Report on
Pharmacy Liaison Committee
and
Drug Utilization Review Board

Virginia Department of Medical Assistance Services

December 15, 2005

AUTHORITY FOR REPORT

Item 326 (I) of the 2005 Appropriations Act directs that the Department of Medical Assistance Services shall implement continued enhancements to the prospective drug utilization review (pro-DUR) program. The Department shall continue (i) the implementation of a disease state management program including physicians, pharmacists, and others deemed appropriate by the Department and (ii) the Pharmacy Liaison Committee. The Department shall continue to work with the Pharmacy Liaison Committee and the Prior Authorization Advisory Committee to implement the disease state management program and such other initiatives for the promotion of cost-effective services delivery as may be appropriate. The Department shall report on the Pharmacy Liaison Committee's activities to the Board of Medical Assistance Services and to the Chairmen of the House Appropriations and Senate Finance Committees and the Department of Planning and Budget no later than December 15 each year of the biennium. This report responds to the requirements of the Appropriations Act.

ACTIVITIES OF THE DRUG UTILIZATION REVIEW (DUR) BOARD

The DUR Board ("the Board") met three times during 2005 (May 12, August 11 and November 11) and completed its evaluation of new drug products released in the last year. The Board composed of physicians, pharmacists and nurse practitioners appointed by the Director of DMAS, is an expert panel empowered to define the parameters of safe medication use according to federal and state guidelines. The new or revised criteria were integrated into the criteria base used in DMAS' pharmacy program. The criteria are used in the two components of the DUR program: (i) Retrospective DUR (RetroDUR); and (ii) Prospective DUR (ProDUR).

The DMAS RetroDUR program examines a history of medication used to identify certain patterns of use. After a computer analysis of claims data, an expert panel of reviewers evaluates a sampling of records and requests the generation of educational intervention letters in appropriate circumstances. Educational letters are customized to each identified case and mailed by the program contractor. Letters may be sent to both patients and prescribers, depending on the specifics of each case.

ProDUR is an interactive on-line, real time process in which pharmacy claims are evaluated during the claims submission process. Potential problems related to the established criteria generate an immediate alert message to the pharmacist. Due to the short turn-around time of 30 seconds or less per transaction, the most serious concerns are the focus of this endeavor. The Board has established a hierarchy of risks and continually reviews the criteria to enhance and improve the program.

KEY DRUG UTILIZATION REVIEW BOARD ACTIVITIES – 2005

During 2005, the Virginia DUR Board reviewed and approved ProDUR and RetroDUR criteria for 13 new drugs including Aptivus, Lyrica, Rozerem, Symlin, Byetta, Boniva, Baraclude, Lunesta, Vesicare, Vytorin, Enablex, Ketek, and Spiriva.. They also reviewed and updated existing criteria for antidepressants, antihypertensives, antipsychotics, antiviral agents, narcotic analgesics, oral hypoglycemic agents, lipotropics, antiarrhythmics, diuretics, and quinolones.. The DUR Board requested and reviewed several reports of criteria. First, the Board reviewed Beer's List Criteria, ProDUR, and RetroDUR Criteria.

Beers List Criteria

The 2003 session of the Virginia General Assembly passed legislation requiring the Department of Medical Assistance Services to review its elderly long-term care enrollees for any inappropriate use of medications as defined by Dr. Mark Beers. Dr. Beers has published several articles describing the inappropriate use of various medications in older adults. The Beers list is used as a national guideline and reference guide for physicians and pharmacists to improve the use of medication in the elderly. The Beers criteria were presented to the Virginia Medicaid DUR Board for review and approval. The Board approved the criteria and agreed that this review would be performed every 6 months as a retrospective review of 1000 enrollee medication profiles. Additionally, the Board recommended that the review should include all Virginia Medicaid enrollees 65 years and older, not just those in long-term care facilities.

Two reviews of Medicaid enrollees to assess their appropriate drug usage based on the Beers list criteria was conducted. October 2004 drug claims were reviewed for the Beers criteria. One thousand medication profiles were generated for all enrollees 65 years and older who met any of the Beers criteria. Letters were sent to prescribers for 240 Medicaid enrollees. There were 289 criteria interventions in a total of 254 letters sent to prescribers whose patients are receiving potentially inappropriate medications or dosages. Many of the letters contained more than one criteria intervention.

The next review evaluated May 2005 drug claims. One thousand medication profiles were generated for all enrollees 65 years and older who met any of the Beers criteria. Letters were sent to prescribers for 356 Medicaid enrollees. There were 466 criteria interventions in a total of 386 letters sent to prescribers whose patients are receiving medications or dosages that are potentially inappropriate for them. Many of the letters contained more than one criteria intervention. If a prescriber responded to a previous letter that the treatment was clinically appropriate, no letter was sent for this review.

Amitriptyline continues to be one of the most commonly prescribed medications from the Beers List, but its utilization in this population has declined by 12% since our first review in April 2004. While there continues to be widespread use of these medications in older adults, there appears to be a gradual decline in their use in our patient population. Decreases in utilization were also seen in other drugs such as fluoxetine and amiodarone.

