



Pharmacy Best Practices and  
Cost Control Report  
2010

Report to: The General Assembly

**Agency of Human Services  
Office of Vermont Health Access  
Pharmacy Unit**

Cynthia D. LaWare, Pharmacy Director

January 21, 2010

## **Table of Contents**

	<u>Page</u>
Section I - Facts and Figures from State Fiscal Year (SFY) 2009	1
Section II - Program Designs	7
Section III - Overview of Pharmacy Benefits Management	13
Section IV - Assessment of SFY 2009	22
Section V - Projections for SFY 2010	24
Section VI – On the Horizon for SFY 2010	26
Section VII - Select Historical Information from Previous Pharmacy Best Practices and Cost Control Reports	27

## Section I - Facts and Figures from State Fiscal Year (SFY) 2009

### **PHARMACY PROGRAMS STATISTICS**

- Vermont's publicly funded health insurance programs covered an average of 150,740 beneficiaries monthly in SFY 2009, a 5.16% increase over SFY 2008, when covered beneficiaries averaged 143,349 per month.
  - 118,913 represented non-Part D programs
  - 31,827 represented Part D wrap programs.
- Compared to SFY 2008, average monthly membership grew primarily in the non-Part D population:

SFY	Part D Beneficiaries	Non-Part D Beneficiaries	Total
2009	31827	118913	150740
2008	31470	111879	143349
<b>% Change</b>	1.13%	6.29%	5.16%

- As of November 2009, membership has grown to 159,582 due, we believe, to the weak economy and job losses. As we go forward, this increase in membership will provide a challenge to the pharmacy benefit management program.
- A total of 2,293,659 pharmacy drug claims were paid for all of Vermont's publicly funded pharmacy programs. This represents a 4.86% increase in the number of pharmacy claims processed over SFY 2008. Of this number:
  - 1,552,424 represented non-Part D programs
  - 741,235 represented Part D wrap programs.
- Gross spending was \$ 125,709,817. This represents an 11.84% increase in gross spending on pharmacy claims. Pharmacy is the highest spending item in OVHA's benefit programs outpacing nursing home care at \$ 119,361,580, which had historically exceeded pharmacy spending.
  - \$ 113,867,778 represented non-Part D programs
  - \$ 11,842,039 represented Part D wrap programs.

The average gross Cost per Claim rose from \$51 in SFY2008 to \$55 in SFY 2009, a year-to-year increase of 6.65%.

- Federal rebates collected in SFY 2009 totaled \$ 37,550,730: This represents a 23% increase in rebates from the prior year.
  - \$ 34,013,399 represented non-Part D programs
  - \$ 3,537,331 represented Part D wrap programs.

Federal rebates that manufacturers pay to states are calculated based on prices and financial concessions manufacturers make available to all entities that purchase their drugs. The two prices used in the calculation are “best price” and the “average manufacturer price” (AMP). The OVHA does not directly influence the amount of Federal rebate for a particular drug. Drugs which historically have large Federal rebates, however, may be preferred. In general, Federal rebate collection increases as utilization increases.

- Supplemental rebates collected in SFY 2009 totaled \$ 6,489,711, representing a 22% increase from the prior year.
  - \$ 5,878,371 represented non-Part D programs
  - \$ 611,340 represented Part D wrap programs

This increase is due to an improvement in rebate contracting on a variety of drug products as well as increases in utilization. In some cases, the Sovereign States Drug Consortium (SSDC) aggressively negotiated more substantial supplemental rebates. For other drugs, new drug categories were added to the Preferred Drug List for drug management in order to be able to accept and realize the supplemental rebates being offered.

- Some relatively small product categories result in substantial supplemental rebate collection. For example, rebate amounts for Diabetic Supplies, originally estimated to be approximately \$ 700,000 annually, exceeded \$1 million for SFY 2009.
- Net of rebates, the total program spend was 6.63% greater in SFY 2009 than in SFY 2008. In comparison, net program spend was 0.49% less in SFY 2008 than in SFY 2007.
  - \$ 81,669,376 represented 2009 net program spend
  - \$ 76,590,881 represented 2008 net program spend

*Pharmacy Best Practices and Cost Control Report 2010*

While total net spend increased by 6.63% in SFY 2009, it should be noted that there was only a 1.40% increase in net spending per beneficiary per month for SFY 2009. Thus, the increase in net spend was primarily driven by the increase in numbers of beneficiaries. OVHA's net pharmacy trend is still well below the projected growth in Medicaid of 12.3% as forecasted by the Centers for Medicare and Medicaid Services (CMS).

Net spending per beneficiary per month increased by 1.4 % for all OVHA beneficiaries. The increase for non-Part D beneficiaries was 1.51% and for Part D wrap beneficiaries there was a 5.24% decrease.

- The Chart below summarizes the cost and utilization data:

	No. of Claims	Total Amount Pd	Cost per Rx	CMS Rebates	Supp Rebates	All Rebates	Net Spending	No. Enrolled Beneficiaries	Net Spending per Beneficiary Per Month
<b>SFY 2009</b>	2,293,659	\$125,709,817	\$55	\$37,550,730	\$6,489,711	\$44,040,441	\$81,669,376	150,740	<b>\$45.15</b>
<b>SFY 2008</b>	2,187,347	\$112,406,224	\$51	\$30,496,900	\$5,318,443	\$35,815,343	\$76,590,881	143,348	<b>\$44.53</b>
		Percent Change from SFY 2008 to 2009:							
<b>% Change</b>	4.86%	11.84%	6.65%	23.13%	22.02%	22.97%	6.63%	5.16%	1.40%

**Non-Part D (traditional populations)**

	No. of Claims	Total Amount Pd	Cost per Rx	CMS Rebates	Supp Rebates	All Rebates	Net Spending	No. Enrolled Beneficiaries	Net Spending per Beneficiary Per Month
<b>SFY 2009</b>	1,552,424	\$113,867,778	\$73	\$34,013,399	\$5,878,371	\$39,891,770	\$73,976,008	118,913	<b>\$51.84</b>
<b>SFY 2008</b>	1,468,610	\$100,624,597	\$69	\$27,300,430	\$4,761,001	\$32,061,432	\$68,563,165	111,879	<b>\$51.07</b>
		Percent Change from SFY 2008 to 2009:							
<b>% Change</b>	5.71%	13.16%	7.05%	24.59%	23.47%	24.42%	7.89%	6.29%	1.51%

**Part D Wrap (Beneficiaries who are eligible for Medicare)**

	No. of Claims	Total Amount Pd	Cost per Rx	CMS Rebates	Supp Rebates	All Rebates	Net Spending	No. Enrolled Beneficiaries	Net Spending per Beneficiary Per Month
<b>SFY 2009</b>	741,235	\$11,842,039	\$16	\$3,537,331	\$611,340	\$4,148,671	\$7,693,368	31,827	<b>\$20.14</b>
<b>SFY 2008</b>	718,737	\$11,781,626	\$16	\$3,196,470	\$557,442	\$3,753,911	\$8,027,715	31,470	<b>\$21.26</b>
		Percent Change from SFY 2008 to 2009:							
<b>% Change</b>	3.13%	0.51%	-2.54%	10.66%	9.67%	10.52%	-4.16%	1.13%	-5.24%

▪ **OVHA Prescription Drug Spending Growth Trend Compared to National Trends**

CMS reports that overall national prescription drug spending growth was projected to slow to 4.0% in 2009, as many consumers fill fewer prescriptions or become increasingly willing to switch to low-cost generic drugs. The offset to this decrease in growth was the projected **increase** in prescription spending in Medicaid, which had been forecast to grow 12.3% in 2009. OVHA's rate of growth in total net drug spend is approximately one-half of national estimates (Please see chart on page 3). Additionally, a November 2009 AARP report showed that the average annual percentage change in manufacturer prices for widely used brand name prescription drugs was 8.7% in CY2008 and was projected to be approximately 9.3% in CY2009.

Net spending per beneficiary per month increased by 1.4 % for all OVHA beneficiaries. The increase for non-Part D beneficiaries was 1.51% and for Part D wrap beneficiaries there was a 5.24% decrease.

These results are primarily due to strict management of our preferred drug list, improvements in generic utilization and pricing due to growth in OVHA's MAC list and increased rebate collections. Clearly, close management of prescription drug spending is especially important at this time.

