Annual Report on the Preferred Drug List Program



Virginia Department of Medical Assistance Services

November 2007

Status Report on Virginia Medicaid's Preferred Drug List Program

Background

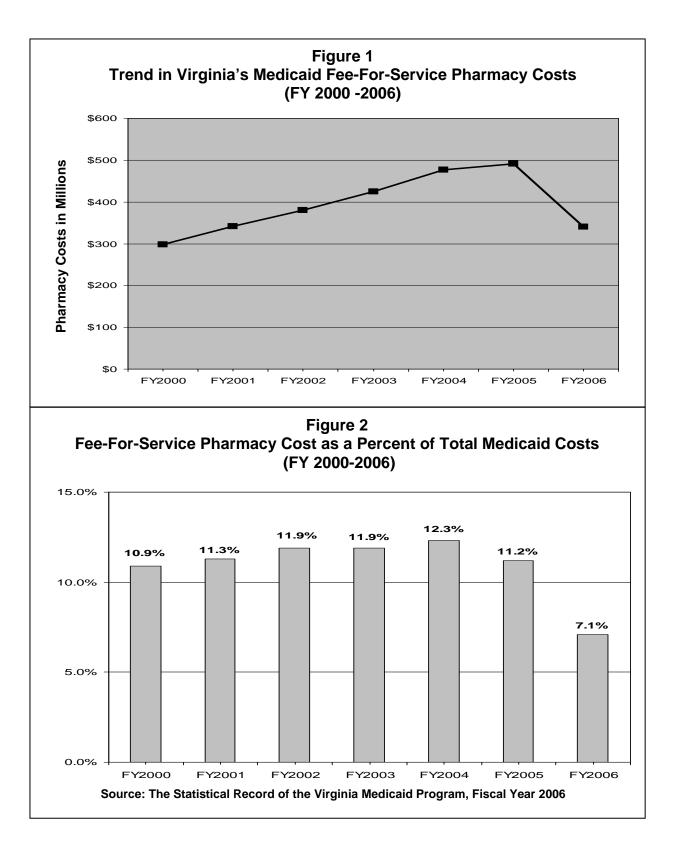
Item 325 ZZ of the 2003 Appropriations Act directed the Department of Medical Assistance Services (DMAS) to establish a preferred drug list program. The program was implemented in January 2004. In February 2004, the Department received approval of its PDL program state plan amendment and its supplemental rebate contracts from the Centers for Medicare and Medicaid Services (CMS).

The Preferred Drug List (PDL) program is a prior authorization plan that divides some Medicaid covered drugs (prescription and over the counter medications) into two categories: those that require prior authorization before they can be dispensed and those that do not. While there are many classifications of drugs that are not subject to the PDL or prior authorization, the PDL contains a wide range of generic and brand name products. The major goal of the PDL program is to make available high quality medications to treat patient illnesses that provide the same therapeutic benefit at a lower price than more expensive equivalent drugs.

Item 302 (S)(8) of the 2007 Appropriations Act requires that DMAS provide annual reports to the General Assembly on the status of the program (Attachment A). DMAS has submitted reports to the General Assembly at least annually since the implementation of the PDL program. In November 2005, DMAS provided an extensive analysis of the outcomes of the PDL program implementation, the estimated savings of the PDL program, and the health effects on recipients. This study found no adverse health impacts for persons who were switched to drugs on the PDL compared to those who were allowed to remain on non-preferred drugs. The 2005 study included an exhaustive analysis of program data, which required extensive agency resources to complete. While a similar study was not completed this year, the Department does continue to monitor for potential adverse health impacts through its Pharmacy & Therapeutics Committee process and interaction with the provider, advocacy and stakeholder communities. No major concerns have been raised with the Department regarding potential negative health effects of the PDL program.