ProDUR

The Virginia Medicaid DUR Board meets quarterly to review, revise and approve new ProDUR criteria. Criteria revisions are incorporated into the Virginia Medicaid specific ProDUR criteria file. Virginia Medicaid ProDUR edits developed and approved by the VA Medicaid DUR Board include denials for early refill and therapeutic duplication. Virginia Medicaid also applies ProDUR edits to drug-drug interactions, drug-diagnosis contraindications and drug-pregnancy contraindications. Pharmacists may override these edits, with the exception of the early refill denial, by entering appropriate override codes established by the Virginia Medicaid DUR Board. Pharmacists must contact First Health Services Call Center to obtain an override for the early refill edit. The Medicaid DUR board approved appropriate ProDUR criteria to apply to all of the new drugs reviewed during 2005. ProDUR edits remain an effective method of alerting pharmacists to potential contraindications before prescriptions are filled.

The committee reviewed the top twenty-five drugs ranked by claim count, by payment amount, the cost and utilization analysis by drug type, ProDur cost savings report and summary of ProDur alerts. Furosemide continues to be in the top three drugs for high total claim count. The percentage claims with ProDur alerts decresed to 25% in January and remained the same through February and March. More recently the committee requested and reviewed Metabolic Syndrome Indicators and hospital admissions for chronic diseasefor the service period January 1, 2005 to July 25, 2005. The results of the Metabolic Syndrome Indicators analysis were inconclusive due to lack of published standards: however, this report has created interest in similar investigations of other disease states.

RetroDUR

RetroDUR profile reviews were performed on the following topics – benzodiazepine usage, seizure threshold, low dose aspirin, medications during pregnancy COX-2 usage in cardiovascular disease, heart failure treatment guidelines, therapeutic duplication, atypical antipsychotic use in the elderly, osteoporosis therapy, and diagnosis of diabetes without concurrent use of an ACE inhibitor or Angiotensin Receptor Blocker.

After the initial review of patient profiles is done and letters have been sent to providers, re-reviews are conducted to verify that recommendations are being accepted. RetroDUR recommendations continue to produce changes in therapy resulting in increased compliance to accepted treatment guidelines.

The Threshold/Polypharmacy initiative has recently been added to the RetroDUR activities. The Threshold program identifies those patients with greater than nine unique prescriptions in a 34 day period and these prescriptions are written by three or more prescribers and filled at three or more pharmacies. Patients who are seen by multiple prescribers and have their prescriptions filled at multiple pharmacies are at increased risk of medication related adverse events. These patients may lack a primary care physician and a single pharmacy to coordinate and optimize their medication regimen. A sample of recipient profiles meeting the Threshold criteria will be reviewed at least once per quarter. This will help identify recipients and alert their providers so that increased coordination can occur which will improve the quality of care of recipients.

ACTIVITIES OF THE PHARMACY LIAISON COMMITTEE

The Pharmacy Liaison Committee (PLC) was scheduled to formally meet three times during 2005 (March 22, July 12, and November 15). Due to the efforts preparing for the implementation of Medicare Part D, the committee did not meet. However, DMAS consulted with individual members of the committee on numerous occasions throughout the year on various pharmacy topics. The PLC includes representatives from: the Community Pharmacy Coalition; Long-Term Care Pharmacists; the Pharmaceutical Research and Manufacturers Association (PhRMA); the Virginia Association of Chain Drug Stores (VACDS); and the Virginia Pharmacists Association (VPhA).

MEDICAID PHARMACY INITIATIVES

Comprehensive NeuroScience Program (CNS)

In April 2005, the Department in partnership with the Department of Mental Health, Mental Retardation, and Substance Abuse Services implemented a new pharmacy quality initiative, the Behavioral Pharmacy Management System (BPMS) program with the full support of the Psychiatric Society of Virginia. The program, administered by Comprehensive NeuroScience (CNS) and supported by Lilly, has been successfully implemented in a number of State Medicaid programs across the country to improve the quality of their behavioral health pharmacy programs.

CNS provides a behavioral pharmacy service that reviews prescribing practices in State Medicaid fee-for-service programs and Medicaid health plans. The CNS service is based on readily available Medicaid pharmacy claims and does not require the special collection of information from prescribers. The analysis is the basis for a CNS prescriber education and outlier management system, called the Behavioral Pharmacy Management System (BPMS). The BPMS focuses on improving the quality of behavioral health pharmacy prescribing practice and, as a result, can reduce the costs of pharmacy expenditures. It is accepted by both mental health clinicians and patient advocates because of its focus on quality improvement as opposed to approaches that restrict drug availability through strategies unpopular with consumers and physicians such as “Fail First” and prior authorization processes

In addition, the program complements the Department’s Preferred Drug List (PDL) program. The General Assembly, as part of the 2005 Appropriations Act, exempted antidepressant and antianxiety medications used for the treatment of mental illness from the Medicaid PDL program. Exempting these drugs from the PDL allows them to be dispensed without being subject to the PDL program’s prior authorization requirements. The BPMS is a peer-to-peer approach to the management of behavior health medications which is of great public concern.