▪ **Generic Dispensing Rates**

The rate of generic dispensing reflects the use of generics as a percentage of all drugs dispensed. The rate of generic substitution reflects the percentage of generic use when a generic equivalent is available. The following chart identifies these rates of dispensing for SFY 2009 and 2008:

	Non-Part D		Part D	
	SFY 2009	SFY 2008	SFY 2009	SFY 2008
Generic use as a percentage of prescriptions for all drugs dispensed	64.63%	62.99%	72.28%	69.86%
Generic use as a percentage of prescriptions when a generic equivalent is available	98.21%	98.39%	97.46%	97.30%

- **CMS “Clawback”**

The Part D design requires that states 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 (“Dual Eligibles”). This is the concept sometimes referred to as “clawback.” For SFY 2009, the Vermont clawback phased-down contribution was \$ 20,779,093. For comparison, SFY 2008 was \$ 20,339,254. This represents a 2.19% increase from SFY 2008 to SFY 2009.

While our percentage of “clawback” progressively decreases (see page 32 for explanation of the phased-down contribution), our total dollar amount has increased due to the increase in Part D drug costs.

- ***Provider Reimbursement***

Nationally, Medicaid programs reimburse individual claims based on a) the lower of a pharmacy’s usual and customary/submitted fee including a dispensing fee, b) a measure of ingredient costs plus a dispensing fee, c) the Centers for Medicaid and Medicare Services established Federal Upper Limit (FUL) plus a dispensing fee, or d) a Maximum Allowable Cost (MAC) amount plus a dispensing fee if the State opts for a MAC list.

OVHA routinely monitors reimbursement to pharmacies serving Vermont’s programs, in addition to monitoring how Vermont reimburses pharmacies compared to other states.

Vermont’s reimbursement for brand drugs is the highest in the northeast. Vermont, however, pays for many generic drugs based on a competitive MAC price. As a result, Vermont’s generic reimbursement is believed to be less than most other New England states as well as the state of New York, although Maine’s MAC list is believed to be more aggressive. Vermont’s dispensing fee for in-state pharmacies is the highest in the region.

The following chart (see next page) compares Vermont’s reimbursement to that of other states in the Northeast for the calendar quarter ending March 2009.

*Pharmacy Best Practices and Cost Control Report 2010*

State	Ingredient Cost	Dispensing Fee	State MAC List for Multi-source Drugs
Connecticut	Ingredient cost is AWP minus 40% for selected multi-source brands and generics; AWP minus 14% (other brands)	Dispensing fee is \$3.15	Y
Maine	Ingredient cost is AWP minus 15%; AWP minus 17% (on direct supply); AWP minus 20% (mail order)	Dispensing fee is \$3.35; \$1.00 (mail order); \$4.35 and \$5.35 (compounding); \$12.50 (insulin syringe)	Y
Massachusetts	Ingredient cost is WAC plus 5% (all drugs except 340B billed drugs); actual acquisition cost (340B billed drugs)	Dispensing fee is \$3.00 (all drugs except 340B billed drugs) \$10 (340B billed drugs)	Y
New Hampshire	Ingredient cost is AWP minus 16%	Dispensing fee is \$1.75	Y
New York	Ingredient cost is AWP minus 16.25% (brand); AWP minus 25% (generic); AWP minus 12% (specialized HIV pharmacies)	Dispensing fee is \$3.50 (brand); \$4.50 (generic)	Y
Rhode Island	Ingredient cost is WAC	Dispensing fee is \$3.40 (outpatient), \$2.85 (long-term care)	N
Vermont	Ingredient cost is AWP-11.9%	\$4.75 (in-state); \$3.65 (out-of-state); compounding: \$19.75 (in-state); \$18.65 (out-of-state);	Y

(AWP=average wholesale price, WAC=wholesaler acquisition cost, FUL=federal upper limit, MAC=maximum allowable cost)

SOURCE: Centers for Medicaid and Medicare Services Approved State Plans

## **Section II - Program Designs**

Some OVHA programs include full health insurance coverage. All included a pharmacy benefit in SFY 2010. These programs include:

*Pharmacy Best Practices and Cost Control Report 2010*

**OVHA Pharmacy Programs (other coverage guidelines apply for Part D and ESI wrap plans and OTC coverage)**

Plan	Benefit	Potential Beneficiaries	Income Limit	Resource Limit	Monthly Premium	Beneficiary Copayment	Coinsurance
Vermont Medicaid / VHAP / Dr. Dynasaur (Covers inpatient and outpatient health care and pharmacy)	Medicaid Covered Drugs	Medicaid: Aged / disabled, children, parents or caretakers of children. VHAP: Age 18 and over, income eligible Dr. Dynasaur: income eligible, under age 18 and pregnant women	VHAP: up to 185% of FPL Dr. Dynasaur: up to 300% of FPL	Applies only to Medicaid	Medicaid: None VHAP: \$0 - \$49 Dr. Dynasaur: \$15 - \$60	Medicaid: \$1, \$2 and \$3, depending on cost of drug. VHAP: \$25 for ER visits and for patients at or above 100% of the FPL, patients are responsible for \$1 or \$2, depending on the cost of the drug. Dr. Dynasaur: no copayments. In addition, beneficiaries through age 20, nursing home residents and pregnant woman are excluded from paying copayments.	None
VHAP Pharmacy (A pharmacy-benefit only program)	Medicaid covered drugs	Aged / disabled with no Medicare coverage and no pharmacy coverage	<= 150% of the FPL	None	\$15 per person	Patient is responsible for \$1 or \$2, depending on the cost of the drug.	None
VHAP Limited	Medicaid covered drugs				\$0 - \$49	For patients at or above 100% of the FPL: Patients are responsible for \$1 or \$2, depending on the cost of the drug. In addition, beneficiaries through age 20, nursing home residents and pregnant woman are excluded from paying copayments.	
Vscript (A pharmacy-benefit only program)	Medicaid covered maintenance drugs	Aged / disabled with no Medicare coverage and no pharmacy coverage	>150% but <= 175% of the FPL	None	\$20 per person	Patient is responsible for \$1 or \$2, depending on the cost of the drug.	None
VScript Expanded (A pharmacy-benefit only program)	Medicaid covered maintenance drugs from manufacturers with a current Vermont Supplemental Rebate Agreement	Aged / disabled with no Medicare coverage and no pharmacy coverage	>175% but <= 225% of the FPL	None	\$50.00 per person	Patients are responsible for \$1 or \$2, depending on the cost of the drug.	None
Healthy Vermonters (A pharmacy-benefit only program)	Beneficiary pays the state's rate for Medicaid covered drugs	Aged / disabled and others with no pharmacy coverage or coverage with an annual limit that has been met	Aged or disabled: up to 400% of the FPL; others: up to 350% of the FPL	None	None at this time	Beneficiary pays the state's rate for drugs	None

### OVHA Pharmacy Programs that "Wrap" Part D Plans

Plan	Benefit	Potential Beneficiaries	Income Limit	Monthly Premium	Beneficiary Copayment/Coinsurance
<b>Full-Benefit Duals</b>	Coverage of defined drugs in classes that are excluded from Medicare Part D coverage. (Note: Full-benefit duals do not have a PDP deductible, donut hole or coinsurance.)	Aged or disabled with Medicare D pharmacy and/or credible coverage. Resource limit applies.		None	Copayments of up to \$6.30 apply to Part D plan coverage; Copayments of \$1, \$2 and \$3, depending on cost of drug, apply to Medicare Part D excluded drugs. In addition, beneficiaries through age 20, nursing home residents and pregnant woman are excluded from paying copayments.
<b>100% LIS-eligible VPharm Members (can be VPharm 1, 2 or 3)</b>	1) PDP copayments of no greater than \$6.30 should be billed to VPharm. Claims greater than this amount will be rejected. 2) Coverage of defined drugs in classes that are excluded from Medicare Part D coverage. (Note: 100% LIS-eligible VPharm members do not have a PDP deductible, donut hole or coinsurance.)	Aged or disabled with Medicare D pharmacy coverage. Requires that Medicare has deemed members eligible for subsidy.	See below: Members can fall into any of the FPL categories listed below for VPharm members.	\$15/\$20/\$50 depending on VPharm plan.	Part D copayment of $\leq$ \$6.30 should be billed to VPharm. Patient is responsible for \$1 or \$2 of the Part D copayment, depending on the cost of the drug.
<b>VPharm 1</b>	1) Payment of the PDP premium not covered by the Low Income Subsidy (LIS) and cost-sharing for drugs covered by beneficiary's PDP and not covered by the LIS (copayment, deductible, coinsurance and "donut hole"), and 2) coverage of defined drugs in classes that are excluded from Medicare Part D coverage.	Aged or disabled with Medicare D pharmacy coverage. No resource limit.	$\leq$ 150% of the FPL	\$15 per person	Part D copayment/coinsurance should be billed to VPharm. Patient is responsible for \$1 or \$2 of the Part D copayment, depending on the cost of the drug.
<b>VPharm 2</b>	1) Payment of the PDP premium and cost-sharing for maintenance drugs covered by beneficiary's PDP (copayment, deductible, coinsurance and "donut hole"), and 2) coverage of defined maintenance drugs in classes that are excluded from Medicare Part D coverage.	Aged or disabled with Medicare D pharmacy coverage. No resource limit.	$>$ 150% but $\leq$ 175% of the FPL	\$20 per person	Part D copayment/coinsurance for maintenance drugs should be billed to VPharm. Patient is responsible for \$1 or \$2 of the Part D copayment, depending on the cost of the drug.

