible to calculating all the expenses that could be directly attributable to the prescription dispensing segment of the business while eliminating those expenses that had no bearing on that activity.

Beginning and ending dates of the business period for the survey had to be established. Ideally, this period had to be uniform for all respondents, recent enough to be as close as possible to present conditions, representative of typical business conditions and long enough to minimize as best as possible variations due to seasonal or extraordinary events. Finally, the study period had to meet all of these criteria while allowing a reasonable amount of time to gather and report the data.

The decision was made with staff at OVHA to select the time period of March 1 through August 31, 2006. The Coalition for Community Pharmacy Action (CCPA) formed through the joint efforts of the National Community Pharmacy Association (NCPA) and the National Association of Chain Drug Stores (NACDS) created and released a nationwide survey on October 17, 2006 using the same study period.

In September 2006, the survey tool was developed to gather all the needed data elements in a way that made the process as simple and straightforward as possible for the pharmacies. This had importance for at least two reasons. First, a goal of the survey was to collect as many complete and usable responses as possible. Second and closely related, time limitations necessitated a survey tool that could be completed, returned, and analyzed within the period available.

A meeting was held at the OVHA office in Williston, Vermont on September 18, 2006 to discuss the draft survey tool with pharmacy stakeholders. Present at the meeting representing practicing pharmacists was Anthony Otis, Legislative Liaison for the Vermont Pharmacists Association. Participating in the meeting via telephone were Brian Bruen, Director, Policy Studies and Research for the NACDS and Philip O'Neill, a Vermont pharmacy owner. The survey draft was discussed and a number of suggestions were made to improve the tool.

A revised draft was prepared and disseminated to the meeting participants for final comments and suggestions. On September 26 the final survey data collection tool and instructions were approved by OVHA and plans were made to produce and mail the surveys.

On September 28 survey forms and instructions were mailed to the attention of pharmacy managers of each of the pharmacies identified by OVHA.<sup>6</sup> The

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<sup>6</sup> A survey tool, cover letter, confidentiality letter and instructions are located in Appendix 4.

pharmacy managers of pharmacies located in states other than Vermont with a history of providing pharmacy services to residents of Vermont were also mailed a survey packet. Generally, these are pharmacies located in states bordering Vermont. Pharmacies that appeared to have no consistent usage and were not located in Vermont or a contiguous state were not mailed a survey packet. In total, 232 surveys were mailed. Of the total survey packets mailed, 146 were to in-state pharmacies.

In addition to each mailing made through the postal system, survey forms and instructions in an electronic format were emailed to Anthony Otis and Brian Bruen as a way to facilitate timely delivery. A version of the survey tool designed to facilitate reporting by companies operating multiple pharmacy outlets was prepared and this was emailed to persons identified by Mr. Bruen as people employed by these companies who could help facilitate the survey reporting process.

On October 3, an evening conference call was arranged by Anthony Otis and Brian Bruen for the purpose of introducing the cost of dispensing survey to the pharmacists of Vermont and facilitating their support of and participation in the process. The call began with an overview of the survey tool and instructions, followed by a question and answer period. An estimated 25 to 30 pharmacists participated in the call. As a result of this call, a change was made to the survey tool to clarify issues regarding primary payment source for the purposes of statistics. A follow up email communication noting the clarification was prepared and disseminated. A concern was also raised with regards to the confidentiality of the sensitive proprietary business data being asked for in the survey process. To address these concerns, a letter was drafted, reviewed and disseminated by OVHA to the pharmacists.

Survey responses were due back at the UCSOP by October 20.

On October 11 a reminder post card was mailed to each of the pharmacy managers. The first completed survey response arrived on October 13. Allowing for possible delays due to potential mail delays, survey responses received as late as November 10, 2006 were included in the analysis.

## Report of Findings from Claims Analysis

For the purpose of any claims analysis, the definitions found in the Acronyms, Definitions, and Identifications found on page 1 of this report have been used. All Vermont expenditures represented are gross payments, including both state and federal portions of cost. All payments are before the collection of any manufacturer rebates.

### Evaluation of Current Reimbursement

The Vermont program reimbursement during the audit time period was the lower of the pricing methods indicated below:

PHARMACY TYPE	DRUG REIMBURSEMENT	DISPENSING FEE
In Vermont	AWP – 11.9%	\$4.75
In Vermont	CMS FUL	\$4.75
In Vermont	OVHA MAC	\$4.75
In Vermont	U&C/Submitted	Included in U&C/Submitted
Out of Vermont	AWP – 11.9%	\$3.65
Out of Vermont	CMS FUL	\$3.65
Out of Vermont	OVHA MAC	\$3.65
Out of Vermont	U&C/Submitted	Included in U&C/Submitted

With no mail order contractor, OVHA does not have differential pricing between retail pharmacies and contracted mail order pharmacies. Thus, there were no such mail order pharmacy claims during the assessment time period.

The review was applied to the 240,747 July and August claims available for comparison. The following pricing options were considered on each claim:

- the pharmacy reported U&C/submitted on the date of service adjusted by the amount of the Vermont programs' dispensing fee to arrive at the reported cost of the product
- the AWP for the product reduced by 11.9% on the date of service
- the OVHA MAC for the product on the date of service
- the CMS FUL as applied on the date of service

Each claim was then “priced” for the purposes of this analysis at the lower of the options.

### Evaluation of Branded and Generic Pricing

#### *Overall Pricing*

Based on the claims review, APC determined that the overall discounts against AWP achieved in Vermont publicly funded programs were as follows:

	Claims	VT paid IC	AWP	Discount
<b>Brand</b>	90,635	\$14,356,176	\$16,297,663	11.913%
<b>Generic</b>	150,112	\$2,884,677	\$7,686,918	62.473%

While OVHA prices branded drugs at AWP minus 11.9%, the slightly higher discount found in claims can be further assessed by reviewing the “basis of cost” that was applied to individual claims for payment purposes.

### ***Branded Pricing***

The chart below indicates the 11.913% discount was achieved on claims that were paid on differing basis of cost. Certain brand medications were paid at a cost basis other than solely AWP:

- In some cases branded drugs were actually paid at the pharmacy’s usual and customary charge.
- In other cases a brand was priced at the generic OVHA MAC or the CMS FUL. While MAC and FUL are usually applied to generic claims, they are the basis of payment for a small number of brand claims when a pharmacy is using a brand product as its “house” generic. In this situation, a pharmacy purchases a brand drug at a discounted price that is comparable to the price of its generic equivalents. When the brand has two or more generic equivalents, the pharmacy receives the generic rather than brand reimbursement.
- On occasion Medi-Span updates AWP prices retrospective to the actual effective date of the price change. This practice results in slight variation in actual AWP discount performance. The Vermont results based solely on AWP are within the level of variation that is expected due to such retroactive price changes.

	Claims	VT paid IC	AWP	Discount
<b>Brand Breakdown</b>				
U&C	2,025	\$218,166	\$247,586	11.883%
Submitted Cost	31,592	\$4,924,823	\$5,589,114	11.885%
OVHA MAC	333	\$5,253	\$11,343	53.684%
CMS FUL	37	\$317	\$558	43.227%
Discount off AWP	56,648	\$9,207,617	\$10,449,062	11.881%

### ***Generic Pricing***

An analysis of generic claims on the basis of cost is also possible. OVHA MAC and CMS FUL prices are applied only to those generic medications that are manufactured and/or distributed by multiple manufacturers. For the July and August period of analysis, MAC and FUL prices were available when there were three or more generic equivalents available. When the generic used was a single source generic product or a generic where only two equivalents were

available, payment would have been based on usual and customary/submitted rates or the AWP discount.

	Claims	VT paid IC	AWP	Discount
<b>Generic Breakdown</b>				
U&C	2,743	\$60,965	\$100,193	39.153%
Submitted Cost	15,424	\$357,633	\$535,226	33.181%
OVHA MAC	99,543	\$1,903,173	\$5,654,027	66.340%
CMS FUL	23,563	\$153,523	\$932,789	83.542%
Discount off AWP	8,839	\$409,384	\$464,683	11.900%

### ***OVHA MAC/CMS FUL Pricing***

In many reimbursement models, CMS FUL prices achieve a discount between 65% and 70% off AWP, depending on the mix of products dispensed. OVHA's CMS FUL performance in July and August was higher because the FUL was only applied when the price was lower (discount was higher) than the OVHA MAC price. The combination of both the CMS FUL and OVHA MAC demonstrates the total Vermont program discount at 68.776%.

	Claims	VT paid IC	AWP	Discount
OVHA MAC	99,543	\$1,903,173	\$5,654,027	66.340%
CMS FUL	23,563	\$153,523	\$932,789	83.542%
Total of MAC and FUL	123,106	2,056,696	6,586,816	68.776%

### **Evaluation of Generic Usage in Vermont Programs**

APC evaluated generic dispensing in the OVHA programs. Use of generic products has been seen to be the single most valuable cost-saving initiative that can be implemented by any insurer.

Generic dispensing rates can be expressed in a variety of ways. The "generic dispensing rate" is a term used to refer to the number of prescriptions dispensed using generic medications as a percentage of all prescriptions dispensed. Not all drugs have generic equivalents available. The "generic substitution rate" is a term used to refer to the number of prescriptions that are dispensed with a generic medication when an equivalent generic version of the drug is available. Generic versions of medications are only available when a brand (innovator) medication has lost patent protection. In general, generic dispensing reflects the extent to which generics are used in a program, while generic substitution represents both the prescribing instructions of the physicians and other prescribers and the dispensing practices of the pharmacies.

The generic dispensing rate for the covered populations in Vermont's programs has been somewhat consistent in the last year. For the fourth quarter of calendar year 2005, the last quarter prior to Medicare Part D implementation, the

generic dispensing rate was 61.37%. For the quarter ending June 30, 2006, the rate was 61.47%. In this project's 240,747 claims during July and August 2006, the rate was 62.4%.

For this analysis, both drugs characterized as generics (Y designation) and branded drugs available from multiple manufacturers (referred to as "multisource drugs"; M designation) are used in the calculation of generic substitution.

In December 2005, the overall generic substitution rate for all generic claims when a generic equivalent was available was 97.7%. This is exactly the rate in the July/August 2006 claims.

To recap, the following chart identifies generic usage in Vermont's publicly funded programs:

<b>Jul – Aug 2006</b>	<b>Percentage of Rx</b>
Generic use as a percentage of all drugs dispensed	62.4%
Generic use when generic equivalent available	97.7%

In the experience of APC, these Vermont program generic indicators are excellent for their respective categories when compared to commercial drug benefit programs.

That success is a tribute to Vermont's generic drug law at 18 V.S.A chapter 91 where pharmacies dispense generics unless the prescriber expressly requires the brand. It can also be attributed to the activities of the Vermont Best Practices and Cost Containment Program established by 33 V.S.A. chapter 19, subchapter 5 and the program's Drug Utilization Review Board that serves as the pharmacy and therapeutics committee for OVHA.

### **Comparison of Current Pricing to Average Manufacturer Price (AMP)/ Potential Savings from Reduced Costs for Generic Reimbursement**

APC compared OVHA's current drug pricing and AWP pricing to the AMP prices that were supplied by CMS to OVHA for July and August 2006.

AWP is reported based on the NDC code of each strength and package size of medication, and prices may differ between packages. AMP is reported for each drug dosage form and strength, regardless of package size. To conduct an assessment of brand pricing, APC used the AWP prices reported for each product by NDC code and compared prices to the actual AMP as reported by CMS for that particular drug on a claim by claim basis.

In addition, assessment of generic drug prices required additional consideration. OVHA MAC and CMS FUL prices were determined through a formula that takes

into account the list prices for a specific drug strength and dosage for all manufacturers that supply the product to the market.

The CMS FUL as currently available applies only when three or more generic equivalents are available. Under the DRA, the CMS FUL will be calculated when there are two or more equivalents. To duplicate the reimbursement levels established in the DRA, APC created a “FUL”-like price using AMP for generics with two or more manufacturers. To further duplicate the DRA methodology, APC applied the lowest AMP reported by any manufacturer for all “like” generic drugs as the basis for calculating the AMP. For example, if five manufacturers each make the same dosage form and strength of a particular medication, they report their AMP for that particular generic drug/strength. The lowest of the reported five prices is used as it would be by CMS applying DRA requirements.

	Claims	AWP	VT paid IC	Current Discount	Proposed VT paid IC with AMP at 100%	Discount at 100% AMP	AMP at 250%	Discount at 250% AMP
<b>Brand</b>	90,635	\$16,297,663	\$14,356,176	11.9%	\$11,794,995	27.6%	\$29,487,488	-80.9%
<b>Generic</b>	150,112	\$7,686,918	\$2,884,677	62.5%	\$493,274	93.6%	\$1,233,185	84.0%
<b>Generic: No OVHA MAC/CMS FUL</b>	27,006	\$1,100,101	\$827,982	24.7%	\$158,956	85.6%	\$397,389	63.9%
<b>Generic: OVHA MAC/CMS FUL</b>	123,106	\$6,586,817	\$2,056,696	68.8%	\$334,318	94.9%	\$835,796	87.3%
<b>Total VT paid IC</b>	240,747	\$23,984,580	\$17,240,854	28.1%	\$12,288,269	48.8%	\$30,720,673	-28.1%
<b>VT paid IC per Rx</b>			\$71.61		\$51.04		\$127.61	

As noted in the above chart, AMP prices are inherently considerably lower than AWP. Using 100% of AMP in place of the current AWP discounted rate on brands would result in a discount of 27.6% as compared to 11.9% off AWP prices based on the drug mix and volume assessed from the OVHA claim sample for July and August 2006. It would also create a discount on all generics. For this two month claim sample the reduction would be nearly \$5 million. The actual amount would depend on market share and prescribing habits, but a per claim decrease of anywhere from \$17 to \$21 across all prescriptions might be expected.

100% of AMP represents the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. In turn the wholesalers set prices to sell the products to pharmacies. Those prices are not available for this analysis but they are certainly not equal to AMP, markups would be expected. Conceptually the DRA methodology of setting the new CMS FUL at 250% of

AMP is at least partially in recognition of that. However, applying 250% to AMP has a very different effect on generics than it does on brands.

Comparing the current reimbursement to the AMP at 250% on the 150,112 prescriptions filled with generic medications results in a reduction in spending of \$1.7 million with a per prescription variance of \$11 for the two month period of analysis. Looking at brand drugs and applying the same 250% methodology results in prices that significantly exceed their AWP prices. This would result in a program reimbursement increase on brands of \$15.1 million based on that two month period.

### **Potential Pharmacy Revenue Losses from Reduced Generic Reimbursement**

Any reduction in program spending based on AMP results is a loss in revenue to community pharmacies. The actual amount is impossible to assess at this time.

The CMS proposed rule to implement the provisions of the DRA pertaining to prescription drugs was published on December 22, 2006. Interested parties have until February 20, 2007 to review and comment. While federal rules are effective as proposed during the comment period, formal questions and comments submitted must be addressed by CMS and changes are likely. At this point it is unknown when the FUL will fully reflect the effect of the use of AMP.

Thus, a true estimation of any related reduction in generic reimbursement is not possible.

### **Assessment of the Impact of Generic Price Reduction on Program Beneficiaries' Out of Pocket Costs**

In Vermont programs, only traditional Medicaid eligibles currently have cost sharing. That cost sharing is in the form of copayments and the amounts depend on the cost of the drug to the Medicaid program as established applying OVHA's pricing methodology:

- \$1.00 for prescriptions costing \$29.99 or less
- \$2.00 for prescriptions costing \$30.00 to \$49.99
- \$3.00 for prescriptions costing \$50.00 or more

If a drug is priced at a lower amount because of AMP and thus the related CMS FUL, a beneficiary may experience a savings of \$1 or \$2 per drug depending on the resulting difference in pricing.

## **Comparison of Current Pricing to Other Pricing Information**

While CMS has not provided any other pricing information in the course of this study, additional information is available on pricing related matters.

### **340B**

The federal 340B Drug Pricing Program makes reduced price prescription drugs available to health care facilities certified by the U.S. Department of Health and Human Services (HHS). Under the 340B Program, the discounted drugs are obtained from manufacturers at a negotiated price that can be comparative to the Medicaid price net of the national federal Medicaid rebates. Under 340B regulations the drugs are not additionally subject to Medicaid rebates since the manufacturer provides the 340B discount.

The 340B Program provides a significant service in the community. However, drugs provided under the Program do not reduce Medicaid spending. Pricing methodologies used in Vermont programs pay 340B facilities exactly as they do all pharmacies without any adjustments. Facilities certified to dispense 340B drugs are not obligated to share their discount with Medicaid when drugs are dispensed on behalf of Medicaid beneficiaries. Unless 340B facilities bill the Vermont Medicaid programs at a price at least equal to their discount, Vermont actually pays more for 340B drugs than drugs obtained in community pharmacies.

### ***Possible Changes in the Use of AWP in Pricing***

In October 2006 the United States District Court, District of Massachusetts ruled on a nationwide lawsuit brought by private insurers against First Databank, Inc. (FDB), a source of prescription drug data and prices in the United States (C.A. No. 1:05-CV-11148-PBS). The suit alleged that First Databank conspired with a leading prescription drug wholesale provider, the McKesson Corporation, to arbitrarily increase the markups between what pharmacies pay wholesalers for prescription drugs through the setting and publishing of AWP. This AWP as published by First Databank and then referenced by major pricing services like Medi-Span is used by many insurers to calculate pharmacy reimbursements for many prescription drugs. AWP is used in Medicaid pricing by forty-eight states and the District of Columbia.

In the settlement of this case FDB agreed to adjust published prices. The projected date of this adjustment is spring 2007. While there is no retroactive adjustment available to public programs like those in Vermont, there will be an impact in the future in the form of a reduction in reimbursement on brand drugs that have been priced based on AWP. Estimates vary from 4-5%. Using the two month claims period available from the claims analysis, the following table estimates a potential two month impact based on 4%:

	Claims	AWP	VT paid IC	Current Discount	AWP reduced by 4%	VT paid IC with 11.9% discount on reduced AWP	Change in VT paid IC
<b>Brand</b>	90,635	\$16,297,663	\$14,356,176	11.9%	\$15,645,756	\$ 13,783,911	\$572,265

### **OVHA MAC**

The OVHA maximum allowable cost (MAC) is applied to generics when three or more generic equivalents (AB rated) are available. The MAC price is established based on the prices of the products as readily available. The use of a MAC list discourages the use of the more expensive generic equivalent alternatives.

### **WAC**

A pricing option used by insurers not otherwise addressed in this project is Wholesale Acquisition Cost (WAC).

Wholesale acquisition cost (WAC) is reported by pharmaceutical manufacturers and represents the “list” price for which a pharmaceutical product is sold to the wholesaler. Actual sale prices are often lower, reflecting contractual terms, payment discounts, and other incentives offered by manufacturers to wholesalers. WAC is often considered the cost basis that is used by pharmaceutical wholesalers for sales to retail pharmacies. Pharmacy purchase prices are commonly in a range that is a few percentage points above or below WAC price, based on payment terms and incentives.

Several state Medicaid programs, including Rhode Island and Massachusetts, have adopted WAC pricing as a basis of payments to pharmacies. To demonstrate the financial impact of this option to OVHA, APC assessed WAC prices against current discounted drug pricing and to AWP pricing that is listed in Medi-Span using NDC codes submitted by the pharmacies. Because WAC price reporting is voluntary, a WAC price is not available for some products. In assessing OVHA’s 240,747 available claims from July-August 2006, WAC price could be determined for only 225,961 claims. The table on the following page outlines the results of this analysis:

	Claims	AWP	VT paid IC	Current Discount	Proposed IC with WAC at 100%	Discount at 100% WAC
<b>Brand</b>	88,990	\$16,190,852	\$14,262,279	11.9%	\$12,934,828	20.1%
<b>Generic</b>	136,971	\$7,146,132	\$2,595,597	63.7%	\$3,524,921	50.7%
<b>Generic: No OVHA MAC/CMS FUL</b>	114,345	\$6,249,458	\$1,938,649	69.0%	\$2,932,875	53.1%
<b>Generic: OVHA MAC/CMS FUL</b>	22,626	\$896,675	\$656,948	26.7%	\$592,046	34.0%
<b>Total VT paid IC</b>	225,961	\$23,336,984	\$16,857,876	27.8%	\$16,459,749	29.5%
<b>VT paid IC per Rx</b>			\$74.61		\$72.84	

### Comparison to Public and Private Insurers

The Vermont Medicaid AWP reimbursement on brands is higher than the rate used by the other New England states and by the state of New York. Massachusetts and Rhode Island both use WAC at a rate that results in a lower reimbursement. Maine, New Hampshire, Connecticut, and New York use AWP discounts that range from 12.75% to 16%.

The Vermont program brand reimbursement is higher than commercial insurers. On average, PBMs and commercial insurers obtain AWP discounts of 15.4% for brand medications dispensed in retail pharmacies in the Northeast.<sup>7</sup> Using the drug analysis on the 240,747 claims where the Vermont programs paid \$14.4 million dollars for branded drugs in July and August 2006, the estimated result of a change in the brand discount rate from the current rate of AWP – 11.9% to AWP -15 % would lower the amount paid for those two months by \$400,000.

The current Medicaid discounts achieved by OVHA for generic drug prescriptions are as deep as or deeper than those obtained by other insurers. These savings are largely associated with the established OVHA MAC program. Its results are comparative to those of Massachusetts Medicaid which uses a similar MAC methodology. They exceed those produced in Medicaid in the other New England states and in the state of New York. The other states use WAC or current CMS FUL for generic reimbursement. OVHA's discount may actually exceed the discounts obtain by commercial benefit programs.

<sup>7</sup> Takeda Prescription Drug Benefit Cost and Plan Design Survey Report, 2006 edition (New England and New York)

## **Evaluation of Non-Standard Pricing Considerations**

### ***Mail Order Pharmacies***

Mail order pharmacies are commonly used by many insurers for beneficiaries with maintenance needs for drugs. Brand discounts for prescriptions filled in mail order pharmacies are higher than those offered in retail pharmacies. In general, brand discounts range from 21% to 23%.<sup>8</sup>

Two major issues exist with mail order pharmacies, waste and access. Mail order pharmacies generally dispense 90 day supplies. Savings may be reduced by an increase in drug waste when drugs dispensed are not used<sup>9</sup>. Coverage design must be carefully planned to minimize this. Assuring accessibility means that savings may only apply to a portion of an insurer's business. To assure accessibility, some insurers have opted to create networks of local pharmacies that contract to provide 90 day supplies of defined drugs at prices comparative to mail order pharmacies.

### ***Specialty Pharmacies***

Specialty pharmacies provide a product or products intended to treat specific issues. Common are:

- Diabetic supplies
- Multiple sclerosis drugs
- Growth hormone drugs
- Hemophilic drugs
- Unique treatment drugs (for example, Synagis® used to treat respiratory syncytial virus, a respiratory ailment unique to newborns that are born prematurely).

For drugs as opposed to diabetic supplies, savings are realized because the cost to have products available may be less for pharmacies who order in sufficient quantities to benefit from discounts. In some cases best savings are likely to be found when contracting with a pharmacy or even a manufacturer based on a drug or drugs to treat a single condition. Amounts are impossible to predict as they are dependent on individual contracts. Actual drug savings may be reduced by options offered by specialty pharmacies but the options may result in better product use and/or health outcomes; for example, counseling.

In the case of products with broad use like diabetic supplies, specialty pharmacies may be an option but it may also be possible to obtain greater savings through supplemental rebate contracts directly with the manufacturer(s). The latter assures that the products remain readily available in the community.

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<sup>8</sup> IBID

<sup>9</sup> American Journal of Health-System Pharmacy. 58(13):1190-1191, July 1, 2001

## ***Compound Drugs***

Compound drugs present challenges to all insurers in the management of the pharmacy benefit. At the direction of a prescriber, a compound drug is one made by a pharmacy by combining a drug or drugs and/or other ingredients to create a unique drug and/or method of administration.

Compound drugs are a small portion of Vermont publicly funded pharmacy programs. In state fiscal year 2006, a total of \$275,211 was paid for compound drugs in comparison to a \$168 million drug spend. With the implementation of Medicare Part D coverage on January 1, 2006 and the transition of 30,000 Vermont program beneficiaries to Part D as primary coverage, the number of compound drug claims has decreased. In calendar year 2005, 4,920 compound drug claims were paid out of a total of 3 million claims. In calendar year 2006, there were 3,632 compound claims out of 2.4 million claims.

Compound drugs were excluded from the claims analysis of pricing in this report because they are priced with logic uniquely different from other pharmacy claims. Since more than one product is necessary to make a compound drug, multiple products are included in a single claim and those products may be a combination of brand and generic entities.

Vermont Medicaid policy at M813.3 allows for the payment of compound prescriptions based on the “lower of the actual amount charged or the price of ingredients plus the dispensing fee plus a compounding fee on file for each minute directly expended in compounding.” The fee for each minute is \$.35.

Prior to 1993 pharmacies submitted claims for compound drugs using paper claims. By late 1993, most all other pharmacy claims could be submitted electronically. There was a significant advantage in electronic claims. Paper claims took as much as 30 days to process to payment. Approved electronic claims paid within two weeks and sometimes within one.

In an effort to expedite payment on compound claims, pharmacies were allowed to use a single NDC-like code to bill for ingredients and time. Initially they were allowed to bill for claims up to \$20. Claims over \$20 required a paper claim indicating the specific ingredients and minutes. This threshold was subsequently raised to \$50 and \$100 in recognition of increasing ingredient costs.

The Deficit Reduction Act of 2005 expressly requires the full identification of all drug ingredients. With the implementation of a new claims processing system as of January 1, 2006, it was possible to electronically bill based on individual ingredients. In turn, those ingredients were paid based on the pricing methodology for each product. Initially the standard dispensing fee was paid: \$4.75 for in-state pharmacies, \$3.65 for out-of-state pharmacies. However, this

did not provide any reimbursement for time compounding. OVHA began paying \$5.25 for each compound claim over and above the standard dispensing fee. This amount is equal to an estimated average time of compounding of 15 minutes at \$.35. Pharmacies have indicated that that is insufficient.

A survey of Medicaid states in March 2006 resulted in twenty-five responses. Nineteen states paid for compound drugs with no additional dispensing fee. Two paid an additional fee of less than \$5. Three paid fees based on varied methods.

Certainly applying a single fee is administratively simpler for claims submittal and processing for all concerned. For some pharmacies with varied compound drugs, this aggregate approach is adequate. However, depending on the type of compounding, some pharmacies may be overpaid while other pharmacies are underpaid. At issue is the level of effort and/or degree of difficulty in preparing the compound product.

Some private insurers apply the same approaches as Medicaid programs. Others recognize some degree of effort and difficulty. The National Council for Prescription Drug Programs, Inc. (NCPDP) sets the standards for electronic drug claims processing. NCPDP does not include standards for time increments but does allow for up to 5 levels of effort in compounding drugs that can be premised on time. Allowing for such levels assures that pharmacies are reimbursed for their specific efforts in compounding drugs.

Many PBMs/PBAs and pharmacy insurers set requirements to address adequate clinical and financial management of compound drugs. Criteria address certain expectations. Prior authorizations are commonly required or compounds are subject to post payment review such that claims are disallowed for failing to meet the criteria. Some criteria examples include:

- the safety and effectiveness of the compound and its prescribed use must be supported by medical and scientific evidence found in peer-reviewed studies, medical journals, peer-reviewed literature, biomedical compendia, and other medical and pharmacological literature;
- compounds cannot be substitutions for combinations of over-the-counter products; one or more prescription ingredient must be included in the compound;
- all prescription ingredients must be FDA approved for medical use in the United States;
- the compounds may not be a copy of a commercially available FDA approved product; and
- the compound may not be a substitution for a readily available FDA approved product.

### ***Vermont's Pharmacy Fee***

On July 1, 2005, Vermont pharmacies began paying a per prescription fee to the state in support of publicly funded health insurance programs. For every prescription filled, regardless of payer, the pharmacy pays \$.10 per claim.

For state fiscal year 2006, Vermont pharmacies paid a total of \$748,733 through January 7, 2007. For the first quarter of state fiscal year 2007 the amount paid was \$193,924 through the same date.

### ***Medicare Part D***

With the implementation of drug coverage under Medicare Part D, 30,000 people were transitioned from Vermont programs to Part D for primary pharmacy coverage. At the same time as many as 60,000 other Medicare eligibles became potentially eligible for Part D. From a pharmacy business position, Part D meant Part D Prescription Drug Plan (PDP) payments and cost sharing replaced payments from Vermont's programs and uninsured customers.

### ***Generic Drug Discount Programs***

In the fall of 2006 major national retail outlets announced generic drug discount programs. Since that time other department and food stores with pharmacy departments have begun or are considering similar programs. These programs do not apply to all generics. Each uses a specific list of generics. Vermont examples are Wal-Mart and Price Chopper.

In the case of Wal-Mart, the program is available to anyone for select generics for \$4 for 30 units. Initially this was reported as 30 days but it has now been amended to "up to" 30 days. This price is available to Vermont publicly funded programs. However, the programs only benefit from the price if beneficiaries can readily access the stores.

Price Chopper offers a 100 unit program for \$10. It is only available to customers who pay cash; Price Chopper will not bill any insurer including Vermont's programs.

While representatives of these stores report that they do not lose money on their programs, some observers believe that their purpose is to increase the stores' other retail business. Thus, the price offered may or may not reflect what other pharmacies can offer.

## Report of Findings from Cost of Dispensing Survey

Copies of the pharmacy survey cover letter, survey collection tool, and survey instructions can be found in Appendix 4.

The following summarizes surveys mailed and the response rate:

	<b>Vermont In-state Pharmacy</b>	<b>Out-of-state Pharmacy</b>	<b>Total</b>
<b>Pharmacy Mailing list</b>	146	92	238
<b>Surveys Mailed</b>	146	86	232
<b>Surveys undeliverable</b>	1	1	2
<b>Total responses</b>	69	2	71
<b>Usable responses</b>	62	0	62
<b>Response rate</b>	47.6 %	2.4 %	29.8 %
<b>Usable response rate</b>	42.5 %	0 %	26.1 %

In total there were 71 survey responses received. Of these, 7 of the responses were either flat refusals to participate or were not usable because data was not supplied in the requested format. Follow up contact to clarify or better organize the data on these 7 was unsuccessful.