MEDICAID PHARMACY INITIATIVES

Preferred Drug List (PDL) and Prior Authorization (PA) Programs

The Preferred Drug List (PDL) program continued to be successful in its second year of implementation. The PDL is a list of preferred drugs by therapeutic class for which the Medicaid program will allow payment without requiring Prior Authorization (PA). In addition, other clinical criteria may apply for each respective drug class. In the designated classes, drug products classified as non-preferred will be subject to PA. There are provisions for a 72-hour supply of necessary medications so that this initiative will not cause an individual to be without an appropriate drug therapy. DMAS implemented the PDL program to provide clinically effective and safe drugs to its clients in a cost-effective manner.

With the recommendations of the Pharmacy and Therapeutics (P&T) Committee in 2005, modifications were made to the PDL based on the annual reviews of the existing PDL drug classes. Six additional drug classes were included in PDL Phase I which will become effective January 2006.

The General Assembly passed four budget amendments in the 2005 Appropriations Act, which affect the PDL program and P&T Committee. All of these mandates have been implemented. These amendments included:
1) Exemption of certain medications (antidepressants and anti-anxiety medications) used for the treatment of mental illness from the PDL;
2) Modification of the composition of the P&T Committee to ensure some members provide services to Medicaid recipients;
3) Requirements for quarterly meetings of the P&T Committee and the consideration of new drugs in PDL eligible drug classes at those meetings; and
4) Annual PDL reporting requirements.

Studies were conducted by DMAS to examine the cost effectiveness of the PDL as well as its effect on the health outcomes of Medicaid recipients subject to the list. The studies found that there is a high compliance rate (93%) without denying access to drugs; the vendor has operated an efficient prior authorization process with more than 60,000 requests to date; estimated savings for the pharmacy program overall total more than $35 million with the majority of those savings attributed to the PDL; and there is no evidence of adverse health impacts on recipients. Please refer to Attachment I for further information on the PDL and the related study results.

Clinical Edit for COX-II Inhibitors

The COX-II Inhibitors drug class was implemented on the PDL in February 2004. There continues to be market changes related to this drug class over the past year. Following the market withdrawal of PDL preferred drug Vioxx in September 2004 and Virginia Medicaid subsequent discontinue of coverage, the drug Bextra was voluntarily withdrawn from the market in April 2005. Prior to this announcement, Bextra was a non-preferred drug in the Cox- II drug class on

the PDL and required prior authorization for coverage. Effective April 7, 2005 prior authorizations are no longer granted for Bextra and it is not reimbursable by Virginia Medicaid.

The only preferred drug in the COX-2 class is Celebrex, which continues to be reimbursed without prior authorization based on the P&T Committee's most recent review of this class.

With the implementation of the clinical edit for COX-2 drugs in July 2004, DMAS allowed an exemption for recipients over age 60. The clinical edit requires patients to try two Non-steroidal Anti-Inflammatory Drugs (NSAIDs) or to have been identified with a designated co-morbid condition prior to approval of a COX-2 drug. These NSAIDs are covered in both prescription strength and over the counter. This exemption for the over-age-60 population expired on August 1, 2005, requiring all recipients to receive prior authorization based on the clinical criteria.

Also under the direction of this Committee, the Department allowed patients under age 60 who were on COX-2 therapy between January and June 2004 to receive a one-year prior authorization to bypass the PDL edits related to this class. All unexpired prior authorizations for these particular patients terminated on June 30, 2005. After the expiration of existing prior authorizations, these patients were required to receive a new prior authorization for the clinical edit to receive the preferred drug, Celebrex®.

Mandatory Generic Program

Effective September 1, 2004, pharmacy claims began to be denied when a brand name drug is inappropriately dispensed rather than a generic. Previously, pharmacy only received a message at point of sale with no action required. In the Commonwealth, pharmacists are required to fill prescriptions for multiple source drugs with a generic drug product unless the physician or other licensed, certified practitioners certifies in their own handwriting "brand necessary" for the prescription to be dispensed as written. DMAS' Mandatory Generic program requires that generics be appropriately dispensed instead of more costly brand name products, unless overridden by physicians. Provisions are in place that ensures claims are paid in those rare situations when the pharmacist must dispense the brand name because no generics are available or mandated by the prescribing physician. The Mandatory Generic program has performed well since its inception. The Mandatory Generic program has shifted generic drug utilization to a current average of 55% as compared to approximately 47% in 2003.

Maximum Allowable Cost (MAC) Program

The 2004 General Assembly, Chapter 4 Item 326 WW (1) - (3), adopted language in the 2004 – 2006 Appropriation Act, which directed the Virginia Department of Medical Assistance Services (DMAS) to modify the methodology used to reimburse pharmacies for providing generic drugs to Medicaid enrollees. The mandate requires DMAS to amend the State Plan to replace an existing pricing methodology, known as the Virginia Maximum Allowable Cost (VMAC) program, with a new pricing methodology referred to simply as Maximum Allowable Cost (MAC).