<u>Virginia Medicaid Pharmacy Program</u>

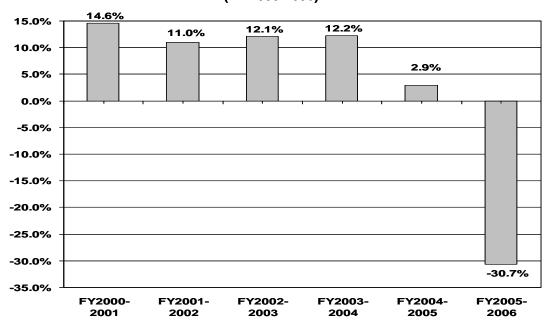
The impetus for the implementation of Virginia Medicaid's PDL program was the growing cost of prescription drugs for its fee-for-service population. Between fiscal years 2000 and 2006, there was an overall increase in prescription drug costs of 12% from \$298 million to \$340 million (see Figures 1 & 2, next page).



The rate of increase was slowed in fiscal year 2006 by two major Medicaid program changes, which contributed to a decrease in the number of recipients eligible for pharmacy benefits: 1) the implementation of the Medicare Part D drug benefit, and 2) managed care expansions. Over 140,000 recipients who previously received their prescription drug

coverage through the Virginia Medicaid program began receiving most of their prescription drug coverage through the federal Medicare Part D program or managed care organizations between September 2005 and January 2006. Consequently, from fiscal year 2005 to fiscal year 2006, there was an overall decrease of approximately 31% in pharmacy payments (from \$491 million to \$341 million), a decline in pharmacy claims of about 59%, and an almost 10% decrease in cost per claim (Figure 3). In October 2007, an additional 14,000 recipients in the Lynchburg area also began to receive drug coverage through various managed care organizations. Consequently, we expect a corresponding decrease in pharmacy claims in fiscal year 2008.

Figure 3
Annual Growth/Decline in Medicaid Expenditures
for Prescription Drug Services
(FY 2000-2006)



Source: The Statistical Record of the Virginia Medicaid Program, Fiscal Year 2006

Pharmacy & Therapeutics Committee

The Pharmacy and Therapeutics (P&T) Committee continues to meet on a regular basis for the maintenance of the PDL. The P&T Committee directs all phases of the PDL program including: 1) selecting the therapeutic drug classes to review for possible inclusion on the PDL; 2) deciding which classes should be included on the PDL; 3) assessing the clinical efficacy of the drugs within each class under review; 4) selecting the "preferred" drugs in each class; 5) establishing clinical criteria; 6) developing appropriate prior authorization procedures; and 7) advising the Department on other pharmacy program initiatives. The PDL has matured to the point that the most significant changes now relate to the introduction of new generics in established PDL-eligible drug classes. The following is a summary of some recent P&T Committee activities:

- The P&T Committee has completed its annual reviews of both PDL Phase I (October 23, 2006 and October 3, 2007) and Phase II (April 17, 2007) drug classes. During annual reviews of PDL drug classes, the P&T Committee determines if each of the classes should remain PDL eligible and the preferred/ non-preferred status of drugs within those classes based on clinical and financial information. Also, at each meeting, the Committee reviews all new drugs in existing PDL classes, which were not available for discussion during the previous annual review. Meetings are scheduled each quarter; however, they are not held if there is no business to be discussed/ addressed. Meeting minutes are available on the Virginia Town Hall and DMAS website at the following link: http://www.dmas.virginia.gov/pharm-p&t_committee.htm.
- P&T Committee meetings are open to the public and clinical presentations to the Committee, which are relevant to the discussion, are accepted. At each P&T Committee meeting, on average more than 50 representatives from pharmaceutical companies, providers, advocates and provider associations attend.
- The Department remains compliant with Committee composition requirements with eight physicians and four pharmacists (Attachment B). Due to the resignation of Mark Szalwinski, who resigned due to other professional obligations, there was a change in positions and Mark Oley, RPh. of Westwood Pharmacy (Richmond), former Chairman of the Virginia Board of Pharmacy, accepted the position of Vice Chairman.
- The P&T Committee has initiated improvements to its policy for the review of new generics in drug classes subject to the PDL. The goal of the policy is to achieve more timely capture of cost savings that result from the market introduction of less expensive, therapeutically equivalent generics in PDL-eligible drug classes. Guidelines are being clarified to allow the Department to take interim actions, in the absence of a P&T Committee discussion, which are in the best financial interest of the Commonwealth. The new generic drug policy will be integrated with existing policies for clarification. In addition, First Health Services Corporation, DMAS' PDL management vendor, will produce the "new generic watch list" that will be updated on an ongoing basis with all new generics in PDL-eligible classes as they enter the market or are anticipated (with FDA-approval). This generic watch list will be shared with the P&T Committee at least on a quarterly basis; however, it may be sent on an ad-hoc basis if pricing changes dictate that more immediate review and action are required by the Department. The P&T Committee's review and implementation of the new policy is pending.
- The P&T Committee management of the PDL has contributed to the increase in the overall generic utilization rate by making generic and over-the-counter (OTC) medications "preferred" in many classes subject to the PDL. In fact, there are several classes in which the majority of preferred drugs are generics and most brand name drugs require prior authorization. Some of these classes include H2 Receptor Agonists (gastrointestinal), proton pump inhibitors (gastrointestinal), and sedative hypnotics/benezodiazepine (central nervous system). The current generic utilization rates among total drugs dispensed are approximately 64% compared to about 54% at the end of FY2005. However, there are numerous cases where the brand named drug is less

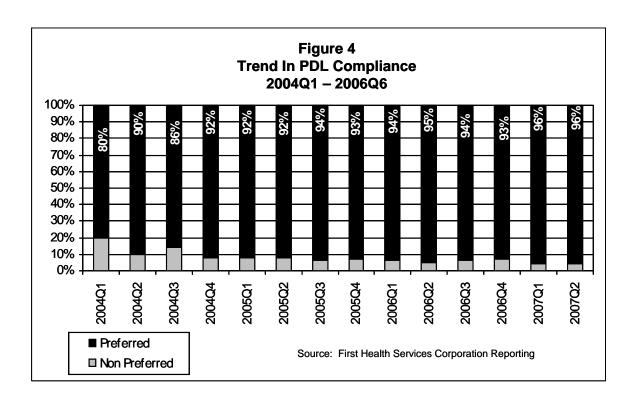
expensive than a generic due to federal and supplemental rebates. In those cases, DMAS and the P&T Committee utilize the most inexpensive option, based on final net cost, in order to maximize savings to the Commonwealth. In turn, generic utilization rates in isolation are not an accurate indicator of cost effectiveness.

<u>Preferred Drug List Program Operations and Performance</u>

A contract amendment was recently finalized with First Health Services Corporation (FHSC) to continue providing clinical and administrative services for the PDL for the third and final optional year following an initial two year contract period. The current administrative costs are \$1.4 million annually. FHSC's services include, but are not limited to, clinical call center management, supplemental rebate contracting, and clinical support of the P&T Committee. In addition, as of January 2006, FHSC began managing most pharmacy point of sale calls through their call center; these calls were formerly managed by DMAS' call center. Point of sale inquiries include those related to Medicare Part D, the National Provider Identification (NPI) number, and the new tamper resistant prescription pad requirement. The following is a summary of call center operational results:

- There have been few complaints and a number of compliments about the clinical call center and the PDL program, in general. Examples of the complaints include service by the DMAS call center, long acting narcotics' prior authorization requirements, the preferred drug options in a few drug classes and general DMAS policies.
- Call center management and the prior authorization processes are working well as
 evidenced by an efficient average speed to answer rate, minimal call time, and low call
 abandonment rate that all meet contractual requirements. The statistics have
 increased slightly because of the additional point of sale inquiries being handled by the
 call center. (The call center's operational statistics are not segregated for PDL related
 services.)
- On July 1, 2007, a new web-based process ("Web PA") became available for pharmacy prior authorization processing. The Web PA provides an alternative method for submission of prior authorization requests for prescription drugs. This is supplemental to the traditional means of phoning or faxing requests, which are still available. Some of the advantages of the Web PA process are: PA can be created online with real-time authorization in many cases; the user may check the status of the request and view the decision at their convenience; and the user may print a complete copy of the request and the decision for the patient's record. The Web PA process and all information exchanged are secured. There was extensive provider education with the introduction of this new system; however, there has been limited utilization to date.
- There were a total of 16,570 PDL PAs (requests for non-preferred drug) and clinical PAs (criteria for both preferred and non-preferred drugs, i.e., step therapy, age requirements, etc) processed in FY 2007. Among these, 73% were approved for the non-preferred drug, 26% were changed to the preferred drug and <1% were denied. The greatest number of PAs were in the antihistamine (2nd generation), proton pump inhibitor (PPI) and sedative hypnotic classes. These are drug classes with high

- utilization, and the brand name drugs are heavily marketed which creates the perception of necessity.
- Most PDL denials have been related to billing issues with pharmacy providers who request authorization of non-preferred drugs after they have been distributed to Medicaid recipients. The denials are common among long-term care providers who bill retrospectively. These are actually denials of payment rather than denial of access to drugs in that the recipient received the medication in advance of the request. There have recently been a few denials in the proton pump inhibitors (PPI) class due to stricter criteria effective January 1, 2007. The new criteria includes "step therapy" that requires a trial of the therapeutically equivalent, less expensive OTC medications and evaluation by a gastroenterologist before the brand name drugs are approved. There have been 14 denials for PPI medications to date. Most Medicaid recipients receive a therapeutically equivalent substitution if PA is denied based on PDL or clinical criteria.
- The compliance rate in terms of "preferred" drugs being prescribed for Medicaid recipients remains high, currently at 96.3% across all classes subject to the PDL. The majority of the drug classes have compliance rates above 90% (Figure 4). These compliance rates exceed the compliance level (85%) needed to achieve the necessary budget savings.



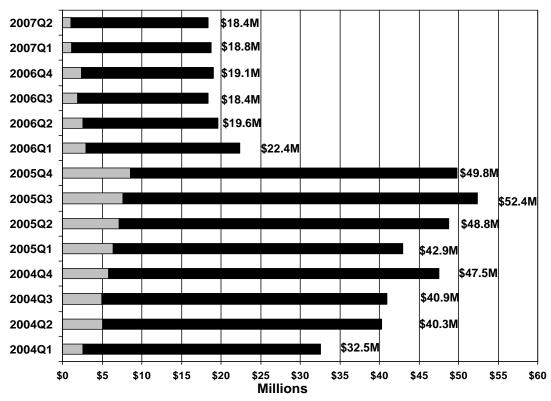
Supplemental Rebate Contracting Process & Savings Estimates

The PDL was developed with significant cooperation from pharmaceutical manufacturers who agreed to provide aggressive drug pricing and supplemental rebates in the design of a

Virginia-specific PDL. The Department solicits Virginia-specific contracts for pricing and supplemental rebates directly with manufacturers for all single-source brand products in the PDL eligible therapeutic classes. To date, this unique supplemental rebate model has out-performed the multi-state pooling approach used by some other states.

The Department has invoiced almost \$60 million in supplemental rebates since the inception of the PDL program in January 2004 (Figure 5). This amount is above the federal rebates also collected for these drugs. Supplemental rebates have declined significantly in recent months because of reduced utilization due to the implementation of Medicare Part D and managed care expansions discussed previously. As of the second quarter of calendar year 2007, total supplemental rebates for 2007 were \$2.2 million, which annualized represents a 55% decrease compared to the same period in 2006 and 85% decline from 2005. Manufacturers' rebate rates have largely been unchanged; however, the reduced claims volume (i.e., Medicare Part D) has created the significant decrease in supplemental rebates. Due to the many interconnected cost savings initiatives in the pharmacy program, it is difficult to determine the savings attributable solely to the PDL. However, the supplemental rebate calculations noted above along with the high compliance rate of using preferred agents illustrate the program is generating substantial savings for the Commonwealth.