All survey responses received were reviewed and checked for completeness and reasonableness. Not all survey responses were received with sufficient information or lacked adequate detail to be included in the final results. To the extent possible, surveys lacking complete information and requiring clarifying information were flagged and the appropriate people at the pharmacies were contacted for the purpose of obtaining the needed information. The flexibility of the data collection team to process data, look for problems and implement strategies to address them was a factor that helped increase the response rate. As a result, survey responses were processed and adjusted well beyond the stated due date of October 20, 2006 and continued up through November 10, 2006.

One of the largest areas of reporting difficulty was with respect to line 41 regarding "Sales taxes paid". The intent of this question was to gather the expenses pharmacies incurred in the process of buying items or services for the operation of their pharmacies. Upon review, it appears many pharmacies reported the sales tax they collected and forwarded to the State of Vermont in the process of their business sales. Using the rationale that the sales taxes would be reported in the other lines of the survey tool as a part of those cost components, the decision was made to eliminate this data element from the analysis.

Another area of difficulty in analyzing responses came from some companies with multiple outlets who aggregated survey data. In some cases, a number of different pharmacy locations were reported as a whole and in some cases, a company chose to report different cost line items as a group or all encompassing number. As survey directions and accuracy of the process made clear the need to separate such data, attempts were made to contact these companies and work with them to break the data into the pieces needed. The attempts were met with mixed results. For that reason, usable survey responses were lower than the total number of responses.

The responses were primarily from retail pharmacies; that is, those with stores in the community. No mail order pharmacies have contracts with OVHA. While six of the survey respondents indicated they provided pharmacy services to patients in long-term care settings, only one of the respondents indicated that was its sole pharmacy activity and that they did not serve “walk-ins”.

Responses came from independently owned pharmacies as well as those operated by national or regional pharmacy companies. As such it is believed that the data adequately represents the practice of community pharmacy in the state of Vermont.

Two pharmacies responding to the survey supplied data yielding costs of dispensing well outside that of the other pharmacies. In both cases, these responses were treated as outliers and they were not included in the calculations.

There was a lack of response from pharmacies located outside of Vermont. With the exception of one pharmacy, there were no responses from the many pharmacies located beyond Vermont’s border. With adequate response, the data could have been a useful tool to perform comparative analysis between different practice types and locations.

The following table summarizes the findings based on the responses of the pharmacies who returned the survey with adequate data:

<b>Mean average cost of dispensing for the pharmacies</b>	\$10.55
<b>Median cost of dispensing for the pharmacies</b>	\$10.01
<b>Reported highest cost of dispensing</b>	\$20.75
<b>Reported lowest cost of dispensing</b>	\$ 7.19
<b>Standard deviation</b>	\$ 2.32

<b>Average hours pharmacy open</b>	67.7
<b>Annualized average number of prescriptions (total)</b>	68,108
<b>Annualized average number of prescriptions billed the OVHA</b>	13,933

The \$10.55 average derived in this study is comparable to the recently published 2006 NCPA Pfizer digest study that reported an average cost of dispensing for the northeast United States of \$10.19, a 3.5% variance. The 2006 study is a 9.32% increase over the 2005 NCPA study reported national average dispensing cost of \$9.24. It should be noted that the data used for both NCPA studies is somewhat older than this study and consisted of states in the northeast region of the United States which includes New York, New Jersey, Delaware, Maryland, and Virginia in addition to New England.

As indicated, this \$10.55 was arrived at based on reports from Vermont pharmacies. Currently, in establishing reimbursement, \$4.75 is applied for each script dispensed at a Vermont pharmacy when Vermont programs are the primary pharmacy insurer. \$4.75 is also used in calculating reimbursement when Vermont programs are secondary to all insurers other than Medicare Part D Prescription Drug Plans (PDPs). A fee is used in establishing payments with Medicare Part D coverage when a drug is covered by Medicaid but excluded from coverage by Medicare. No Vermont dispensing fee is considered or paid when Medicare Part D coverage is primary for Medicare covered drugs; reimbursement is limited to PDP cost sharing as allowed under Vermont VPharm rules.

The effective date of \$4.75 as the Vermont dispensing fee was July 1, 2005. Prior to that date the fee was \$4.25. In state fiscal year 2006 this increase alone is estimated to have generated over \$1.3 million in revenues to Vermont pharmacies. With the transition of many Vermont program beneficiaries to Medicare Part D, there has been a reduction in claims volume for which a dispensing fee is paid. However, it is estimated that the increase was still worth \$278,378 in the first quarter of state fiscal year 2007.

For comparison purposes, the \$4.75 dispensing fee for OVHA programs to Vermont pharmacies is greater than all other states in New England where the Medicaid dispensing fees range from \$1.75 to \$3.40 and greater than the state of New York where the Medicaid dispensing fees are \$3.50 for brands and \$4.60 for generics.

## Conclusions

This study assessed the potential impact of the Deficit Reduction Act of 2005 on Medicaid generic reimbursement. However, at this time the final federal requirements have not been established. Thus, the effect cannot be determined.

The study found that Vermont programs are paying less than cost in reimbursement for dispensing.

Regarding Vermont programs' drug reimbursement the results are:

1. Vermont's current dispensing fee for in-state pharmacies is the highest dispensing fee of any New England Medicaid program for any pharmacy. That fee is also higher than the dispensing fees of New York Medicaid.
2. The price currently paid for brand drugs by OVHA programs is Average Wholesale Price reduced by 11.9% (AWP minus 11.9%). That is a higher price than paid by pharmacy benefit managers (PBMs) and commercial insurers in the Northeast where discounts against AWP are as much as 15.4%.
3. The Vermont Medicaid AWP reimbursement on brands is higher than the rates used by the other New England states and by the state of New York.
4. The Maximum Allowable Cost (MAC) discount/reimbursement structure for generics used by OVHA often pays less than the CMS Federal Upper Limit (FUL) generic reimbursement method commonly used by Medicaid programs in the region.
5. The OVHA MAC reduces payments more frequently than the current federal CMS FUL generic reimbursement model. With payments on generics based on the lesser of OVHA MAC, CMS FUL, usual and customary (U&C) charge, or AWP minus 11.9%, the frequency of use in this report's claims sample was OVHA MAC 66.3%, CMS FUL 15.7%, U&C 12.1%, and AWP pricing 5.9%. Thus the OVHA MAC is more commonly less than the CMS FUL and, when it is, it results in lower payments on generics than the CMS FUL.
6. The DRA proposes to set the CMS FUL at 250% of the AMP. At that level, Vermont overall program costs would be less for generics assuming that the AMP rates available in July and August of 2006 are representative of the AMP rates as they will be used in calculating the CMS FUL.
7. While the use of AMP pricing logic for brand name medications is not called for under the DRA, at 250% of AMP the Vermont program reimbursement would increase on brands.
8. Wholesale Acquisition Costs (WAC) is considered a measure close to actual cost. OVHA currently pays more than WAC on brands but less than WAC on some generics.

In summary, Vermont publicly funded programs are paying:

- less than reported cost in the reimbursement for dispensing,
- more for dispensing than other Medicaid programs in New England and in the state of New York,
- more for brands than PBMs and other insurers in the Northeast region and Medicaid programs in other New England states and in New York state,
- more than WAC, a measure considered close to actual cost, on brands but less than WAC on some generics, and
- generally less than the generic reimbursement used by Medicaid programs in the region.

Pharmacy business is both cost of dispensing and cost of products. The cost of dispensing is known.

Current reimbursement to pharmacies is better than other insurers and Medicaid programs in the region on brands. Current generic reimbursement while low compared to regional Medicaid programs is more likely, as a result, to be closer to the DRA CMS FUL when calculated based on AMP at 250%. That means that generic reimbursement changes in Vermont programs as a result of the DRA may not be as dramatic as they may be in other states.

Many changes are underway that may affect the reimbursement for products. Those changes and their resulting impact cannot be fully determined at this time.

As a result, it is premature to make any conclusions on the need for revisions in reimbursement.

## Appendices

1. Federal regulation: the Social Security Act, Title XIX (Medicaid), Payment For Covered Outpatient Drugs per Section 1927 (42 U.S.C. 1396r-8) as found at [http://www.ssa.gov/OP\\_Home/ssact/title19/1927.htm](http://www.ssa.gov/OP_Home/ssact/title19/1927.htm)
2. Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005, Report of the Office of Inspector General, Dated May 2006 as found at <http://oig.hhs.gov/oas/reports/region6/60600063.pdf>
3. Selected survey reference materials
4. Pharmacy survey cover letter, confidentiality letter, survey collection tool and instructions

# PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. [42 U.S.C. 1396r-8] (a) Requirement for Rebate Agreement.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992<sup>[104]</sup>) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section<sup>[105]</sup>, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement

in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act<sup>[106]</sup> with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph<sup>[107]</sup>.

(B) COVERED ENTITY DEFINED.—In this subsection, the term “covered entity” means an entity described in section 340B(a)(4) of the Public Health Service Act and a children’s hospital described in section 1886(d)(1)(B)(iii) which meets the requirements of clauses (i) and (iii) of section 340B(b)(4)(L) of the Public Health Service Act and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section<sup>[108]</sup>, the following requirements shall apply:

(i) Entities.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(ii) State agency.—Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) Effect of subsequent amendments.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992<sup>[109]</sup>.

(E) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, and would have entered into an agreement under such section (as such section was in effect at such time), but for

a legislative change in such section after the date of the enactment of this paragraph.

(6) REQUIREMENTS RELATING TO MASTER AGREEMENTS FOR DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS AND CERTAIN OTHER FEDERAL AGENCIES.—

(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code<sup>[110]</sup>, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments.—In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(C) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS –

(A) SINGLE SOURCE DRUGS. – In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

(B) MULTIPLE SOURCE DRUGS. –

(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS. – Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) REQUIREMENT. – In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.- Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) HARDSHIP WAIVER. – The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(2) State provision of information.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each month of a rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)), customary prompt pay discounts extended to wholesalers and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection

(c)(2)(B)) for covered outpatient drugs for the rebate period under the agreement,<sup>[111]</sup>;

OR strike clause (i) and insert the following:

(i) not later than 30 days after the last day of each rebate period under the agreement –

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug and Cosmetic Act); and<sup>[112]</sup>

(iii)<sup>[113]</sup> for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size), and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.—

(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and  
(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii).

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.

Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).

(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE.—The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if

the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C) PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

- (i) as the Secretary determines to be necessary to carry out this section,
- (ii) to permit the Comptroller General to review the information provided,
- (iii) to permit the Director of the Congressional Budget Office to review the information provided,
- (iv) to States to carry out this title, and
- (v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.

The previous sentence shall also apply to information disclosed under section 1860D-2(d)(2) or 1860D-4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D-31(i)(1).

(4) LENGTH OF AGREEMENT.—

(A) In general.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination.—

(i) By the secretary.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) NOTICE TO STATES.—In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) APPLICATION TO TERMINATIONS OF OTHER AGREEMENTS.—The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.<sup>[114]</sup>

(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of Amount of Rebate.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or  
(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) Minimum rebate percentage.—For purposes of subparagraph (A)(ii)(II), the “minimum rebate percentage” for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;  
(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;  
(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;  
(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and  
(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—  
(I) before January 1, 1992, exceed 25 percent of the average manufacturer price;  
or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) Best price defined.—For purposes of this section—

(i) IN GENERAL.—The term “best price” means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code<sup>[115]</sup>, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V)<sup>[116]</sup> the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D-31; and

(VI)<sup>[117]</sup> any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA-PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.

(ii) SPECIAL RULES.—The term “best price”—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(D) LIMITATION ON SALES AT A NOMINAL PRICE. —

(i) IN GENERAL. — For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) FACTORS. — The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION. — Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, 14 Unites States Code.

(2) Additional rebate for single source and innovator multiple source drugs.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1900, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting “the first full calendar quarter after the day on which the drug was first marketed” for “the calendar quarter beginning July 1, 1990” and “the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed” for “September 1990”.

(3) Rebate for other drugs.—

(A) IN GENERAL.—The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and  
(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A)(i), the “applicable percentage” for rebate periods beginning—

(i) before January 1, 1994, is 10 percent, and  
(ii) after December 31, 1993, is 11 percent.

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));  
(ii) the drug is contained in the list referred to in paragraph (2);  
(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or  
(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

- (A) Agents when used for anorexia, weight loss, or weight gain.
- (B) Agents when used to promote fertility.
- (C) Agents when used for cosmetic purposes or hair growth.
- (D) Agents when used for the symptomatic relief of cough and colds.
- (E) Agents when used to promote smoking cessation.
- (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- (G) Nonprescription drugs.
- (H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- (I) Barbiturates.
- (J) Benzodiazepines.
- (K)<sup>[118]</sup> Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) REQUIREMENTS FOR FORMULARIES.—A State may establish a formulary if the formulary meets the following requirements:

- (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).
- (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).
- (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act<sup>[119]</sup> but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations<sup>[120]</sup>, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) EFFECT ON STATE MAXIMUM ALLOWABLE COST LIMITATIONS.—This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and

rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more (or, effective January 1, 2007, two or more) products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) USE OF AMP IN UPPER PAYMENT LIMITS – Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.

**(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.-**

(1) SURVEY OF RETAIL PRICES. –

(A) USE OF VENDOR.- The Secretary may contract services for –

(i) the determination on a monthly basis of retail survey prices for covered out patient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.- If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) USE OF COMPETITIVE BIDDING.- In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in-

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such provisions as the Secretary determines appropriate.

(D) ADDITIONAL PROVISIONS.- A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be available for a term of 2 years.

(E) AVAILABILITY OF INFORMATION TO STATES.- Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT. – Each State shall annually report to the Secretary information on-

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.-

(A) COMPARATIVE ANALYSIS. – The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.- The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION. – Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services \$5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication,

drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(IV) [Stricken.]

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations<sup>[122]</sup>.

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following, or to require verification of the offer to provide consultation or a refusal of such offer:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation.

(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this

subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the “DUR Board”) either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

- (i) The clinically appropriate prescribing of covered outpatient drugs.
- (ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.
- (iii) Drug use review, evaluation, and intervention.
- (iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 \*\*\*<sup>[123]</sup> licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

- (i) Retrospective DUR as defined in<sup>[124]</sup> (2)(B).
- (ii) Application of standards as defined in section (2)(C).
- (iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:
  - (I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;
  - (II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;
  - (III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and
  - (IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the

impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or<sup>[125]</sup> rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title.

(j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1903(m), are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.— (A) IN GENERAL. – Subject to subparagraph (B), the term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS EXTENDED TO WHOLESALERS. – The average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers.

(C) INCLUSION OF SECTION 505(c) DRUGS. – In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term “covered outpatient drug” means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act<sup>[126]</sup> or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations<sup>[127]</sup>) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act<sup>[128]</sup>) or

an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or (iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITING DEFINITION.—The term “covered outpatient drug” does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) NONPRESCRIPTION DRUGS.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as “over-the-counter” drugs), if they are prescribed by a physician (or

other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) MANUFACTURER.—The term “manufacturer” means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or  
(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) MEDICALLY ACCEPTED INDICATION.—The term “medically accepted indication” means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act<sup>[129]</sup>, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

(A) Defined.—

(i) MULTIPLE SOURCE DRUG.—The term “multiple source drug” means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there at least 1 other drug product which—  
(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”),  
(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and  
(III) is sold or marketed in the State during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term “innovator multiple source drug” means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug.—The term “noninnovator multiple source drug” means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug.—The term “single source drug” means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) REBATE PERIOD.—The term “rebate period” means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term “State agency” means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

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<sup>[104]</sup> November 4, 1992.

<sup>[105]</sup> November 5, 1990.

<sup>[106]</sup> See Vol. II, P.L. 78-410.

<sup>[107]</sup> November 4, 1992 (P.L. 102-585; 106 Stat. 6943).

<sup>[108]</sup> November 4, 1992.

<sup>[109]</sup> November 4, 1992.

<sup>[110]</sup> See Vol. II, Title 38.

<sup>[111]</sup> As an original; comma should probably be deleted.

<sup>[112]</sup> P.L. 108-173, §303(i)(4)(B)(ii), struck out the period and substituted “; and”, effective December 8, 2003.

<sup>[113]</sup> P.L. 108-173, §303(i)(4)(B)(iii), added clause (iii), effective December 8, 2003.

<sup>[114]</sup> See Vol. II, P.L. 78-410, §340B and Title 38, §8126.

<sup>[115]</sup> See Vol. II, Title 38.

<sup>[116]</sup> P.L. 108-173, §103(e)(1)(C), added subclause (V), effective December 8, 2003.

<sup>[117]</sup> P.L. 108-173, §103(e)(1)(C), adds this subclause (VI), to be applicable to prices charged for drugs dispensed on or after January 1, 2006.

<sup>[118]</sup> P.L. 109-91, §104(a), added subparagraph (K), applicable to drugs dispensed on or after January 1, 2006.

<sup>[119]</sup> P.L. 75-717.

<sup>[120]</sup> See Vol. II, Title 42, CFR.

<sup>[121]</sup> P.L. 103-66, §13602(a)(1); 107 Stat.613.

<sup>[122]</sup> See Vol. II, Title 42, CFR.

<sup>[123]</sup> As in original.

<sup>[124]</sup> As in original. Probably should be “paragraph”.

<sup>[125]</sup> As in original. Probably should be “of”.

<sup>[126]</sup> See Vol. II, P.L. 75-717.

<sup>[127]</sup> See Vol. II, Title 21, CFR.

<sup>[128]</sup> See Vol. II, P.L. 75-717.

<sup>[129]</sup> P.L. 75-717.

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**DETERMINING AVERAGE  
MANUFACTURER PRICES FOR  
PRESCRIPTION DRUGS UNDER  
THE DEFICIT REDUCTION  
ACT OF 2005**



Daniel R. Levinson  
Inspector General

May 2006  
A-06-06-00063

# ***Office of Inspector General***

<http://oig.hhs.gov>

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

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## **EXECUTIVE SUMMARY**

### **BACKGROUND**

#### **Medicaid Drug Rebate Program**

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP to calculate a unit rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States. The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount by the number of units of the drug dispensed to Medicaid beneficiaries.

#### **Deficit Reduction Act of 2005**

The Deficit Reduction Act (DRA) of 2005 requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements.

The DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Pursuant to the DRA, CMS must promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

### **OBJECTIVE**

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

### **SUMMARY OF RESULTS**

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work, which has primarily focused on how manufacturers calculate AMP, has found that the manufacturers reviewed interpret AMP requirements differently. Specifically, our findings demonstrate the need to clarify the definition of retail class of trade and the treatment of

pharmacy benefit manager rebates and Medicaid sales in AMP calculations. In addition, work related to the use of AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, they raised additional issues related to the implementation of DRA provisions.

Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

## **RECOMMENDATIONS**

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
  - administrative and service fees,
  - lagged price concessions and returned goods,
  - the frequency of AMP reporting,
  - AMP restatements, and
  - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

## **CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS**

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance. CMS's comments are included as Appendix G.

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## INTRODUCTION

### BACKGROUND

#### Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP and, in some cases, best price data to calculate a per unit (e.g., per pill) rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States.<sup>1</sup> The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount for a specific drug by the number of units dispensed to Medicaid beneficiaries.

#### Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 contains several provisions affecting the Medicaid drug rebate program and Medicaid drug reimbursement. Sections 6001(c) and (g) of the DRA require the calculation of AMP without regard to customary prompt pay discounts effective January 1, 2007. Section 6001(b) requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements. Section 6001(a) of the DRA requires that, effective January 1, 2007, Federal upper limits will be based on 250 percent of AMP for the drug with the lowest AMP rather than 150 percent of the lowest published price for therapeutically equivalent products.

Section 6001(c)(3)(A) of the DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Section 6001(c)(3)(B) requires that CMS promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

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<sup>1</sup>Section 1927(c)(1)(C) defines best price as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity, excluding certain sales.

## **Centers for Medicare & Medicaid Services Guidance**

Since the Medicaid drug rebate program began in 1991, CMS has issued a regulation (42 CFR § 447.534) addressing only manufacturers' record retention requirements and time limits for submitting AMP recalculations. CMS has also issued guidance to manufacturers in the form of a standardized drug rebate agreement with manufacturers and memorandums called Medicaid drug program releases (releases).

The rebate agreement further defines AMP and provides a definition of wholesalers:

- AMP is defined as “the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number).” The rebate agreement further specifies that cash discounts and all other price reductions that reduce the actual price paid are included in AMP (section I(a) of the rebate agreement).
- A wholesaler is defined as “any entity (including a pharmacy or chain of pharmacies) to which the labeler [manufacturer] sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug” (section I(ee) of the rebate agreement).

Section I(a) of the rebate agreement also provides that the AMP “for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.” Manufacturers can have payment arrangements with entities that do not take title to or possession of drugs. These arrangements can affect the price realized by the manufacturer without changing the price paid by the purchaser that takes title to or possession of the drugs.

To provide additional clarification on rebate issues, CMS sent 72 releases to drug manufacturers from 1991 through March 2006. These releases typically focused on specific definitional or calculation-related concerns.

## **Medicaid Reimbursement of Covered Outpatient Drugs**

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations (42 CFR § 447.331(b)) require, with certain exceptions, that a State’s reimbursement for drugs not exceed, in the aggregate, the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider’s usual and customary charge to the public for the drugs. CMS allows States flexibility in defining estimated acquisition cost.

For certain drugs, States also use the Federal upper limit to determine reimbursement amounts. CMS has established Federal upper limit amounts for more than 400 drugs that meet specified criteria. Pursuant to 42 CFR § 447.332(b), Federal upper limit amounts are currently based on 150 percent of the lowest published price for therapeutically equivalent products.

States have generally based estimated acquisition cost on readily available published prices, typically the average wholesale price (AWP). OIG has found that Medicaid drug reimbursement based on AWP often exceeds pharmacies' actual acquisition costs and the prices paid by other Federal programs. AWP data have several critical flaws. AWP is not defined in statute or regulation, is not necessarily linked to actual sales transactions, and is not easily verifiable. While certain aspects of AMP need to be addressed, AMP has several advantages over AWP as a basis of reimbursement. In contrast to AWP, AMP is statutorily defined, is calculated from actual sales transactions, and is subject to audit.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

### **Scope**

We limited our review to information obtained through OIG work since 1991 and discussions with representatives of stakeholders in the Medicaid drug rebate program (manufacturers, pharmacies, distributors, and States). The audit objective did not require that we identify or review any internal control systems.

We performed our fieldwork during March and April 2006.

### **Methodology**

To accomplish our objective, we:

- reviewed the appropriate sections of the DRA, section 1927 of the Act, the rebate agreements between CMS and drug manufacturers, and applicable CMS releases;
- met with congressional staff to discuss the OIG requirements in the DRA;
- interviewed CMS officials;
- analyzed and compiled past and ongoing OIG work related to drug manufacturers, AMP calculations, and the use of AMP;<sup>2</sup>
- met with three manufacturer groups, three pharmacy groups, one distributor group, and one State government group to discuss their concerns related to AMP calculations and the DRA; and
- analyzed written comments provided by six of these groups.

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<sup>2</sup>Many of the OIG reports contain proprietary information and are therefore not available to the public.

We conducted our review in accordance with generally accepted government auditing standards.

## **RESULTS OF REVIEW**

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work has demonstrated that the manufacturers reviewed interpret AMP requirements differently. Consistent with our findings, industry groups also emphasized the need to clarify requirements. Further, they raised additional issues related to the implementation of DRA provisions. Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

## **SUMMARY OF OFFICE OF INSPECTOR GENERAL WORK**

Our work on Medicaid drug rebates has focused on how manufacturers calculate AMP and how CMS and other agencies use AMP. Findings in these areas demonstrate the need to clarify the definition of retail class of trade and the treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales in AMP calculations. One issue fundamental to the proper treatment of PBM and other rebates is whether AMP should represent the net price realized by manufacturers or the price paid by purchasers that take possession of the drugs. Our findings also highlight the need to consider the implications of previously reported problems in the timeliness and accuracy of manufacturer-reported AMPs.

### **Calculating Average Manufacturer Price**

Our first review, initiated in 1991, found that four drug manufacturers used three different methods to calculate AMP; they based the calculations on gross sales to wholesalers, net sales to wholesalers, or direct retail sales and retail sales reported by wholesalers. We recommended that CMS survey other manufacturers to identify the methods used to determine AMP and develop a more specific policy for calculating AMP that would protect the Government's interest and be equitable to manufacturers.

At CMS's request in the mid-1990s, we reviewed the AMP submissions of two manufacturers that had revised their AMP calculation methodologies. For the first manufacturer, we were unable to express an opinion on the revised methodology because the manufacturer lacked adequate documentation to support its changes. The second manufacturer's methodology revision primarily involved the inclusion of price concessions to customers that the manufacturer considered to be retail. For example, the manufacturer decided that price concessions to mail-order pharmacies, nursing home pharmacies, PBMs, independent practice associations, and clinics represented the retail class of trade. Based on our limited review, we disagreed with the manufacturer's designation of these customers as part of the retail class of trade; therefore, we believed that the price concessions should not have been included in AMP. However, at the time, no guidance addressed the retail class of trade issues that we reviewed. Subsequent to that review, CMS issued release 29, which provided guidance on the treatment of some of these customers.

In 2003, we initiated reviews of four manufacturers. We selected these manufacturers because they had reported to CMS that they had changed their AMP calculation methodologies and had, as a result, received State refunds of previously paid rebates. We once again found differences in the ways that manufacturers treated certain elements of their AMP calculations. As discussed below, these reviews identified significant issues related to the treatment of PBM rebates and Medicaid sales.

#### *Treatment of Pharmacy Benefit Manager Rebates*

A major factor contributing to inconsistencies in manufacturers' AMP calculations is the business relationship between a manufacturer and various groups involved in distributing drugs. PBMs, in particular, have assumed a prominent role in the drug distribution network.

Health plans and third-party payers often hire PBMs to help manage the drug benefits paid by those plans. PBMs may act on behalf of many types of customers, of which some could be considered a part of the retail class of trade. Unless a PBM has a mail-order component, it generally does not purchase drugs or take delivery of or title to the drugs.

PBMs may negotiate and receive rebates and other payments from manufacturers based on services provided (e.g., formulary development and communications to patients) and/or based on a drug's utilization or market share. PBMs may share or "pass through" to their customers some or none of the rebates or fees they receive from manufacturers. Manufacturers are generally not parties to the contracts between PBMs and their customers. Manufacturers have indicated that they may not know how much, if any, of the rebates received by a PBM are passed on to the PBM's customers. Retail pharmacy groups have indicated that PBM rebates do not get passed on to pharmacies.

Three of the four manufacturers audited as part of our ongoing work reduced their AMP values for rebates paid to PBMs. The inclusion of PBM rebates in an AMP calculation reduces AMP, resulting in lower Medicaid rebates to the States.

- Two manufacturers included all rebates paid to PBMs when calculating AMPs. One manufacturer believed that PBMs act like wholesalers because they manage the flow of drug products through their network of pharmacies. The other manufacturer indicated that, with the lack of formal guidance addressing how to handle PBM rebates, nothing precluded it from including payments to PBMs.
- The third manufacturer included a portion of its PBM rebates in the calculation of AMP based on an analysis of the health plans represented by PBMs. The manufacturer determined the percentage of health plans that it considered to be "retail," allocated rebates paid to PBMs for those plans, and included that percentage of the rebates in the AMP calculations.

Conversely, the fourth manufacturer did not include rebates paid to PBMs in its AMP calculations. This manufacturer decided not to characterize transactions with PBMs as "sales"

because PBMs do not take possession of drugs; therefore, this manufacturer believed that including the rebates in AMP would not be consistent with section 1927 of the Act.

Neither section 1927 of the Act nor the rebate agreement addresses the issue of how to treat rebates that manufacturers pay to PBMs. CMS issued three releases in 1997 that discussed PBMs. Releases 28 and 29 stated that “drug prices to PBMs” had no effect on AMP calculations unless the PBM acted as a wholesaler as defined in the rebate agreement. (CMS did not explain what it meant to act as a wholesaler in the context of PBMs, which do not typically take delivery of and title to drugs.) In release 30, CMS recognized existing confusion relating to the treatment of PBMs and stated that it intended to reexamine the PBM issue and hopefully clarify its position in the future. However, to date, CMS has not done so.

### *Treatment of Medicaid Sales*

Another factor contributing to inconsistencies in manufacturers’ AMP calculations is the different interpretation of what sales should be included/excluded in the calculations. For example, our recent reviews found that some manufacturers excluded from the calculations a portion of sales to pharmacies that dispense prescription drugs to Medicaid beneficiaries. Two manufacturers subtracted Medicaid sales from their AMP calculations. Removing Medicaid sales from gross sales generally lowered AMP for these manufacturers.

Medicaid does not directly purchase drugs from manufacturers or wholesalers but reimburses pharmacies after the drugs have been dispensed to Medicaid beneficiaries. Because a pharmacy that dispenses drugs to Medicaid beneficiaries likely dispenses drugs to non-Medicaid patients from the same containers of the product, it would be nearly impossible for a manufacturer to specifically identify a sale that would be considered a Medicaid sale. However, two manufacturers estimated Medicaid sales amounts to subtract from the AMP calculations by multiplying the number of units that States reported when billing the manufacturer for rebates by the price the wholesaler paid for the drug.

The two manufacturers justified removing Medicaid sales for different reasons. One manufacturer indicated that because the rebate agreement did not allow a reduction of gross sales by the value of Medicaid rebates paid in calculating AMP, the sales associated with the rebates should also be excluded. The other manufacturer likened Medicaid sales to State Pharmaceutical Assistance Programs, which provide drug coverage to certain qualified individuals. CMS’s release 29 provides that sales under these programs should not be considered in AMP, so the manufacturer concluded that Medicaid sales should also not be considered.

Like Medicaid, State Pharmaceutical Assistance Programs do not purchase drugs from manufacturers or wholesalers but reimburse pharmacies for dispensing the drugs and may receive rebates from manufacturers. However, release 29 did not address the question of whether only the rebates paid to the programs should be excluded from AMP calculations (similar to the statutory requirement to exclude Medicaid rebates) or whether the underlying sales associated with the rebates should also be excluded.

We disagree with the reasoning of both manufacturers. The exclusion of Medicaid sales is not addressed in section 1927 of the Act, the rebate agreement, or any of the releases. In addition, retail pharmacies that very often dispense drugs to the Medicaid population would seem to fall squarely within the plain language of the “retail pharmacy class of trade” provision of the AMP definition.