Effective December 1, 2004, the reimbursement for multiple source generic drugs became subject to a new maximum allowable cost (MAC) program. This program works together with the Mandatory Generic Program and the Preferred Drug List to ensure enrollees are receiving quality products in a cost-effective manner. By instituting a new MAC reimbursement methodology for multiple source generics, DMAS reimburses pharmacies an amount that more accurately reflects their acquisition cost with a reasonable profit margin. If a pharmacy provider discovers that the MAC price does not accurately reflect the drug cost, and there are no alternative suppliers, a pricing review may be requested for resolution. The MAC list is updated monthly and available on the Department's web site.

The MAC program has proceeded with only one provider dispute to date and less than 50 calls to its call center since it became operational on November 28, 2004. The MAC program is expected to reach its estimated net savings for each of the 2004-2006 biennium of $5.15 million (GF). All systems interface with the Department's fiscal agent, drug file vendor and pharmacy point of sale systems have also been successful to date. The first annual MAC report to the General Assembly was published in January 2005 (see Attachment II) and second report will be submitted to the General Assembly in December 2005.

Dispensing Fee for Generic Drugs

As required by the *2004 Appropriations Act*, effective July 1, 2005, the dispensing fee for generic drug products was increased to $4.00. This increase from the prior dispensing fee ($3.75) began to be applied to all pharmacy claims with dates of service on or after July 1, 2005. The dispensing fee for brand name drugs remains the same ($3.75). This increase in dispensing fees for generic drug products further promotes the use of these less costly, clinically equivalent medications.

Default Provider Identification Numbers

In December 2003, DMAS eliminated one of four default prescribing provider identification numbers. Prior to this change, pharmacy providers were allowed to use four default numbers on DMAS claims rather than a valid prescriber identification number. The use of default provider identification numbers has been significantly reduced (from 32% to 20%). While this is a tremendous improvement, there continue to be some issues with the use of these default numbers which affects DMAS' ability to evaluate prescribing providers for pharmacy quality and utilization review programs. The inability to accurately identify the prescriber in our system places the success of these programs in jeopardy. This also affects program compliance as prescribers cannot be accurately identified in investigations of fraud and abuse. In the coming year, DMAS will take additional steps to ensure the appropriate use of prescribing provider identification numbers. In addition, DMAS is preparing for the federal level implementation of the "National Provider Identification" number with expected implementation in May 2007.

Termination of Coverage of Erectile Dysfunction Drugs

Effective as of May 27, 2005, the Virginia Medicaid Program ended coverage of erectile dysfunction (ED) drugs for individuals convicted of a sex offense. Governor Mark R. Warner signed an Emergency Regulation giving DMAS the authority to terminate this Medicaid benefit for convicted sex offenders, including 52 enrollees who had received ED drugs paid for by Medicaid prior to this change. The Governor also directed DMAS to initiate appropriate administrative procedures to ensure that convicted sex offenders do not receive ED drugs paid for by Medicaid going forward.

Subsequently, federal legislation was passed to end Medicaid payments for erectile dysfunction drugs as of January 1, 2006. Accordingly, Virginia Medicaid will terminate coverage of erectile dysfunction drugs on this date. Virginia Medicaid has covered erectile dysfunction drugs with a quantity limit of four per thirty day period with the aforementioned coverage restrictions applied to registered sex offenders.

Over the Counter (OTC) Drugs

In August 2004, DMAS revised and published the listing of reimbursable OTC drugs. This initiative expanded the coverage of OTC drugs for non-institutionalized Medicaid enrollees, created web-based listing (monitored and updated regularly) of these drugs, and noted exclusions. This initiative offered a method of notifying prescribers and pharmacy providers of a covered, viable alternative to prescription medications. DMAS covers OTC designated drugs if they are prescribed by a licensed provider through a prescription (oral or written) which should be used as a less expensive alternative to the covered legend drug. The revised listing and education to providers has produced an approximate 10% increase in claims for OTC medications between fiscal years 2004 and 2005.

DMAS will report on the results of the implementation of these new pharmacy initiatives in its report to be filed by December 15, 2006.

ACKNOWLEDGEMENTS

DMAS wishes to acknowledge the many representatives of the pharmacy community who have assisted the Department in developing and implementing the cost savings initiatives listed above, as well as the advice and expertise they have shared with the agency during 2005. The cooperative efforts of the provider community have been essential to the success of these pharmacy program initiatives.