**OVHA Pharmacy Programs that "Wrap" Part D Plans (Continued)**

Plan	Benefit	Potential Beneficiaries	Income Limit	Monthly Premium	Beneficiary Copayment/Coinsurance
<b>VPharm 3</b>	1) Payment of the PDP premium and cost-sharing for maintenance drugs covered by a beneficiary's PDP (copayment, deductible, coinsurance and "donut hole"), and 2) coverage of defined maintenance drugs in classes excluded from Medicare Part D coverage.	Aged or disabled with Medicare D pharmacy coverage. No resource limit.	>175% but <= 225% of the FPL	\$50 per person	Part D copayment/coinsurance for maintenance drugs should be billed to VPharm. Patient is responsible for \$1 or \$2 of the Part D copayment, depending on the cost of the drug.
<b>Healthy Vermonters with Medicare Part D Coverage</b>	Beneficiary pays the state's rate for drugs in classes that are excluded from Medicare Part D coverage.	Aged, disabled with no pharmacy coverage other than Medicare Part D, or coverage with an annual limit that has been met. No resource limit.	Aged or disabled: up to 400% of the FPL; others up to 350%	None at this time	Beneficiary pays the state's rate for drugs

Note: Effective August 1, 2009, OVHA will only cover the cost-sharing (deductible, donut hole and coinsurance) for select statins (HMG COA reductase inhibitors) and proton pump inhibitors (PPIs) for VPharm Part D-eligible beneficiaries. • Statins – all dosage strengths of simvastatin, lovastatin and pravastatin. • PPIs – omeprazole RX 10 mg and 20 mg and Prilosec OTC 20 mg. • Most of the drugs no longer covered by VPharm under this pilot do not require prior authorization (PA) from the Part D Plans. However, if a beneficiary obtains a PA from his/her Part D Plan, the drug will continue to be covered by VPharm. • A VPharm coverage exception may be possible for a non-covered drug but only when a prescriber can provide, through the OVHA exception process, a detailed explanation regarding drugs that were either found to be ineffective or resulted in adverse or harmful side effects, or were expected to be ineffective or result in harmful or adverse side effects.

**OVHA Employer-Sponsored Insurance "Wrap"**

Plan	Benefit	Potential Beneficiaries	Income Limit	Resource Limit	Monthly Premium	Beneficiary Copayment / Coinsurance
<b>Employer-Sponsored Insurance (ESI) - "WRAP" (A pharmacy-benefit only program)</b> ESI beneficiaries are those Vermonters who receive financial assistance from the state to help pay the monthly premiums associated with the health insurance plans offered by their employers. For these beneficiaries, the state provides secondary coverage.	1) For ESI beneficiaries not eligible for VHAP, the program pays the cost sharing for Medicaid-covered medications used to treat the following chronic health conditions: Asthma, Depression, Hyperlipidemia, Hypertension, Diabetes, Arthritis, COPD, Ischemic Heart Disease, Congestive Heart Failure, Chronic Renal Failure and Low Back Pain. Cost-sharing coverage will pay co-pays, coinsurance and deductibles for Medicaid-covered medications for these conditions only.	Enrollees in Vermont's Employer Sponsored Insurance (ESI) Plans not eligible for VHAP.	Vermonters up to 300% of the FPL	None	There is a monthly ESI premium balance that is the employee's responsibility. It can range from \$60 to \$185 for an individual and \$120 to \$370 for a couple.	None
	2) For ESI beneficiaries who meet VHAP eligibility requirements, wraparound coverage will apply to all VHAP covered drugs. Wraparound coverage for these beneficiaries is not limited to medications for the chronic care health conditions listed above.	Enrollees in Vermont's Employer Sponsored Insurance (ESI) Plans who are eligible for VHAP.	See VHAP eligibility requirements	None	There is a monthly ESI premium balance that is the employee's responsibility. It can range from \$7 to \$49 for each person.	For VHAP beneficiaries who are at or above 100% of the FPL: patients are responsible for \$1 or \$2, depending on the cost of the drug. In addition, beneficiaries through age 20, nursing home residents and pregnant woman are excluded from paying copayments.

*Pharmacy Best Practices and Cost Control Report 2010*

OVHA Over-The-Counter (OTC) Pharmacy Coverage	
Vermont Medicaid, VHAP, VHAP Pharmacy, Dr. Dynasaur, State Children's Health Insurance Program (SCHIP)	<ol style="list-style-type: none"> <li>1. Medicaid OBRA rebate agreement required.</li> <li>2. OTC coverage requires a prescription, and the drug must be part of the medical treatment for a specific current health problem.</li> <li>3. PA may be required.</li> </ol>
VHAP Limited (Medicaid by 1115 Waiver)	<ol style="list-style-type: none"> <li>1. Medicaid OBRA rebate agreement required on drugs.</li> <li>2. OTC coverage limited to diabetic supplies, syringes, needles, loratidine, cetirizine, smoking cessation drugs, Prilosec OTC®, and Non-steroidal Anti-inflammatory analgesics (NSAIDS). A prescription is required, and the drug must be part of the medical treatment for a specific current health problem.</li> <li>3. PA may be required.</li> </ol>
VScript (Medicaid by 1115 Waiver), VScript Expanded (100% State funded)	<ol style="list-style-type: none"> <li>1. Maintenance drugs coverage only.</li> <li>2. Medicaid rebate agreement required for VScript.</li> <li>4. PA may be required.</li> <li>5. OTC coverage limited to diabetic supplies, loratidine, cetirizine, Prilosec OTC® and Non-steroidal Anti-inflammatory analgesics (NSAIDS). A prescription is required, and the drug must be part of the medical treatment for a specific current health problem.</li> </ol>
VPharm 1 (100% State funded for deductible, coverage gap, coinsurance and copayments)	<ol style="list-style-type: none"> <li>1. Medicaid OBRA rebate agreement required for Part D excluded drugs</li> <li>2. OTC coverage limited to those drugs that are not covered by PDP. A prescription is required, and the drug must be part of the medical treatment for a specific current health problem.</li> <li>3. PA may be required.</li> </ol>
VPharm 2 & 3 (100% State funded for deductible, coverage gap coinsurance and copayments)	<ol style="list-style-type: none"> <li>1. Maintenance drugs coverage only.</li> <li>2. Medicaid OBRA rebate agreement required for VPharm 2 and 3 Part D excluded drugs</li> <li>3. OTC coverage limited to diabetic supplies, loratidine, cetirizine, Prilosec OTC® and Non-steroidal Anti-inflammatory analgesics (NSAIDS) when not covered by PDP. A prescription is required, and the drug must be part of the medical treatment for a specific current health problem.</li> <li>5. PA may be required.</li> </ol>
Employee Sponsored Insurance (ESI) Wrap - Eligible for VHAP (Medicaid by 1115 Waiver)	<ol style="list-style-type: none"> <li>1. Medicaid OBRA rebate agreement required.</li> <li>2. Coverage wraps ESI plan OTC coverage. A prescription is required, and the drug must be part of the medical treatment for a specific current health problem.</li> <li>3. PA may be required.</li> </ol>
Employee Sponsored Insurance (ESI) Wrap - Not eligible for VHAP (100% State funded)	<ol style="list-style-type: none"> <li>1. Medicaid OBRA rebate agreement required.</li> <li>2. OTC coverage limited to those drugs used to treat the 11 chronic conditions: Asthma, Depression, Hyperlipidemia, Hypertension, Diabetes, Arthritis, COPD, Ischemic Heart Disease, Congestive Heart Failure, Chronic Renal Failure and Low Back Pain.</li> <li>3. PA may be required.</li> </ol>

## **Section III - Overview of Pharmacy Benefits Management**

### **Mission**

The Agency of Human Services (AHS) has the widest reach in state government and one of the most critical missions: to improve the conditions and well-being of Vermonters today and tomorrow, and protect those who cannot protect themselves.