Figure 5
Trend in Federal and Supplemental Rebates Invoiced (FY2004-2007)



■ Supplemental Rebates
■ CMS Rebates

Source: First Health Services Corporation, Rebate Department

Communications and Public Input

DMAS maintains a specific section on its website (www.dmas.virginia.gov) at which stakeholders can receive notices and information about the PDL program. Stakeholders can access all documents related to the PDL, P&T Committee as well other pharmacy program initiatives. DMAS also has a dedicated email address (pdlinput@dmas.virginia.gov) for interested parties to submit PDL-related comments, concerns, or information to the Department and/or the P&T Committee.

Conclusion

The Virginia Medicaid PDL Program continues to operate efficiently and effectively with very few complaints from providers or clients. Medicaid clients are receiving high quality prescription medications at a substantially reduced cost to the Commonwealth. Despite a significant decline in fee-for-service pharmacy clients and expenditures due to the implementation of Medicare Part D and managed care expansions, the PDL continues to be a very successful program. Much of the success of the program is attributable to a highly effective P&T Committee.

Acknowledgements

DMAS wishes to acknowledge the medical and pharmacy providers, members of the DMAS Pharmacy and Therapeutics Committee, public and private stakeholders, and pharmaceutical manufacturers who have participated in the development, implementation and maintenance of the preferred drug list program and other pharmacy program initiatives.

Attachment A. – Item 302 (S) of the 2007 Appropriations Act

The department shall provide to the Governor; the House Committees on Appropriations, and Health, Welfare and Institutions; the Senate Committees on Finance, and Education and Health; and the Joint Commission on Health Care a report on the Preferred Drug List (PDL) Program no later than November 1 of each year. The report shall include the direct savings attributed to the PDL for the prior fiscal year, an estimated savings of the program for the next fiscal year, and the cost to administer the PDL. The report shall also include an analysis of the impact of the program on patient health including, but not limited to, hospitalizations and emergency outpatient visits.

Attachment B. - P&T Committee Members and Profession

NAME	PROFESSION
Randy Axelrod, Chairman	Physician
Gill Abernathy	Pharmacist
Roy Beveridge	Physician
Avtar Dhillon	Physician
Arthur Garson, Jr.	Physician
Mariann Johnson	Physician
Mark Oley, Vice Chairman	Pharmacist
James Reinhard	Physician
Tim Jennings	Pharmacist
Renita Driver	Pharmacist
Katherine Nichols	Physician/Pharmacist
Rachel Selby- Penczak	Physician

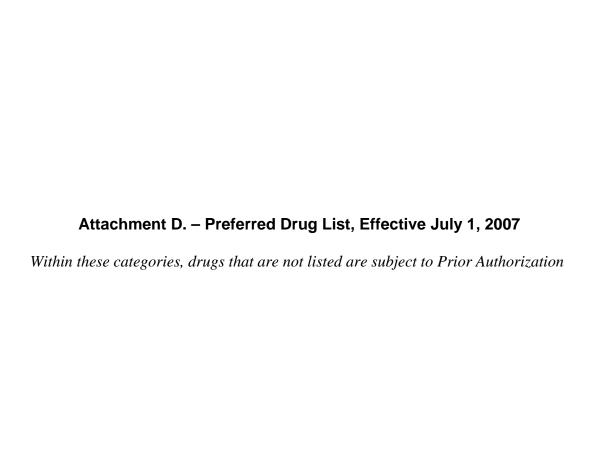
Attachment C. - Drug Classes Currently Included on the PDL

PDL Phase I Drug Classes - Preferred drug status revised on January 1st of each year