ATTACHMENT I

Virginia's Preferred Drug List: Program Implementation Outcomes and Recipient Health Effects

Virginia Department of Medical Assistance Services

October 2005

Virginia's Preferred Drug List: Program Implementation Outcomes And Recipient Health Effects

At the recommendation of the Secretary of Health and Human Resources, the Governor proposed in his 2003 budget that the Department of Medical Assistance Services (DMAS) develop and use a Preferred Drug List (PDL) for the Medicaid prescription drug program. During the 2003 session of the Virginia General Assembly, legislators granted DMAS the authority to implement this program. The major goal of the PDL is to reduce the use of more expensive drugs to treat patient illnesses when alternative medications are available that provide the same therapeutic benefit but at a lower price. Recognizing the potential impact a successfully implemented PDL program could have on Medicaid expenditures for prescription drugs, the 2003 General Assembly directed DMAS to generate PDL savings of $18 million in FY 2004 and $36 million in FY 2005.

The general findings of this study are as follows:

- DMAS has successfully designed and implemented a PDL program that has produced a high compliance rate without denying recipients access to drugs.

- Nearly seven of ten prescriptions that were written for non-preferred drugs prior to the implementation of the PDL were switched to preferred drugs once the program started.

- When persons who were switched to drugs on the PDL are considered along with others whose initial prescriptions were written for drugs on the PDL, the overall program compliance rate is 93 percent. This exceeds the 85 percent rate needed by DMAS to meet the legislatively established savings target for the program.

- The vendor for the PDL program has operated an efficient call center, handling more than 61,400 requests without denying any patients access to drugs.

- Since the PDL program was implemented in January 2004, the estimated savings in the overall Medicaid pharmacy program total more than $35 million.

- Though more research is needed, 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.

Introduction

The impetus for DMAS' PDL proposal was the growing cost of the Medicaid prescription drug program. From the period of 1997 to 2003, Virginia's expenditure rate for prescription drugs substantially outstripped spending on other components of the Medicaid program (Figure 1). More important, additional analysis work found that these higher expenditures could not be explained by a growth in the number of Medicaid recipients who were receiving prescription drugs or by comparable growth in the number of drug claims.

At the time DMAS considered proposing a PDL, there was strong opposition to these programs because they involve the use of more restrictive formularies than have been traditionally been used in Virginia's Medicaid program. Among the staunchest critics of PDLs are pharmaceutical manufacturers, patient advocacy groups, physicians, and to a lesser degree, representatives for pharmacists. At varying levels, each of these groups expressed opposition to Virginia's program during its development.

Chief among the concerns of patient advocates and physicians was whether Virginia's PDL program would emphasize saving money at the expense of patient access to medications. Although representatives for these groups were aware that safeguards had been built into the system to ensure that patient access would not suffer, they contended that in other states, the process for triggering these protections were unnecessarily cumbersome for patients, physicians, and pharmacists.

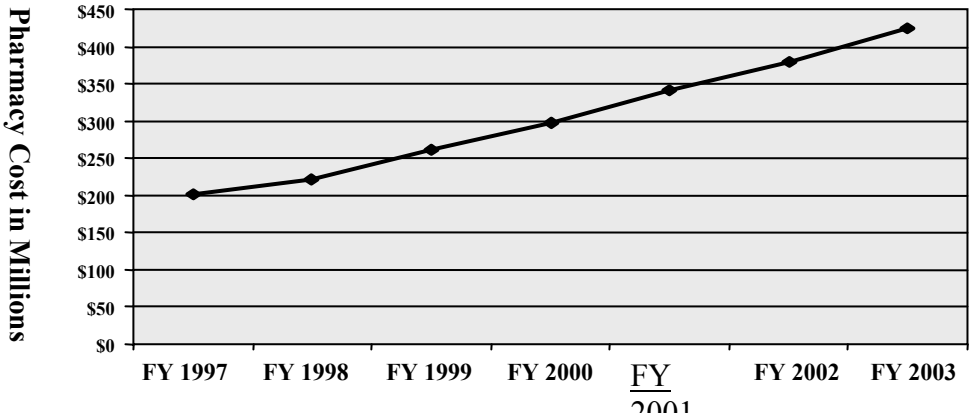
Even if patients are moved from high-cost drugs to less expensive medications without breaks in service, opponents of the PDL believe that shifting so many patients from the drugs to which they are accustomed will create adverse health effects, resulting in much higher utilization of various healthcare services. Primarily for these reasons, critics of the program argued that Virginia's PDL should have been voluntary with physicians having the option of gradually changing their prescribing patterns towards the use of less expensive drugs.

DMAS officials were aware of these concerns and noted that several steps were taken to minimize the anticipated problems. First, as required by federal regulations, any Medicaid-covered drug for which no therapeutic equivalent exists was automatically included on the State's PDL. Second, physicians would be allowed to seek approval for prescribed drugs that are not on the PDL through a federally required prior authorization process.