### **Using Average Manufacturer Price in Reimbursement Calculations**

Concerns related to AMP calculations take on additional significance given that the DRA has expanded the use of AMP. Prior to the DRA, AMP was primarily used as the fundamental component in determining the amount of Medicaid drug rebates. However, the DRA provides for the use of AMP as a basis for Medicaid reimbursement for the first time. Issues arising from the use of AMP in connection with the 340B drug-pricing program provide useful lessons as CMS (and potentially the States) prepares to use AMP as a basis for Medicaid reimbursement.

The 340B program, established by the Veteran’s Health Care Act of 1992, is a drug discount program for certain qualified covered entities (including Public Health Service and other safety-net providers) that serve vulnerable patient populations. Under the 340B program, manufacturers agree to charge participating covered entities prices that are at or below a specified maximum price (known as the ceiling price) for purchases of outpatient drugs (42 U.S.C. § 256b(a)(1)). The ceiling prices are based, in part, on the reported AMP and unit rebate amounts for covered drugs (42 U.S.C. § 256b(a)).

In our review of the 340B program, we found two primary issues that have implications for the use of AMP as the basis of Medicaid reimbursement: the timely submission of AMP data by manufacturers and the accuracy of reported AMP data.

Our review found that manufacturers did not always report AMP in a timely manner or, in some cases, did not report AMP at all.<sup>3</sup> For example, the 340B ceiling price file for the first quarter of 2005 was missing 28 percent of the prices necessary to calculate 340B ceiling prices. For 70 percent of these missing prices, the file did not contain the AMP.

Manufacturers are required to report their drugs’ AMPs and, where applicable, the best price within 30 days after a quarter’s end so that CMS can calculate the drug’s Medicaid unit rebate amount (section 1927(b) of the Act). CMS staff reported that if the data were late, they typically contacted the manufacturers that submitted incomplete data and requested prompt submission. According to CMS, most manufacturers were responsive to these contacts and typically provided the missing data with their next quarter’s submission.

While timely submission of AMP data is important to the Medicaid rebate program, it will become even more critical when Medicaid uses AMP data as a basis for reimbursement. Late submissions of AMP data may delay, rather than prevent, State Medicaid agencies’ rebate collections. However, late submissions may prevent CMS from calculating accurate Federal upper limit prices and hinder States’ ability to accurately reimburse pharmacies.

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<sup>3</sup>“Deficiencies in the Oversight of the 340B Drug Pricing Program” (OEI-05-02-00072, October 2005).

Our reviews have also found issues related to the accuracy of reported AMP data. CMS's edit of a manufacturer's AMP submission is designed to reject an AMP that is 50 percent higher or lower than the manufacturer's submission for the previous quarter. When the edit detects aberrant AMP values, CMS sends a report to the manufacturer requesting corrected information. While inaccuracies may ultimately be corrected, inaccurate AMP submissions also affect the timeliness of CMS's receipt of the correct AMPs and could affect reimbursement made before the data are corrected.

In our review of States' accountability and control over Medicaid rebate collections, we noted problems with unit rebate amounts of zero that resulted from inaccurate AMPs and the untimely reporting of AMPs.<sup>4</sup> This created accountability problems in some States' administration of their rebate programs and could also create problems for reimbursement based on AMP.

## **SUMMARY OF INDUSTRY GROUP PERSPECTIVES**

We met with eight groups that represented a cross-section of interested stakeholders, including manufacturers, pharmacies, distributors, and States, and invited the groups to provide written comments for our consideration. Six of the eight groups provided written comments. We have summarized some of their comments and suggestions below and have included their complete written comments in Appendixes A through F. We believe that the industry comments provide CMS with valuable information to use in clarifying requirements related to calculating AMP, using AMP in reimbursement calculations, and implementing provisions of the DRA.

### **Calculating Average Manufacturer Price**

#### *Definition of Retail Class of Trade*

Consistent with our own findings, industry groups emphasized the need for clarification of entities included in the retail class of trade for AMP calculations. The manufacturer groups commented that CMS had not fully addressed which classes of trade are to be considered "retail" for purposes of calculating AMP. Release 29 clarified the retail status of some classes of trade but not all. The manufacturer groups pointed out the lack of guidance for classes of trade such as physicians, clinics, and patients (i.e., coupons or other patient discount programs).

While they agreed on the need for clarification, respondents presented different suggestions for addressing this issue. One manufacturer group suggested that the retail class of trade be defined to include only entities that dispense drugs to the general public on a walk-in basis (e.g., retail, independent, and chain pharmacies) and mail-order pharmacies that dispense drugs to patients who do not receive other specialized or home care services from the entity. Another manufacturer group did not recommend a particular definition but encouraged a definition that stipulates the criteria or rationale used to determine whether classes of trade are retail or nonretail.

The pharmacy groups advocated that the retail class of trade be limited to traditional retail outlets such as chain and independent pharmacies. These groups also believed that manufacturer sales

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<sup>4</sup>"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048, July 6, 2005).

to mail-order and nursing home pharmacies should not be considered retail for the purposes of calculating AMPs.

The decision to include or exclude certain entities has important implications for AMP. The entities in question, i.e., physicians, clinics, and mail-order and nursing home pharmacies, may not all purchase drugs at the same price, so including or excluding sales to these entities may have the effect of decreasing or increasing AMP.

#### *Treatment of Pharmacy Benefit Manager Rebates*

Also in keeping with our findings, respondents raised issues surrounding the treatment of PBM rebates. One manufacturer group commented that CMS's limited PBM guidance had caused confusion. This group did not want any requirement that obligates manufacturers to gather information from "downstream" entities (e.g., PBM customers). The group indicated that contracts between PBMs and their customers do not have uniform provisions on the sharing of manufacturer rebates, and the group was not sure whether manufacturers could contractually require the information. Additionally, the group noted that it would be difficult to incorporate such information into AMP calculations.

The pharmacy groups and the distributor group all favored excluding PBM rebates from the AMP calculation (i.e., not subtracting rebate payments from the sales dollars) because the rebates are not passed on to the retail pharmacies.

#### *Treatment of Administrative and Service Fees*

Industry groups also sought clarification of the treatment of administrative and service fees, and respondents raised some specific points for CMS to consider in determining how to treat these fees. One manufacturer group noted that release 14 was the only guidance addressing fees and that it did not provide needed specificity. Release 14 states that administrative fees should be included in AMP if they are paid to an entity whose sales are included in the AMP calculation and if the fees ultimately affect the price realized by the manufacturer.

Another manufacturer group suggested that if CMS were to apply the average sales price criteria to service and administrative fees, it should clarify whether the definition of bona fide service is satisfied in relation to traditional wholesaler functions (e.g., pick, pack, and ship services).<sup>5</sup> In addition, one manufacturer group did not want the decision to include or exclude fees to require a manufacturer to obtain information regarding transactions between downstream entities.

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<sup>5</sup>The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the average sales price as the basis for determining reimbursement amounts for most Medicare Part B drugs. CMS guidance (question and answer 3318 on the CMS Web site at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>) indicates that administrative fees are included in the average sales price if they are paid to an entity whose sales are included in the average sales price calculation and if they ultimately affect the price realized by the manufacturer. Additionally, question and answer 4136 indicates that "bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on" to the entity's clients or customers are not included in average sales price calculations because the fees would not ultimately affect the price realized by the manufacturer. Ongoing OIG audits have shown that manufacturers treat average sales price-related administrative and service fees inconsistently.

The pharmacy groups and the distributor group, however, did not believe that these fees should be used to reduce sales values included in AMP calculations.

Including these fees would generally result in lower AMPs and, therefore, lower rebates and reimbursement (for those drugs with reimbursement based on AMP).

#### *Lagged Price Concessions and Returned Goods*

The industry groups indicated that the timing of price concessions and returned goods could create inconsistent AMPs from one period to the next, thereby creating problems with using AMP as a basis for reimbursement.

One manufacturer group stated that a methodology should be prescribed to account for late-arriving discount and rebate data. Another manufacturer group did not specifically mention lagged price concessions but commented that AMP should be calculated in such a way that would avoid the need for retroactive adjustments. The group noted that returns should be addressed. Yet another manufacturer group recommended that CMS encourage “smoothing” to accommodate transaction timing.

One pharmacy group and the distributor group recommended that lagged rebates and discounts be smoothed over a rolling 12-month period, similar to the manner in which average sales price is calculated. They also recommended that returned goods not be considered in AMP calculations.

#### **Using Average Manufacturer Price in Reimbursement Calculations**

One manufacturer group stated that AMP should not be used to set reimbursement rates until a standardized methodology for calculating AMP has been established. The group noted that the use of AMP in setting the Federal upper limits is scheduled to start January 1, 2007, but CMS is not required to issue its regulation until July 1, 2007. Another manufacturer group commented that the regulations should ensure that AMPs used in reimbursement are calculated in a way that avoids the need for restatements and unnecessary quarter-to-quarter volatility. The group also recommended that OIG caution States about potential volatility in AMP that may occur as a result of this report and CMS’s expected regulation. A third manufacturer group commented that large-volume purchasers such as large national chain drug stores could affect AMP and result in inadequate reimbursement for independent pharmacies.

The pharmacy groups expressed concern about using AMP, which was created for rebate purposes, as a benchmark for reimbursement.

## **Deficit Reduction Act Implementation Issues**

### *Frequency of Average Manufacturer Price Reporting*

The manufacturer groups noted that the DRA required monthly AMP reporting but did not change the quarterly rebate-reporting period in the Act. Because of this discrepancy, the groups indicated that it was unclear whether manufacturers would be required to calculate and report:

- a monthly AMP using 1 month's data;
- a monthly AMP using the most recent 3 months' data (e.g., a rolling average methodology);
- a monthly AMP using a methodology different from that used for rebate purposes;
- a quarterly AMP separate from the monthly AMPs; or
- a quarterly AMP that is an average of the monthly AMPs.

### *Average Manufacturer Price Restatements*

One manufacturer group wanted to know whether AMP calculations would be considered final when submitted or whether manufacturers would be able, or even required, to restate their AMP calculations when they recognize that a prior AMP calculation was incorrect. Another manufacturer group asked whether AMP resubmissions would be permitted. A third manufacturer group believed that manufacturers should be able to restate quarterly AMPs, but not the monthly AMP.

### *Baseline Average Manufacturer Price*

Baseline AMP represents the AMP calculated for the first full quarter a drug is on the open market. It is used to determine whether an additional rebate is owed to the Medicaid program. Essentially, if an AMP rises in value faster than the baseline AMP (after adjusting for inflation) the manufacturer must pay an additional rebate. Pursuant to the DRA, prompt pay discounts should no longer be considered in calculating the current quarter's AMP. Previously, section 1927(k)(1) of the Act required that prompt pay discounts be used to reduce the sales values included in the baseline AMPs. Excluding these discounts could potentially result in an increase in AMPs that exceeds the inflation adjustment, thereby triggering the additional rebate. Two manufacturer groups expressed concern that manufacturers could be penalized if baseline AMPs were not adjusted to conform to the new AMP definition. The groups indicated that manufacturers would pay an unfair amount of additional rebates related to the methodology change unless the baseline AMP is also adjusted.

One manufacturer group recommended that manufacturers be allowed, but not required, to adjust baseline AMPs. The group was concerned that a requirement to adjust baseline AMPs would be impractical for some manufacturers due to data availability and operational burden issues.

Another manufacturer group recommended that CMS work with manufacturers to develop reasonable methodologies to adjust baseline AMPs.

As a related issue, two manufacturer groups commented that any changes in AMP methodology should be made only prospectively and not retrospectively.

## **RECOMMENDATIONS**

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of PBM rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
  - administrative and service fees,
  - lagged price concessions and returned goods,
  - the frequency of AMP reporting,
  - AMP restatements, and
  - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

## **CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS**

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance.

CMS's comments are included as Appendix G. Attached to those comments were technical comments, which we addressed as appropriate.

# **APPENDIXES**



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

March 31, 2006

Marcia Sayer  
External Affairs  
Office of the Inspector General  
330 Independence Ave, SW  
5<sup>th</sup> Floor, Room 5541  
Washington, DC 20201

The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide comments to the Department of Health and Human Services Office of Inspector General (OIG) regarding the content of its report to the Secretary and Congress, due June 1, 2006. That report is to contain recommendations regarding the calculation and reporting of Average Manufacturer Price (AMP) under section 1927 of the Social Security Act.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

BIO accepted the OIG's invitation to meet on March 15, 2006 to describe our views about the requirements for, and the manner in which, average manufacturer prices are determined. At that meeting, the OIG representatives requested that BIO supplement its discussion in the meeting with a written submission, by March 31, 2006. This letter responds to that request. As we noted in that meeting, the central principle of BIO's comments is that the OIG's recommendations should promote consistency, clarity, and economic fairness in the calculation and reporting of AMP.

#### Monthly Reporting of AMP

The Deficit Reduction Act (DRA), at section 6001(b)(1), changes the current quarterly reporting timetable for Average Manufacturer Price (AMP) and Best Price (B) to a monthly period. This monthly reporting is meant to facilitate the use of AMP figures to set monthly Federal Upper Payment Limits, or FULs, under

1225 EYE STREET, N.W., SUITE 400  
WASHINGTON, D.C. 20005-5958

202-962-9200  
FAX 202-962-9201  
<http://www.bio.org>

DRA section 6001(a) for multiple source drugs. While the DRA did change the AMP and BP reporting timetable, the DRA did not change the statutory definition of "rebate period," i.e. the period for each state rebate claim, contained at 42 U.S.C. § 1396r-8(k)(8), which remains "a calendar quarter or other period specified by the Secretary." Given the intended use of AMPs to set reimbursement rates and the current inconsistency between the statutory reporting and rebate periods, BIO requests that the OIG's recommendations address the following issues:

**1. Monthly calculation of AMP figures.** The OIG recommendations should specify whether or not the new monthly timetable for reporting AMP figures also requires manufacturers to calculate AMP figures on a monthly basis, as opposed to requiring manufacturers to report a quarterly AMP figure on a monthly basis. This clarification is of paramount importance and necessary so that manufacturers can prepare for the 2007 implementation timetable.

**2. The calculation methodology for monthly AMP figures.** If the OIG recommends that the DRA be interpreted to require monthly calculation and reporting of AMP figures, then the OIG recommendations should also address the methodology for calculating AMP on a monthly basis. The use of monthly AMP figures to set reimbursement rates suggests that such figures, like Average Sales Price, should be final when submitted and not subject to manufacturer revisions during the three year restatement period currently permitted by regulation (42 C.F.R. § 447.534(h)(2)(i)). The OIG recommendations should address this issue. In doing so, the OIG recommendation should consider the significant added administrative burden and operational complexity that a requirement to restate monthly AMP figures would impose on manufacturers, CMS, and the States.

If the OIG recommendation is that monthly AMP figures should not be subject to subsequent revision by manufacturers, then the OIG recommendations should also address in specificity the methodology that manufacturers should use to estimate late-arriving data that is used to quantify AMP-eligible discounts and rebates and AMP-ineligible sales, the level of accuracy needed for such calculations, as well as the process for manufacturers to follow should they discover errors in previously submitted figures.<sup>1</sup> Whether the OIG recommends for or against the continued availability of the restatement period, given the prevalence in the industry of quarterly performance periods under discount and rebate contracts, the OIG recommendations also should address how such quarterly discount measurements should be accounted for in a monthly calculation.

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<sup>1</sup> While the DRA does not direct the OIG to also provide recommendations regarding the calculation of Best Price, should the OIG recommend that AMP and BP figures not be subject to revision, BIO requests that the OIG also recommend a methodology for accounting for late-arriving data in the calculation of Best Price.

**3. The statutory rebate period.** The OIG recommendations should address whether the rebate period should continue to be a quarterly one, and if so, how the quarterly rebate amount will be derived from reported monthly AMP and BP figures.<sup>2</sup> For a quarterly rebate period, a possible solution is to require manufacturers to submit a quarterly weighted average AMP figure with its monthly submission for the third month of the quarter, with the quarterly weighted average AMP being derived from the AMPs reported for each of the months in the quarter and weighted based on AMP-eligible units for each month. Another approach would be to have manufacturers calculate monthly AMPs for the first two months of the quarter, but have the AMP for the third month of a quarter be calculated as a quarterly figure. Either approach would also provide a solution for calculating future base date AMP figures, which the Medicaid statute requires be determined based on the statute's quarterly rebate period, see 42 U.S.C. § 1396r-8(c)(2)(A), as well as for deriving Public Health Service Ceiling Prices, which federal law also requires to be derived from quarterly prices, see 42 U.S.C. § 256b(a)(2).

The OIG recommendations should also address whether manufacturers would be permitted to revise such quarterly AMP figures to reflect late-arriving data relating to AMP-eligible discounts and rebates and AMP-ineligible sales. Even if the OIG were to recommend against the availability of such revisions in relation to the AMP figures reported on a monthly basis and used to set reimbursement rates, the OIG recommendations should separately address the availability of such revisions for the AMP figures used to calculate Medicaid unit rebate amounts, and if the ability to make such revisions remains available, whether such revisions are mandatory. The continued availability of the 3-year restatement period would permit manufacturers to ensure that the AMP figures used to calculate rebate amounts are as accurate as possible and based on actual sales and discount data. However, given the added administrative burden of such revisions to both manufacturers and the States, should the OIG recommend against the availability of restatements for monthly AMP figures and direct the use of estimation methodologies for that reason, the OIG should permit manufacturers also to choose to rely on those monthly AMP figures for purposes of deriving an AMP for the rebate calculation. Manufacturers should be permitted to revise those AMP figures, to reflect late-arriving actual sales data, but not be required to do so.

**4. Effective date for monthly reporting.** The DRA, at section 6001(b)(1), requires CMS to begin its own monthly reporting of AMP figures to the States on July 1, 2006, using "the most recently reported average manufacturer prices." The DRA change to a monthly reporting timetable for manufacturers does not include its own effective date, and therefore appears to be governed by section 6001(g) of the DRA, which provides for an effective date of January 1, 2007

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<sup>2</sup> BIO notes that any recommendation to change to a rebate period that is shorter than a quarter would require a significant implementation preparation period for manufacturers as well as the States.

where effective dates are not otherwise provided. Given the significance of this effective date to manufacturers, the OIG recommendations should confirm that that the monthly reporting obligation for manufacturers begins with the AMP and BP figures for January 2007.

**5. Use of AMPs for Reimbursement Rates Prior to Issuance of Methodology Guidance.** The DRA, at section 6001(a)(2), requires the use of AMP to set federal upper payment limits for multiple source drugs effective January 1, 2007, but, at section 6001(c)(3), does not require CMS to issue its rule regarding the AMP calculation until July 1, 2007. BIO believes that any AMPs used to set reimbursement rates should be calculated using a standardized methodology that is the result of input from all government and private-sector stakeholders, to ensure that the resulting reimbursement rates are fair and equitable as well as to ensure that patient access is not adversely impacted by variation in manufacturer methodology assumptions. The OIG therefore should recommend that CMS either postpone the use of AMPs to set reimbursement rates until the effective date of its rule regarding the AMP methodology, or that CMS in the short term issue interim guidance that will apply to the AMP calculation until the rule is issued and effective.

#### Inflation Penalty Rebate Calculation and the Prompt Pay Discount

The DRA, at section 6001(c)(1), directs that customary prompt payment discounts extended to wholesalers no longer be included as a reduction to AMP starting January 2007.<sup>3</sup> The inflation penalty component of the quarterly rebate calculation requires the comparison of an inflation-adjusted AMP for the first full quarter of sales (the base date AMP) with the current quarter's AMP. Where the current quarter AMP exceeds the inflation-adjusted base date AMP, the difference is added to the Medicaid rebate. If customary prompt payment discounts are excluded from AMP only for the current quarter's AMP, and not also for the base date AMP, this comparison will falsely conclude that an inflation penalty is due for that proportion of the increase in the current quarter's AMP caused by the exclusion of the prompt pay discount.

The OIG recommendations should include a proposed methodology for avoiding this result. One approach would be to permit, but not require, manufacturers to recalculate their base date AMP figures to exclude customary prompt payment discounts, and to use those recalculated base date AMP figures for rebate calculations effective in 2007. The OIG should not require such a recalculation because, for certain manufacturers, data availability and the operational burden of such recalculations may make such recalculations impractical. For example, this approach would require many manufacturers to access pricing data that is many years old, stored in legacy information technology systems, and possibly relating to quarters outside of the 10 year document retention period specified in

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<sup>3</sup> The OIG recommendations should also confirm whether the definition of "wholesaler" in the Medicaid Agreement is the definition that should be used when interpreting this provision.

42 C.F.R. § 447.534(h). This approach also would require manufacturers and CMS to store and track two different base date AMP figures: one for rebate calculations relating to quarters prior to 2007 and one for quarters in 2007 and later years. As the recalculation of base date AMP would serve only to lower rebate liability, should the OIG choose this approach, manufacturers should be permitted to choose whether or not to recalculate their base date AMP figures.<sup>4</sup>

An alternative, and more streamlined, solution would be to revise the calculation methodology for the inflation penalty component of the rebate calculation so as to mathematically offset the impact of excluding prompt pay discounts for AMPs reported for January 2007 and later. One method for doing so would be to direct that the inflation penalty calculation include a standardized, formula-based upward adjustment to the base date AMP. For example, if the OIG were to conclude that the customary prompt payment discount percentage was 2%, then the OIG could recommend that the inflation penalty rebate calculation be adjusted to divide each reported base date AMP by .98, before applying the CPI-U based inflation factor, so as to upwardly adjust that base date AMP so that it no longer reflects customary prompt payment discounts. In this example, if the base date AMP is \$98, where it would be \$100 without inclusion of the prompt pay discounts, dividing that \$98 base date AMP by .98 will result in a revised base date AMP of \$100. This formula-based approach would have the advantage of avoiding the calculation and maintenance by CMS and manufacturers of separate base date AMP figures for rebate periods before and after 2007. This approach would also ensure that all manufacturers address this issue in the same manner.

### Classes of Trade

The definition of AMP remains “the average price paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1)A(). Very little written guidance exists from CMS regarding the definition of the retail pharmacy class of trade. The OIG recommendations should define the retail pharmacy class of trade with specificity. This definition should address particular classes of entities, examples of which are discussed below, but also include the general rule that the OIG recommends be used when evaluating entities not otherwise addressed by OIG or CMS guidance. Such a general rule will provide manufacturers with a crucial baseline for use in evaluating new entity types, and will promote the important goals of consistency, clarity, and economic fairness.

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<sup>4</sup> If the OIG recommendation is to permit manufacturer recalculation of base date AMPs, the recommendation should also address whether the manufacturer must use the same AMP methodology the manufacturer had in place during the base date quarter. Many manufacturers have revised their AMP methodologies over time to address CMS guidance, and a legacy AMP methodology also may no longer be supported by a manufacturer’s information technology. For these reasons, the OIG recommendation should permit manufacturers to use their current AMP methodology to recalculate the base date AMP.

**1. Classes of trade for which guidance is needed.** Current CMS guidance either does address, or does not address with sufficient specificity, the retail or non-retail status of: physicians, clinics, patients (including coupon arrangements for discounts or non-contingent free product), Part D utilization, Specialty Pharmacy, Competitive Acquisition Program or CAP sales, Pharmacy Benefit Manager mail order and retail pharmacy utilization, State Pharmacy Assistance Program (SPAP) and Medicaid program utilization, and health care plan utilization. The OIG recommendations should address each of these entity types, define each such class of trade in a manner specific enough to permit manufacturers to readily determine into which category any entity should be placed, and specify the OIG's rationale for the recommended retail or non-retail status of each class.

**2. Calculation treatment of discounts and units.** The OIG recommendations should specify for each class of trade the treatment of gross sales, discount dollars, net sales, if applicable, and the respective sales units associated with that class of trade. Specifically, the OIG recommendations for each class of trade should specify (1) whether gross sales, net sales, and/or discounts extended to that class of trade should be used to reduce the AMP numerator, and (2) whether the units associated with that class of trade, whether identified through sales or reimbursement transactions, should remain in the AMP denominator. This specificity is necessary to ensure clear guidance regarding treatment of a given class of trade in the AMP numerator (sales dollars) and denominator.

#### Additional AMP Methodology Issues

In addition to the issues identified above, BIO requests that the OIG recommendations also address the following issues:

**1. Prospective application only.** The OIG recommendations should specify that any clarifications and/or changes in CMS directions regarding the calculation of AMP are to be applied on a prospective basis only. The very nature of the OIG recommendations and CMS' implementation of them suggests that they are changes to existing practice, provided because of the absence of guidance in the past. These changes therefore should be prospective only. Moreover, given the complexity of the DRA changes to the AMP calculation and reporting timetable, and the operational complexity that implementing those changes presents to manufacturers, the OIG recommendations also should specify that CMS implement the DRA changes using a single, prospective implementation date that provides manufacturers with a minimum of six months lead time to make the necessary preparations.

The OIG recommendations should also include a recommendation that any and all CMS guidance in the future specify whether that guidance is to be applied prospectively and or retrospectively. Should the OIG recommend that

monthly AMP and BP figures not be open to revision by manufacturers during the three year regulatory period, and should CMS adopt that approach, it will be even more imperative that any future CMS guidance regarding calculation issues be prospective in application only.

**2. Service and administrative fees.** The OIG recommendations should address the treatment of service and administrative fees paid to entities included in the calculation of AMP. Such guidance does exist as to the calculation of ASP, in the form of two Q&As (numbered 3318 and 4136 at the FAQ link at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>). However, the existing guidance for AMP is limited to that contained in Release to Participating Manufacturers 14, and does not provide needed specificity regarding the circumstances under which such fees may and may not be included in the AMP calculation. If the OIG recommends use of the same criteria in the AMP calculation as CMS has directed be used in the calculation of ASP, the OIG recommendations should clarify whether the definition of “bona fide service” is satisfied in relation to traditional wholesaler functions such as pick, pack, and ship services.

**3. Methodology change review and approval process.** The OIG recommendations should also address a process and timeline for approval of manufacturer-proposed AMP methodology changes. The current CMS process is described by CMS itself as one through which manufacturers submit requests for approval, and as to which CMS provides no response or resolution. The OIG should recommend a process that details the information needed with a submission, the criteria for approval, and a deadline for CMS resolution.

In conclusion, BIO appreciates this opportunity to provide comments to the OIG regarding its recommendations to CMS as to the calculation and reporting of Average Manufacturer Price. We hope our suggestions will help the OIG to identify and provide substantive recommendations that will help manufacturers submit the data needed to calculate appropriate Medicaid reimbursement and rebate amounts for drugs and biologicals. Please contact me at 202-312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Jayson Slotnik  
Director, Medicare Reimbursement and  
Economic Policy  
Biotechnology Industry Organization



April 20, 2006

Office of the Inspector General  
Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC

*Re: HHS OIG study of Average Manufacturer Price*

As discussed during our March 16 meeting, GPhA has concerns over the implementation of the Medicaid reform legislation. These concerns are in the areas of reimbursement methodology and program administration. We recognize that there is a need for the Medicaid Program to realize savings through the continued and expanded use of generic prescription medicines. To that end, we need to work together to ensure that all entities in the supply chain retain incentives for the continued manufacturing and dispensing of generic medicines.

Methodology for Calculating AMP:

In order to understand GPhA's concerns regarding the importance of a clearly defined methodology for calculating Average Manufacturer Price (AMP), it is important to understand the typical chain of distribution for the products of generic pharmaceutical manufacturers. Generic pharmaceutical manufacturers currently distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.). For reference, warehousing chain pharmacies include, but are not limited to, Brooks / Eckerd, CVS, Rite Aid, Walgreens, and Wal\*Mart; mail order pharmacies include Caremark, Medco, and Express Scripts; and wholesalers include AmerisourceBergen, Cardinal, and McKesson. (Note: Some large chains like Walgreens and CVS also have mail order divisions.)

The legislation contemplates not only the publication of manufacturer AMP data, but also changes to the methodology for calculating. As we understand it, the AMP is intended to account for all recorded sales and discounts within the reported period; however, as you are undoubtedly aware, fluctuating order patterns and erratic timing of transactions result

in unpredictable fluctuations in AMP from month to month, or quarter to quarter based on customer mix, discount payments, returns and other normal business transactions. Moreover, given the ambiguity in the current regulatory guidance for calculating AMP, different manufacturers may very well be employing different assumptions either on their own or in conjunction with regulatory counsel to calculate their respective AMPs, which results in a variability across AMPs that prevents a true apples-to-apples comparison of pricing data across manufacturers.

It is also important to note that a manufacturer's AMP is actually a weighted average price, heavily influenced by the purchasing power of large national chain drug stores, and mass merchants. The prices paid by these volume purchasers generally are not available to others in the pharmacy community, including the independent pharmacies that portions of the Medicaid population rely upon.<sup>1,2</sup> In areas where this is true, this inequity in pricing creates the potential for access to be a significant issue in the implementation of the proposed Medicaid reform. Whether sales to such volume purchasers should be included in AMP is just one of the questions raised by this legislation.

Another question concerns the legislation's current approach of using the lowest AMP reported for multi-source products upon which to base reimbursement. This model does not provide a means to measure:

1. De minimis sales volume associated with a given manufacturer's AMP,
2. A manufacturer's decision to sell a product to a single entity, regardless of volume, at a discounted price which would not represent a widely available price,
3. Discounts available to large volume purchasers based on the purchase of bulk package sizes; thereby creating a potential for reimbursement to be based on pricing that is not widely available, and in fact a statistical outlier,
4. The widespread availability to all pharmacy purchasers of certain manufacturers products,
5. The continued availability of a product for which an AMP is generated, and
6. Substantial wholesaler/distributor markup fees that apply to a majority of 30,000+ independent retailers/small chains (this subset represents almost 60% of U.S. retail pharmacy) that primarily purchase through wholesalers.

Whatever the answers to these questions, we ask only that your recommendations include a clear and concise methodology for calculating AMP that leaves no room for doubt as to the methodology that should be employed by each manufacturer in calculating AMP.

#### Program Administration:

In addition to the issues identified around the AMP calculation methodology, there are numerous procedural issues raised and many questions still surrounding the

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<sup>1</sup> 2005 NCPA- Pfizer Digest

<sup>2</sup> 2005 NACDS Chain Pharmacy Industry Profile

administration of the program. As an initial matter, despite the inherent ambiguity in the current AMP calculation methodology, the legislation appears to require CMS to make public the most recent manufacturer AMP data on or about July 1, 2006. Not only does this raise the variability issues, set forth above, but publishing this data not just to the states, but to the public at large, raises serious concerns about the evisceration of the private sector reimbursement model by displaying data known to be flawed. It is one thing to demand transparency under the guise of government accountability and provide this information to the states; it is quite another to eliminate certain pro-competitive advantages that one manufacturer may have over another in the public sector by publishing a baseline price as to each product of every manufacturer. CMS has the responsibility to publish a price that accurately reflects the market, nothing more.