- HMG CoA Reductase Inhibitors (Statins)
- Cox-2 Inhibitors
- Proton Pump Inhibitors (PPIs)
- Angiotensin Receptor Blockers (ARBs) (formerly named Angiotensin Receptor Antagonists)
- Angiotensin Converting Enzyme Inhibitors (ACE Inhibitors)
- Inhaled Corticosteroids
- Nasal Steroids
- Beta Adrenergics
- COPD- Anticholinergics (formerly included with Beta Adrenergics)
- Beta Blockers
- Calcium Channel Blockers
- H2 Antagonists
- Second Generation Antihistamines (LSAs)
- Benzodiazepine Sedative Hypnotics (formerly included with Sedative Hypnotics)
- Other Sedative Hypnotics (formerly included with Sedative Hypnotics)
- Electrolyte Depleters
- Urinary Tract Antispasmodics
- Topical Immunomodulators
- Lipotropics Non-Statins: Fibric Acid
- Lipotropics Non-Statins: Niacin Derivatives
- Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension

PDL Phase II Drug Classes - Preferred drug status revised on July 1st of each year

- Oral Hypoglycemics (Second Generation Sulfonylureas, Alpha-Glucosidase Inhibitors, Biguanides, Biguanide Combination Products, Meglitinides, Thiazolidinediones)
- Leukotriene Modifiers
- Non-Steroidal Anti- Inflammatory Drugs (NSAID)
- Serotonin Receptor Agonists (Triptans)
- Oral Antifungals for Onychomycosis
- Bisphosphonates for Osteoporosis
- Second Generation Cephalosporins (Antibiotics)
- Third Generation Cephalosporins (Antibiotics)
- Second Generation Quinolones Systemic (Antibiotics)
- Third Generation Quinolones Systemic (Antibiotics)
- Macrolides Adult and Pediatric (Antibiotics)
- Antihyperkinesis/CNS Stimulants (Medications for ADD/ADHD)
- Alpha-2 Adrenergic Ophthalmic
- Beta-blockers -Ophthalmic
- Carbonic Anhydrase Inhibitors-Ophthalmic
- Prostaglandin Inhibitors -Ophthalmic
- Long Acting Narcotics
- Ophthalmic Anti-Inflammatory
- Ophthalmic Quinolones
- Ophthalmic Antihistamines
- Ophthalmic Mast Cell Stabilizers
- Herpes Antivirals
- Influenza



ANALGESICS

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

Diclofenac Potassium Diclofenac Sodium

Diflunisal Etodolac

Etodolac SR

Fenoprofen

Flurbiprofen Ibuprofen

Indomethacin

Indomethacin SR

Ketoprofen

Ketoprofen SR

Ketorolac

Meclofenamate Sodium

Nabumetone Naproxen

Naproxen Sodium

Oxaprozin Piroxicam

Sulindac

Tolmetin Sodium

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ANTIINFECTIVES
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ONYCHOMYCOSIS

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Omnicef Capsules[®]
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Spectracef[®]

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Azithromycin Suspension
Clarithromycin Tablet
Clarithromycin ER
Clarithromycin Suspension
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Erythromycin Estolate Suspension
Erythromycin Stearate
Erythromycin Stearate
Erythromycin W/Sulfisoxazole

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Ciprofloxacin suspension
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Claritin Syrup OTC[®]
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Loratadine tablet (All OTCs)

Loratadine Tab- Rapids (All OTCs) Loratadine Syrup (All OTCs)

Loratadine D12hr (All OTCs)

Loratadine D24hr (All OTC names)

Zyrtec[®] Syrup (PA required except for children under age 2)

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ACTING
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Captopril /HCTZ

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Nadolol Pindolol Propranolol

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Dynacirc[®]CR
Felodipine ER
Nicardipine
Nifediac CC[®]
Nifedical XL[®]

Nifedipine Nifedipine ER Nifedipine SA Norvasc® Plendil® Sular®

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Diltiazem HCL
Diltiazem XR
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(No PA req. IF under age 12)
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(No PA req. IF under age 12)

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