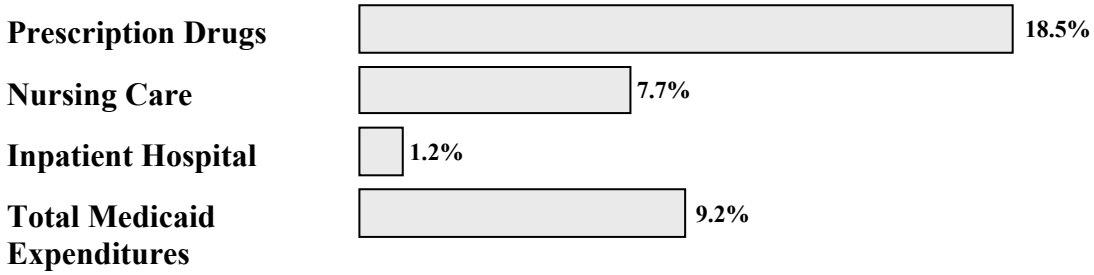
Third, because of the inherent problems associated with establishing an effective drug regimen for persons who are on psychotropic medications, DMAS excluded anti-psychotic medications from the PDL. Fourth, unlike the experience of a few other states, the committee of physicians responsible for establishing the

Figure 1

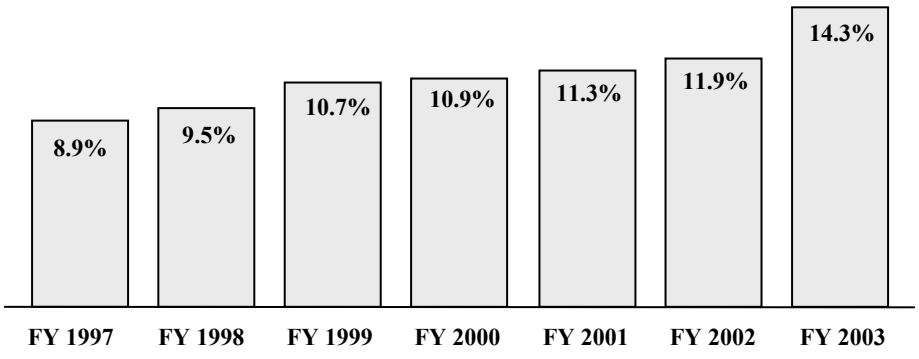
Trend in Virginia's Medicaid Fee-For-Service Pharmacy Costs (FY 1997-2003)



Average Annual Growth in Medicaid Expenditures for Selected Services (FY 1997-2003)



Fee-For-Service Pharmacy Cost as a Percent of Total Medicaid Costs (FY 1997-2003)



Source: DMAS Policy and Research staff analysis of data from The Statistical Record of the Virginia Medicaid Program, 2003.

PDL in Virginia would not be asked to move a large number of drug classes onto the PDL in a short time period. By gradually bringing drug classes onto the PDL, the number of patients who are initially affected by the new program was minimized, allowing for a smoother transition period for the new system. The skill and expertise of the Pharmacy and Therapeutics Committee members were critically important in the successful implementation of the program. In addition, DMAS created a new PDL implementation Advisory Group, which was comprised of pharmaceutical manufacturers, advocates, providers, and other stakeholders to provide input to the education process.

Finally, in the event that a physician decides to appeal an unfavorable decision following a request for prior authorization of a non-preferred drug, DMAS established a policy to ensure that the patient receives the prescribed drug until the case is resolved.

Notwithstanding these actions, the agency director and the General Assembly required DMAS' Policy and Research staff to conduct an ongoing evaluation of Virginia's PDL program. This evaluation must focus not only on the savings generated by the program, but the impact of the PDL on both Medicaid patients and providers.

This report provides an analysis of DMAS' implementation of the PDL program using data on all of the drug claims that were submitted for payment by pharmacists participating in the Medicaid program. In addition, the report provides a separate review of the prior authorization process, an analysis of the savings in DMAS' overall pharmacy program, and an assessment of whether the PDL program has adversely impacted the health of Medicaid recipients. The next section of this report describes the PDL program design.

Virginia's PDL Program Design

In its simplest form, the PDL program establishes a formulary for select therapeutic drug classes with prescription drugs that have the same clinical effectiveness, but whose manufacturers have agreed to sell their products to the State's Medicaid program at lower price. This allows DMAS to generate savings in its prescription drug program while ensuring that Medicaid patients have continued access to drugs, which have a proven efficacy.

The PDL Program Model

The process for building a PDL in Virginia begins with the State's Pharmacy and Therapeutics (P&T) Committee. This committee of physicians and pharmacists first reviews certain classes of drugs (e.g. cardiac medications) and determines whether they are candidates for the PDL. Once a class of drugs is selected for the PDL, the committee assesses the clinical efficacy of each drug in the class and recommends whether it should be considered for the PDL. Manufacturers of those drugs in the selected class must then negotiate with the vendor for the program to determine what discounts they will provide to Medicaid. The final selection of "preferred" drugs is based first and foremost on clinical efficacy, and, then price. In every instance, the P&T Committee makes these decisions.

How the Program Works. Once the PDL is in place, physicians must first decide whether to prescribe drugs that are on the PDL. If the doctor chooses a drug on the PDL for his patient, the process is straightforward. The pharmacist receives the prescription from the patient and electronically submits the claim to First Health Services Corporation (FHSC), which is the vendor for the program. Because the prescription is for a PDL drug, this claim is approved at point-of-sale and the pharmacist subsequently dispenses the medication to the patient.