Moreover, as outlined above, fluctuations and timing within the generic market make AMP reporting erratic and unpredictable. This currently occurs with the existing quarterly reporting requirements, and would only be exacerbated with monthly reporting. Products with low unit volume will have a disproportionate influence on the lowest AMP than potential higher AMP products with higher unit volume. This again reflects concerns over a system not designed around a widely available price, as the current FUL. AMPs could result from pricing available only to a certain minority of providers, yet become the reimbursement standard for the total pharmacy community. "Smoothing" will also have a huge impact on AMPs due to the large dollar value of chargebacks processed for wholesaler sales for generic products. CMS has been silent on smoothing in the quarterly AMPs, although CMS does require smoothing for ASP pricing for Medicare Part B. Generic manufacturers should be encouraged to smooth data in the AMP calculation for reimbursement to accommodate transaction timing.

GPhA and its member companies appreciate the opportunity to share our concerns and thoughts with the OIG and stand ready to provide additional assistance and input as this process moves forward.

Sincerely,



Kathleen D. Jaeger  
President and CEO

Attachment: Questions to Consider

**Additional questions for consideration by OIG**

Once more clarity exists around the AMP calculation methodology, we would like to reserve the opportunity to discuss issues identified, which may include, but are not limited to the following:

- 1) Will manufacturers be required to submit a monthly AMP for FUL and quarterly AMP for rebates?
- 2) Will the government provide class of trades for all reimbursable entities in the US, so that these codes are not subjectively assigned by manufacturers? This will ensure consistency across manufacturers when calculating AMPs.
- 3) Will AMP for FUL be calculated at the 9 or 11 digit NDC? The price would be more accurate if calculated at the 9-digit level.
- 4) Explain the exclusion of wholesaler cash discounts? Does this apply to all customers?
- 5) Explain the separate reporting requirement for cash discounts
- 6) How does a manufacturer report a negative AMP calculation for reimbursement?  
Comment: For the quarterly AMP for Medicaid rebates, CMS requires that the last quarterly positive AMP be reported.
- 7) Please explain how AMP and BP are to be calculated for brands/authorized generics? Will the AG give data to the brand for the brand's submission? If so, at what level of detail? Or will CMS calculate based on the Brand and AG's submission?
- 8) Similar to current AMPs/BPs, will the supplied monthly/quarterly AMP information for each manufacturer be kept confidential, not subject to the FOIA? It could have a negative effect on manufacturers if individual AMPs were posted.
- 9) Would a manufacturer be permitted to resubmit a monthly AMP for a prior submission?
- 10) Will there be an incentive to purchase generics via dispensing fees? Will the fees be a flat dollar amount or based on a percentage of AMP?

## RECOMMENDATIONS FOR REGULATIONS DEFINING AMP

### EXCLUDE PROMPT PAY DISCOUNTS

#### RECOMMENDATION

**The regulations should affirmatively state that customary prompt pay discounts are not to be deducted when AMP is calculated.**

#### RATIONALE

The Deficit Reduction Act of 2005 (DRA) amended the statutory definition of Medicaid Average Manufacturer Price (AMP) in Social Security Act § 1927(k)(1) by deleting the requirement for “deducting customary prompt pay discounts” when AMP is calculated. HDMA understands Congress took this action because prompt pay discounts are a common practice widely accepted across many industries and should be viewed as a financial transaction representing the time value of money and risk mitigation, not as a component of the cost of the product.

Regulations affirmatively addressing the proper handling of prompt pay discounts are needed to ensure that manufacturers are alert to the statutory change in the definition of AMP that Congress chose to make by deletion. Such an alert is particularly important since the requirement to deduct prompt pay discounts from AMP has been in place since the Medicaid drug rebate program began in 1991.

The DRA includes a safeguard provision designed to ensure that the elimination of the deduction of customary prompt pay discounts from AMP is not abused in that it requires manufacturers to report on “customary prompt pay discounts extended to wholesalers” when they report AMP. This safeguard, coupled with the industry’s longstanding use of prompt pay discounts, removes the need for implementing regulations that further define customary prompt pay discounts.

## EXCLUDE WHOLESALER SERVICE FEES

### RECOMMENDATION

**The regulations should affirmatively state that fair-market-value (FMV) fees paid to pharmaceutical distributors for distribution services that are actually provided by the distributor are not to be deducted when AMP is calculated so long as there is no implicit or explicit agreement between the manufacturer and the distributor requiring the fees to be passed on, in whole or in part, to the distributors' customers.**

**Service fees, derived from manufacturer – distributor negotiations, are structured in a variety of ways. The preamble to the AMP regulation should discuss factors that manufacturers and distributors should consider in determining FMV.**

**The preamble also should recognize that manufacturers may treat service fees as a reduction from total revenues for purposes of financial accounting even though the AMP rule instructs them not to deduct the fees when they calculate AMP.**

### RATIONALE

Both Finance Committee Chairman Grassley and Energy and Commerce Committee Chairman Barton stated in separate floor statements that, “It was not the intent of the conferees to suggest that by dropping bona fide service fees from the final agreement [Deficit Reduction Act of 2005] that those service fees should be included in the calculation of the Medicaid Average Manufacturer Price (AMP) reimbursement methodology as established in the pharmacy reimbursement provisions of the conference agreement.”

CMS has provided guidance to the industry as a whole in the form of a Frequently Asked Question (FAQ) and directly to HDMA and Specialty Biotech and Distributors Association (SBDA) in a Dec. 9, 2004 letter, indicating that bona fide, FMV services fees should not be deducted when the Average Sales Price (ASP) is calculated. The stated rationale for the ASP instruction applies equally in the AMP context. Specifically, so long as service fees are not passed on to the distributors' customers, they “would not ultimately affect the price realized by the manufacturer.”

In spite of the FAQ, manufacturers have not handled service fees consistently in their ASP calculations. Some manufacturers have elected to deduct service fees when ASP is calculated despite the FAQ instruction. These manufacturers have expressed concerns about how to determine whether fees are FMV. To avoid this same confusion in the AMP context, it is imperative for the AMP regulation itself or for the preamble to that rule to discuss how manufacturers can establish that service fees, including those set based on a percentage of associated drug costs and other services, are FMV.

Some manufactures have expressed concerns about the fraud and abuse risks associated with accounting for service fees differently for financial accounting and ASP purposes. They note that GAAP-accounting principals mandate treating fees as reductions to revenue when the fees are paid to a distributor that takes title to products and argue that failure to treat the fees as a price concession for ASP purposes creates an unacceptable disconnect between ASP reporting and financial reporting. They also note that accounting rules permit service fees to be treated as an expense on the income statement when a third-party logistics company is retained to distribute drugs without taking title to the products. As a result, these manufacturers argue that they must contract with such services rather than use traditional wholesalers to safely avoid having to deduct distribution costs from ASP, even if doing so is more costly or less efficient.

It is inappropriate and inequitable for the costs for very similar services, such as the distribution of drugs to providers, to be treated differently under a price reporting rule. There is already precedent for a similar disconnect between accounting and price reporting with respect to AMP. The IRS has ruled that Medicaid drug rebates should be treated as reductions to revenue even though the Rebate Agreement prohibits manufacturers from deducting the rebates when AMP is determined (Revenue Ruling 2005-28, published in Internal Revenue Bulletin 2005-19 (May 9, 2005)).

OIG and CMS should anticipate such accounting concerns in the AMP context and address them either in the regulation or the rule's preamble, by stating that bona fide, FMV service fees are not to be deducted when AMP is calculated regardless of whether those fees are paid to wholesalers or distributors that take title or to third-party logistics companies that do not, or incurred internally by a manufacturer that self-distributes.

## MINIMIZE PERIOD-TO-PERIOD VARIABILITY IN AMP

### RECOMMENDATION

**The regulation should specify a smoothing methodology for accounting for all price concessions in the AMP calculation in a manner like that specified for use with lagged discounts under the ASP rule. The methodology should be well-defined enough to ensure consistent treatment by all manufacturers.**

### RATIONALE

The current instructions for calculating AMP are silent on whether chargebacks, rebates and other lagged discounts should be accounted for on an as-paid or an as-earned basis. As a result, different manufacturers have adopted different approaches. Some use the as-paid methodology for both chargebacks and rebates. Others use as-paid for chargebacks because the amount of chargebacks paid during a period is readily available within a few days after the period closes, but use an accrual approach for rebates. Still others accrue for both chargebacks and rebates.

Many large purchasers often buy pharmaceuticals in bulk and then sell from inventory for many months. The buying pattern can result in periods when a manufacturer's sales outstrip price concessions accounted for on an as-paid basis leading to an artificially high AMP, followed by one or more periods when discounts outstrip sales, leading to an artificially low AMP. Monthly reporting of AMP likely will exacerbate this problem. If a manufacturer elects to address this problem by accounting for lagged discounts on an accrual basis, it must periodically true-up AMP and Best Price reports to address accrual errors. Such true-ups can tax the capabilities of the rebate processing teams at the state Medicaid programs as well as the price reporting teams at the manufacturers. Moreover, the true-up approach, while it does allow for the eventual payment of the correct amount of Medicaid rebates, is inconsistent with the use of AMP prospectively as the reimbursement metric that will set the Federal Upper Limit (FUL) for multiple source drugs and, possibly, by some state Medicaid programs as a

reimbursement metric in formulas that determine the payment amounts that retail pharmacies will receive for drugs dispensed to Medicaid patients.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time can also distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, OIG/CMS should implement a well-defined smoothing methodology for handling all price concessions that must be considered in AMP that operates like the methodology specified for quantifying lagged discounts under the ASP rule. If OIG/CMS are not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates despite the availability of as-paid chargeback data for a period within days after the period close because such chargebacks can often relate back to sales several periods prior.

## EXCLUDE RETURN GOODS

### RECOMMENDATION

**The regulation should instruct manufacturers to disregard return goods when they calculate AMP.**

### RATIONALE

Returns to a manufacturer during a period of slow sales can actually result in a negative AMP. This, of course, is inconsistent with the use of AMP as a reimbursement metric, even for the limited purpose of setting FULs. There are two approaches to address this issue. First, as is the current CMS practice for rebate purposes, the government could revert to the last positive AMP for reimbursement purposes. Alternatively, returns could be disregarded in the calculation of AMP as they are in the ASP calculation. Given that comparisons between ASP and AMP are one of the pricing safeguards built into the ASP system, we favor the adoption of parallel rules for treating various parameters where appropriate. This would seem to be one of those situations.

## PROVIDE FOR THE CALCULATION OF AMP AT 11-DIGIT LEVEL

### RECOMMENDATION

**The regulation should stipulate that manufacturers must calculate and report AMP at the 11-digit NDC level.**

### RATIONALE

Currently, in accordance with the terms of the Medicaid Rebate Agreement, manufacturers calculate and report AMP as a weighted average for a given drug, strength and dosage form across all package sizes. In other words AMP is tied to the first 9-digits of the National Drug Code (NDC) number and ignores the last two digits which represent package size.

The weighted average AMP reporting process can become problematic when the weighted average value is overshadowed by sales of one package that is significantly larger than other packages of the same drug name/strength/dosage form. The difficulty with applying the weighted average approach across all products is that physicians often dictate the package size a pharmacy must dispense. For example, a physician may prescribe a 15-gm tube of cream to treat a small rash. The price per gram for the larger 60-gm tube is typically less. Applying the 9-digit NDC price may cause an AMP-based reimbursement rate to be too low to fairly reimburse the pharmacy for the 15-gm tube.

Similarly, averaging the typically higher costs of products used extensively in long-term care (LTC) facilities (due to the added cost of packaging as unit doses) with the cost of the same product packaged for retail settings, artificially inflates the AMP of the product and simultaneously depresses the AMP for the LTC setting.

The definition of AMP in Social Security Act § 1927(k)(1), as amended by DRA, does *not* require AMP to be calculated as a weighted average across all package sizes. This approach was adopted by CMS when it

drafted the Rebate Agreement used in lieu of regulations to implement the Medicaid drug rebate program in 1991. Accordingly, CMS has the authority to change course and require 11-digit NDC-specific reporting of AMP, just like it has required 11-digit NDC-reporting of ASP. It is important to do so since States will be permitted to incorporate AMP into reimbursement formulas that will be applied to drugs dispensed to Medicaid patients by retail pharmacy.

## EXCLUDE REBATES PAID TO PBMs ON RETAIL NETWORK SALES

### RECOMMENDATION

**The regulation should stipulate that rebates that do not reduce the effective price, such as those paid to PBMs on retail network sales, are not to be taken into consideration when AMP is calculated regardless of whether those rebates are linked to sales to Part D PDPs or MA-PD plans.**

### RATIONALE

Brand manufacturers typically pay rebates to pharmacy benefit managers (PBMs) for prescriptions dispensed to enrollees at retail pharmacies that participate in the PBM's retail network. The rebate payments are made to PBMs, even though the PBM does not actually purchase or dispense drugs to which the rebates are attached. Those monies are not shared with the retailers and should not be treated as a price concession that reduces AMP now that AMP will be used to set FUL and may become an element in the formulas that some state Medicaid programs use to reimburse retail pharmacies.

CMS has never issued clear guidance on how manufacturers should treat rebates paid to PBMs for retail network sales for purposes of AMP and manufacturers have adopted differing approaches.

To encourage manufacturer discounting under Part D, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 excluded rebates paid to Part D PDPs and MA-PDs, or the PBMs that operate these plans, from the calculation of Best Price. The MMA did not, however, address how Part D rebates should be handled for purposes of AMP.

CMS has historically excluded price concessions carved out of the Best Price formula from consideration when AMP is calculated and it should take a consistent approach with respect to the Part D Best Price carve out. Doing so would be consistent with the need to carve PBM retail network rebates out of AMP when those rebates are on non-Part D sales.

March 16, 2005

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OFFICE OF INSPECTOR  
GENERAL

March 21, 2006

The Honorable Daniel Levinson  
Inspector General  
U.S. Department of Health and Human Services  
Wilbur J. Cohen Building  
330 Independence Ave., S.W.  
Washington, D.C. 20201

**Subject: Chain Pharmacy Recommendations Relating to Definition of Average  
Manufacturers Price (AMP)**

Dear Inspector General Levinson:

The purpose of this letter is to supplement the comments that representatives of the National Association of Chain Drug Stores (NACDS) and the chain drug industry provided to staff of the HHS Office of the Inspector General (OIG) at our March 15, 2006 meeting regarding the calculation of the average manufacturers price (AMP). As you know, OIG is directed by the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171) to make recommendations to the Centers for Medicare and Medicaid Services (CMS) by June 1, 2006 regarding the factors and methods that should be included in the calculation of the AMP.

NACDS represents more than 200 companies that operate more than 35,000 community retail pharmacies. Collectively, our membership base dispenses more than 70 percent of all retail prescriptions in the United States. Our membership will be significantly impacted by the use of AMP as a reimbursement benchmark because it could result in significant underpayments for prescription medications if not accurately redefined.

In general, "AMP is the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP was created specifically in OBRA 90 to approximate the amounts that states were paying retail pharmacies for prescription drugs." In theory, the calculation of AMP is supposed to provide manufacturers with a credible value on which to base the rebates that they pay to states.

However, starting in January 2007, AMP will be used for the first time to set generic reimbursement rates for pharmacies. In addition, AMP values for single source and multiple source drugs will be made public and provided to the states starting this July. Therefore, accurate and consistent calculation of AMP is critical. AMPs must be calculated such that they are reflective of the prices at which retail community pharmacies purchase medications, or pharmacies will be underpaid for these medications.

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

Although AMP has been calculated by manufacturers for over 15 years, clear direction and guidance has never been given to manufacturers by CMS. This has resulted in wide inconsistencies in these calculations. In addition, the definition of AMP has not kept pace with changes in the pharmaceutical marketplace since 1990. For example, when AMP was originally defined, there were few PBMs in the marketplace. However, rebates, discounts and price concessions given by manufacturers to PBMs and health plans have become an important component of today's pharmaceutical marketplace. In this letter, we reiterate the key points made at our meeting about the factors that we believe should be considered in the calculation of AMP.

- **Include Only Manufacturers' Sales to Wholesalers for Traditional Retail Pharmacies:** Only manufacturers' sales to wholesalers for products that are ultimately sold to traditional community retail pharmacies – traditional chain, independent, mass merchandise pharmacies, and supermarket pharmacies – should be included in the calculation of AMP. In our view, these are the only entities that should be considered the “retail class of trade.” Past audit reports done by the OIG appear to agree with that interpretation of “retail class of trade.” We also note that in CMS' final rule implementing the Medicare Part D prescription drug benefit program, the agency defines “retail pharmacy” as “any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” Thus, it would be consistent with CMS' current Part D definition of “retail pharmacy” for the agency to indicate that only sales to true retail pharmacy establishments represent the “retail class of trade” for the purpose of calculating the AMP.

Given this suggested definition, only incentive-based discounts, rebates or other price concessions that are ultimately received by retail pharmacies should be deducted by the manufacturer from total retail pharmacy sales in calculating the AMP. Manufacturers should deduct chargebacks only to the extent that they know that these were provided for products sold by wholesalers to retail pharmacies. It is fair and reasonable that only amounts paid by manufacturers that are actually passed through to retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

- **Omit Mail Order and Nursing Home Sales in AMP Calculation:** Including manufacturers' sales of pharmaceuticals to wholesalers that are eventually sold to mail order pharmacies and nursing home pharmacies is inappropriate, in our view, even though CMS has instructed manufacturers to include sales to these purchasers. That is because these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts. These discounts are either retained by the PBM, or passed through in whole or part by the PBM to the payer. They are not made available to retail pharmacies. Thus, including these sales or rebates would lower the AMP for traditional retail pharmacies below their acquisition costs.
- **Omit Rebates paid by Manufacturers to PBMs:** When AMP was originally created in OBRA 90, PBMs had little prominence in the pharmaceutical marketplace. Now, most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies.

Manufacturers should not deduct these amounts from their sales to retail pharmacies when calculating the AMP. That is because retail pharmacies do not receive these price concessions. Including PBMs' sales and discounts unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. Medicaid also loses millions of dollars each year in manufacturer rebate revenues by including these non-retail sales in the definition of AMP.

- **Omit Customary Prompt Pay Cash Discounts Extended to Wholesalers:** As defined by law (and as amended by the Deficit Reduction Act of 2005), the AMP should be calculated without regard to prompt pay cash discounts extended by manufacturers to wholesalers. Cash discounts are provided to some retail pharmacies based on financing terms negotiated between the wholesaler and the pharmacy. These are not performance-based discounts. That is, a pharmacy may receive a small discount from the wholesalers or manufacturers for paying for the drugs in a shorter period of time than other purchasers. In addition, because not all pharmacies have the distribution infrastructure (i.e. warehousing and logistical capabilities) and cash flow to capitalize on these more favorable terms, the inclusion of prompt pay cash discounts in the calculation of AMP would be inappropriate. Given that the current rebate agreement defines wholesalers as "any entity (including a pharmacy or chain of pharmacies) to which the labeler sells covered outpatient drugs...", prompt pay discounts extended to chain warehouses that are also licensed as wholesalers should also be excluded from the AMP calculation.
- **Omit Payments made by Manufacturers for Bona Fide Service Fees:** Payments made by manufacturers to entities such as wholesalers and pharmacies for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's retail pharmacy sales when calculating AMP. These payments reduce manufacturers' revenues from the sale of their drugs, but they do not lower the pharmacies' costs of purchasing prescription drugs. Moreover, not all pharmacies are able to participate in these agreements, so deducting them when calculating AMP would be unfair to many retail pharmacies. CMS has already determined that such fees should be omitted from the calculation of the "average sales price," the basis of payment for Medicare Part B drugs. Specifically, CMS has indicated that bona fide service fees are "expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer, which would have been paid by the manufacturer at the same rate had these services been performed by other entities." OIG should recommend that a similar approach be adopted for AMP.
- **Omit Manufacturer Payments for Pharmaceutical Returns:** Each year, billions of dollars in expired and recalled pharmaceuticals must be returned by pharmacies and wholesalers to manufacturers. Manufacturers issue credit to wholesalers and pharmacies for these goods. Unfortunately, the level of credit provided is insufficient to cover the products' replacement value, the pharmacy's inventory cost of carrying the product to expiration, the reverse logistics cost of returning the expired and recalled product, as well as the administrative expense incurred by wholesalers and pharmacies to manage this process. A manufacturer's payment to a wholesaler or a pharmacy for expired and recalled merchandise as well as the fees for the associated services should be excluded from the manufacturer's AMP calculation.

If these payments and service fees are included in the AMP calculation, community pharmacies will actually incur not only the deficiency in the level of manufacturer's credit for the product and service, but also a reduction in reimbursement going forward for the associated products. Payments for expired and recalled pharmaceuticals and the associated services should not be interpreted as discounts or rebates and should be omitted from the AMP.

- **Omit Manufacturer Payments for Patient Care Programs:** Many pharmacies receive payments from manufacturers for performing certain patient care services, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation. These services provide valuable benefits to patients and overall the health care system because they improve patients' understanding of their medications and enhance patient compliance. Although they reduce the revenue that manufacturers receive on the sales of these drugs, they do not reduce the retail pharmacy's cost of purchasing the drugs. If these payments are included in AMP, pharmacies would lose incentive to offer these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, not all pharmacies participate in these programs so it would be unfair to many pharmacies to include these payments in the AMP.

Because of the wide inconsistencies in the way that manufacturers currently calculate AMP, we urge OIG to recommend that CMS not make the AMP data public this July until the agency publishes a final rule that defines AMP. We believe that a great disservice will be done to states, payers, consumers, and especially pharmacies by releasing data that have wide variability in their meaning, and are likely unreflective of the approximate prices paid by retail pharmacies for prescription medications. Only when the marketplace completely understands the methodology that is used to calculate AMP, as well as its relationship to the prices paid for pharmaceuticals by retail pharmacies, should the data be made public.

We also urge OIG to make several recommendations to CMS on how the agency applies the new Federal Upper Limit (FUL) for generic drugs which, beginning in January 2007, will be based on 250% of the lowest published AMP for a generic. In order to encourage continued generic drug dispensing in Medicaid, it is critical that the FUL be based on prices for products that are currently widely available in the marketplace. For example, we believe that only a generic product that is AB-rated in the FDA Orange Book, and is widely and nationally available to pharmacies for purchase in consistent supplies, should be used as the reference product to set the FUL.

In addition, the AMP used as the reference product to set the FUL should be weighted by sales across all the package sizes of the particular dosage form and strength of the drug. The sales included in this weighted calculation should be those to retail pharmacies only. This will assure that the AMP is weighted according to the package size most frequently purchased by pharmacies. As we discussed at our meeting, we also believe that OIG should recommend that CMS adopt a process that would allow manufacturers, when calculating AMP for a quarter, to "smooth" over a rolling 12-month period of time any discounts or rebates that are passed through to retail pharmacies. This will help reduce the potential for any significant fluctuations in AMP from quarter to quarter, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturers' calculation of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement.

Without this process, it is very possible that upper limits for generics could be based on AMPs that are simply not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

Finally, to assure that generic drug dispensing in Medicaid can be maintained or even increased, we urge that the FUL amount be the minimum payment that states make for a particular dosage form and strength of a generic drug. We believe that State Maximum Allowable Cost (MAC) programs for generics should be discouraged because further reductions in state payment for generics can ultimately result in reduced generic dispensing. States should also be advised of the need to consider increases in generic drug dispensing fees for 2007 to assure that pharmacies have appropriate incentives to continue to dispense lower-cost generic drugs.

We appreciate the opportunity to meet with you and provide our views on these important issues. Please contact us if we can provide any additional insight on these specific recommendations. We look forward to reviewing OIG's recommendation and to discussing these matters further. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Lee L. Verstandig".

Lee L. Verstandig  
Senior Vice President, Governmental Affairs

To:           OIG, HHS

From:        Charlie Sewell, Vice President, Government Affairs

Date:        March 16, 2006

Re:         NCPA Comments on AMP provisions of Deficit Reduction Act of  
              2005

The National Community Pharmacists Association (NCPA) appreciates your continued interest in community pharmacy and for taking the time to meet today to discuss the issues, challenges and problems arising from implementation of the Deficit Reduction Act of 2005 (“the Act”). Most specifically, we are providing you with this comment memorandum regarding implementation of the Act and how its problematic use of a nebulously defined benchmark could have significant, harmful effects on Medicaid recipients, community pharmacies, local economies and states.

**NCPA’s Request:**

In sum, NCPA requests that: 1) you use your authority to ensure that the definition of AMP covers all of pharmacists’ acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of these major changes in the Medicaid program.<sup>1</sup>

**The Troubling Result From Using AMP:**

NCPA represents the nation’s community pharmacists, including the owners of more than 24,000 pharmacies that dispense nearly half of the nation’s retail prescription medicines. Because many Medicaid recipients depend on their local community pharmacies to provide them with needed medication, NCPA is compelled to alert you to language in the Act that negatively affects the costs savings that could otherwise benefit drug purchasers, States and the federal government.

As you know, the Act greatly reduces pharmacy reimbursement on generic drugs for Medicaid prescription drug recipients. The law ties reimbursement to a price index known as the Average Manufacturers Price (AMP). Leading generic drug manufacturers estimate that, as currently defined by the Manufacturers Rebate Agreement, **AMP will, on average, only reflect 50% of actual ingredient**

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<sup>1</sup> The new Medicaid law requires that CMS disclose, starting July of 2006, the AMP pricing data to state Medicaid programs and the public. Unfortunately, the Secretary is not required to implement a regulation defining AMP until July 2007, one year after the AMP data are made public.

**cost for generic drugs.** Considering the unknown reliability of AMP and insufficient dispensing fees, the planned Federal Upper Limit (FUL) as contained in **the Act will effectively gut the reimbursement for generic drugs** under the Medicaid program. In stark contrast, brand name drugs are unaffected, and will be the only drugs on which pharmacists will be able to recoup their costs.

The result of promoting the use of brand name drugs over generics would be very costly. For every one percent of market share filled with a brand name drug that could be filled with a generic, Medicaid – and thus needy beneficiaries and taxpayers – will lose hundreds of millions of dollars. The lowest generic fill rate among states failing to promote generic drugs is 42%. If AMP is not correctly defined, and if dispensing fees are not increased, the potential for savings from generic drug utilization will be lost. An inadequate reimbursement level and concomitant decrease in use of generics will drive many pharmacies from the Medicaid program. Access in rural areas of the country could be particularly harmed. This resulting lack of access to quality prescription care will drive state Medicaid expenses higher as more patients require emergency room or nursing home care.

This outline of resulting harm is realistic, yet difficult to quantify. Estimating the real financial impact on retail pharmacies is extremely difficult because CMS has not publicly released AMP or issued clear guidance on how manufacturers should calculate AMP.

Based on how AMP is currently reported by manufacturers, it is clear that harmful consequences would follow from using the current AMP. NCPA respectfully urges you to use the wide statutory authority granted HHS regarding the definition of AMP to ensure that it covers 100% of pharmacists' acquisition costs. Doing so would ensure adequate reimbursements for generic drugs, thus promoting savings to the government and the health care system.

**Problems With Using AMP as the Bench Mark to Determine Reimbursement Amounts and Rates:**

In theory, AMP data approximates the prices at which retail pharmacies purchase medications from manufacturers via wholesalers.<sup>2</sup> For various reasons that are discussed below, however, AMP data is not at all likely to reflect the prices at which retail pharmacies purchase drugs. Because AMP was created, and is used, as a benchmark for rebate payments paid by manufacturers to state Medicaid programs, there is an inherent incentive on the part of the manufacturer to report the lowest price possible – a price that does not reflect true market costs for community pharmacy.

This fundamental problem in creating, using and monitoring the use of AMP is manifest in the following structural flaws:

- Currently, each manufacturer defines AMP differently, thus creating great inconsistencies in what is reported to CMS. In a February 2005 study (GAO-05-102), the Government Accounting Office reported that these inconsistencies are documented in the four Office of Inspector General (OIG) reports on audits of manufacturer-reported prices since the programs inception in 1991 (the reports were issued in 1992, 1995, 1997 and 2001). The GAO reported that the OIG reviews found “considerable variation in the methods that manufacturers use to determine AMP and some methods could have reduced the rebates state Medicaid programs received.” (GAO-05-102)

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<sup>2</sup> AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the real pharmacy class of trade. *See* 42 U.S.C. §1396r-8(k)(1). There is no definition in the statute for “retail pharmacy class of trade.”

at p.5). Furthermore, “in four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, by a lack of manufacturer documentation, or by both.” (*Id.*, p.4).

- The GAO study found that **clear guidelines on how AMP is to be calculated have not been issued by CMS, nor has CMS resolved price determination problems.** “OIG found problems with manufacturers’ price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved” (*Id.*).
  - Examples of some manufacturers taking advantage of the opportunity to alter AMP include:
    - Sales to mail order pharmacies and nursing homes when calculating AMP. Because mail order and nursing homes pay lower prices than retail pharmacies, including them in the calculation lowers the AMP below the price a traditional retail pharmacy pays.
    - Rebates paid to health plans and Pharmacy Benefit Managers (PBMs) when calculating AMP. These discounts are typically extended to bulk purchasers such as chain pharmacies, major wholesalers, and mail-order facilities that buy directly from the manufacturer. These discounts are simply not available to independent pharmacies, further widening the gap between AMP and market price.
    - These price concessions, however, are not available to retail pharmacies and therefore do not lower the pharmacies' costs of purchasing prescription drugs. Including PBMs' sales and discounts may lower the AMP to a level that does not reflect the cost to a retail pharmacy.
    - As the manufacturer must pay rebates based on AMP, the manufacturer then has an incentive to report the lowest numbers possible.
  - Wholesaler costs and margins will not be covered by AMP. Federal law also makes few provisions for state determined dispensing fees which will become critical in ensuring that the professional services of pharmacists remain available to Medicaid patients.
  - State MAC lists currently are lower than the FUL – significantly lower for some products and in some states. If states follow their current practice, often states will reimburse below the 250%. A study is needed to evaluate what currently happens and to find out how much below 250% of AMP states are reimbursing.