The Office of Vermont Health Access assists beneficiaries in accessing clinically appropriate health services; administers Vermont's public health insurance system efficiently and effectively; and collaborates with other health care system entities in bringing evidence-based practices to Vermont Medicaid beneficiaries.

### **Program Goals**

In support of the Agency and Office goals, the goals of the Vermont Health Access Pharmacy Benefit Management Program are to:

- Assure the availability of clinically appropriate services, and
- To do so at the most reasonable cost possible

With the fiscal challenges facing the state over the next few years, at stake is preserving, to the greatest extent possible, the benefits that have evolved in Vermont's programs.

### **Vermont Strategies in Pharmacy Benefits Management**

The Vermont pharmacy best practices and cost control program was authorized in 2000 and established in SFY 2002 by Act 127. This program, as the Vermont Health Access Pharmacy Benefits Management (PBM) Program, is administered by the OVHA.

Operational strategies include:

- Partnering with a vendor with skills and expertise in pharmacy benefit administration
- Managing and processing claims
- Managing benefit design
- Monitoring and managing utilization through retrospective and prospective drug utilization review
- Evaluating new-to-market drug and preferred drug list placement
- Procuring supplemental rebates on drugs used
- Managing reimbursement
- Responding to change

## **Pharmacy Benefit Administration**

Pharmacy benefit management (PBM) services support the program in the following areas:

- Claims operations
- Benefit management
- Utilization review and management
- Drug Utilization Review Board coordination
- Rebate management
- Analysis and reporting

The OVHA contracts with MedMetrics Health Partners of Worcester, Massachusetts as the Pharmacy Benefits Manager (PBM) for Vermont's programs. MedMetrics is a non-profit, full-service pharmacy benefit manager, wholly owned by Public Sector Partners (PSP) and affiliated with the University Massachusetts Medical School and the University of Massachusetts Memorial Medical Center. MedMetrics was selected as OVHA's PBM contractor through a competitive bid process in 2005. The contract was for three years with an option to extend for two additional years. OVHA chose that option in 2008. Thus, the PBM contract was scheduled to be rebid in 2010.

It is however, OVHA's intent to issue a unified RFP for both pharmacy benefit management services and the Medicaid Management Information System (MMIS); the current MMIS contract with EDS does not expire until December 31, 2012. Consequently, OVHA has received permission to extend the current MHP contract to December 31st, 2012. This 26-month extension will allow both the EDS and MedMetrics contracts to expire at the same time and position us to conduct a comprehensive bid for these services.

## **Managing and Processing Claims**

Claims processing activities include accepting drug claims according to the rules of coverage under Vermont programs; providing the mechanisms to support the application of the generic and alternative drug requirements authorized by transmitting program requirement messages to pharmacies as drugs are dispensed and claims are processed (e.g., eligibility verification, federal/state drug rebate requirements, coverage limitations, prior authorization needs, automated step therapy review, quantity limits, prospective and retrospective drug utilization review (DUR) issues, etc.); and authorizing payments according to the reimbursement rules. Claims are submitted by pharmacies enrolled to provide benefits in Vermont's programs. As of June 2009, 277 pharmacies in and out of state were enrolled and processing claims.

The maximum reimbursement is established on a per-claim basis at the individual drug level in all cases but VPharm. In SFY 2009 the reimbursement amount was the lesser of:

- Average wholesale price (AWP) 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.

Effective July 1, 2009, reimbursement on drugs subject to AWP pricing moved from AWP less 11.9% to AWP less 14.2% plus a dispensing fee.

The beneficiary in the Healthy Vermonters Program pays the rate established applying this methodology. For programs other than VPharm, Vermont pays the difference between the rate set and any other insurance payment.

OVHA provides a wrap-around benefit to Medicare Part D coverage. For traditional Medicaid beneficiaries who have Part D, OVHA covers those drug classes excluded from Medicare Part D health plan coverage (Part D excluded drugs).

Under VPharm, Medicare beneficiaries receive coverage for covered drugs in classes excluded from Medicare Part D coverage (Part D excluded drugs), as well as coverage for coinsurance, copayments, and the coverage gap for drugs that are covered by the Part D plan. This coverage gap, or "donut hole," as it is often referred to, is the period in a coverage year when there is a lapse in Part D coverage.

### **Drug Utilization Review (DUR) Board**

The Drug Utilization Review (DUR) Board of the Office of Vermont Health Access (OVHA) is a committee composed of physicians and pharmacists. In SFY 2009 the Board membership included five Vermont physicians and four pharmacists. The DUR Board meets as often as monthly. In SFY 2009 the Board met eight times. Its goal is to optimize the pharmaceutical care received by OVHA Members. The Preferred Drug List has been developed with the assistance of the DUR Board acting as the Program's Pharmacy and Therapeutics (P&T) Committee. The Board also routinely reviews therapy by examining patterns in prescribing, dispensing and consumption of medications. As an outcome of these reviews, the Board identifies specific therapeutic and clinical behaviors that, if altered, may improve patient outcomes and lower costs.

In SFY 2009, the DUR Board activities included:

- 21 New Drug Reviews
- 6 New Dosage Form Reviews
- 12 Revised Clinical Coverage Criteria (including new indications for drugs already on the preferred drug list)
- 5 New Managed Drug Classes
- 78 Therapeutic Class Reviews
- 40 Quantity Limits established for new or previously reviewed drugs
- 1 new duration of therapy limit
- 17 FDA Safety Alerts reviewed
- 7 RetroDur analyses
  - Compounded Topical Analgesic Products
  - Lidoderm<sup>®</sup> Transdermal Patches
  - Smoking Cessation Duration of Therapy
  - Provigil<sup>®</sup>
  - Desmopressin
  - Triptans in Migraines
  - Vivitrol<sup>®</sup> for alcohol dependence

Other notable topics of discussion at DUR Board meetings in SFY 2009 included treatment of fibromyalgia, criteria for approval of new-to-market drugs not yet reviewed by the DUR Board, cosmetic use of drugs, atypical antipsychotics in major depressive disorder, specialty pharmacy, opiate dependency treatment, establishment of specific clinical criteria for expensive dosage forms and shortening of length of prior authorization approvals to be able to take advantage of changes in the marketplace and introduction of new generics.

In the course of DUR activities, the DUR Board may select certain drugs to target for review to ensure that clinical criteria and prescribing patterns are appropriate. Staff makes recommendations for targeted areas and the Board selects those most relevant. When this occurs, OVHA relies on MedMetrics to access clinical researchers from the University of Massachusetts' School of Medicine. Specific providers may be polled regarding the patients affected, and the Board reviews their responses. The Board then determines if follow-up is appropriate either with the identified prescribers or with a clinical advisory to all providers.

In the event a preferred drug is changed to a non-preferred status and specific beneficiaries are affected, prescribers are provided with a list of all the patients who were prescribed the specific drug that is being changed and a profile unique to each patient with the drug change listed. This creates a record for use in the patient's file.

The PBM Program relies on the Drug Utilization Review (DUR) Board for advice on how to best educate providers and address the impact of pharmacy manufacturers

*Pharmacy Best Practices and Cost Control Report 2010*

advertising, in particular. In the DUR Board meetings counter-detailing opportunities are considered.

To educate providers on general PBM Program coverage activities, various methods are used. Most frequently mailings are prepared around both general and specific changes and they are targeted to prescribers and pharmacies separately. Examples include 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 Association. The OVHA and MedMetrics have also begun to publish a periodic pharmacy bulletin to provide timely updates on claims processing and clinical issues.

Providers may find all general pharmacy benefit management materials posted on the OVHA webpage at <http://ovha.vermont.gov/>. These materials include the description of the PBM Program; DUR Board information; the Preferred Drug List and Criteria; prior authorization and exception information and forms; bulletins and mailings; and other information, instructions, and alerts.

**Prior Authorization Requirements**

Through prior authorizations prescribers can access any non-preferred drug on the PDL. Under the Vermont Health Access PBM Program, criteria are available for these exceptions. MedMetrics' clinical pharmacists manage the criteria. Criteria have been and continue to be developed as classes are selected for management. They are then reviewed annually. New criteria and proposed changes are reviewed, modified, and approved by the DUR Board acting as the Vermont Health Access PBM Program's Pharmacy and Therapeutics Committee.