In some cases, physicians will unknowingly write a prescription for a non-preferred drug. In this case, once the patient submits this prescription at the pharmacy, the claim will be rejected at point-of-sale and the pharmacist will contact the prescribing physician to request that the prescription be changed to a preferred drug. If the physician requests the non-preferred drug, the pharmacist will instruct the doctor to contact FHSC and provide a medical justification for the non-preferred drug.

This step in the process effectively allows the physician the opportunity to make a case for the drug that is not on the PDL with FHSC staff. If that effort fails, the dispute will be escalated to a FHSC pharmacist. If at any point during this process the physician's request is granted, the pharmacist is notified and the prescription is dispensed. Further, while this process is unfolding, the pharmacist, may at his professional discretion, contact FHSC and request a 72-hour emergency supply of the prescribed drug for the patient if he believes such a supply is warranted. This is done to ensure the patient does not leave the drug store without the necessary medication.

At other times, physicians will be aware that the drug that they would like to prescribe is not on the PDL. In these cases, the State must give the doctors an opportunity to request prior authorization to prescribe the non-preferred drug. This request is made directly to FHSC. The process that subsequently unfolds mirrors the previously discussed steps.

The Appeals Process. If FHSC ultimately denies the physician's request to prescribe a drug that is not on the PDL, DMAS policy requires FHSC to notify the doctor of the decision and inform him of the appeals process. Also, at the point of the denial, the lead pharmacist is required to enter a prior authorization into the system permitting any pharmacy the authority to dispense a 34-day supply of the originally prescribed drug.

Upon notice of denial and the opportunity for appeal, the physician and or recipient will have 30 days to file an appeal. DMAS' appeals division will review the case and issue an opinion within 21 days. If, for some reason, the appeal is not resolved in 34 days, FHSC is required to re-authorize the prescribed drug for another 34 days.

The next section in this report presents DMAS findings from its review of the implementation of the program.

PDL Program Design and Implementation Outcomes

The issue of whether the PDL has been successfully implemented turns on the following questions:

- Are persons who were on drugs that were not on the PDL prior to the start date for the program, switched to drugs on the PDL without creating access problems?

- Is the overall compliance rate for the program sufficient to meet the savings targets established by the General Assembly for the state's pharmacy program?

- Are the prior authorization requests for drugs not on the PDL which are made to the Call Center handled efficiently and effectively without creating problems of access for Medicaid recipients?

The findings of this study indicate that the implementation of the PDL over the first 18 months of the program has been an unqualified success. The program has achieved an exceptionally high compliance rate (93 percent), the vendor for the program is operating the call center effectively and efficiently, and patients are not being denied drugs.

DMAS Has Successfully Implemented the PDL Program during the First 18 Months

As noted earlier, DMAS management made the decision to gradually phase-in the PDL program to ensure a smooth transition of this new policy. As shown in Table 1, 13 classes of drugs were placed on the PDL in January 2004. Over the next year, 18 additional classes were added to the program. Together, these classes accounted for only three of every 10 drug claims that were submitted for payment to the Medicaid pharmacy program over this 18-month time period. This phase-in process allowed DMAS pharmacy staff to better manage the provider education and outreach activities that were conducted prior to establishing each new class of drugs on the PDL.

Table 1

Phase-In Schedule For Virginia's Preferred Drug List (PDL) Program

Date Classes Were Added To The PDL	Number of Classes Added
January 2004	13
April 2004	6
August 2004	11
January 2005	1
Total Drug Classes On PDL	31

Note: The 31 drug classes on the PDL account for 31 percent of the drug claims submitted to the Medicaid pharmacy program.