**Conclusion:**

Since all reimbursement cuts will come from generic prescription drugs, the AMP must be defined to cover acquisition costs or a perverse incentive will be created to dispense brands that could end up costing the program much more. To avoid the drastic consequences employing AMP in a situation for which it was not designed, NCPA respectfully requests that you recommend that: 1) HHS use its authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the major changes in the Medicaid program.



April 7, 2006

**VIA HAND DELIVERY AND E-MAIL**

Daniel R. Levinson, Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Cohen Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: Average Manufacturer Price Recommendations**

Dear Mr. Levinson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide the following information on the determination of Average Manufacturer Price (AMP) in response to the Office of Inspector General's (OIG's) request for input on these issues. PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in working with the government to develop clear and carefully-considered rules on the calculation of Medicaid rebates and the reimbursement of pharmaceutical products. Given this interest, and the Government Accountability Office's (GAO's) finding that clearer guidance is needed regarding AMP calculations,<sup>1</sup> we were pleased that Congress recently charged the OIG with reviewing "the requirements for, and manner in which" AMP is determined and submitting any recommendations it considers appropriate "for changes in such requirements or manner" to the Centers for Medicare and Medicaid Services (CMS) and Congress.<sup>2</sup> We believe this mandate provides an important vehicle for helping to improve the clarity and

<sup>1</sup> GAO, Medicaid Drug Rebate Program, Inadequate Oversight Raises Concerns about Rebates Paid to States, GAO-05-102, 4 (Feb. 2005).

<sup>2</sup> Deficit Reduction Act of 2005, P.L. 109-171, § 6001(c)(3) (2006). Following its receipt of the OIG's recommendations, CMS must issue regulations clarifying AMP calculations, taking into consideration the OIG's recommendations, by July 1, 2007.

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***Pharmaceutical Research and Manufacturers of America***

consistency of AMP calculations, which will now, in addition to affecting Medicaid rebates, affect pharmacies' Medicaid reimbursement rates for certain pharmaceuticals.

We appreciate the recent opportunity OIG provided to PhRMA to meet and discuss these issues, and we have focused our written comments on several of the issues raised by OIG during that meeting. Specifically, our comments address the following topics: the function of AMP, defining the "retail pharmacy class of trade," the ability to capture transactions between downstream entities in manufacturers' AMP calculations, the timing and application of changes in AMP, the issues associated with using AMP as a reimbursement metric, and the frequency of AMP reporting. These comments are preceded by general principles that PhRMA hopes the OIG will consider as it develops recommendations concerning the methodologies and manner in which AMP is calculated.

- As a general matter, AMP calculations should result in a calculated price that represents the amount realized by the manufacturer for product sold and distributed to wholesalers in the relevant period for purchasers who are in the retail pharmacy class of trade.
- Guidance concerning the calculation of AMP should be formalized in regulations that give stakeholders adequate opportunity for notice and comment.
- CMS should apply its regulations prospectively and give manufacturers ample time to operationalize systems, policies, and procedures to support the new AMP calculation.
- CMS should issue regulations to ensure that AMPs that now will be used in reimbursement formulas are calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts; and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims.
- Any procedures developed by CMS should recognize that there may be instances that call for restatements of AMP notwithstanding efforts to ensure the accuracy of reported data.
- Because the DRA changes the definition of AMP, CMS should develop a mechanism to conform baseline AMPs to the revised statutory definition of AMP for purposes of the additional rebate.

\* \* \*

## **A. Retail Pharmacy Class of Trade**

AMP is defined by statute as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”<sup>3</sup> As Congress recognized in the Deficit Reduction Act of 2005 (the DRA) when it directed the OIG to develop recommendations, and CMS to issue regulations concerning AMP, there is a need for clear and consistent guidance concerning the definition and calculation of AMP. This need for clarity is particularly critical given the use of AMP to establish Medicaid drug rebates. Moreover, it will take on even greater significance because AMP also will be used to establish upper payment limits for State Medicaid prescription drug payments beginning in 2007. Notably, the statute does not define AMP as a metric that approximates pharmacy acquisition costs. As discussed above, AMP is defined as the “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”<sup>4</sup> The statute does not define AMP as retail pharmacy acquisition costs. Moreover, Congress further demonstrated its understanding that AMP does not directly measure pharmacies’ acquisition costs when it chose to apply a 2.50 multiplier to establish FULs for multiple source drug products.

CMS has issued guidance previously regarding the definition of AMP in the Medicaid Rebate Agreement, certain Medicaid Rebate Releases, and proposed rules, but it has not defined the term “retail pharmacy class of trade” or provided a comprehensive listing of which entities fall inside and outside the retail pharmacy class. The language in the Rebate Agreement bearing on this issue provides that:

[AMP] means . . . the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP.<sup>5</sup>

In the preamble to proposed (but never finalized) regulations published in 1995, CMS similarly stated that:

[S]ales that a manufacturer makes to other than the retail class of trade must be excluded [from AMP]. Thus, sales where the buyer relabels or repackages the drug with another NDC number and sales through wholesalers where the manufacturer pays a chargeback for sales to an

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<sup>3</sup> 42 U.S.C. § 1396r-8(k)(1). Under the DRA section 6001, customary prompt pay discounts extended to wholesalers will be excluded from AMP calculations by 2007.

<sup>4</sup> Id.

<sup>5</sup> Medicaid Rebate Agreement, § I(a), *available at*, <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf>.

excluded buyer, such as a hospital, would not be considered sales to the retail class of trade.

We would also exclude from this definition direct sales to hospitals, health maintenance organizations and to distributors where the drug is relabeled under that distributor's NDC number because these entities are not considered the retail pharmacy class of trade. We would also exclude Federal Supply Schedule (FSS) prices from the calculations of AMP since the statute does not include FSS and FSS does not represent a retail level of trade.<sup>6</sup>

Finally, in Medicaid Rebate Release 29 (1997), CMS listed certain categories of sales as either included in or excluded from AMP. Specifically, the release provided that: (1) AMP includes mail order and retail pharmacy sales, "nursing home primary/contract pharmacy sales," and "sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC"<sup>7</sup>; (2) AMP excludes direct sales to hospitals, HMO sales, Public Health Service (Section 340B) covered entity sales, "state-funded only-pharmacy assistance programs," "VA/DoD excluded sales," Federal Supply Schedule sales, and "sales to other manufacturers who repackage/relabel under the purchaser's NDC"; and (3) sales to wholesalers are included in AMP "except for sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories."<sup>8</sup> Although Release 29 clarified some issues, it did not address a variety of entities and arrangements that could affect the calculation of AMP. Moreover, Release 29 is likely outdated given the continuously evolving nature and functions of various entities in the pharmaceutical distribution chain.

For example, CMS has not specified whether other specific categories of sales are included in or excluded from AMP. Some of the customers not addressed in Release 29 include, for example, physician groups, clinics other than Section 340B covered entities, and patients (i.e., there is no guidance on whether patient coupons or other patient discount programs affect AMP calculations).<sup>9</sup> There has also been a lack of clear guidance regarding whether rebates to PBMs or payors (including Medicare Part D plans) should be excluded from AMP calculations, and (if so) whether manufacturers should simply exclude the rebates themselves from AMP calculations or should remove from the AMP numerator and denominator the underlying sales to wholesalers to which the rebates are attributed.

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<sup>6</sup> 60 Fed. Reg. 48442, 48462 (Sept. 19, 1995).

<sup>7</sup> The Rebate Agreement defines a "wholesaler" as "any entity (including a pharmacy or chain of pharmacies) to which the [manufacturer] sells the Covered Outpatient Drug, but that does not repackage or relabel the Covered Outpatient Drug." Rebate Agreement, § I(ee).

<sup>8</sup> Rebate Release No. 11 (1994) also states that "sales of hemophilic drugs to home health care providers must be included in the calculation of AMP," indicating that home health care providers would be considered part of the retail pharmacy class of trade. (Emphasis omitted.)

<sup>9</sup> CMS has issued guidance on this topic in the Best Price context.

As a result of the unaddressed questions regarding the “retail pharmacy class of trade,” the GAO found that manufacturers made different assumptions about which entities were considered within the class.<sup>10</sup> Consequently, to reduce manufacturers’ uncertainties and increase the consistency of AMP calculations, it will be important for the OIG to make strong recommendations regarding the clarification of these definitional issues.

In an evolving marketplace, terms such as “wholesaler” and “retail” may be interpreted in different ways by different companies and entities. Entities are more appropriately categorized for purposes of defining AMP by the actual functions they perform rather than by the names by which they generally are known at any given time. Thus, PhRMA believes that an optimum approach is to use function-based analysis that recognizes that the function of an entity in the distribution chain may govern whether particular transactions should be included in the calculation of AMP. We suggest the following function-based definitions for the key AMP terms: “wholesaler” and “retail class of trade.”

- i. **Wholesaler** shall mean those entities that purchase covered outpatient prescription drugs as defined in Section 1927(k) directly from the manufacturer, or its authorized agent, and that take legal title to the prescription drug product.
- ii. **Retail Class of Trade** (a) shall mean, subject to subsection (b), those entities or such subdivisions, departments or lines of business that:
  1. dispense covered outpatient drugs to patients, who are members of the general public on a walk-in basis, pursuant to a prescription, including for example, retail, independent, and chain pharmacy;
  2. dispense covered outpatient drugs to patients through the mail (or other common carrier) pursuant to a prescription and the patient does not receive other specialized or home care services in addition to the dispensed drug;and (b) shall not include such entities or such subdivisions, departments or lines of business that:
  1. only dispense covered outpatient drugs to inpatients of the entity (e.g., inpatient hospitals);

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<sup>10</sup> GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concern, at 16.

2. administer the drug "incident to" a physician or other licensed prescriber's services' (e.g., physician offices);
3. dispense only to a defined and exclusive group of patients who have access to dispensing services (e.g., closed pharmacy, staff model HMO, or correctional facility);
4. are federal, state, or local government purchasers and those purchasing under the federal supply schedule (e.g., VA);
5. are exempt from best price (e.g., 340B entity, SPAP, Part D Plans);
6. are other wholesalers or distributors that do not dispense to patients;
7. negotiate or arrange for pricing terms for third parties but that do not take possession of the drug product (e.g., GPO);
8. repackage or relabel under the entity's own NDC; or
9. are entities to which sales below 10% of AMP are considered to be nominal sales under Section 1927(c)(1)(D).

All parenthetical examples are for illustrative purposes and manufacturers may document that sales to such an entity should be included or excluded in the retail class of trade based on its function in a manner that differs from the illustrative example. Two areas where it would be helpful for the OIG to provide recommendations concern the application of these functional standards to long-term care facilities, PBMs, and other entities that reimburse for drugs but do not take title or possession of the drug product.

**B. Taking Into Account Transactions Between Downstream Entities in AMP Calculations**

In PhRMA's recent meeting with the OIG, the OIG expressed interest in obtaining additional information on the pharmaceutical distribution chain and the flow of payments within the pharmaceutical system. The OIG also indicated that it was interested in this information on the pharmaceutical supply chain and payment system partly in order to gain an understanding of whether manufacturer payments were passed through by their recipients to other parties. In addition, the OIG asked whether it would be feasible for manufacturers to require contractually that recipients of

payments inform the manufacturer about whether the payments had been passed through to others.

As noted at the meeting, PhRMA does not obtain information on member companies' pricing practices due to antitrust concerns, and information on pricing and payment arrangements between many of the participants in the pharmaceutical system is closely held and generally unavailable to manufacturers in any case. However, we have included in the appendix a brief general overview of the pharmaceutical distribution chain and payment system, based on information from publicly available reports.<sup>11</sup> In addition, we address the question raised in the meeting about the feasibility of requiring contractual reporting of downstream payments.

In past guidance, CMS has sometimes suggested that whether a certain manufacturer payment should be taken into account in the manufacturer's pricing calculations may depend on whether the payment is passed through by its recipient to another party.<sup>12</sup> In recent Average Sales Price (ASP) guidance on service fees paid to buyers, CMS stated that "[b]ona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on in whole or in part to a client or customer of an entity" should be excluded from ASP because "these fees would not ultimately affect the price realized by the manufacturer."<sup>13</sup> However, the ASP analysis may not adequately capture the fluid nature of certain transactions with and among downstream entities or the role of different entities in the distribution chain. Accordingly, PhRMA believes that OIG and CMS should clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities.<sup>14</sup> We believe that such a requirement would create serious problems and urge the OIG not to recommend this approach. Manufacturers have no authority to demand that payment recipients disclose to the manufacturer whether they have shared the payment in question with their own customers or clients, and there is no guarantee that payment recipients would agree voluntarily to such disclosures. The payment recipient might reject such disclosure provisions due to, for example, concerns about its ability to

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<sup>11</sup> Our discussion is based exclusively on publicly available sources cited in the appendix. Principal among the sources are (1) Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies*, Aug. 2005 (FTC report); (2) *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, report prepared for The Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005 (*Follow the Pill*); (3) *Navigating the Pharmacy Benefits Marketplace*, report prepared for the California HealthCare Foundation by Mercer Human Resource Consulting, Jan. 2003 (*Navigating the Pharmacy Benefits Marketplace*); (4) *Study of Pharmaceutical Benefit Management*, report by PricewaterhouseCoopers LLP for the Health Care Financing Administration, June 2001 (PricewaterhouseCoopers report); and (5) Department of Health and Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices*, April 2000 (HHS report).

<sup>12</sup> CMS alluded to pass-through issues in its rebate guidance on PBMs (which has caused interpretive difficulties), stating in part that "where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations." *Medicaid Rebate Release No. 29* (1997).

<sup>13</sup> CMS Frequently Asked Question ID 4136 (last updated Feb. 14, 2006).

<sup>14</sup> At the same time, OIG and CMS should recognize the need for clear guidance concerning these transactions and their role (if any) in AMP calculations.

preserve the confidentiality of this competitively sensitive information once it was routinely disclosed to manufacturers; concerns about the administrative burdens associated with such reporting obligations; or concerns about the potential liability risks associated with furnishing manufacturers with information that would be used in the manufacturer's AMP calculations, and that could thus result in incorrect rebate payments and Medicaid reimbursement rates if the information turned out to be inaccurate in some respect. Consequently, manufacturers simply might be unsuccessful in negotiating contractual provisions requiring disclosure of pass-through information, or they could experience prolonged delays in negotiating contracts important to their ability to sell products or to acquire needed services.

Moreover, even if manufacturers could negotiate and enforce pass-through reporting provisions, the resulting information could be difficult to incorporate into a manufacturer's systems for calculating and reporting AMP. As discussed in the appendix, for example, PBMs' contracts with their clients do not have uniform provisions on the sharing of manufacturer rebates. To report whether the rebates paid by a manufacturer for a specific quarter were passed through, the PBM might need to determine the clients to which those rebates were attributable and separately identify pass-through and non-pass-through rebates. In turn, the manufacturer could not rely on a standard protocol specifying that (say) PBM rebates are taken into account in AMP calculations; instead, each AMP-reporting period, manufacturer personnel would need to review each PBMs' disclosure report and make case-by-case decisions about the appropriate treatment of PBM rebates in the AMP calculation. These kinds of frequent manual interventions in the AMP-calculation process could substantially increase the complexity of these calculations and heighten the risk of error, thus making it difficult for manufacturers to provide CMS with accurate AMP data on a timely basis. Similarly, delayed pass-through reports from payment recipients could complicate AMP calculations and cause overly burdensome restatements in previously reported AMP figures.

Given the problems with requiring that manufacturers contract with customers to obtain information on pass-through issues and then incorporate that information into their AMP calculations, we urge the OIG to recommend that CMS not adopt such an approach.

### **C. Other Issues**

During PhRMA's meeting with the OIG on March 16<sup>th</sup>, PhRMA raised a number of issues concerning implementation of the AMP provisions in the DRA and changes to the definition and methodology used to calculate AMP. PhRMA's written comments and recommendations concerning several of these issues are set forth below.

### 1. Conforming Baseline AMPs to the New AMP Definition

The “additional rebate” for innovator drugs equals the current-period AMP minus the inflation-adjusted baseline AMP (usually the AMP from the first full quarter after launch).<sup>15</sup> Because the DRA changes the definition of AMP, it raises the question of what mechanism should be used to conform baseline AMPs (as of the quarter when the AMP definition changes to exclude prompt pay discounts) to the revised statutory definition of AMP. The OIG may wish to recommend that CMS work with companies to develop reasonable methodologies to make this correction.<sup>16</sup>

### 2. Prospective Application of Clarification of AMP Guidance

The OIG should recommend that CMS issue regulations and guidance that make only prospective changes in AMP calculations. This recommendation would be consistent with the DRA, which calls for regulations that clarify “the requirements for, and manner in which, average manufacturer prices are determined,” not were determined in the past, and would recognize GAO’s finding that manufacturers have historically had to rely on reasonable assumptions in certain areas due to the absence of clear guidance.<sup>17</sup> Prospective application of changes to AMP calculations would also avoid the difficulties and disruptions associated with industry-wide retrospective recalculations of past period AMPs.

### 3. Timing Issues Associated With Changes in AMP

The DRA contains a number of AMP-related provisions that take effect (or have deadlines) at different dates, which could result in a series of sequential changes to AMP calculations unless CMS makes an effort to synchronize the changes.<sup>18</sup>

Recognizing that manufacturers need sufficient lead time to change their systems and collect any additional data that may become relevant to AMP calculations, OIG should issue a recommendation that CMS provide adequate phase-in periods for any changes in AMP. The OIG also should recommend that CMS issue proposed and final AMP regulations as promptly as possible and seek to avoid a series of sequential changes in AMP calculations; frequent changes in AMPs due to a series of regulatory

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<sup>15</sup> See 42 U.S.C. § 1396r-8(c)(2).

<sup>16</sup> We note that any changes in the existing requirements for calculating AMP that CMS adopts in its regulations on AMP calculations could raise similar questions regarding the baseline AMP.

<sup>17</sup> DRA § 6001(c)(3). (Emphasis added.)

<sup>18</sup> Some of the relevant dates for DRA AMP provisions are: June 1, 2006 (deadline for OIG recommendations regarding the requirements for and manner in which AMP is determined); July 1, 2006 (CMS must provide AMP data on a website accessible to the public); January 1, 2007 or earlier (AMP definition changes to exclude customary prompt pay discounts extended to wholesalers); January 1, 2007 (DRA section 6003 takes effect, which modifies the AMP definition “[i]n the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act”); and July 1, 2007 (deadline for CMS to issue regulations on AMP).

changes could heighten instability for providers that receive AMP-based payments for multiple source drugs, confuse the public (which will soon have access to AMP data), and require repeated changes in manufacturers' data collection and reporting systems. Similarly, the OIG may wish to caution manufacturers that changing their AMP reporting systems in response to the OIG recommendations could exacerbate these problems, as the final AMP regulations issued by CMS could differ from the OIG recommendations, and require that manufacturers adopt a different set of changes in AMP calculations.

#### 4. Issues Associated With Using AMP as a Reimbursement Metric

Effective January 1, 2007, the DRA bases the Medicaid federal upper limit for multiple source drugs on AMP. Any recommendations or regulations should ensure that AMPs that are used in reimbursement formulas can be calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts;<sup>19</sup> and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims. This could raise issues regarding AMP similar to issues that have been raised in the context of ASP (the drug reimbursement metric generally used under Medicare Part B).<sup>20</sup> Notwithstanding efforts to ensure the accuracy of reported data, there may be instances that call for restatements of AMP. This raises a dilemma given AMP's new role as a reimbursement metric, because the restatement could occur after a state has set the AMP-based reimbursement rates for a particular period. The OIG may want to formulate recommendations on a method for resolving this dilemma.

Moreover, the OIG also may wish to caution the states about the potential volatility associated with using AMPs that may change substantially due to sequential changes that will occur as the OIG issues recommendations in June 2006, and CMS issues a regulation by July 2007, concerning the new definition and clarification of AMP.<sup>21</sup>

#### 5. AMP Reporting Frequency Issues

Section 6001 of the DRA appears to amend SSA § 1927(b)(3)(A)(i) to call for monthly reporting of AMP and Best Price.<sup>22</sup> However, section 6003 then strikes section

<sup>19</sup> Zero or negative amounts should not be an issue under existing CMS guidance, which provides that if a zero or negative AMP occurs in a given quarter, the manufacturer should report the last calculated AMP with a value greater than zero. Medicaid Rebate Release No. 38 (1998).

<sup>20</sup> As in the ASP context, returns should also be addressed.

<sup>21</sup> The DRA requires the Secretary to make available to the states the AMPs for single source and multiple source drugs beginning in July 1, 2007. These AMPs may be substantially different from AMPs calculated after January 1, 2006 because of the newly promulgated definition of AMP which now directs manufacturers to exclude prompt pay discounts to wholesalers. Moreover, AMPs may change as a result of OIG's recommendations (due in June 2006) and CMS regulations (due July 1, 2007).

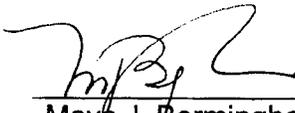
<sup>22</sup> Section 6001(b)(1)(A) amends Social Security Act § 1927(b)(3)(A)(i) to state that manufacturers with rebate agreements shall report AMP and Best Price to the Secretary "not later than 30 days after the last day of each month of a rebate period under the agreement . . . ." (Emphasis added.)

1927(b)(3)(A)(i) and replaces it with new language that refers to AMP and Best Price being reported "not later than 30 days after the last day of each rebate period."<sup>23</sup> Thus, it appears that the law did not effectively change the frequency of manufacturers' reporting obligations. In the event that the DRA were to be interpreted to call for monthly reporting of AMP and Best Price, a number of issues would arise, and it may be helpful for OIG to develop recommendations on these points should they become relevant. OIG should recommend how quarterly rebates should be calculated and should recommend against basing rebates on weighted averages of monthly AMPs. In addition, OIG should recommend that restatements of quarterly AMPs continue to be permitted and that any monthly AMPs (should the statute ultimately be interpreted to require such calculations) not be restated.

\* \* \*

PhRMA hopes that these comments will be helpful to the OIG as it formulates its recommendations to CMS and the Congress regarding AMP reporting and looks forward to providing additional input. We appreciate the time taken by OIG staff to meet with us and consider our comments, and the substantial effort your office is making to develop recommendations that can lead to clearer ground rules for AMP reporting and an improved system. Please do not hesitate to contact us with any questions or requests for additional information.

Sincerely,



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Maya J. Birmingham  
Assistant General Counsel



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Ann Leopold Kaplan  
Assistant General Counsel

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<sup>23</sup> DRA § 6003(a)(1).

## Appendix

### Overview of the Pharmaceutical Payment System<sup>24</sup>

While there is variation in the way that prescription drugs are distributed, the payment and pricing system is much more complex than the distribution system, and continually is evolving. Partly this increased complexity is because payment and pricing arrangements involve additional parties that generally do not play a role in the physical distribution of pharmaceuticals: in particular, PBMs and payors. As summarized in one report, “while the flow of products through the pharmaceutical chain is relatively straightforward, the flow of money involves a wider range of players and complex financial relationships.”<sup>25</sup> The discussion below begins with a general summary of the payment arrangements between the key entities involved in the distribution chain — manufacturers, wholesalers, and pharmacies — and then briefly describes some of the other participants in the payment system and the roles they play.

As noted earlier, manufacturers most commonly sell to wholesalers that resell to pharmacies. Manufacturers’ list prices to wholesalers are known as wholesale acquisition cost (WAC).<sup>26</sup> Wholesalers typically purchase at a discount off of WAC<sup>27</sup>; examples of discounts for branded products include prompt pay discounts, volume discounts, and “short-dated” product discounts (where the wholesaler assumes the risk that the product will expire before it can be resold).<sup>28</sup> In recent years, the major wholesalers have sought to move to a “fee-for-service” model in which they negotiate fees with manufacturers for activities such as distribution and inventory management.<sup>29</sup>

Pharmacies that purchase from wholesalers pay an amount negotiated with the wholesaler. According to one report, pharmacies typically pay wholesalers WAC plus some negotiated percentage.<sup>30</sup> In some cases, pharmacies or other “end-user” customers that purchase through wholesalers may negotiate rebate agreements with manufacturers, or they may negotiate a contracted price with the manufacturer. When

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<sup>24</sup> As noted earlier, this appendix provides a brief general overview of the pharmaceutical distribution chain and payment system based on information in publicly available reports. Particularly given the complexity of the payment system, there may be arrangements or practices not captured in these reports.

<sup>25</sup> Navigating the Pharmacy Benefits Marketplace at 18.

<sup>26</sup> As defined in the Medicare Modernization Act, WAC represents “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug and biological pricing data.” Social Security Act §1847A(c)(6)(B).

<sup>27</sup> Follow the Pill at 18.

<sup>28</sup> Id.

<sup>29</sup> See, e.g., R. David Yost, New Economics of the Pharmaceutical Supply Chain, 62 Am. J. Health-System Pharm. 525 (March 2005).

<sup>30</sup> Follow the Pill at 18.

wholesalers sell to customers that have a contract price with a manufacturer, they charge the contract price and then bill the manufacturer for a “chargeback”; the chargeback equals the differential between WAC and the contract price.<sup>31</sup>

Smaller pharmacies also may use group purchasing organizations (GPOs) in some cases to negotiate prices with wholesalers or manufacturers.<sup>32</sup> GPOs are entities that negotiate discounted prices on behalf of their members (which primarily are hospitals and other healthcare providers) from manufacturers and distributors of pharmaceuticals and other healthcare products. Pharmaceutical manufacturers and other vendors pay administrative fees to GPOs, which (at least in the case of six GPOs that were studied by the OIG) distribute a portion of their administrative fee revenues to their members.<sup>33</sup>

PBMs play a number of roles in the pharmaceutical payment system. Normally PBMs are not directly involved in the product supply chain, since they do not take physical possession or control of pharmaceuticals as part of their core pharmacy benefit management functions.<sup>34</sup> However, many PBMs own and operate mail order pharmacies and (in their capacity as mail order pharmacies) buy drugs from wholesalers or manufacturers and dispense them to patients.<sup>35</sup>

PBM clients can generally be described as “payors.” That is, a PBM’s clients usually are entities that provide prescription drug insurance to their enrollees or members, such as self-insured employers, insurers, and HMOs and other managed care organizations.<sup>36</sup> The specific services a PBM performs will vary depending on its contract with particular clients, but PBM functions generally include forming pharmacy networks and negotiating discounted reimbursement rates with network pharmacies; developing and administering formularies and related features of the plan design (e.g., formulary tiering structures, utilization management tools such as prior authorization); negotiating rebates with manufacturers; and processing claims.<sup>37</sup>

Payments that PBMs negotiate with manufacturers of brand-name drugs include rebates, and administrative fees that compensate the PBM for formulary-related administrative activities.<sup>38</sup> The effect of manufacturer rebates to PBMs on

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<sup>31</sup> Id. at 19.

<sup>32</sup> Navigating the Pharmacy Benefits Marketplace at 25; Follow the Pill at 19-20.

<sup>33</sup> See HHS OIG, Review of Revenue From Vendors at Three Group Purchasing Organization and Their Members, A-05-3-00074, Jan. 2005 (the GPOs studied collected \$1.8 billion in administrative fee revenue during the audit period and distributed \$898 million to members); HHS OIG, Review of Revenue From Vendors at Three Additional Group Purchasing Organizations and Their Members, A-05-04-00073, May 2005 (GPOs studied collected \$513 million in administrative fee revenue during the audit period and distributed \$217 million to members).

<sup>34</sup> Follow the Pill at 14-15; FTC report at 7.

<sup>35</sup> Follow the Pill at 14-15; FTC report at 5-6.

<sup>36</sup> FTC report at v; PricewaterhouseCoopers report at 17. In some cases, these entities can be purchasers of drugs as well as payors; for example, some “staff model” HMOs operate on-site pharmacies at their facilities.

<sup>37</sup> See, e.g., PricewaterhouseCoopers report at 50-58.

<sup>38</sup> See, e.g., FTC report at 50-55. In some instances manufacturers also may pay PBMs fees for compliance, therapeutic interchange, and other programs related to particular drugs. Id. at 55. In addition to entering into

pharmaceutical prices has been described as follows: "This rebate does not affect the price paid by a wholesaler to a manufacturer for the drug, the price paid by a retail pharmacy to the wholesaler, or the price paid by the PBM to the pharmacy. It is a separate transaction between the PBM and the manufacturer and thus affects the total amount spent by the PBM. To the extent that a portion of the rebate is passed along, the insurer, employer, or beneficiary may realize a part of these savings."<sup>39</sup>

Both the FTC's recent study on PBMs and an earlier study by PricewaterhouseCoopers reported that PBMs commonly pass through a share of manufacturer rebates, but not administrative fees, to their clients.<sup>40</sup> In addition, both studies indicated that the share of rebates passed through to a PBM's clients varies considerably from contract to contract.<sup>41</sup> For example, the FTC examined the retention rates for all pharmaceutical manufacturer payments (including non-pass-through administrative fees) on 11 PBM contracts, and found that in 2003 the PBMs' retention rates on these contracts ranged from 25% to 91% (*i.e.*, pass-through rates ranged from 75% to 9%).<sup>42</sup> The PricewaterhouseCoopers study reported that the percentage of rebates PBMs share with their clients can range from zero to 100%.<sup>43</sup>

The FTC also noted that the percentage of manufacturer rebates that a PBM passes through to a client cannot be viewed in isolation, because clients make payments to PBMs (*e.g.*, administrative fees for claims processing and other services, and reimbursement for the drugs dispensed to plan beneficiaries) and a client could negotiate lower payments in exchange for receiving a lower percentage of manufacturer rebates. Thus, "PBMs could adjust any of a number of terms (*e.g.*, dispensing fees, discounts off of ingredient costs) to make the contract more attractive to plan sponsors" and "in this way manufacturer payments to PBMs could be passed on to plan sponsor clients through a complex array of adjustments to contract provisions relating, for example, to the services that would be provided by the PBM and the prices and fees that would be paid by plan sponsor clients."<sup>44</sup>

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agreements with PBMs providing for rebates and administrative fees, manufacturers may enter into similar agreements with insurers or other health plan sponsors that manage their own drug benefits, as well as with public programs that provide drug coverage.

<sup>39</sup> HHS report at 104.

<sup>40</sup> PricewaterhouseCoopers report at 9, 16, 52; FTC report at 59.