The following chart reports the incidence of prior authorization requests in SFY 2009 compared with SFY 2008:

	<b>Number of Prior Authorization Requests</b>	<b>Number of Prior Authorizations Approvals</b>	<b>Number of Prior Authorization Changes</b>	<b>Number of Prior Authorizations Denials</b>
Totals for <b>SFY '09</b>	<b>18,244</b>	<b>14,048</b>	<b>1,051</b>	<b>3,145</b>
Percent of Totals (rounded)	<b>100.00%</b>	<b>77%</b>	<b>5.76%</b>	<b>17.24%</b>
Totals for <b>SFY '08</b>	<b>18,331</b>	<b>14,610</b>	<b>1,503</b>	<b>2,218</b>
Percent of Totals	<b>100.00%</b>	<b>80%</b>	<b>8.20%</b>	<b>12.10%</b>
<b>Difference</b>	<b>-0.47%</b>	<b>-3.85%</b>	<b>-30.07%</b>	<b>41.79%</b>

While the number of prior authorization requests has remained steady, the more aggressive management of the preferred drug list has resulted in an increased

percentage of denials of non-preferred products. Additionally, with the request from the OVHA for a less costly clinical call center, pharmacy associates can now issue denials (in the past, only pharmacists issued denials) which we suspect increases the number of denials while decreasing the number of prior authorization changes (changes in therapy) agreed to and documented at the time of the request. These changes in therapy likely occur after the prior authorization request call and, therefore, are not documented.

### **Preferred Drug List (PDL)**

The PDL is a key feature in the pharmacy benefits management program. The PDL identifies drugs in which specific clinical criteria have to be met in order for them to be covered. It 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, or an exception, for the drug to be covered.

The PDL features clinically appropriate, low-cost options including:

- OTCs as prescribed by physicians when medically necessary
- generics;
- lower-cost brands;
- brands where manufacturers pay a level of federal Medicaid rebates that makes the net cost of the drug comparative to other products in the drug's therapeutic class; and
- brands where manufacturers pay Vermont rebates supplemental to required federal Medicaid rebates to make their products more affordable.

### **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 there is the ability to message the pharmacist on that individual claim. Messaging occurs on specific utilization issues as claims are processed. 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 before a prescription may be filled. The other messages alert the pharmacist to potential problems, but do not require intervention to fill the prescription.

### **Dose Consolidation Opportunities**

The DUR Board continues to review for opportunities to consolidate dosages to save money when clinically possible. This refers to the activity of establishing daily allowed

quantity limits in the number of lower-strength tablet/capsules to encourage the use of higher-strength dosage forms. For a number of drugs, all dosage strengths cost the same amount, so using two or three of a lower strength dosage may cost two to three times more than one of a higher-strength dosage. Considerations are the pill burden for patients, the complexity of drug regimens, and the impact on patient adherence to therapy. Reviews occur as classes are reviewed.

## **Monitoring and Managing Utilization**

### *Generic Utilization*

Vermont's alternative drug selection law described at 18 V.S.A chapter 91 requires pharmacies to dispense the lowest priced drug which is chemically and therapeutically equivalent, 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 and low cost alternatives 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.

In some instances, the net cost of a brand name drug after rebates may be less than the cost of a generic (this is particularly true of newly launched generics). In this situation, OVHA may prefer the brand. When a brand is preferred over a generic, the generic dispensing rate is artificially lowered.

The generic dispensing rate for the covered populations in Vermont's programs has increased with the efforts of both Vermont's programs and Medicare Part D Pharmacy Drug Plans to promote generics and the number of generics that have reached the market.

### *Buprenorphine Utilization*

An ongoing activity of the DUR Board has been the review of utilization and cost patterns for the buprenorphine products Suboxone<sup>®</sup> and Subutex<sup>®</sup>, FDA approved for use in patients with a diagnosis of opiate dependence. Subutex<sup>®</sup> is more likely to be

diverted and abused than Suboxone<sup>®</sup> so it important to ensure that adequate safeguards are in place to encourage appropriate prescribing and use.

In December 2007, management of this drug class began and prior authorization was required for all new patients being prescribed either Subutex<sup>®</sup> or Suboxone<sup>®</sup>. Coverage was limited to those with a diagnosis of opiate dependency and requests are denied for pain indications. Prescribers are required to have a DATA 2000 waiver ID number. Additionally, prior authorization requests for Subutex<sup>®</sup> are only approved if the patient is pregnant or has a documented allergy to naloxone which would preclude Suboxone<sup>®</sup> use. At the time of implementation, all current users of either Subutex<sup>®</sup> or Suboxone<sup>®</sup> were “grandfathered”; that is, they were allowed to continue use of the products without having to demonstrate they met the criteria for coverage.

In SFY 2009, the following refinements to the management of this drug class occurred:

- August 2008 - grandfathering of Subutex<sup>®</sup> users ended in order to ensure the use of that specific preparation only when medically necessary.
- June 2009 – clinical criteria for Subutex<sup>®</sup> approval was strengthened to include the requirement that allergic reactions to naloxone must be witnessed by a health care professional to prevent self declared allergic reactions.
- June 2009 – quantity limits of 3 tablets per day (6 mg/day of 2 mg tablets or 24 mg/day of 8 mg tablets) were implemented to encourage dose consolidation as well as maximum doses within the 16 – 24 mg/day range. Specific prior authorization must be obtained to exceed this quantity limit and prescribers are asked about plans to taper the patient to a lower dose.

Despite the strengthened management, buprenorphine utilization continues to escalate at a rate that outpaces growth in other areas of the pharmacy benefit. The number of total unique beneficiaries receiving Subutex<sup>®</sup> or Suboxone<sup>®</sup> on a monthly basis increased 19.7 % during the time period July 2008 through June 2009 (from 1320 to 1580) and monthly gross expenditures increased 30.88 % (from \$ 486,777.92 to \$ 637,078.73) while plan cost per Beneficiary per month increased 20.18 % (from \$ 4.41 to \$ 5.30). Encouragingly, the percentage of beneficiaries on buprenorphine who are using the Subutex<sup>®</sup> preparation decreased 3.2 % (from 13.26 % to 10.06%).

### *Specialty Pharmacy Initiatives*

In 2008, two specialty pharmacies were selected to serve Medicaid beneficiaries: Wilcox Medical dba Wilcox Home Infusion and ICORE Healthcare, LLC, partnering with our pharmacy benefits manager, MedMetrics Health Partners. Wilcox Medical is the specialty pharmacy for respiratory syncytial virus (RSV) and ICORE Healthcare/MedMetrics is the specialty pharmacy for all other conditions. Dispensing of identified specialty medications is limited to these pharmacies for Medicaid beneficiaries where Medicaid is the primary insurer.

*Pharmacy Best Practices and Cost Control Report 2010*

Both providers were selected based on a combination of the quality and the value of the services they offered and the price of the products involved. Operating in Rutland, Wilcox Medical represents the pharmacy that served the majority of Medicaid RSV patients in the last two RSV seasons. They came with local clinical recommendations including the physician who has been the primary prescriber for most Medicaid RSV patients. In addition, this physician is the Medical Director of the Neonatal Medical Follow-up Clinic at Fletcher Allen Health Care. MedMetrics Health Partners of Worcester, Massachusetts has been OVHA's pharmacy benefit manager for the last three years. ICORE is their specialty pharmacy partner and is located in Plantation, Florida. ICORE is a wholly owned subsidiary of Magellan Health Services, Inc. and provides specialty pharmacy services for 35 managed care contracts covering 60 million subscribers. The partnership of MedMetrics and ICORE assures the coordination of our pharmacy benefit management initiatives with our specialty pharmacy approach.

As of October 1, 2008 Wilcox Medical began providing services for Synagis<sup>®</sup>, the drug used to prevent respiratory syncytial virus (RSV). As of November 3, 2008 ICORE Healthcare, LLC, with MedMetrics Health Partners, began providing services for hemophilia factors, growth hormones, multiple sclerosis self-injectables, hepatitis C (ribavirin and injectables) treatments, and Elaprase<sup>®</sup> (for Hunter's Syndrome). On February 15, 2009, self-injectables for rheumatoid arthritis, psoriatic arthritis, juvenile arthritis, psoriasis, Crohn's Disease and ankylosing spondylitis were added to the program. Additionally, Pulmozyme<sup>®</sup> and Tobi<sup>®</sup> for cystic fibrosis patients were added to the program on April 1, 2009.