<sup>41</sup> The FTC found that PBMs and their clients have agreements with three different types of rebate sharing models. In addition to contracting for a certain percentage of manufacturer rebates, PBM clients may also negotiate arrangements in which they receive a specific dollar amount per brand-name drug prescription from the PBM rather than receiving a share of the actual rebates paid to the PBM, or arrangements in which they receive a specified share of rebates subject to a guaranteed minimum rebate payment. FTC report at 57-58.

<sup>42</sup> FTC report at 59.

<sup>43</sup> PricewaterhouseCoopers report at 88. See also HHS report at 105 (noting that industry sources report that PBM clients typically receive 70-90% of rebates).

<sup>44</sup> FTC report at 60. CMS made a similar point in a recent "call letter" to Medicare Part D plans; CMS stated there that "[w]e must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, *i.e.*, the sponsor receives a price concession from the PBM." CMS PDP Call Letter April 3, 2006, at 10.

As noted earlier, PBMs also establish networks of retail and mail-order pharmacies where patients with PBM-administered benefits can fill prescriptions, and negotiate the reimbursement rates network pharmacies receive (*i.e.*, the total payment the pharmacy receives, including the PBM payment and the patient copayment or coinsurance amount). These negotiated reimbursement rates are lower than the rates that pharmacies charge to uninsured “cash-paying” patients, and usually vary depending on the restrictiveness of the pharmacy network (*i.e.*, pharmacies can obtain more business by participating in a more exclusive network, and may thus be willing to accept lower reimbursement rates).<sup>45</sup> The drug (“ingredient cost”) reimbursement rates negotiated between PBMs and network pharmacies reportedly are often based on a discount from Average Wholesale Price for brand-name drugs and a Maximum Allowable Cost limitation for generics;<sup>46</sup> pharmacies usually also receive a dispensing fee. The amount that the PBM itself is reimbursed by its clients may or may not equal the amount paid by the PBM to the pharmacy (*i.e.*, ingredient cost plus dispensing fee minus patient copay/coinsurance); the PBM may be paid for pharmacy costs based on a contractually-specified pharmacy reimbursement rate, and could thus experience a profit or loss on pharmacy costs.<sup>47</sup>

The amount paid to the pharmacy by a patient depends on whether the patient is insured. Patients with insurance pay the copayment or coinsurance amount set by their insurer for the drug in question; uninsured patients usually would pay the “cash price.”<sup>48</sup> By one estimate, the cash price is approximately 15% higher than the pharmacy’s total payment (*i.e.*, insurance payment plus patient copay) for an insured patient.<sup>49</sup> Of course, insured patients ordinarily pay a premium for their coverage as well as the payments they make on prescriptions.

Although this brief overview of the pharmaceutical payment system cannot catalogue all of the system’s complexities, it suggests that the “price” of a pharmaceutical product is not easily captured and will depend on the perspective one wishes to examine. Rather than being a single number, the average “price” for a product at a particular time may vary depending on whether one examines the amount realized by the manufacturer; the amount paid by wholesalers; the amount paid by pharmacies; the amount paid by PBMs; the amount paid by PBM clients such as insurers or other health plan sponsors; or the amount paid by patients.

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<sup>45</sup> FTC report at 5; PricewaterhouseCoopers report at 57, 70.

<sup>46</sup> PricewaterhouseCoopers report at 86-87; FTC report at 4-5; Follow the Pill at 19.

<sup>47</sup> PricewaterhouseCoopers report at 71; FTC report at 9-10.

<sup>48</sup> Patients with traditional indemnity insurance also may pay the cash price at the pharmacy counter and then submit a claim for reimbursement to their insurer.

<sup>49</sup> HHS report at 96.



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Centers for Medicare &amp; Medicaid Services

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OFFICE OF INSPECTOR  
GENERAL

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Mark B. McClellan, M.D., Ph.D.  
Administrator

A handwritten signature in black ink, appearing to read "Mark McClellan".

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-00063)

Thank you for the opportunity to comment on the above draft report. This report looks at the manner in which the Medicaid average manufacturer price (AMP) is determined for drugs under the Deficit Reduction Act of 2005 (DRA).

As discussed in this report, the provisions of the DRA affected not only the Medicaid drug rebate program, but Medicaid reimbursement for drugs, as well. The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers. The DRA requires the OIG to review the requirements for and manner in which AMP is determined and recommend changes to the Secretary by June 1, 2006. The DRA also requires the Secretary to clarify the requirements for and the manner in which AMPs are to be determined by publishing a regulation no later than July 1, 2007.

Prior to the enactment of the DRA, AMP under the Medicaid program has been used solely to calculate drug manufacturer rebates. The DRA allows AMP to be used as a basis for reimbursement. States may use the publicly available AMP in setting their payment methodologies for retail pharmacies. The Centers for Medicare & Medicaid Services (CMS) will use the information to set Federal upper limits (FULs) on payments for multi-source drugs.

The OIG based its recommendations on information gathered through prior investigations. It also met with staff from CMS, Congressional staff, and stakeholder groups and analyzed written comments from six of the stakeholder groups.

#### **OIG Findings and Recommendation**

The OIG found that existing requirements for determining certain aspects of AMPs are not clear and comprehensive and that manufacturers' methods of calculating AMPs are inconsistent. While the OIG notes the history of CMS actions in clarifying the definition of AMP and recommends that CMS should consider further modification, it does not recommend a specific definition of AMP.

Page 2- Daniel R. Levinson

**Recommendations:** The OIG recommends that CMS clarify requirements related to retail class of trade, the treatment of rebates to pharmacy benefit managers (PBMs), and the treatment of Medicaid sales. In addition, the OIG recommends that CMS consider addressing other issues that were raised by industry groups, specifically, administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMP. Finally, the report recommends that CMS issue guidance in the near future addressing the implementation of the AMP-related reimbursement provisions of the DRA and encourage States to analyze the relationship between AMP and pharmacy acquisition cost when using this data source to determine payment rates to pharmacies.

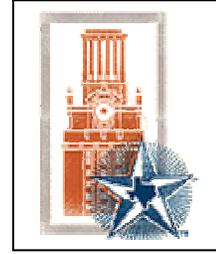
#### **CMS Response to Findings**

The CMS acknowledges that the OIG has reported some confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP. This is an extremely complex and technical topic that has been made more difficult due to changes in the chain of sales and the evolution of new entities, especially PBMs. For this reason, CMS had hoped that the OIG would have provided more specific recommendations for us to consider as we develop a proposed rule to address this topic. However, we appreciate the efforts of the OIG in the past, as well as this report, and we look forward to continuing to work with the OIG on this important issue.

#### **CMS Response to Final Recommendation**

In our proposed regulation to implement the AMP and reimbursement provisions of the DRA, CMS will take the opportunity to address each of the areas recommended by the OIG in this report as well as each of the areas raised by the stakeholders in the meetings with the OIG and subsequent written comments. We will issue the Notice of Proposed Rulemaking as expeditiously as possible. Likewise, we will review and respond quickly to public comments on the regulation, so that a final rule can be put in place as soon as possible. CMS will evaluate the need for additional guidance and provide this as we believe it would be beneficial.

Attachment



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## METHODOLOGICAL CONSIDERATIONS FOR CONDUCTING PHARMACY COST OF DISPENSING STUDIES

Michael Johnsrud, PhD

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### Study Methodologies

Surveys have been recently conducted within State Medicaid programs to estimate the pharmacy costs related to dispensing prescriptions to Medicaid recipients.<sup>1,2</sup> Below is a summary of data elements used in collecting data for such studies, in addition to other elements and considerations for measuring and interpreting results. The intent of this paper is to provide guidance to states in designing appropriate survey methodologies to estimate the costs related to dispensing prescription drugs. These elements should serve as a framework for collecting adequate data to develop a sound prescription drug reimbursement policy.

### Pharmacy Sampling

In order to derive a representative sample of pharmacies within a state, the survey results should include a sufficient number of pharmacies to allow for statistical comparisons between groups of pharmacies across selected stratifications (pharmacy type, location, etc.) It is suggested that at least **25%** of in-state pharmacies be included in the comparison of results, due to variance in the types of pharmacies that typically participate in Medicaid programs. States with relatively fewer pharmacies participating in the program may require a larger percentage of pharmacies in the final sample to make appropriate comparisons.

### Recommended Data Elements

1. Labor Expenses
  - a. Salary for sole proprietor;
  - b. Salary and wages for staff and relief pharmacists;
  - c. Salary and wages for pharmacy technicians, clerks and support staff;
  - d. Salary and wages for pharmacy interns;
  - e. Salary and wages allocated as a percent of time by areas of responsibility for other employees, including centralized corporate functions (human resources, managed care contract negotiations, etc.) to be allocated across stores on a revenue basis;
  - f. Employee benefits, including sign-on bonuses.

2. Operating Expenses (prorated where appropriate between prescription sales and nonprescription sales)
  - a. Depreciation;
  - b. Taxes;
    - i. Personal property taxes
    - ii. Real estate taxes
    - iii. Payroll taxes (including employees share of FICA)
    - iv. Sales taxes
    - v. Other taxes
  - c. Rent;
    - i. Building rent (estimate fair market rate for ownership)
    - ii. Equipment
  - d. Repairs;
  - e. Insurance;
    - i. Workman's compensation
    - ii. Employee medical premiums
    - iii. Other
  - f. Interest paid on pharmacy-related debt;
  - g. Bad debts;
    - i. Uncollected copayments
  - h. Accounting, legal and professional fees;
  - i. Professional organization dues;
    - i. Scientific publications
    - ii. Pharmaceutical reference library subscriptions
    - iii. Continuing Education
  - j. Charitable contributions (corporations only);
  - k. Utilities;
    - i. Telephone
    - ii. Heating
    - iii. Water/wastewater
    - iv. Electricity
    - v. Internet/broadband connection fees
    - vi. Garbage disposal

- l. Operating and office supplies (no prescription containers or labels);
  - m. Advertising (including provision of specialized services);
  - n. Prescription computer services (purchase or lease);
    - i. Point of Sale (POS) transaction fees
  - o. Prescription delivery expenses (not to include labor);
  - p. Prescription containers and labels;
  - q. Other business expenses (examples below).
    - i. Professional organization dues
    - ii. Janitorial services
    - iii. Equipment inspections
    - iv. Parking space rent
3. Total Pharmacy Sales and Floor Space
- a. Total prescription and non-prescription sales;
  - b. Cost of goods sold for prescription and non-prescription sales;
  - c. Pharmacy department and counseling areas as a percentage of total pharmacy floor space.

### **Variables for Comparison**

The statewide dispensing cost per prescription should be calculated across the following categories and appropriate statistical comparison of the unweighted means should be made to identify significant differences between categories of pharmacy characteristics. In addition, appropriate statistical models should be developed to determine relationships between costs of dispensing and continuous variables:

1. Independents (1 to 4 pharmacies) vs. Chains (5 or more) vs. Long Term Care
2. Urban (Metropolitan Statistical Areas) vs. Rural (non-Metropolitan Statistical Areas)
3. Sole Proprietors vs. Partnerships vs. Limited Partnerships vs. Corporations
4. Property Ownership (Lease vs. Owner)
5. Total hours of operation per week (continuous variable)
6. Total Medicaid prescription volume (continuous variable)
7. Medicaid prescription volume as a percentage of total volume (continuous variable)
8. Percent of prescriptions dispensed to Long Term Care facilities (continuous variable)
9. Percent of prescriptions dispensed as sterile/non-sterile compounds (continuous variable)
10. Percent of Medicaid prescriptions with non-collected copays (continuous variable)

## Additional Considerations

- Overall cost of dispensing per prescription should be reported descriptively as an unweighted median value of all reporting pharmacies (n=number of pharmacies reporting). This allows for determining the middle point of pharmacy's cost of dispensing per the total number of pharmacies.
- Attempts to limit the contribution of owner's salary to overall operating expenses, as well as models that introduce adjustments for this, should be avoided without direct evidence that these do not contribute to daily operations within the pharmacy.
- Attempts to limit the contribution of centralized operational functions provided by corporations should be avoided. This includes operations that centralize the purchase and warehousing of drug products (typically chain pharmacies and larger long term care pharmacies). Reasonable means of including these costs (revenue allocation) should be undertaken.
- Projected growth in costs of dispensing should factor in growth in medical employee wages by including such indexes as the Employment Cost Index, published the US Bureau of Labor Statistics, US Department of Commerce.
- Finally, all methods for extrapolation and assumptions used should be clearly described and, when possible, statistical models used in calculating results should be adequately reported. Reports of means should be reported with accompanying measures of distribution.

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<sup>1</sup> Reeder CE, "Estimation of Average Dispensing Cost and Drug Acquisition Cost for the South Carolina Medicaid Program," Submitted to the South Carolina Department of Health and Human Services, June 15, 2003, University of South Carolina College of Pharmacy.

<sup>2</sup> Myers and Stauffer, LC, "Determination of the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program," Prepared for the Texas Health and Human Services Commission, August 2002.

# IssueBrief

## Elements of a Pharmacy Dispensing Fee

This brief describes the importance of paying an adequate pharmacy dispensing fee and the components that comprise the cost to dispense. This brief outlines many components that go into the provision of pharmacy services, and which should be considered when developing accurate pharmacy supplying fees.<sup>1</sup>

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

<b>Elements of Pharmacy Service Costs</b>	
<b>I. Staffing</b>	
	Salaries (pharmacists, technicians, managers, cashiers, etc.) Licensure and/or continuing education for pharmacists, technicians
<b>II. Store operations and overhead</b>	
	Rent or mortgage Cleaning, repairs and security Utilities (heat, light, telephones) Computer systems, software and maintenance Marketing and advertising Accounting, legal and professional fees Insurance, taxes and licenses Interest paid on pharmacy-related debt Depreciation Complying with federal and state regulations (e.g., HIPAA) Corporate overhead (central management, etc.)
<b>III. Preparing and dispensing prescriptions</b>	
	Prescription dispensing materials (packages, labels, pill counters, etc.) Compounding the Rx (if necessary) Special packaging (unit dose, blister packs, bingo cards) Special supplies (syringes, inhalers)
<b>IV. Assuring appropriate use of medication</b>	
	Drug use review Consumer/patient counseling Consulting with prescribers Disease management Education and training
<b>V. Reasonable profit</b>	

(703) 549-3001

Fax (703) 836-4869

[www.nacds.org](http://www.nacds.org)

<sup>1</sup> The survey instrument from a South Carolina Medicaid dispensing fee study and a listing of included elements of a pharmacy dispensing fee from Myers and Stauffer's California dispensing fee study are included with this memo as background material.

**Staffing:** Staffing is listed as the first item in Figure 1 because it is probably the most important factor in determining an accurate pharmacy supplying fee. Labor costs include total salaries, payroll taxes and benefits. Prior studies that estimated dispensing costs typically allocated these costs based on employees' time spent in the prescription department. Owner compensation, particularly in the case of pharmacist owners, may require special modifications to account for differences unrelated to the normal compensation for a typical employee or employee pharmacist. Corporate overhead must be considered in any cost of dispensing calculation.

Pharmacy staffing costs are particularly important in California. California has one of the highest average salaries in the nation for pharmacists, an estimated \$91,170 as of May 2003. The national average pharmacists' salary for the same period was \$78,620. California also has a very low technician-to-pharmacist ratio, 1:1 for the first pharmacist and 2:1 for additional pharmacists. Many states allow ratios of 3:1 or higher. Given that the average technician salary in California was just over \$32,000 in May 2003, this low technician ratio leads to higher costs for California's pharmacies. In fact, Myers and Stauffer's June 2002 study of Medi-Cal Pharmacy Reimbursement highlights higher pharmacist salaries as the primary reason why California has a higher cost of dispensing than other states that they have observed.

**Overhead & Other Dispensing Costs:** Overhead and other dispensing costs are important factors that can be difficult to quantify, particularly by outside observers. In its June 2002 study, Myers and Stauffer considered the following costs to be entirely prescription-related:<sup>2</sup>

- Prescription department fees
- Prescription delivery expense
- Prescription computer expense
- Prescription containers and labels
- Continuing professional education for a pharmacist

Overhead costs that Myers and Stauffer did not allocate as prescription expenses include income taxes (because they are based on profit), bad debts, advertising and contributions. South Carolina appears to allocate all taxes based on the prescription department's sales ratio, and also includes prescription department advertising under the cost of dispensing.

Most other overhead costs were partially allocated as prescription costs by both Myers and Stauffer and South Carolina. Some overhead costs were allocated as a percentage of floor space, such as real estate taxes, rent, janitorial service, and utilities.

Repairs and depreciation were allocated based on floor space by Myers and Stauffer, but sales ratio by South Carolina. Other overhead costs were allocated based on sales ratio by both studies, including: personal property and other taxes, insurance, interest, accounting and legal fees, telephone and supplies, dues and publications.

<sup>2</sup> NACDS prepared an analysis of the Myers and Stauffer study that indicated key shortcomings of and exclusions from their dispensing fee estimates. This document is available from NACDS.

# Cost of Dispensing

One definition of "profit" is the money difference between what it costs to produce and sell a product and the revenue from its sale. In the pharmacy, knowing your cost of dispensing is an indispensable tool in maintaining or improving cash flow and profitability,

To determine the cost of dispensing, the pharmacy owner or manager needs to conduct a departmental cost analysis that assigns direct costs and allocates indirect costs to the prescription department. The total cost allocated to the prescription department divided by the number of prescriptions dispensed is the average cost of dispensing. This average cost of dispensing is the average amount that it costs the pharmacy to dispense a prescription.

## Cost of Dispensing Formula

$$\text{Cost of dispensing} = \frac{\text{Total annual costs allocated to prescription department}}{\text{Total annual number of prescriptions dispensed}}$$

Cost of dispensing includes all direct costs (e.g., prescription bottles and labels, delivery service, and pharmacy computer expense) related to operating a prescription department and a share of the indirect costs. The share of indirect costs (e.g., rent, salaries, and advertising) is estimated by allocating a portion of the cost to the prescription department. There are multiple methods that can be used to allocate costs. Although there is no universally accepted method for allocating indirect costs, the basis of allocation should seem logical. In pharmacy, the following methods have been used to allocate indirect expenses:

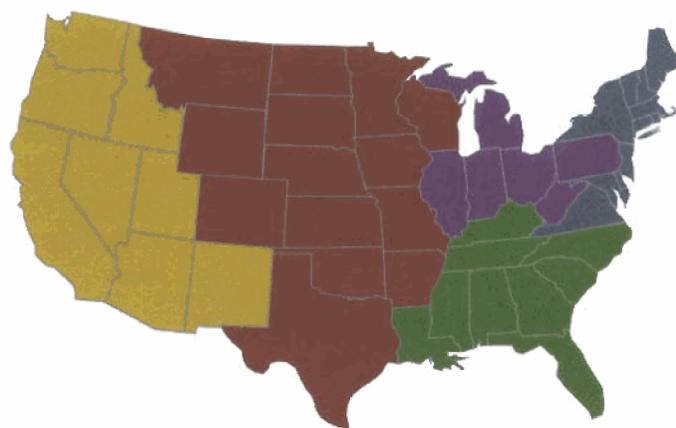
- A percentage of prescription sales to total sales
- A percentage of prescription department square feet to total square feet
- A percentage of prescription department inventory to total inventory
- A percentage of time the asset is used for the prescription department activities to total time used.

Pharmacy owners and managers can select one method to use or they can use multiple methods to allocate indirect expenses. Having classified all costs and allocated them to

the prescription department, the cost of dispensing can be estimated. As previously stated, the cost to dispense a prescription is found by dividing the total cost of operating the prescription department by the total number of prescriptions dispensed.

## NCPA-Pfizer Digest Analyses

We used the *Digest* data to calculate cost of dispensing for 2005. It is important to note that this calculation only covers the cost of dispensing and does not include a profit. The 2006 *Digest* pharmacy's cost of dispensing is \$10.53, up from 59.24 last year. Expenses increased as new personnel were added, stores were kept open longer hours, and pharmacists provided value-added services, like educating patients about Medicare Part D. So while expenses increased, the small increase in prescription volume did not offset the increase in expenses, resulting in a higher cost of dispensing. We also calculated the cost of dispensing in various geographic regions, as shown below. The West region has the highest cost of dispensing at \$11.18, and the West Central region has the lowest at \$9.52.



- West = \$11.18 (AK, AZ, CA, HI, ID, NV, NM, OR, UT, WA)
- West-Central = \$9.52 (AR, CO, IA, KS, MN, MO, MT, NE, ND, OK, SD, TX, WI, WY)
- East-Central = \$9.80 (IL, IN, MI, OH, PA, WV)
- Northeast = \$10.19 (CT, DE, DC, ME, MD, MA, NH, NJ, NY, RI, VT, VA)
- Southeast = \$9.71 (AL, FL, GA, KY, LA, MS, NC, SC, TN)

If a pharmacy is to make a profit, the reimbursement rate or the price charged must cover the product cost, the cost of dispensing, plus a surplus for profit. Thus, for pharmacy owners and managers to make sound business decisions on whether to accept a contract or not, they need to know what it costs them to dispense a prescription. It is suggested that pharmacy owners estimate their own cost of dispensing and then carefully evaluate each third-party contract before signing it. Additionally, all usual and customary charges should include the cost of dispensing, and pharmacy benefit managers should reimburse to cover cost of dispensing.



September 2006

Dear Pharmacy Provider:

The Office of Vermont Health Access (OVHA) is studying the impact of the generic drug provisions of the Deficit Reduction Act of 2005 on Vermont pharmacists and program participants in Medicaid.

The Deficit Reduction Act (DRA) of 2005 proposes two pharmacy-related changes of particular note: It will make the Average Manufacturer Prices (AMP) available to state Medicaid agencies and will use AMP in establishing the Federal Upper Limit (FUL) for generic drugs when two or more are available as of January 1, 2007.

Understanding pharmacies' true cost of dispensing prescriptions will be an important factor in determining the future reimbursement model needed to sustain a strong network of pharmacies able to serve the beneficiaries of the OVHA. To ensure that the OVHA has the most comprehensive information available, we encourage you to take part in this confidential survey that is being conducted by the University Of Connecticut School Of Pharmacy on behalf of the OVHA.

We also urge you to complete a national survey that will be conducted by the National Association of Chain Drug Stores in collaboration with the National Community Pharmacy Association (NCPA). You will be receiving that survey in the next few weeks.

Sincerely,

A handwritten signature in black ink that reads "Ann L. Bennett".

Ann L Bennett  
Director of Pharmacy Benefit Programs

**Office of Vermont Health Access**  
312 Hurricane Lane, Suite 201  
Williston, Vermont 05495  
802-879-5900

*Agency of Human Services*

October 20, 2006

Dear Vermont Medicaid Pharmacy Provider:

As you know, the Office of Vermont Health Access (the OVHA) is studying the impact of the generic drug provisions of the Deficit Reduction Act of 2005 on Vermont pharmacists and program participants in Medicaid. This study was authorized by Act 215 of the Vermont General Assembly of the 2005-2006 Legislative Session (H.881). Understanding pharmacies' true cost of dispensing prescriptions is an important factor in this study. To that end we have asked you to take part in a confidential survey that is being conducted by the University Of Connecticut School Of Pharmacy on behalf of the OVHA.

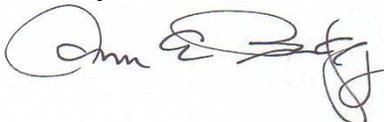
Some of you have asked for specific assurances that the information provided regarding your businesses will be protected from disclosure. I can assure you that, consistent with the Act 215 requirements, the information that is gathered will only be made available in the aggregate in OVHA's report to the Vermont Legislature's Health Access Oversight Committee and Joint Fiscal Committee. Pharmacy specific information will not be made available to anyone without the express authorization of the specific pharmacy.

Some of you have asked how the OVHA will handle a public records request for this information. This detailed information is protected from disclosure under Vermont statutes regarding access to public records and documents. While Title 1, Chapter 5, 1 V.S.A. § 317 (b) defines "all papers, documents, machine readable materials or any other written or recorded matters, regardless of their physical form or characteristics, that are produced or acquired in the course of agency business" as a public record, § 317 (c) exempts certain documents from disclosure. We strongly believe that information you provide as part of the survey is exempt under § 317 (c) (9) as it constitutes "trade secrets, including, but not limited to, any formulae, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within a commercial concern, and which gives its user or owner an opportunity to obtain business advantage over competitors who do not know it or use it." Should the OVHA receive a public records request, in addition to declaring it as exempt, the OVHA will also notify you so that you can take any appropriate legal steps.

I would suggest that if you are further concerned about the disclosure of this information that you provide us with a notice that states that you provided it with the understanding that the information constitutes trade secrets that are protected from disclosure as a public record under Title 1, Chapter 5, 1 V.S.A. § 317 (c) (9). In this way you expressly indicate the status of your information as "trade secrets".

I appreciate the commitment that you have shown in working with us on this study but I can well understand your business concerns. I hope this letter addresses them so that we can assure that your individual interests are represented in our study.

Sincerely,



Ann E. Rugg  
Deputy Director



**The Office of Vermont Health Access/University of Connecticut School of Pharmacy  
Cost of Prescription Dispensing Survey**



Office of Vermont Health Access  
Agency of Human Services



<b>Prescription &amp; Pharmacy Statistics:</b>	
<b>Please note: Data reported is for the period March 1, 2006 - August 31, 2006</b>	
Number of new prescriptions filled:	11
Number of refilled prescriptions filled:	12
Total number of prescriptions filled:	13
Total number of prescriptions filled for the OVHA programs on a primary billing basis:	14
Number of prescriptions covered by an insurance program on a primary billing basis:	15
Number of prescriptions covered on a cash basis:	16
Number of prescriptions prepared for Long-Term Care Patients:                      Is this pharmacy long-term care only?	17
Number of prescriptions compounded:	18
Do you provide home infusion/IV pharmacy services?	19
Do you provide delivery services for prescription medications?	20
Number of hours per week the pharmacy is open:	21
Do you own your building or lease it from yourself or a related party such as a family member or a related business entity?	22
On a per-patient basis, please estimate the amount of time you spend counseling a patient regarding prescription drug coverage issues: Circle one:   <5min    5-10 min    10-15 min    >15 min	23
<b>Building Space Information (please measure)</b>	
Location total floor space (all products and services)	24
Floor space devoted to prescription services only	25
<b>Sales Information</b>	
Total location sales net of sales tax collected	26
Total location prescription sales net of taxes collected	27

**The Office of Vermont Health Access/University of Connecticut School of Pharmacy  
Cost of Prescription Dispensing Survey**



Office of Vermont Health Access  
Agency of Human Services



Professional and Ancillary Staffing Costs	Total salary/wages	Per-cent of time devoted to prescription activity	
<b>Non Pharmacist owner and partner salaries/wages</b>			28
<b>Pharmacist owners and partner salaries/wages</b>			29
<b>Employee Pharmacists (full, part-time and relief)</b>			30
<b>Pharmacy Technicians</b>			31

**The Office of Vermont Health Access/University of Connecticut School of Pharmacy  
Cost of Prescription Dispensing Survey**



Office of Vermont Health Access  
Agency of Human Services



<b>Professional and Ancillary Staffing Costs</b>	<b>Total salary/wages</b>	<b>Per-cent of time devoted to prescription activity</b>	
<b>Pharmacy Interns/Pharmacy Students</b>			32
<b>Customer Service Staff</b>			33
<b>Delivery Staff</b>			34
<b>Third-Party Reconciliation and Bookkeeping Staff</b>			35
<b>Maintenance/Cleaning/Utility Staff</b>			36
			37
<b>Total location payroll (all departments, goods &amp; services)</b>			38
<b>Total location pension, retirement and employee benefit plans (do not include employee health)</b>			39

**The Office of Vermont Health Access/University of Connecticut School of Pharmacy  
Cost of Prescription Dispensing Survey**



Office of Vermont Health Access  
Agency of Human Services



<b>Overhead Expenses</b>	
<b>Please note: Data reported is for the period March 1, 2006 - August 31, 2006</b>	
<b>Depreciation (not accumulated)</b>	40
<b>Taxes</b>	41
Personal property taxes	
Real estate taxes	
Payroll taxes	
Sales taxes paid	
State income taxes (corporations only)	
Vermont pharmacy provider tax	
Any other taxes (please specify)	
<b>Pharmacy license fees</b>	42
<b>Rent:</b>	43
Building/Location	
Equipment rental	
<b>Insurance:</b>	44
Workers compensation	
Property, casualty, flood Insurance	
Employee health insurance	
Other insurances (please specify)	
<b>Repairs</b>	45
<b>Interest</b>	46
<b>Legal, accounting and professional fees</b>	47
<b>Non-interest banking fees and charges</b>	48
<b>Dues and publications</b>	49
<b>Bad debt for prescriptions</b>	50
<b>Charitable contributions (corporations only)</b>	51
<b>Telephone, electric, heat, sewer, refuse &amp; any other utilities</b>	52
<b>Office and operational supplies</b>	53
<b>Advertising</b>	54
<b>Pharmacy computer expenses-please refer to instructions</b>	55
<b>Prescription vials</b>	56
<b>Prescription labels</b>	57
<b>Pharmacy bags</b>	58

**The Office of Vermont Health Access/University of Connecticut School of Pharmacy  
Cost of Prescription Dispensing Survey**



Office of Vermont Health Access  
*Agency of Human Services*



<b>Overhead Expenses-Continued</b>	
<b>Specialty prescription packaging</b>	59
<b>Pharmacy adjudication/transaction charges</b>	60
<b>Prescription delivery expenses (do not include staffing costs)</b>	61
<b>Other prescription related expenses not noted above (please provide details)</b>	62
<b>Central office/corporate overhead pharmacy related expenses:</b>	63



## INSTRUCTIONS FOR *TIME-SENSITIVE* SURVEY

**All data is due back at the University of Connecticut School of Pharmacy by  
October 20, 2006  
A postage paid return envelope is enclosed**

### ***Important Information for Recipient of this Survey***

If you have any questions regarding the survey, or would like to receive this survey via email, please contact me at: [peter.tyczkowski@uconn.edu](mailto:peter.tyczkowski@uconn.edu)

If you have received this survey and need to forward it to a supervisor or corporate office, please do so ASAP so that your company's information can be included in this important survey.

### ***Pharmacies with Multiple Locations***

If you are part of a larger organization that has multiple outlets, please complete a separate survey form for each pharmacy participating in OVHA programs and allocate central costs to individual pharmacy locations.

### ***Confidentiality***

While each survey form filled out will have pharmacy identification information, this will only be used to track survey response progress and provide contact information should we need to contact you for the purposes of clarifying the information you provide. Individual pharmacy data collected in the survey will only be shared with the OVHA in a format devoid of pharmacy identification. Likewise, reports and analysis derived from survey responses will not contain pharmacy identification.

### ***Timeliness of Survey Results***

Time is of the essence in this process. Given the large changes in the pharmacy environment and the need to gather a representative sample, we are asking for data for activity during the period of **March 1, 2006 through August 31, 2006**. A report analyzing the data collected will be sent to the OVHA by November 13, 2006. To participate and be counted, your response to this important survey is due back by Friday, **October 20th**.

### ***Exclusions***

Pharmacies that have not completed at least one full fiscal year of operation as well as pharmacies that have changed ownership during the fiscal year prior to receiving this survey are asked to please return the survey noting the reason for their exclusion.

### ***Required Cost Data***

In completing this survey, please keep in mind that its purpose is to accurately determine the actual cost of preparing a prescription medication and dispensing it to a patient. For that reason, a number of elements of financial and cost information will need to be gathered and where needed, adjusted to reflect the true cost of this important service.

This survey attempts to identify all of the possible costs encountered in filling and dispensing prescription medications while at the same time separating those costs that are not related to prescription dispensing. For example, you may have a pharmacist on staff that spends a portion of his/her time dispensing medications while another portion of his/her time is devoted to the operation of a durable medical equipment portion of the operation or other duties such as ordering front store merchandise, etc. For that reason, this pharmacist's costs, and others on your staff, will need to be adjusted. We are asking you to make an accurate estimation of the percentage of time your staff spends on prescription dispensing activities.

For some expenses, you will be asked to the amount directly related to the prescription processing activity such as pharmacy license fees. For other expenses, you will be directed to include the full amount from your records and we will make an appropriate adjustment based on factors such as sales or space ratios. If there is a line on the survey that you have no cost information on or does not apply to your practice, please note N/A on the survey line so that we know you have considered this potential cost element. An example would be in the area of delivery expenses for a pharmacy practice that does not make deliveries.

## INSTRUCTIONS FOR LINE ITEMS

**All data reported is for the period of March 1, 2006 through August 30, 2006.**

### **Professional and Ancillary Staffing Costs:**

Please enter only information for those people who are involved in prescription medication preparation, delivery, ordering, reconciliation etc. Please do not report staffing costs for any owners, managers or employees who have no prescription department duties or responsibilities. For staff who spend all of their work time and effort involved in some aspect of prescription services, note 100 percent in the appropriate column. Likewise, please note a lower percent for employees who share time with other aspects of the store operation. Please pay particular attention to Consultant Pharmacists, Technicians, Supervisory, Customer Service, Bookkeeping and Reconciliation, Delivery and Cleaning/Maintenance staffs who often spend time in non prescription processing responsibilities. For any owners please report only salary, wages or drawings. Do not include profit. Please do not include individual names.

### **Overhead Expenses:**

Please report your expenses for the period of March 1, 2006- August 30, 2006 as instructed below. In many instances, expenses will be allocated based on the relative area or sales of the prescription department.

### **Depreciation (line 40)**

Please enter only data from the period 3/01/06-08/30/06 not accumulated depreciation.

### **Taxes: (line 41)**

Please enter only the taxes here that apply directly to the operation of this one pharmacy location only. Likewise, include the employer portion of FICA and Medicare taxes and unemployment taxes.

### **Pharmacy License fees: (line 42)**

Please include any fees for licenses, federal, state or local required by law to operate the pharmacy.

### **Rent: (line 43)**

Please include rent only for the pharmacy location and equipment rented at that location.

### **Insurance: (line 44)**

Please report worker's compensation, employee medical, property and casualty, flood and other insurances used to protect the pharmacy.

### **Repairs; (line 45)**

Please report store and equipment repairs. Please do not report delivery vehicle repairs (see line 61)

**Interest expense: (line 46)**

Please report interest expenses for the operation at the pharmacy location.

**Legal, accounting and professional fees: (line 47)**

Include only those fees directly related to the operation of the pharmacy location.

**Non-interest banking fees and charges: (line 48)**

Include bank fees, credit card fees and other bank non interest related expenses.

**Dues and publications: (line 49)**

Please report pharmacy professional dues, reference books and publications only.

**Bad Debt for prescriptions: (line 50)**

Please report only that portion of your bad debt due to prescription sales. You may include uncollectible prescription co-pays.

**Charitable contributions (corporations only): (line 51)**

Please report all monies, value of goods donated charitable organizations.

**Telephone, electric, heat, sewer, refuse & any other utilities: (line 52)**

Please do not include any expenses for on line claims adjudication or any expenses incurred for locations other than the pharmacy. Do include expenses for all telephone, fax and data lines used.

**Office and operational supplies: (line 53)**

Do not include prescription labels, vials and bags in this cost area.

**Advertising: (line 54)**

Please report all advertising expenses.

**Pharmacy computer expenses: (line 55)**

If your pharmacy computer is used only in the pharmacy department, please report the all costs under this heading. If the computer is used for pharmacy **and** other purposes, please report this cost under: "Other prescription related expenses not noted above (please provide details)" line on the survey.

**Container & Packaging Costs: (lines 56-59)**

Please report the costs of prescription bottles, vials, labels, bags used for prescriptions and any other special packaging (long term care blister cards, compliance packaging etc.) on the lines as noted. Do not include the cost of general merchandise bags or other non prescription related packaging.

**Pharmacy adjudication/transaction charges: (line 60)**

Please report the total expenditures for prescription on line claims adjudication paid.

**Prescription delivery expenses: (line 61)**

Please include fuel, maintenance and vehicle expenses for prescription deliveries only. If deliveries are made for other purposes, please deduct these costs from your total delivery expenses to arrive at a total expense for prescription deliveries. Likewise, if the company provides transportation for other activities or key employees/ owners, please do not include these expenses. Please do not include delivery staffing costs in this calculation as they are included in another area (line 34).

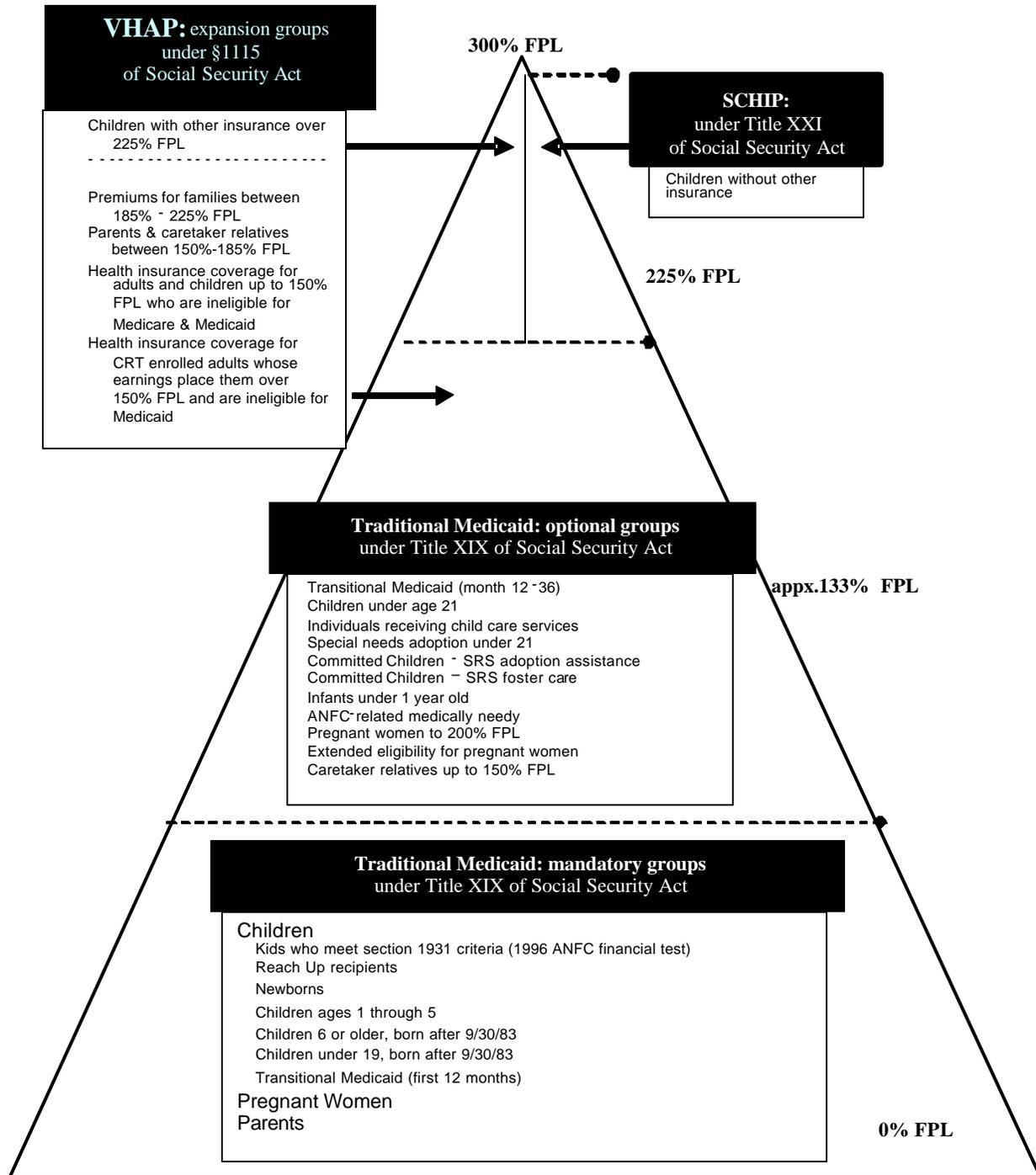
**Other prescription related expenses not noted above: (line 62)**

Please report other expenses such as physical inventory expenses or other expenses related to the operation of the pharmacy.

**Central office/corporate overhead pharmacy related expenses: (line 63)**

Please include only those expenses directly related to dispensing prescription medications that are captured and reported on a central office basis. For example, the expenses charged to a location for a third party claims trouble shooting support center may be included whereas expenses related to operation of the warehouse operation would not be.

## Appendix 11: Medicaid Coverage Groups for Children and Families



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**PHARMACY BEST PRACTICES  
AND  
COST CONTROL REPORT  
2007**

*February 23, 2007*

**The Office of Vermont Health Access  
The Vermont Agency of Human Services**

## **Report Highlights**

- In SFY 2006, a total of 2.9 million claims for drugs were processed for all of Vermont's publicly funded pharmacy programs.
- In December 2005, the overall generic substitution rate for all generic claims when a generic equivalent was available was 97.7%.
- The incidence of the need for prior authorizations in SFY 2006 changed dramatically with the transition of 30,000 beneficiaries to primary coverage under Medicare Part D. It is estimated that 95.9% of elderly beneficiaries and 46.8% of disabled beneficiaries became Part D covered.
- Beginning in October 2002 Vermont began securing Vermont-only supplemental rebate agreements.
- Supplemental rebates are a valuable resource in the Vermont Health Access PBM Program. SFY 2006 collections on calendar year 2005 utilization were \$10.4 million.
- Dispensing fee comparisons:
  - The average reported cost of dispensing individual prescriptions in pharmacies serving Vermont Medicaid is \$10.55.
  - The \$4.75 dispensing fee for the OVHA programs to Vermont pharmacies is greater than all other states in New England where the Medicaid dispensing fees range from \$1.75 to \$3.40 and greater than the state of New York where the Medicaid dispensing fees are \$3.50 for brands and \$4.60 for generics.

## **Overview**

Vermont's publicly funded health insurance programs covered 145,947 beneficiaries monthly in state fiscal year (SFY) 2006. Some of these programs include full health insurance coverage. All of them include a pharmacy benefit. These programs are:

- Programs for Adults:
  - Traditional Medicaid
  - VHAP
- Programs for Children:
  - Traditional Medicaid
  - Dr. Dynasaur
- Pharmacy Only Benefits:
  - Pharmacy Benefit
    - VHAP-Pharmacy
    - VScript
    - VScript Expanded
  - Medicare Part D Wrap Benefit
    - VPharm
  - Discount Benefit
    - Healthy Vermonters

Pharmacy is the top spending item in Vermont's programs. In SFY 2006, gross spending was \$168 million. This is a decrease from \$191 million in SFY 2005. However, 30,000 program beneficiaries transitioned to Medicare Part D as their primary pharmacy coverage as of January 1, 2006.

### ***Critical Issues***

At all times, the goals of the Vermont Health Access Pharmacy Benefit Management (PBM) Program are:

- To assure the availability of clinically appropriate services as they are available and as they are developed and
- To do so at the most reasonable cost possible.

At stake is preserving the benefit that has evolved in Vermont's programs to the greatest extent possible.

### ***Vermont Strategies in Pharmacy Benefits Management***

The Vermont pharmacy best practices and cost control program was authorized in 2000. The program was established in 2002 by Act 127. This program, as the Vermont Health Access Pharmacy Benefits Management (PBM) Program, is administered by the Office of Vermont Health Access (OVHA). Operational strategies include:

- Partnering with a vendor with skills and expertise in pharmacy benefit administration
- Claims management and processing
- Managing the benefit design
- Monitoring and managing utilization
- Procuring supplemental rebates on drugs used
- Managing reimbursement
- Responding to change

### ***Pharmacy Benefit Administration***

Pharmacy benefit administration (PBA) services support the program in the following areas:

- Claims operations
- Benefit management
- Utilization review and management
- Rebate management
- Analysis and reporting

When the Vermont Health Access PBM program was implemented, Vermont contracted with First Health Services Corporation of Glen Allen, Virginia. In March 2005 OVHA issued a Request for Proposal to provide pharmacy benefits management (PBM) services for Vermont's publicly funded programs. The existing contract was due for renewal. It was felt that with the number of needed pharmacy initiatives that were critical to immediate needs; the advantages and potential opportunities in care management in existing operations and those under the Global Commitment; and the planned implementation of the Medicare Part D benefit, that it would be wise to explore a new contract. The intention was to assure that the OVHA had the appropriate resources to adequately respond to the rapidly developing environment.

In September 2005, OVHA selected a new Pharmacy Benefits Administrator (PBA), MedMetrics Health Partners of Worcester, Massachusetts. It is estimated that this contract will save Vermont \$1.1 million over three years in administrative expenditures. MedMetrics is a non-profit, full-service pharmacy benefit manager, wholly owned by Public Sector Partners (PSP) and affiliated with the University of Massachusetts Medical School and the University of Massachusetts Memorial Medical Center. MedMetrics provides Drug Utilization Review services for the Commonwealth of Massachusetts and pharmacy benefit management services for the Massachusetts Medicaid program through a designated managed care organization, Neighborhood Health Plan. Additionally, MedMetrics provides program management and benefit coordination services for Massachusetts' State Pharmacy Assistance Program. As such they are a regional presence with clinical, pharmacy, and Medicaid experience.

### ***Claims Management and Processing***

Claims processing activities include accepting drug claims according to the rules set for coverage under Vermont programs; providing the mechanisms to support the application of the generic drug requirements authorized by Title 19, Chapter 91 of the Vermont Statutes; messaging at the pharmacy point of sale during drug claims processing about program requirements (e.g., eligibility, coverage limitations, etc.), prior authorization needs, and prospective and retrospective drug utilization review (DUR) issues; and authorizing payments according to the reimbursement rules. Claims are submitted by pharmacies enrolled to provide benefits in Vermont's programs. As of January 1, 2007, 244 pharmacies were enrolled.

The maximum reimbursement is established on a per claim basis at the individual drug level in all cases but VPharm. The amount is the lesser of:

- Average wholesale price less 11.9% plus a dispensing fee,
- The Centers for Medicaid and Medicare Services established Federal Upper Limit (FUL) plus a dispensing fee,
- The MedMetrics managed Vermont Maximum Allowable Cost (MAC) amount plus a dispensing fee, or

- The pharmacy's usual and customary/submitted fee including a dispensing fee.

The beneficiary pays the rate established with this methodology in the Healthy Vermonters Program. For the remainder of the programs, Vermont is the payer of last resort paying the difference between the rate set and any other insurance payment.

VPharm provides a wrap benefit to Medicare Part D coverage for drugs for those beneficiaries who previously received their primary coverage through Medicaid, VHAP-Pharmacy, VScript, and VScript Expanded. Coverage is limited to drugs that would be covered if they were still receiving that primary coverage. Medicaid beneficiaries receive coverage for Medicaid covered drugs in classes excluded from Medicare coverage. VHAP-Pharmacy, VScript, and VScript Expanded beneficiaries receive coverage for the VHAP-Pharmacy, VScript, and VScript Expanded drugs in the form of the Part D Prescription Drug Plan (PDP) cost-sharing including deductibles, coinsurance, copayments, and coverage in the "donut hole", which is the period in a coverage year when there is a lapse in Part D coverage. These latter beneficiaries also are covered for drugs covered in their original coverage under VHAP-Pharmacy, VScript, and VScript Expanded that are in classes excluded from Medicare coverage. Details are outlined below.

In SFY 2006, a total of 2.9 million claims for drugs were processed for all of Vermont's publicly funded pharmacy programs.

### ***Managing Benefit Design***

#### *General Design*

Benefit management activities occur in all programs for all beneficiaries. Fundamental is identifying the individual drugs covered in the specific programs:

- Medicaid, Dr. Dynasaur, VHAP, and VHAP-Pharmacy: All drugs for which a rebate is paid to the federal Medicaid program. Limitations may apply.
- VScript: All maintenance drugs for which a rebate is paid to the federal Medicaid program. Limitations may apply.
- VScript Expanded: All maintenance drugs for which a rebate is paid to the State of Vermont. Limitations may apply.
- Healthy Vermonters Program: All Medicaid covered drugs.
- VPharm:
  - Coverage for Medicaid drugs in classes excluded from Medicare coverage (Medicaid).
  - Cost sharing to Medicare Part D coverage and coverage for drugs in classes excluded from Medicare coverage; both limited to Medicaid covered drugs (VPharm1).

- Cost sharing to Medicare Part D coverage and coverage for drugs in classes excluded from Medicare coverage; both limited to VScript maintenance drugs (VPharm2).
- Cost sharing to Medicare Part D coverage and coverage for drugs in classes excluded from Medicare coverage; both limited to VScript Expanded maintenance drugs for which a rebate is paid to the State of Vermont for VScript Expanded (VPharm3).

### *Preferred Drug List (PDL)*

When limitations apply, the OVHA PBM Program utilizes a Preferred Drug List (PDL). The PDL is a key feature in the program. The PDL identifies drugs where clinical limitations apply. The PDL also identifies drugs that are clinically effective, but less costly. If a drug is not listed as "preferred" in a particular category on the PDL, it requires Prior Authorization in order for the drug to be covered.

The PDL has been developed with the help of the Vermont Medicaid Drug Utilization Review (DUR) Board acting as the Program's Pharmacy and Therapeutics (P&T) Committee. The Board consists of Vermont doctors and pharmacists. When the PDL features clinically appropriate, low-cost options they include:

- OTCs as prescribed by physicians
  - Without restriction for Medicaid and VHAP Pharmacy and
  - Limited to Loratadine (generic Claritin® and the like), Prilosec OTC®, non-steroid anti-inflammatory drugs, and smoking cessation products;
- generics;
- lower-cost brands; and
- brands where manufacturers pay rebates supplemental to required federal Medicaid rebates to make their products affordable.

In March 2002, the first iteration of the PDL was completed, with PA required for any drug not identified as "Preferred" in designated PDL classes. Throughout 2002, additional classes were systematically rolled out. By 2003, the foundation of the PDL was set.

Since that time, the PDL has been modified to reflect changes in clinical approaches, prescribing practices, product availability, and supplemental rebate opportunities.

### *Implementation of the Management of Mental Health Drugs*

At the time of the implementation of Vermont Health Access Pharmacy Benefit Management Program in 2002, drugs used to treat severe and persistent mental illness (SPMI) were exempt from management. All other major cost categories of drug

treatment were subject to management. In SFY '05, 31.7% of the total drug spending was for mental health drugs.

In 2005, Act 71 approved the management of mental health drugs subject to the review of the DUR Board. It was agreed that mental health drug classes could be managed through the Preferred Drug List (PDL). The proposed PDL changes identified the most cost-effective, clinically appropriate drugs in specified classes. These drugs included generic equivalents and alternatives as well as other low-cost alternatives. More expensive alternatives would be available with prior authorization using criteria developed through literature review of acceptable standards, particularly the Texas Algorithm (TIMA), the International Psychopharmacology Algorithm Project (IPAP), class reviews from the Oregon Evidence Based Practice Center, the Veterans' Administration, and the Micromedex® Health Series.

The Board recommended that certain beneficiaries' active treatment should be "grandfathered" so as not to risk destabilization. It was decided that patients of all ages currently using antipsychotics, antidepressants, and/or mood stabilizers would continue to use existing drug therapies. For drugs without generic equivalents, lapses in treatment of four months or longer or changes in treatment would result in the application of the PDL and its clinical criteria. For drugs with generic equivalents, grandfathering would continue for four months to allow prescribers to transition patients to the generic option. The PDL and the criteria would apply to all new patients.

A report on the review and the board's deliberations was submitted to the Legislature's Health Access Oversight Committee (HAOC) for comments or recommendations on September 1, 2005. The Committee heard testimony from prescribers and advocates. As a result, they recommended that Central Nervous System (CNS) Agents used to treat ADHD be included in the "grandfathering" provisions. This recommendation was approved at the DUR Board meeting in September 2005.

A claims processing implementation plan was developed, provided to the DUR Board, and further reviewed with the Medical Director of the Division of Mental Health (DOH) and the DUR Board's psychiatrist member.

Following provider notification in December 2005, the plan was implemented in January 2006. MedMetrics claims processing systems pharmacy claims history was used wherever possible to determine if the criteria had been met to minimize the impact on prescribers who would otherwise have to request an authorization.

With the implementation of Medicare Part D many beneficiaries transitioned to Part D coverage. With the Part D implementation problems, patient care was at risk and provider services were under considerable pressure. As a result, the plan to limit grandfathering on drugs with generic equivalents to four months was not enacted

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immediately. On August 16, 2006, OVHA sent a letter to prescribers notifying them that this provision would be effective October 1, 2006.

With Part D the full impact of the transition to managing mental health classes cannot be assessed. To date it appears the transition to managing the mental health drug classes has caused little disruption to patient care.

Indications are that new patients or patients with a lapse in therapy of four months or more attempt therapy with preferred drugs. Between January and November 2006, prior authorization requests for non-preferred mental health drugs dropped by 26%.

<b>Mental Health Drug Prior Authorization Requests - January 2006 and November 2006</b>		
	<b>January 2006</b>	<b>November 2006</b>
Anti-depressants - Novel	231	197
Anti-depressants - SSRI	300	236
Anti-depressants - Tricyclics	0	1
Anti-psychotics - Atypical & Comb.	159	59
Anti-psychotics - Typical	0	0
CNS Stimulants - Anti-Obesity	16	34
Anti-Hyperkinesis - ADHD, ADD, Narc	86	101
Sedative Hypnotics - Benzo	6	0
Sedative Hypnotics - Non-Benzo	212	98
Anti-Anxiety - General	10	28
Totals	1,020	754
Percentage Reduction		26.1%

*Claims Review Oversight*

Claims review routinely provides information on opportunities for modifying the benefit. One such review found that prescribers were authorizing over-the-counter prescriptions of branded cough and cold preparations. The DUR Board moved all branded cough and cold preparations to a non-preferred status effective June 1, 2006. Pharmacists are now messaged with preferred choices when they submit a claim for the branded product.

*Dose Consolidation Opportunities*

The OVHA has instituted reviews to determine when there are opportunities to consolidate dosages when clinically possible to save money. In 2006 a prevalence of dosing inefficiency with patients receiving lower-strength forms of drugs in quantities greater than one unit per day was detected. This prompted concerns surrounding the increased pill burden for patients, the added complexity of drug regimens, and a

potentially negative impact on patient adherence to therapy. As a result, the DUR Board implemented quantity limits on the lower strengths of five medications, effective October 1, 2006. The DUR Board continues to review drugs for dose consolidation opportunities.

### *Educating Health Care Providers*

The Vermont Health Access PBM Program faces the challenge of counteracting the impact of manufacturers who advertise nationally and locally. The Office of the Vermont Attorney General has estimated that \$3.11 million was spent in marketing in Vermont alone in SFY 2004 and another \$2.17 million in SFY 2005. This advertising creates a situation where it is necessary to distinguish between what may be wanted and what is needed.

The Program relies on the Drug Utilization Review (DUR) Board for advice on how to best educate providers, in general, and ameliorate the impact of pharmacy manufacturers advertising, in particular. The DUR Board meets as often as monthly. In calendar year 2006 the Board met eight times. In these meetings counter detailing opportunities are considered.

In the course of activities, the DUR Board may select certain drugs and/or prescribing practices to target for review of actual use and/or application. Staff makes recommendations for targeted areas and the board selects those they feel are most relevant. When this occurs, specific providers are polled regarding the patients affected and the board reviews their responses to determine if any follow-up is appropriate either with the identified prescribers or with a clinical advisory to all providers.

To educate providers on other PBM Program coverage activities, various methods have been used. Most frequently mailings are prepared around both general and specific changes and they are targeted to prescribers and pharmacies separately. Examples include changes to the PDL, the criteria for the authorization of non-preferred drugs, and clinical advisories and alerts. These mailings are also sent electronically to provider affiliates and representatives so that these organizations can use their proprietary methods to distribute the materials. Examples of these organizations include the Vermont Medical Society and the Vermont Pharmacists Associations. OVHA and MedMetrics have also begun to publish a periodic pharmacy newsletter to provide timely updates on claims processing and clinical issues.

All general pharmacy benefit management materials are posted on the OVHA webpage at [www.ovha.vermont.gov](http://www.ovha.vermont.gov). These materials include the Preferred Drug List and Drugs that Require Prior Authorization, the description of the PBM program, DUR Board meeting information (minutes, agendas), newsletters and alerts.

In the event of a change of a drug to a non-preferred status where specific beneficiaries are affected, prescribers are provided with two tools as recommended by the DUR Board. One is a list of all the patients who were prescribed the specific drug that is being changed. The second is a patient profile specific to each patient with the drug change listed. This creates a record for use in the patient's file.

### ***Monitoring and Managing Utilization***

#### *Generic Utilization*

Vermont's generic drug law at 18 V.S.A chapter 91 requires pharmacies to dispense generics unless the prescriber expressly requires the brand. The Vermont Health Access PBM Program with the support of the DUR Board heavily promotes the use of generics in general and directly through identified classes in the PDL.

Generic dispensing rates can be expressed in a variety of ways. The "generic dispensing rate" is a term used to refer to the number of prescriptions dispensed using generic medications as a percentage of all prescriptions dispensed. Not all drugs have generic equivalents available. The "generic substitution rate" is a term used to refer to the number of prescriptions that are dispensed with a generic medication when an equivalent generic version of the drug is available. Generic versions of medications are only available when a brand (that is, innovator) medication has lost patent protection. In general, generic dispensing reflects the extent to which generics are used in a program, while generic substitution represents both the prescribing instructions of the physicians and other prescribers and the dispensing practices of the pharmacies.

The generic dispensing rate for the covered populations in Vermont's programs has been consistent in the last year. For the fourth quarter of calendar year 2005, the last quarter prior to Medicare Part D implementation, the generic dispensing rate was 61.37%. In the first quarter of calendar year 2006, utilization measurement is difficult with the Part D problems and Vermont temporarily reinstating Vermont program coverage for Part D beneficiaries. For the quarter ending June 30, 2006, with most people re-transitioned to Part D, the rate was 61.47%. In a study of July and August 2006, a point at which Part D transition was effectively complete, the rate was 62.4%.

In December 2005, the overall generic substitution rate for all generic claims when a generic equivalent was available was 97.7%. This is exactly the rate in the July/August 2006 claims.

To recap, the following chart identifies generic usage in Vermont's publicly funded programs:

<b>Jul – Aug 2006</b>	<b>Percentage of Rx</b>
Generic use as a percentage of all drugs dispensed	62.4%
Generic use when generic equivalent available	97.7%

### *Prior Authorization Requirements*

Through prior authorizations prescribers can access any non-preferred drug on the PDL. Under the Vermont Health Access PBM program, criteria is available for these exceptions. The PBA's clinical pharmacists manage the criteria. In 2006 MedMetrics reviewed the criteria as developed and implemented by First Health and made recommendations for change as they felt appropriate. These and all criteria changes are reviewed, modified, and approved by the DUR Board acting as the Vermont Health Access PBM Program's Pharmacy and Therapeutics Committee.

An example of a change in 2006 was related to the use of samples to stabilize patients on non-preferred drugs. Some prescribers were found to be supplying manufacturers' free samples of non-preferred drugs to patients so that it could be demonstrated that the patient was "stabilized" on the non-preferred item. The DUR Board decided that this was circumventing the intentions of the approved criteria where trials of preferred drugs were required to access non-preferred drugs. The DUR Board voted to not permit this practice effective September 12, 2006.

The frequency of the use of prior authorization is one measure of the utilization of preferred drugs. The incidence of the need for prior authorizations in SFY 2006 changed dramatically with the transition of 30,000 beneficiaries to primary coverage under Medicare Part D. It is estimated that 95.9% of elderly beneficiaries and 46.8% of disabled beneficiaries became Part D covered. Historically beneficiaries who are elderly and disabled are major users of Vermont drug programs' coverage, particularly in many of the drug classes managed in the Vermont PDL.

Another change in the frequency of prior authorization occurred with the transition to MedMetrics as the claims processor. MedMetrics began identifying areas where assessments could be applied in claims processing to determine if certain criteria elements had been met without requiring paper/phone requests from prescribers. This is effectively automated prior approval. Examples of areas where this can apply include age criteria, use of preferred drugs, use of preferred drugs for prescribed periods, etc. On January 1, 2006, such "step-therapy protocols" were implemented for six drug categories.

While prior authorization requests decreased in 2006, denials increased. This is a result of the application of a DUR Board requested legislative change that no longer allows prescribers to override approved criteria without concrete clinical justification.