In the first year of the Specialty Drug Program (November 2008 through October 2009), annual savings was \$796,833:

Drug Class Name	Actual Paid	Estimated Drug Cost	Savings
ANTIHEMOPHILIC PRODUCTS	\$719,832.42	\$1,041,114.14	\$321,281.72
HEPATITIS AGENTS	\$936,078.52	\$1,133,885.17	\$197,806.65
MULTIPLE SCLEROSIS AGENTS	\$1,299,546.62	\$1,385,500.53	\$85,953.91
GROWTH HORMONES	\$673,546.64	\$737,237.01	\$63,690.37
SOLUBLE TUMOR NECROSIS FACTOR RECEPTOR AGENTS	\$544,362.14	\$576,776.02	\$32,413.88
ANTI-TNF-ALPHA - MONOCLONAL ANTIBODIES	\$511,962.36	\$543,851.73	\$31,889.37
CYSTIC FIBROSIS AGENTS	\$388,737.44	\$410,561.91	\$21,824.47
AMINOGLYCOSIDES	\$314,154.09	\$335,065.14	\$20,911.05
HEMATOPOIETIC GROWTH FACTORS	\$169,247.17	\$183,814.67	\$14,567.50
ANTINEOPLASTIC ENZYME INHIBITORS	\$34,029.07	\$35,998.96	\$1,969.89
ALKYLATING AGENTS	\$27,013.94	\$28,424.93	\$1,410.99
PARENTERAL THERAPY SUPPLIES	\$2,776.35	\$4,029.25	\$1,252.90
INTERLEUKIN-1 RECEPTOR ANTAGONIST (IL-1RA)	\$14,234.88	\$15,164.61	\$929.73
ANTIPSORIATICS	\$8,280.74	\$8,757.76	\$477.02
ANTIMETABOLITES	\$7,999.52	\$8,432.65	\$433.13
ANTINEOPLASTIC - HORMONAL AGENTS	\$504.97	\$535.56	\$30.59
HEPARINS AND HEPARINOID-LIKE AGENTS	\$154.29	\$175.27	\$20.98
SODIUM	\$810.01	\$778.42	-\$31.59
<b>TOTAL:</b>	<b>\$5,653,271.17</b>	<b>\$6,450,103.72</b>	<b>\$796,832.55</b>

## **Section IV - Assessment of SFY 2009**

2009 was a year marked with great challenge and considerable change. As the Vermont Health Access Pharmacy Benefit Management Program continues to mature, opportunities for easily obtainable significant drug cost savings are more difficult to identify. Cost containment, therefore, must be achieved through many smaller drug management initiatives and appropriate PDL placement and clinical criteria for new drugs coming to market. During the year we continued to focus on cost containment, renewed our commitment to resolve a number of outstanding program administration and operational issues and remained focused on assuring that beneficiaries had access to clinically appropriate services at the most reasonable cost.

From a fiscal perspective, OVHA saw an increase of 6.63% in net total pharmacy spend during the year. It is important to understand that the state's average monthly enrolled beneficiaries increased by 5.16% from SFY 2008 to SFY 2009, while the state's eligible beneficiary population grew by 7.46% from the beginning to end of SFY 2009. OVHA's net spending per eligible beneficiary increased by only 1.40%. Additionally, enrollment increased an additional 1.94% from June 2009 through November 2009. During the same period, however, these trends were offset somewhat by a 23% increase in Federal Rebates and a 22% increase in supplemental rebates.

Further, the Centers for Medicare and Medicaid Services (CMS) forecasted prescription spending in Medicaid would grow by 12.3% in 2009<sup>1</sup>. OVHA's increase in net total pharmacy spend was approximately one half of the nationally forecasted trend for Medicaid plans. Our continued success is due to the strict management of our preferred drug list, improvements in generic utilization and associated MAC (Maximum Allowable Cost) pricing and increased rebate collection. For a summary of Drug Utilization Review Board activity, please refer to page 13.

In addition to aggressively managing the fiscal aspect of the pharmacy programs, we renewed our commitment to resolve outstanding program administration and operational issues with a focus on efficiency and process improvement. The following progress has been made. We have:

- Automated the claims extract file transfer from our claims processor, SXC, to our fiduciary partner, EDS, which drives the weekly payments to the providers.
- Fully identified long standing issues surrounding the funding source coding of pharmacy claims and planned the implementation of necessary system changes. These changes position the pharmacy program to increase its annual rebate collection by approximately \$22 million going forward and identify an opportunity to collect up to \$21 million in retroactive rebates.
- Focused considerable attention, in conjunction with our PBM, on the development of a comprehensive system risk assessment and security plan.

*Pharmacy Best Practices and Cost Control Report 2010*

- Planned the implementation of legislative changes to be effective for SFY 2010 to include a co-pay structure for the VPharm program, the 90 day fill requirement for selected maintenance medications, the 2% reduction in provider reimbursement and the VPharm Therapeutic Equivalency Pilot Program.
- Analyzed the impact of The U.S. District court for the District of Massachusetts Final Order and Judgment approving a class action settlement that involved two major publishers of drug pricing information, First DataBank and Medi-Span.
- With litigation surrounding sections of Act 80 of the Vermont General Assembly on the 2007-2008 Legislative Session (S.115) resolved, OVHA worked to implement the collection of the manufacturer's fee which was established to fund the evidenced-based education program which includes the Generic Voucher Pilot Program. OVHA has collected \$887,000 of the estimated \$1.1M owed. As such, we have been working closely with the Vermont Department of Health as they remain the lead with regard to evidenced-based education programs.

<sup>1</sup> Centers for Medicaid and Medicare Services. Table 11: Prescription Drug Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2003-2018.

## **Section V - Projections for SFY 2010**

We will continue to focus on the goals of the PBM program to ensure that beneficiaries have access to clinically appropriate services provided at the most reasonable cost and that the program is administered as efficiently as possible.

OVHA will monitor very closely the potential impact of the Federal Health Care Reform legislation. As it is currently written there is the potential for the legislation to significantly reduce to supplemental rebates manufacturers are willing to pay to states.

### **Educating Health Care Providers**

The Vermont Health Access PBM Program continues to face the challenge of counteracting the influence of manufacturers' national and local marketing and advertising.

Effective July 1, 2009, Vermont law began banning some gifts and requiring new reporting of marketing expenditures, including expenditures for clinical trials, for manufacturers of pharmaceutical products, biological products, and medical devices. The law also required companies with expenditures to register with the Attorney General's Office by July 1, 2009.

### **Cost Containment in VPharm**

In SFY 2009, the General Assembly of the State of Vermont voted, as part of 2009 Special Session Act 1, Section E.309 to implement a pilot program to maximize the use of over-the-counter (OTC) and generic drugs. The pilot applies to the statin and proton pump inhibitor (PPI) drug classes for individuals enrolled simultaneously in a Medicare Part D prescription drug plan and Vermont's VPharm Program.

Prior to the implementation of the pilot, VPharm covered the majority of cost sharing for these drug classes, whether it was a co-pay on a generic or branded drug or the entire claim cost for patients in the deductible or the Part D coverage gap. As a way to preserve as robust a VPharm benefit as possible without impacting clinical care, the legislature sought cost savings in select drug classes. These two drug classes were chosen as there are significantly less costly generic and over-the-counter (OTC) drug choices available that have been proven to be equally efficacious and well-tolerated compared to the more expensive branded products. In addition, within the VPharm program, Vermont spends the greatest amount of money in these two drugs classes. As such, this pilot was projected to save \$500,000 in state fiscal year 2010. Preliminary review indicates that we are on target to meet this projection.

## **VITL's Electronic Medication History Service**

Late in 2006, Vermont Information Technology Leaders, Inc. (VITL) initiated planning on a pilot project for a service designed to support the Blueprint for Health's Chronic Care Information System.

The service makes insurers' medication history data available electronically to hospital emergency departments. A patient can allow emergency room personnel to quickly review his or her drug utilization using an electronic query transmitted to the claims history databases of participating insurers. Access to this information can lead to faster diagnosis and improved medical treatment for individuals who may not be able to provide a complete medication history, often due to the acute nature of their illness or injury.

The pilot began in the spring of 2007 with two hospitals: Rutland Regional Medical Center in Rutland, Vermont, and Northeastern Regional Vermont Hospital in St. Johnsbury, Vermont. The service utilizes software provided by G.E. Health Care in South Burlington, Vermont.

Drug history claims data is available from several health insurance claims payers, the largest being the OVHA through its PBM, MedMetrics. Other payers include Blue Cross and Blue Shield of Vermont, MVP Health Care, CIGNA Health Care and some Part D Plans.

The service has now completed its pilot phase and is being offered to additional hospitals in Vermont. Both hospitals involved in the pilot are still participating as is Brattleboro Memorial Hospital in Brattleboro which began using the service at the end of 2008.