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The following chart reports the incidence of prior authorizations in SFY 2006:

	Number of Prior Authorization	Number of Prior Authorizations	Number of Prior Authorization	Number of Prior Authorizations
	Requests	Approved	Changes	Denied
July	2,515	1,998	482	35
August	2,569	2,102	432	35
September	2,767	2,336	368	63
<b>Q1 2006 Totals</b>	<b>7,851</b>	<b>6,436</b>	<b>1,282</b>	<b>133</b>
October	2,661	2,230	414	7
November	2,852	2,363	468	21
December	2,556	2,056	476	24
<b>Q2 2006 Totals</b>	<b>8,069</b>	<b>6,649</b>	<b>1,358</b>	<b>52</b>
Jan	2,914	2,684	42	188
Feb	1,859	1,575	64	220
March	1,470	1,249	73	148
<b>Q3 2006 Total</b>	<b>6,243</b>	<b>5,508</b>	<b>179</b>	<b>556</b>
April	1,388	1,193	65	130
May	1,766	1,439	126	201
June	1,542	1,261	117	164
<b>Q4 2006 Totals</b>	<b>4696</b>	<b>3893</b>	<b>308</b>	<b>495</b>
<b>Totals for SFY '06</b>	<b>26,859</b>	<b>22,486</b>	<b>3,127</b>	<b>1,236</b>
Percent of Totals	100.0%	83.7%	11.6%	4.6%
<b>Totals for SFY '05</b>	<b>42,432</b>	<b>36,139</b>	<b>5,329</b>	<b>336</b>
Percent of Totals	100.0%	85.2%	12.6%	0.8%
<b>Decrease/(Increase)</b>	<b>15,573</b>	<b>13,653</b>	<b>2,202</b>	<b>(900)</b>

*Utilization Review Events*

Pharmacies use computer systems to transmit claims “real time”; that is, as they prepare drugs for dispensing. A claim identifies information about the beneficiary, the prescriber, and the drug. With the ability to electronically submit a claim is the ability to respond to the pharmacist or “message” him/her on a claim level. Messaging occurs as claims are processed on specific utilization issues. The issues include drug-drug interactions, early refills, therapeutic duplication, ingredient duplications, drug-disease interactions, drug-age precautions, and others. The drug-drug interactions, early refills, and therapeutic duplication edits require the pharmacist to override or otherwise resolve the potential problem in order to fill the prescription. The other messages alert the pharmacist to potential problems, but do not require intervention to fill the prescription.

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The incidence of these issues in SFY 2006 also changed dramatically with the transition of 30,000 beneficiaries to primary coverage under Medicare Part D.

The following chart reports the incidence of messages in SFY 2006:

	Q1 SFY 2006	Q2 SFY 2006	Q3 SFY 2006	Q4 SFY 2006	Totals	Percent
Drug-Drug Interaction(DD)	205,076	215,768	95,229	72,176	588,249	21.1%
Early Refill (ER)	84,042	90,073	17,123	10,659	201,897	7.3%
Drug-Disease (MC)	238,597	238,829	16,872	11,808	506,106	18.2%
Ingredient Duplication (ID)	74,352	78,337	31,699	21,727	206,115	7.4%
Drug-Age Precaution (DA) (formerly Geriatric Precaution)	269,886	279,160	16	11	549,073	19.7%
Therapeutic Duplication (TD)	204,794	215,726	151,493	122,356	694,369	24.9%
Miscellaneous	18,035	19,327	0	0	37,362	1.3%
Totals	1,094,782	1,137,220	312,432	238,737	2,783,171	100%

Notes: 1. Therapeutic categories changed effective January 1, 2006.  
 2. Part D effectively eliminated the need for drug-age precaution.

**Supplemental Rebates**

Federal law requires that manufacturers pay rebates for drugs to be covered by the Medicaid Program. It also allows states to separately negotiate with manufacturers to secure rebates subject to the approval of the Centers for Medicare and Medicaid Services.

When states develop a preferred drug list they “prefer” clinically appropriate products because they are singularly clinically appropriate. When multiple products are clinically

appropriate, products may be preferred because they are inherently cost effective or because the manufacturer has offered to make them cost effective.

Beginning in October 2002 Vermont began securing Vermont-only supplemental rebate agreements. From April 2003 until December 2005, Vermont was a member of the National Medicaid Pooling Initiative (NMPI) with eight other states under the management of the PBA vendor for all of the states, First Health Services Corporation. In the fall 2005, Vermont committed to the Sovereign States Drug Consortium (SSDC), the first in the nation state-administered Medicaid pooling initiative for supplemental rebates. Member states are Iowa, Maine, and Vermont.

A number of other states are considering the Consortium. In it member states are able to pool collective lives as well as state staff and pharmacy benefit management contractor resources to negotiate supplemental rebate agreements with drug manufacturers. This approach provides much administrative efficiency. It also results in greater state involvement with the actual agreements in assuring unique drug coverage customization for each state. This provides greater opportunities for multi-state collaborations in publicly funded health insurance arenas. This also creates a pool that is not dependent on a single contracted vendor and is portable for the future regardless of a state's affiliation with a PBA vendor.

The fall of 2005 marked the first SSDC engagement to secure rebates. As of January 2006, 48 contracts were in place pending federal approval. On July 20, 2006 federal approval was received. While finalizing the 2006 contracts with the federal conditions, the SSDC began the procurement process for 2007. As of January 2007, 50 contracts have been secured.

Supplemental rebates are a valuable resource in the Vermont Health Access PBM Program. SFY 2006 collections on calendar year 2005 utilization were \$10.4 million. With the transition of 30,000 beneficiaries and their utilization to Medicare Part D collections for SFY 2007 are anticipated to be \$3.9 million, representing a reduction of 62.6%. However, that amount is still an asset to Vermont's programs.

### ***Managing Reimbursement***

As a matter of routine OVHA monitors reimbursement to pharmacies serving Vermont's programs.

Section 107a of Act 215 of the Vermont General Assembly of the 2005-2006 Legislative Session (H.881) authorized a Medicaid generic reimbursement reduction and dispensing fee study. A major factor in this authorization was the federal Deficit Reduction Act of 2005 that proposes to change Medicaid reimbursement on generics in calendar year 2007.

In order to assure a thorough analysis in the study, OVHA opted to include all possible aspects of drug reimbursement in programs. The study has been completed and distributed to the Legislative Health Access Oversight Committee and the Legislative Joint Fiscal Committee and is available on OVHA's website at [www.ovha.vermont.gov](http://www.ovha.vermont.gov).

The findings of that study are:

1. The full potential impact of the DRA cannot be determined until federal rules proposed in December 2006 are finalized during 2007.
2. The average reported cost of dispensing individual prescriptions in pharmacies serving Vermont Medicaid is \$10.55.

The study indicates the following regarding current reimbursement:

1. The amount paid for the highest cost category, branded drugs, is higher than Medicaid programs in NE and NY and commercial PBMs and insurers.
2. The generic reimbursement is less than regional Medicaid programs.
3. In comparison to Wholesale Acquisition Costs (WAC), which is considered a measure close to actual cost, the current payment is more than WAC on brands but less than WAC on some generics.

At this point, OVHA believes that many things may change in national Medicaid reimbursement in 2007 including generic and brand pricing and that until more is known it is premature to propose any changes in product reimbursement.

Regarding the dispensing fee, the current in state fee is \$4.75. The effective date of that was July 1, 2005. Prior to then the fee was \$4.25. In state fiscal year 2006 this increase alone is estimated to have generated over \$1.3 million in revenues to Vermont pharmacies. With the transition of many Vermont program beneficiaries to Medicare Part D, there has been a reduction in claims volume for which a dispensing fee is paid. However, it is estimated that the increase was still worth \$278,378 in the first quarter of state fiscal year 2007.

For comparison purposes, the \$4.75 dispensing fee for OVHA programs to Vermont pharmacies is greater than all other states in New England where the Medicaid dispensing fees range from \$1.75 to \$3.40 and greater than the state of New York where the Medicaid dispensing fees are \$3.50 for brands and \$4.60 for generics.

In 2007 OVHA will be monitoring all aspects of reimbursement until the impact of these changes can be assessed.

## ***Responding to Change***

### *Implementation of Medicare Part D*

On January 1, 2006, Medicare drug coverage authorized under the Medicare Modernization Act (MMA) of 2003 was implemented. 30,000 Medicaid, VHAP Pharmacy, VScript, and VScript Expanded beneficiaries were transitioned to primary drug coverage under Part D. Almost instantly it was apparent that there were problems and they were not immediately solved.

With the difficulties, the Legislature appropriated \$11 million in state funds to support the reinstatement of Vermont program provisions as they existed on December 31, 2005. The Governor approved and ordered this on January 5, 2006 and the changes were implemented on January 6, 2006. This provided an answer for assuring both beneficiary access and pharmacy reimbursement while Medicare Part D system issues were being resolved.

In March 2006, OVHA determined that the Medicare Part D Prescription Drug Plans (PDPs) had demonstrated their ability to handle the coverage of their beneficiaries. At that time OVHA began transitioning people back to Part D coverage. This was completed by July 2006.

Between January and July, Vermont spent an estimated \$11.7 million on drugs as part of Medicare Part D bailout coverage. Vermont is participating in Medicare Section 402 Demonstration Project to receive reimbursement for select eligibles. Thus far, \$5 million has been recovered against the \$11.7 million as well as an addition \$923,000 in administrative costs. OVHA continues to work with the Medicare vendor to collect remaining claims and administrative expenses. Any expenditures not recovered through Medicare will be pursued through the PDPs.

### *Applying Maintenance Definition to VScript Expanded*

VScript was implemented in 1989. At the time pharmacies were permitted to designate what drugs were for "maintenance use". In September of 2005 the Drug Utilization Board considered classes generally characterized as non-maintenance. The Board approved those classes where drugs would never be used for maintenance purposes. Statutory language required a rule change in VScript policy to apply this change. The change was effective January 1, 2006.

Implementation occurred on January 1, 2006. Since that time, cases have been identified where certain drugs generally not used for maintenance purposes are used that way for individual beneficiaries. Procedures have been developed to allow a prescriber to request an authorization for an exception.

### *Apply Pharmacy Fee*

Vermont pharmacies began paying a per prescription fee to the state in July 2005. For every prescription filled, regardless of payer, the pharmacy pays \$.10 per claim.

Payments were first received in September. Some pharmacies had early difficulties in reporting the number of claims they processed. These problems are now largely resolved.

For state fiscal year 2006, Vermont pharmacies paid a total of \$748,733 through January 7, 2007.

### *Vermont State Auditor of Accounts Report on \$2.2 Million in Questioned Pharmacy Claims*

In December 2006 the Office of the Vermont State Auditor released a report questioning \$2.2 million in claims payments.

OVHA is committed to addressing the concerns raised in this report and will do so in calendar year 2007.

### **Assessment of SFY 2006**

Assessing the performance of the Vermont Health Access Pharmacy Benefit Management Program is difficult in 2006. In the early years of the program, the major drug classes in terms of expenses were gastric acid reducers, anti-inflammatory drugs, and analgesic pain relievers. It was easy to focus on such classes where utilization was high. Success was measured in terms of millions of dollars in reduced spending as beneficiaries were moved to the least expensive alternatives, largely generics.

The program has saved money in these and other major categories as still more generics have become readily available and as one-time blockbuster products have become available over the counter. Examples of such products include Prilosec OTC<sup>®</sup> and Claritin<sup>®</sup> variations.

Another major development was the loss of confidence in certain anti-inflammatory products. The most notable example would be Vioxx<sup>®</sup> which was withdrawn from the market for clinical reasons. As a result many prescribers began opting for older, proven, and less expensive alternatives.

Now, with the maturing of the Program, success in drug class management has not been readily measured in terms of money saved but in terms of expenses avoided. This is where generic use and supplemental rebates come into play as the greatest

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savings have resulted from the promotion of generics and the acquisition of supplemental rebates on drugs utilized in Vermont's programs.

As indicated before, Vermont programs' generic usage is:

<b>Jul – Aug 2006</b>	<b>Percentage of Rx</b>
Generic use as a percentage of all drugs dispensed	62.4%
Generic use when generic equivalent available	97.7%

The University of Connecticut, School of Pharmacy assisted OVHA in the production of the Generic Reimbursement Reductions and Dispensing Fee Study. They procured an independent vendor, Advance Pharmacy Concepts (APC), knowledgeable in pharmacy operations to assist them in data analysis. APC reports that the use of generic products has been seen to be the single most valuable cost-saving initiative that can be implemented by any insurer. APC indicated that the generic use performance in Vermont programs is excellent compared to commercially administered drug benefits.

For the study, APC used paid claims on non-Medicare Part D beneficiaries with dates of service in July and August 2006. In this two month sample, payments on branded drugs were equal to the manufacturers' declared Average Wholesale Price (AWP) minus 11.9%. Payments on generic drugs were at AWP minus 62.5%.

	<b>Claims</b>	<b>Percentage of Total Claims</b>	<b>AWP</b>	<b>VT Payment</b>	<b>VT Discount</b>
<b>Brand</b>	90,635	37.6%	\$16,297,663	\$14,356,176	11.9%
<b>Generic</b>	150,112	62.4%	\$ 7,686,918	\$ 2,884,677	62.5%

As previously described, supplemental rebates continue to be a valuable tool in Vermont. Even with the transition of 30,000 beneficiaries and their utilization to Medicare Part D, supplemental rebates have an estimated value of \$3.9 million in SFY 2007.

This does not mean that managing the benefit no longer needs to occur. If anything it must be managed more vigilantly to achieve returns. Between SFY 2004 and 2005, gross spending increased 24.3% with relatively little change in caseload. The reasons for that increase were specifically related to product cost and beneficiary utilization. For that period claims history showed a:

- 20.4% increase in product costs,
- 12.6% increase in the number of prescription fills and refills, and
- 12.6% increase in the total days supply.

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With the 2006 transition of 30,000 Vermont program beneficiaries to primary coverage under Medicare Part D, it is estimated that 95.9% of elderly beneficiaries and 46.8% of disabled beneficiaries became Part D. Historically beneficiaries who are elderly or disabled are major users of Vermont drug programs' coverage, particularly in many of the drug classes managed in the Vermont PDL.

The following chart illustrates the impact of this change with Vermont processed claims volume counted by age. The 2005 figures show program activity with all Vermont programs primary. The 2006 figures show activity with Vermont programs primary for those beneficiaries who were not Part D eligible. For those ages 65 and older the vast majority of primary claims have now transitioned to Part D. For those ages 21 to 64, a number of primary claims transitioned to Part D because of disabled Medicare beneficiaries:

Primary Vermont Program Paid Pharmacy Claims				
Ages	Jul-Dec 2005 with Medicare		Jul-Dec 2006 no Medicare	
0-12	102,669	6.44%	101,069	14.57%
13-20	83,588	5.25%	84,179	12.14%
21-40	257,055	16.13%	208,159	30.01%
41-50	233,532	14.66%	142,441	20.54%
50-64	303,070	19.02%	151,549	21.85%
65 and older	613,326	38.50%	6,156	0.89%
Totals	1,593,240		693,553	

In SFY 2005, the top five drug classes in terms of expenditures were:

1. Antipsychotics, atypical, dopamine, & serotonin antagonists
2. Anticonvulsants
3. Lipotropics
4. Gastric acid reducers
5. Selective serotonin reuptake inhibitors (SSRIs)

At that time antipsychotics, atypical, dopamine, & serotonin antagonists; anticonvulsants; and selective serotonin reuptake inhibitors (SSRIs) were not managed classes. They began experiencing management in SFY 2006 with the implementation of management steps on mental health drugs. Lipotropics and gastric acid reducers had long been on the PDL and managed to the extent possible to meet clinical needs.

In SFY 2006 the top five classes for all eligibles including transition coverage for Part D eligibles were:

1. Antipsychotics, atypical, dopamine, & serotonin antagonists
2. Lipotropics

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3. Gastric acid reducers
4. Anticonvulsants
5. Analgesics, narcotics

While selective serotonin reuptake inhibitors (SSRIs) were no longer in the top five they were #6.

Removing Medicare Part D eligibles' usage has not changed class utilization significantly. In the last six months of 2006 the top five classes were:

1. Antipsychotics, atypical, dopamine, & serotonin antagonists
2. Anticonvulsants
3. Analgesics, narcotics
4. Gastric acid reducers
5. Lipotropics

What this means is that while the ranking and the volume has changed with the transition of many beneficiaries to primary Medicare Part D coverage, the areas requiring attention remain the same.

Looking at overall utilization in the whole of SFY 2005 and SFY 2006, with all eligibles including Part D eligibles in transition, the following occurred:

All Paid Pharmacy Claims for All Beneficiaries		
	SFY 2005	SFY 2006
Claims	3,068,938	2,832,959
Days Supply	80,259,369	73,625,601
Paid	\$ 191,397,998	\$ 167,532,603
Average monthly eligibles	134,690	132,240
Claims per Eligible per Month	1.9	1.8
Days Supply per Eligible per Month	49.7	46.4
Paid per Eligible per Month	\$ 118.42	\$ 105.57

The reduction in paid per eligible per month can largely be attributed to eligibles moving to Part D coverage and out of primary coverage in Vermont's programs. Removing Medicare eligibles from the picture produces the following:

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All Paid Pharmacy Claims for Beneficiaries Without Medicare Coverage		
	Jul - Dec 2005	Jul - Dec 2006
Claims	670,086	693,553
Day Supply	16,112,242	16,488,946
Paid	\$44,584,687	\$45,784,079
Average monthly eligibles	103,857	104,363
Claims per Eligible per Month	0.5	0.6
Days Supply per Eligible per Month	12.9	13.2
Paid per Eligible per Month	\$ 35.77	\$ 36.56
Percentage Increase		2.19%

According to the AARP Rx Watchdog, in a study of a sample of 193 branded drugs and 75 generic drugs in the twelve months ending in September 2006, manufacturers increased prices, on average, 6.2% on brands and 0.7% on generics.

The preceding represents a new post-Medicare Part D baseline from which the Vermont Health Access Pharmacy Benefit Management Program will operate.

***Planned for SFY 2007***

Activities not previously mentioned but planned in the coming year include:

- Shifting focus to the population now managed since the implementation of Medicare Part D;
- Reviewing and updating the PDL as needed;
- Continuing to manage generic utilization;
- Coordinating activities with OVHA's Chronic Care Management and Care Coordination Programs;
- Partnering with the newly-formed OVHA Program Integrity Unit to identify areas where program operations can be improved and developing strategies to make that happen;
- Reviewing the dispensing of drugs under medical procedure codes (J, Q, and 99 codes) to assure availability in medical setting while containing costs and adhering to the related requirements of the Deficit Reduction Act of 2005;
- Reviewing the reimbursement methodology for compound drugs;
- Continuing to educate on appropriate days supply dispensing;
- Assuring that products are obtained from pharmacies at the most reasonable cost possible; and
- Responding to Medicare Part C development as it becomes available in Vermont.

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**FY08 As Passed - OVHA**

**Governor's Recommend**

	GF	IdptT	FF	MEDICAID GCF	INVESTMENT GCF	Total
<b>OVHA Administration - As Passed FY07</b>	<b>0</b>	<b>362,794</b>	<b>0</b>	<b>28,167,196</b>	<b>0</b>	<b>28,529,990</b>
<b>FY08 Changes</b>						
<b>Personal Services:</b>						
Pavact (FY '07 raises in FY '08)				135,374		135,374
Fringe benefits increases				51,383		51,383
8 FTEs to operationalize Catamount and ESI				372,410		372,410
Adjustment of approp. to account for historical federal grant funding			250,000	(250,000)		0
Move DCF atty. position to DCF				(69,000)		(69,000)
Move DCF Asset Test Transfer to DCF				(243,163)		(243,163)
Move DCF Operating to DCF				(30,000)		(30,000)
Move DCF LTC attv. to DCF				(200,000)		(200,000)
Move EQRO contract to AHS				(257,744)		(257,744)
Move Milliman contract to AHS				(155,000)		(155,000)
Medicare Modernization Act - additional pay & chase				214,849		214,849
Medicare Modernization Act - additional Maximus time spent with beneficiaries				480,194		480,194
Contract to data match to third-party insurers				15,000		15,000
Incr in Maximus responsibility - citizenship mandate, ESI, Catamount				560,355		560,355
Chronic Care Management contract - enhanced need				??TBD		0
Chronic Care Management staffing need				178,026		178,026
Move grants expenditures previously classified as contracts to grants				(1,000,000)		(1,000,000)
MITA assessment regarding MMIS re-bid	50,000		450,000			500,000
System coordination for Blue Print - electronic health record				300,000		300,000
Reduce one-time ESI and Catamount implementation funding				(1,000,000)		(1,000,000)
Marketing and Outreach for Catamount Health/ESI				1,316,167		1,316,167
One-time administrative expense related to dental initiative				275,000		275,000
<b>Operating Expenses:</b>						
VISION/HRMS				88,744		88,744
One-time startup expenses for FTEs - ESI and Catamount				40,000		40,000
Operating expenditures related to ESI and Catamount				293,321		293,321
<b>Grants:</b>						0
Move grants expenditures previously classified as contracts to grants				1,000,000		1,000,000
<b>FY08 Subtotal of changes</b>	<b>50,000</b>	<b>0</b>	<b>700,000</b>	<b>2,115,916</b>	<b>0</b>	<b>2,865,916</b>
<b>FY08 Gov Recommend</b>	<b>50,000</b>	<b>362,794</b>	<b>700,000</b>	<b>30,283,112</b>	<b>0</b>	<b>31,395,906</b>

**OVHA Global Commitment - As Passed FY07**

	GF	IdptT	FF	MEDICAID GCF	INVESTMENT GCF	Total
<b>OVHA Global Commitment - As Passed FY07</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>389,504,923</b>	<b>0</b>	<b>389,504,923</b>
<b>FY08 Changes</b>						
<b>Grants:</b>						
ABD Adults - \$504.88 to \$552.33 (\$47.45 chg.)				8,820,215		8,820,215
ABD Adults - Enrollment Change from 15,491 to 15,725 (234 chg.)				1,552,819		1,552,819
ABD Dual Eligibles - \$343.21 to \$335.48 (<\$7.73> chg.)				(745,784)		(745,784)
ABD Dual Eligibles - Enrollment Change from 8,042 to 8,354 (312 chg.)				1,256,599		1,256,599
BD Children - \$617.44 to \$692.17 (\$74.73 chg.)				3,028,563		3,028,563
BD Children - Enrollment Change from 3,377 to 3,371 (-6> chg.)				(52,595)		(52,595)
General Adults - \$319.01 to \$345.18 (\$26.17 chg.)				2,497,739		2,497,739
General Adults - Enrollment Change from 7,952 to 7,921 (<31> chg.)				(128,827)		(128,827)
General Children - \$168.59 to \$184.47 (\$15.88 chg.)				10,071,030		10,071,030
General Children - Enrollment Change from 52,839 to 52,910 (71 chg.)				157,528		157,528
VHAP - \$274.55 to \$300.53 (\$25.98 chg.)				7,481,849		7,481,849
VHAP - Enrollment Change from 23,995 to 24,789 (794 chg.)				2,862,226		2,862,226
Underinsured Children - \$77.66 to \$102.04 (\$24.38 chg.)				567,699		567,699
Underinsured Children - Enrollment Change from 1,941 to 1,520 (<421> chg.)				(515,853)		(515,853)
Global Pharmacy				(2,170,245)		(2,170,245)
Buy-In				9,228,532		9,228,532
Legal Aid				110,236		110,236
Rate Setting				31,594		31,594
Lund Home				(149,983)		(149,983)
Catamount Health				12,468,165		12,468,165
Insurance premium projection				274,503		274,503
SLMB-QMB-QI1 100% Federal Reimbursement Program				(3,259,070)		(3,259,070)
<b>FY08 Subtotal of changes</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>53,386,943</b>	<b>0</b>	<b>53,386,943</b>
<b>FY08 Gov Recommend</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>442,891,866</b>	<b>0</b>	<b>442,891,866</b>

**OVHA - Medicaid Program - non-GC LTC Waiver**

	GF	IdptT	FF	MEDICAID GCF	INVESTMENT GCF	Total
<b>OVHA - Medicaid Program - non-GC LTC Waiver</b>	<b>70,960,289</b>		<b>101,357,072</b>			<b>172,317,361</b>
<b>FY08 Changes</b>						
<b>Grants:</b>						
LTC - \$3,397.90 to \$3,252.30 (<\$145.60> chg.)	(2,969,904)		(4,275,531)			(7,245,435)
LTC - Enrollment Change from 4,147 to 4,723 (576 chg.)	9,209,491		13,258,162			22,467,654
<b>FY08 Subtotal of changes</b>	<b>6,239,588</b>	<b>0</b>	<b>8,982,631</b>	<b>0</b>	<b>0</b>	<b>15,222,219</b>
<b>FY08 Gov Recommend</b>	<b>77,199,877</b>	<b>0</b>	<b>110,339,703</b>	<b>0</b>	<b>0</b>	<b>187,539,580</b>

**OVHA - Medicaid Matched Non-Waiver Expenses**

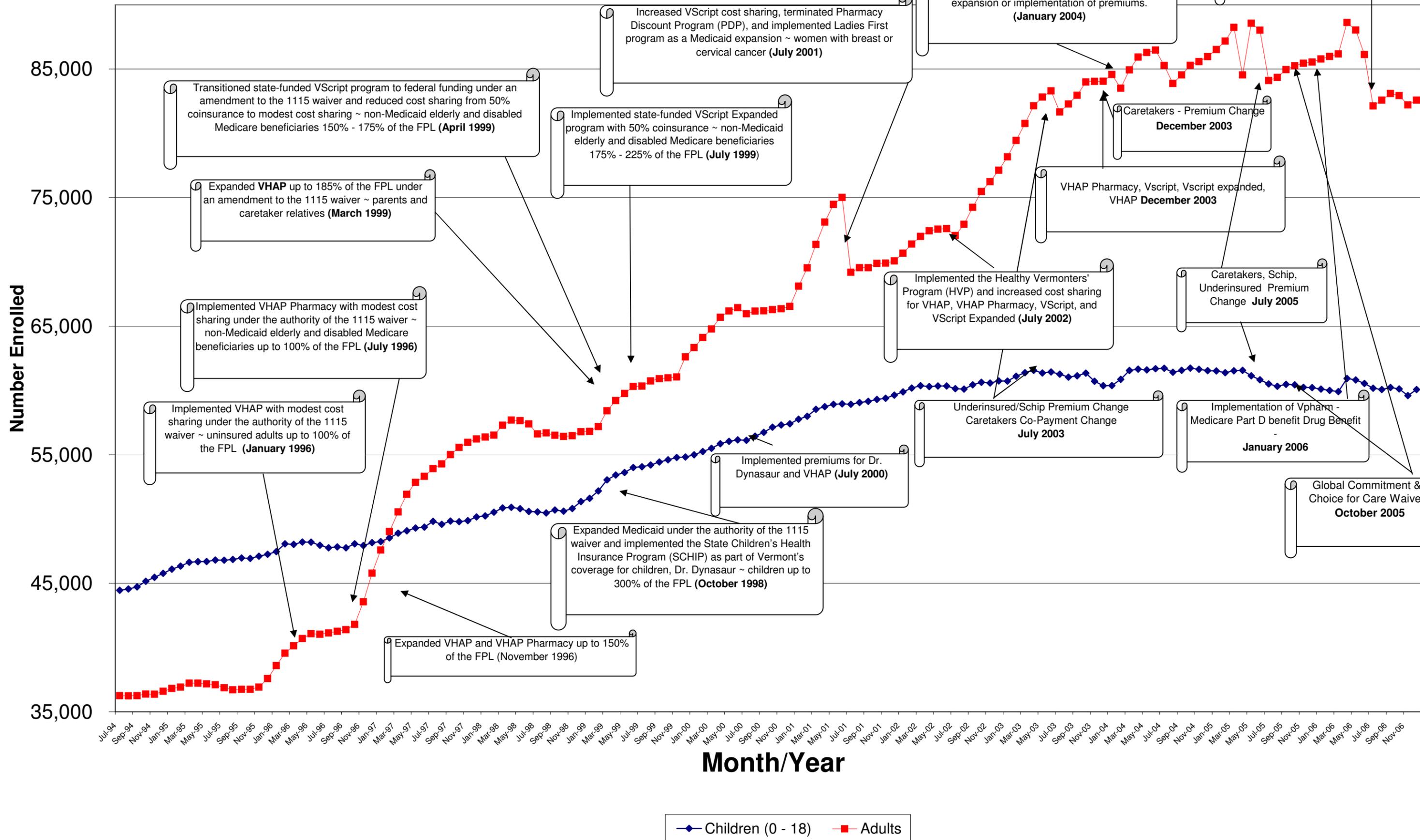
	GF	IdptT	FF	MEDICAID GCF	INVESTMENT GCF	Total
<b>OVHA - Medicaid Matched Non-Waiver Expenses</b>	<b>24,589,781</b>		<b>36,604,771</b>			<b>61,194,552</b>
<b>FY08 Changes</b>						
<b>Grants:</b>						
DSH Decrease	(2,971,893)		(4,278,396)			(7,250,289)
SCHIP - \$121.27 to \$125.46 (\$4.19 chg.)	49,023		121,790			170,813
SCHIP - Enrollment Change from 3395 to 4070 (675 chg.)	291,783		724,882			1,016,665
SLMB-QMB-QI1 100% Federal Reimbursement Program			3,259,070			3,259,070
<b>FY08 Subtotal of changes</b>	<b>(2,631,087)</b>	<b>0</b>	<b>(172,654)</b>	<b>0</b>	<b>0</b>	<b>(2,803,741)</b>
<b>FY08 Gov Recommend</b>	<b>21,958,694</b>	<b>0</b>	<b>36,432,117</b>	<b>0</b>	<b>0</b>	<b>58,390,811</b>

**OVHA - Medicaid Program - State Only**

	GF	IdptT	FF	MEDICAID GCF	INVESTMENT GCF	Total
<b>OVHA - Medicaid Program - State Only</b>	<b>28,437,916</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1,184,007</b>	<b>29,621,923</b>
<b>FY08 Changes</b>						
<b>Grants:</b>						
State-Only Pharmacy	181,634				(928,821)	(747,187)
Clawback	249,780					249,780
<b>FY08 Subtotal of changes</b>	<b>431,414</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>(928,821)</b>	<b>(497,407)</b>
<b>FY08 Gov Recommend</b>	<b>28,869,330</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>255,186</b>	<b>29,124,516</b>

<b>TOTAL FY08 OVHA</b>	<b>128,077,900</b>	<b>362,794</b>	<b>147,471,820</b>	<b>473,174,978</b>	<b>255,186</b>	<b>749,342,679</b>
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# Enrollment Growth Trend July 1994 - December 2006



◆ Children (0 - 18)    ■ Adults