VITL is a multi-stakeholder corporation formed by a broad base of providers, payers, employers, patients, and state agencies. The efforts of VITL are being coordinated with other state and federal initiatives, including the National Health Information Network (NHIN) of the federal Office of the National Coordinator for Health Information Technology (ONC), the national eHealth Initiative, and the Vermont Blueprint for Health. VITL's work helps to facilitate communication among Vermont's health information technology experts and creates the foundation for future health information technology collaboration.

## **Section VI - On the Horizon for SFY 2010**

- Continuing to focus on IT security and documentation;
- Implementing the Therapeutic Equivalency Pilot Program;
- Continuing to look for opportunities to manage drug expenditures associated with VPharm;
- Supporting the OVHA Member Card Replacement Project which is designed to replace social security numbers with Unique ID numbers;
- Continuing to implement and expand the Specialty Pharmacy Initiative to support beneficiaries in managing complex health conditions;
- Supporting VITL in their efforts to significantly expand the use of e-prescribing statewide;
- Supporting the expansion of VITL's Electronic Medication History Service to hospitals in Vermont
- Evaluating OVHA's reimbursement methodology for out-of-state pharmacies dispensing limited-distribution drugs;
- Addressing changes in pharmacy benefits coverage in Vermont's publicly funded programs in light of dwindling cash resources to support them;
- Reviewing and updating the PDL as needed;
- Managing the cost and utilization in specific therapeutic categories where appropriate;
- Promoting over-the-counter medications when they are less expensive alternatives to prescription medications;
- Continuing to review the dispensing of drugs under medical procedure codes;
- Continuing to establish criteria for appropriate dose consolidation and optimization;
- Coordinating activities with the OVHA's Chronic Care Initiative;
- Coordinating activities with the Office of Alcohol and Drug Abuse Programs on treatment approaches for opiate dependence;
- Coordinating activities with the Department of Health on treatment options for smoking cessation;
- Coordinating activities with the Department of Health in addressing needed vaccines;
- Coordinating activities with the Department of Mental Health on treatment options for mental illness;
- Partnering with the OVHA Program Integrity Unit and other state and law-enforcement agencies to identify areas where program oversight can be improved; and
- Working with the University of Vermont Area Health Education Centers (AHEC) on the creation of an evidence-based prescription drug education program to promote the most appropriate therapeutic and cost-effective utilization of prescription drugs.

## **Section VII - Select Historical Information from Previous Pharmacy Best Practices and Cost Control Reports**

### **Development of the Preferred Drug List**

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 implemented. By 2003, the foundation of the PDL was established. Since that time, the PDL has been modified to reflect changes in clinical approaches, prescribing practices, product availability, and supplemental rebate opportunities. From January 1, 2006 through June 2008, the PDL has been expanded by almost 60%, from 79 drug classes to over 140 drug classes. Automated step-therapy protocols and over 100 new product-specific dispensing limits were also instituted during that time.

### **Management of Mental Health Drugs**

In 2002, when the Vermont Health Access Pharmacy Benefit Management Program's PDL was implemented, 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.

In the summer of 2005 the DUR Board 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 were made available with prior authorization using criteria developed through literature review of acceptable evidence-based standards, including the Texas Implementation of Medication Algorithms (TIMA), the International Psychopharmacology Algorithm Project (IPAP), class reviews from the Oregon Evidence Based Practice Center, the Veterans' Administration, and the Micromedex<sup>®</sup> Health Series.

At the time, the Board recommended that certain beneficiaries' active treatment be "grandfathered" so as not to risk destabilization. For that it was decided that patients of all ages, 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 DUR Board's deliberations was submitted to the Legislature's Health Access Oversight Committee (HAOC) for comment on September 1, 2005. The Committee heard testimony from prescribers and advocates and 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 DUR Board's psychiatrist member and with the Medical Director of the Division of Mental Health at the Department of Health.

Following provider notification, the plan was implemented in January 2006. MedMetrics claims processing system's 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 a prior authorization.

With the implementation of Medicare Part D in January 2006 many beneficiaries transitioned to Part D coverage. With 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 immediately. On August 16, 2006, the OVHA sent a letter to prescribers notifying them that this provision would be effective October 1, 2006.

In 2007 it was reported that the transition to managing the mental health drug classes appeared to cause little disruption to patient care. That situation continued in 2008. Indications are that new patients or patients with a lapse in therapy of four months or more attempt therapy with preferred drugs. Between January 2006 and November 2008, prior authorization requests for non-preferred mental health drugs dropped by 62.45%. From 2008 to 2009, requests increased by 4.4%.

From a funding perspective, it is clear that continued mental health management is necessary. Drug spending for mental illness treatment continues to be a significant. In SFY'05, the top twenty drug classes in terms of spending included seven specific classes identified for the treatment of SPMI. Those seven classes represented 28.1% of the total drug spending in that year.

In 2008 individuals in the community involved with mental health issues expressed their concerns about the use of mental health drugs, particularly with children. The Department of Mental Health has formed a workgroup of stakeholders to determine the questions the system of care should be asking about usage patterns and potential policy statements on the use of psychotropic medications for Vermont's children and youth with significant mental health concerns. OVHA representatives are and will continue to be members of this workgroup in its deliberations.

## **Specialty Pharmacy Services**

In 2005, the Administration proposed to allow the PBM Program to require the purchase of selected pharmacy products using mail order options. The intention was to assure that when beneficiaries received drug treatments for complex medical conditions that those treatments were obtained in the most economical way possible and that the patients had the opportunity to obtain the best health outcomes through the availability of disease and case management services to assure optimal results from product use. The Legislature approved this requirement with the addition of V.S.A. 33 §1998a. This allowed the use of the mail order services of specialty pharmacies.

In 2007 the OVHA sought bids from specialty pharmacies to provide this additional tool in chronic care management. This serves as a resource in the treatment of complex conditions which do not require the level of support of those addressed in the OVHA Chronic Care Initiative.

Targeted were services for the treatment of such conditions as hemophilia, growth hormone deficiency, multiple sclerosis, and respiratory syncytial virus (RSV) (a condition that is the leading cause of pneumonia and bronchitis in infants). Additional potential conditions identified included hepatitis, cystic fibrosis, cancer, and deep vein thrombosis. It was stated that additional treatments might be identified over time.

## **Diabetic Testing Supplies**

Diabetic testing supplies are a specialty need. In 2005, when the Administration proposed managing specialty pharmacy services, they were identified as a target area. However, the use of such supplies generally does not require any specialty disease management services. As a result, the OVHA opted to address this by limiting the product choices available in local pharmacies while seeking rebates from preferred manufacturers, rather than using a specialty pharmacy service.

This initiative began with a partnership between the states of Maine, Utah, North Dakota, and Vermont. Diabetic supply manufacturers were approached in the summer of 2007 and offered preferred status for their products in exchange for rebates against states' utilization in their Medicaid programs.

Abbott and Lifescan were the manufacturer lines chosen by Vermont because all product needs could be met. These products were most commonly used by Vermont program beneficiaries. In addition, there was be no cost to pharmacies, patients, or the Vermont programs for the transition. For patients who had to change to Abbott or Lifescan products, coupons were provided to pay pharmacies for the manufacturer-specific glucometers required in conjunction with the products.

This approach was reviewed and unanimously approved by the DUR Board for an implementation in February 2008.

### **Physician-Administered Drugs**

Historically, drugs administered in physician offices have often been billed with other physician services. As such they have not been managed in the same manner as drug dispensed in pharmacies where in the course of claims processing the pharmacy receives messages regarding coverage requirements and conditions. Managing physician-administered drugs promotes consistency in administering the PBM Program's clinical criteria for drug coverage.

In SFY 2007, the OVHA began reviewing physician-administered drugs to identify where and how management techniques should apply. Since then drugs have been identified that are limited to dispensing through pharmacies where prior authorization requirements and utilization review conditions can apply prior to dispensing. Other drugs that must be available in physician offices are subject to prior authorization to assure that established clinical criteria apply. In the process, mechanisms have been established to facilitate the process for the offices. Evaluating physician-administered drugs for clinical management is an ongoing project.

### **Compound Drugs**

Compound drugs are produced by a pharmacist combining individual ingredients. Generally insurers cover a compound drug when the prescription is determined to be medically necessary, there is no equivalent manufactured alternative available, and its ingredients meet coverage criteria including program rebate requirements. Prior to 2006, the OVHA's pharmacy claims processing systems were unable to accept the report of individual ingredients. Beginning January 2006 and throughout state fiscal year 2007 the OVHA worked with compounding pharmacists to develop an approach to account and claim reimbursement for compound drugs that assures that they are managed under the PBM Program. The claims processing system now requires that all rebateable ingredients be identified on the claim and only those ingredients that meet coverage criteria are paid. Types of drugs that previously were compounded have since been reviewed by the DUR Board to determine if coverage should require prior authorization. Guidelines for the coverage of compounded products are now described in the Clinical Criteria Manual of the Preferred Drug List.

### **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 started 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 PBM 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 were Iowa, Maine, and Vermont. Since membership has grown with Utah in 2007, Wyoming in 2008, and West Virginia as of January 1, 2009. A number of other states are considering the Consortium.

As SSDC members, states pool their collective lives, state staff and pharmacy benefit management contractor resources to negotiate supplemental rebate agreements with drug manufacturers. This approach provides significant administrative efficiency. In addition it provides a greater opportunity for state involvement; state-specific drug coverage customization; multi-state collaboration in publicly funded programs; and creates a pool not dependent upon a single contract vendor or a state’s affiliation with a PBM vendor.

In the spring of 2007 on behalf of the SSDC, the OVHA released a Request for Proposal for a vendor to act as the rebate procurement agent to negotiate with drug manufacturers for Medicaid supplemental rebates for the SSDC. A contract was awarded to GHS Data Management of Augusta, Maine for two years with an optional contraction extension of up to two additional years. This contract began in September 2007 and is managed by the OVHA for the SSDC.

### **Dispensing Fee Study**

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. The findings of that study were:

The average reported cost of dispensing individual prescriptions in pharmacies serving Vermont Medicaid was \$10.55.

## **Phased-Down Contribution**

The pharmacy benefit under Medicare is conceptually a federal benefit. However, in the case of full benefit dual eligible beneficiaries (those Medicare beneficiaries who are also eligible for the health insurance benefit of 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 Part D design requires that states 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:

- Based on Medicaid full benefit eligible state expenditures in calendar year (CY) 2003 adjusted for inflation (excluding VHAP-Pharmacy, VScript, and VScript expanded in Vermont since no portion of those expenditures were for Medicaid full benefits eligible beneficiaries).
- Calculated on expenditures net of drug rebate.
- Premised on states retaining a specified portion in support of providing other coverage to their dual eligible beneficiaries.

Based on these concepts, for calendar year (CY) 2008, Vermont was expected to pay the phased-down state contribution of 86.67 % of the estimated CY state share of Medicaid/Medicare pharmacy expenditures net of rebate.

The contribution in future years will be progressively less:

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%

## **Coordination of Benefits with Medicare Part D**

On January 1, 2006, when 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 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, the 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 the OVHA began transitioning people back to Part D coverage. This was completed by July 2006.

Between January and July 2006, Vermont spent an estimated \$11.7 million on drugs as part of Medicare Part D bailout coverage. Vermont participated in the Centers for Medicare and Medicaid Services (CMS) Medicare Section 402 Demonstration Project to receive reimbursement for administrative expenses and claims on select eligible beneficiaries. Claims ineligible for or denied under the 402 Demonstration Project must be billed to the Medicare Prescription Drug Plans (PDPs). The OVHA's Pharmacy and Coordination of Benefits (COB) Units developed a process to submit the claim billings and its Administrative Services Unit managed the collection of administrative expenses.

With the implementation of Medicare Part D and the transition of 30,000 beneficiaries to primary coverage under 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. Prior to Part D, much of the PBM Program's focus was directed to Medicare eligible beneficiaries.

### **Tamper-Resistant Prescription Drug Pads**

Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007 set requirements regarding the use of tamper-resistant prescription drug pads in Medicaid. This was signed into law on May 25, 2007. Initially the Centers for Medicare and Medicaid Services (CMS) intended to impose this requirement as of October 1, 2007. However with many concerns raised, President Bush signed legislation into law on September 29, 2007 delaying implementation until April 1, 2008.

The following were the conditions for Medicaid program reimbursement as of April 1, 2008:

- All written prescriptions for outpatient covered drugs must be written on tamper-resistant prescription paper.

*Pharmacy Best Practices and Cost Control Report 2010*

- To be considered tamper-resistant, prescription paper must contain one of the following three characteristics:
  - one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
  - one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
  - one or more industry-recognized features designed to prevent the use of counterfeit prescription drug forms.

As of October 1, 2008, all of the above-referenced characteristics were required for the prescription paper to be considered tamper-resistant.

With implementation, CMS will be requiring that state Medicaid programs audit pharmacies to assure compliance. Pharmacy documentation will be necessary. If it is determined that a payment was made on a claim for a prescription that was not in compliance with the Medicaid tamper-resistant prescription requirements, payments must be recovered. Provisions allow for federal auditors to audit state audit samples to assure that audits occur.

**Act 80 of the Vermont General Assembly of the 2007-2008 Legislative Session (S.115)**

In the spring of 2007 the Legislature enacted Act 80, *An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information*. This Act:

- Implemented a joint pharmaceuticals purchasing consortium.
- Increased transparency of drug pricing information.
- Increased the federal poverty level for eligibility for the Healthy Vermonters program from 300% to 350% for those who are less than age 65 or not eligible for Medicare or Social Security disability benefits.
- Required increased oversight of pharmacy benefit managers (PBMs) and their practices.
- Established an evidence-based education program.
- Established a generic drug voucher pilot project.
- Protected the confidentiality of prescription information.
- Established a fee for drug manufacturers to fund the education program including the voucher pilot project.
- Enhanced consumer protections.

The following outlines the status of each of these items:

- Joint pharmaceuticals purchasing consortium (JPPC): The JPPC provides a vehicle to negotiate rebates on behalf of non-Medicaid programs. Preliminary

design discussions have occurred exploring options to pool covered lives with other states to maximize opportunities. Implementation of this will require the authorization and funding of OVHA staff.

- Drug pricing information: This component requires drug manufacturers to report to the OVHA the same pricing information reported to the Centers for Medicare and Medicaid (CMS) for Medicaid drug rebate purposes. A quarter of information was collected in 2008 but the effort proved to be very labor intensive. Full implementation of this will require the authorization and funding of OVHA staff.
- Healthy Vermonters' Program: The Act increased the eligibility income test level from 300% to 350% of the Federal Poverty Level for those who are less than age 65 or not eligible for Medicare or Social Security disability benefits. This change was implemented on July 1, 2007. The Act also proposed securing rebates from manufacturers for this program with the approval of CMS. This latter provision will require the authorization and funding of OVHA staff to implement.
- Pharmacy benefit management regulations, registration, audit and oversight of practices: These aspects are related to regulatory oversight taken on by the Department of Banking, Insurance, Securities and Health Care Administration (BISHCA).
- Establishment an evidence-based education program: This program charges the Vermont Department of Health in collaboration with the Office of the Attorney General (AG), the University of Vermont Area Health Education Centers (AHEC), and the OVHA with the establishment of an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs. Litigation has been filed impacting the funding of these activities. The OVHA's participation in the education program is dependent on the authorization and funding of staff. The AHEC Program's participation is dependent on funding.
- Establishment of a generic drug voucher pilot project: This project is a part of the evidence-based education program. Design meetings have been held. Drug selection and plans for determining where and how the pilot might be implemented are outstanding issues. Claims processing specifications have been developed. Litigation has been filed impacting the funding of this component of the evidence-based education program. Implementation of the project will require funding for the benefit, the authorization and funding of OVHA staff to administer the benefit, and funding for claims processing requirements.
- Prescription information confidentiality: This piece of the Act is subject to litigation.
- Consumer protection enhancements: These entail consumer protections in terms of advertising and insurance marketing. These are provisions that provide improved controls for the AG's office and for BISHCA in their respective roles.
- Establishment of a fee for drug manufacturers: This fee is intended to fund collection and analysis of information on pharmaceutical marketing activities, analysis of prescription drug data needed by the AG's office for enforcement activities, and the education-based drug education program's activities including

the drug voucher pilot program and the work of the AHEC Program. On August 13, 2008, the Legislative Committee on Administrative Rules approved OVHA's Bulletin 08-03, Pharmaceutical Manufacturer Fee. This authorizes the fee at 0.5% of the previous calendar year's prescription drug spending by OVHA assessed based on labeler codes in the rebate program. This bases the fee on spending in Vermont's publicly funded pharmacy benefit programs. With these programs covering nearly 25% of the total population, this method is a proxy for manufacturer market share in Vermont and applies a greater portion of the fee to those manufacturers with the greater market share.