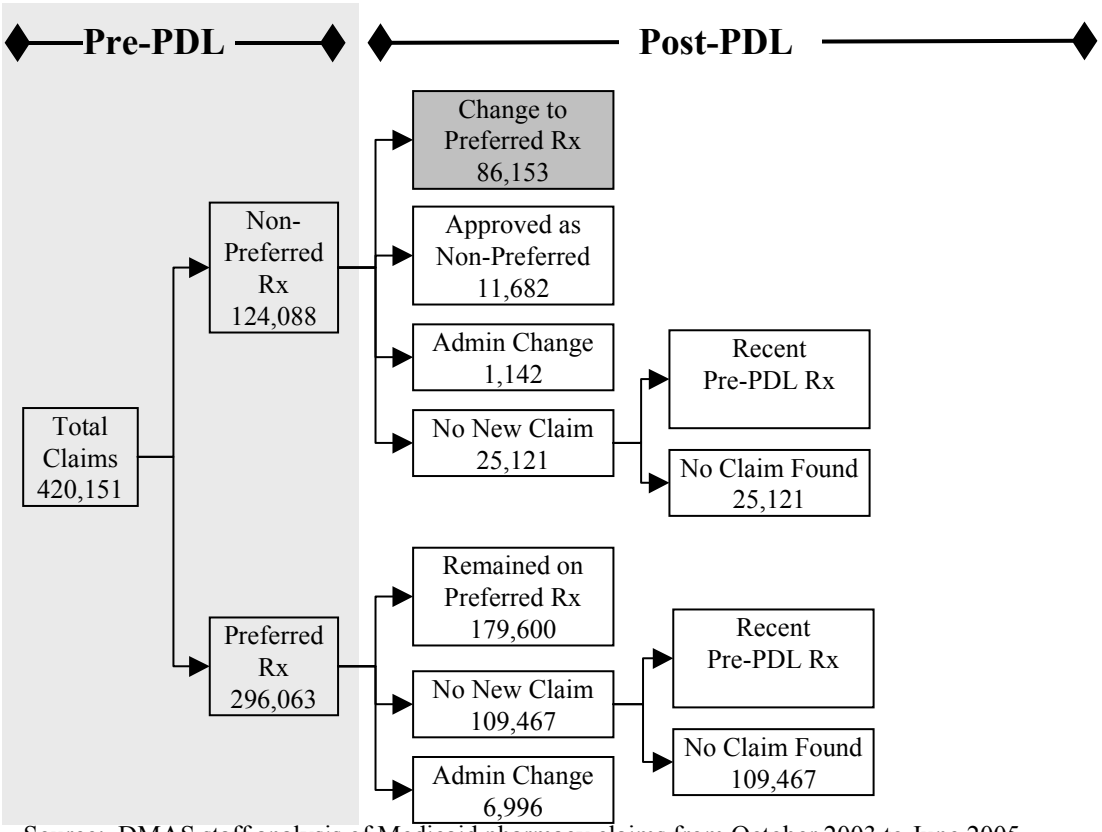
From an evaluation perspective, however, the degree to which the program was successfully implemented involves much more than the manner in which the program was phased in. The implementation issues examined in this report centered on the following:

- The degree to which the status of prescriptions changed as drug claims are moved through the PDL system;
- The degree to which physicians comply with the program by writing prescription for drugs on the PDL;
- The volume and processing of prior authorization requests made of Call Center.

Tracking Prescription Status Changes. To track the movement of prescriptions through the system, all recipient drug claims that were submitted for payment in the three-month period before the PDL program started were identified by drug. Thus when subsequent recipient prescriptions for the same drugs were submitted after the start date for the program, DMAS staff could determine the rate at which drugs were switched from non-preferred to preferred status. In addition, it was also possible to assess the degree to which recipients may have refused to fill prescriptions possibly because their drugs were switched from non-preferred to preferred status.

Figure 2 summarizes the results of this analysis. As shown, DMAS staff identified more than 420,000 paid prescriptions for drugs that were submitted in the three-month period prior to the start of the PDL. Of that number, roughly 29 percent of the prescriptions -- 124,088 -- were for drugs that would have not been on the PDL had the program been in place at that time.

Figure 2
Tracking The Status Change For Prescriptions Following Implementation Of The PDL Program



Source: DMAS staff analysis of Medicaid pharmacy claims from October 2003 to June 2005.

Figure 2 further reveals that 69 percent of the prescriptions that were not on the PDL in the pre-PDL period -- 86,153 -- where switched to prescriptions on the PDL when subsequent prescriptions were presented by the same recipients for the same drugs. Of the remaining prescriptions from the pre-PDL period, nine percent -- 11,682 -- were approved as non-PDL drugs when subsequent claims were received in the post-PDL period.

A smaller number of claims -- 1,142 -- were submitted for drugs that were actually removed from the PDL by the P&T Committee because of health problems that were traced to the use of those medications. These claims are labeled as "Admin Change" in Figure 2.

For 20 percent of the non-PDL drug claims submitted during the pre-PDL period, DMAS staff could not locate a subsequent claim in the post-PDL period. However, there is no evidence to indicate that this reflects a patient access problem or the degree to which recipients have "walked away" from their prescriptions because of the switch in drugs. In fact, data presented in the bottom half of Figure 2 indicates that the proportion of claims that could not be found in cases

where the patients' initial drugs were already on the PDL and therefore not switched upon the start of the program was 36 percent. This is 80 percent higher than the rate observed for prescriptions that were written for drugs that were not on the PDL in the pre-PDL period. Thus, the absence of subsequent claims in both of these categories likely reflects the fact that these prescriptions were written in the pre-PDL period to address non-recurring health problems; hence no additional prescriptions were needed.

Measuring the Program's Overall Compliance Rate. The analysis of post-PDL drug claims thus far has focused on tracking subsequent prescriptions for those that were initially written and paid before the PDL program went into effect. A second method for examining the implementation success of the program is to calculate a compliance rate for all paid PDL-eligible prescriptions regardless of whether they originated in the period before the program went into effect. With this approach, the compliance rate is defined as the number of paid prescriptions written for medications on the PDL, divided by the number of all paid PDL-eligible prescriptions. During the planning phase for the program, it was determined if DMAS were to meet its savings target, 85 percent of all paid prescriptions for PDL-eligible drugs needed to be written for drugs actually on the PDL.

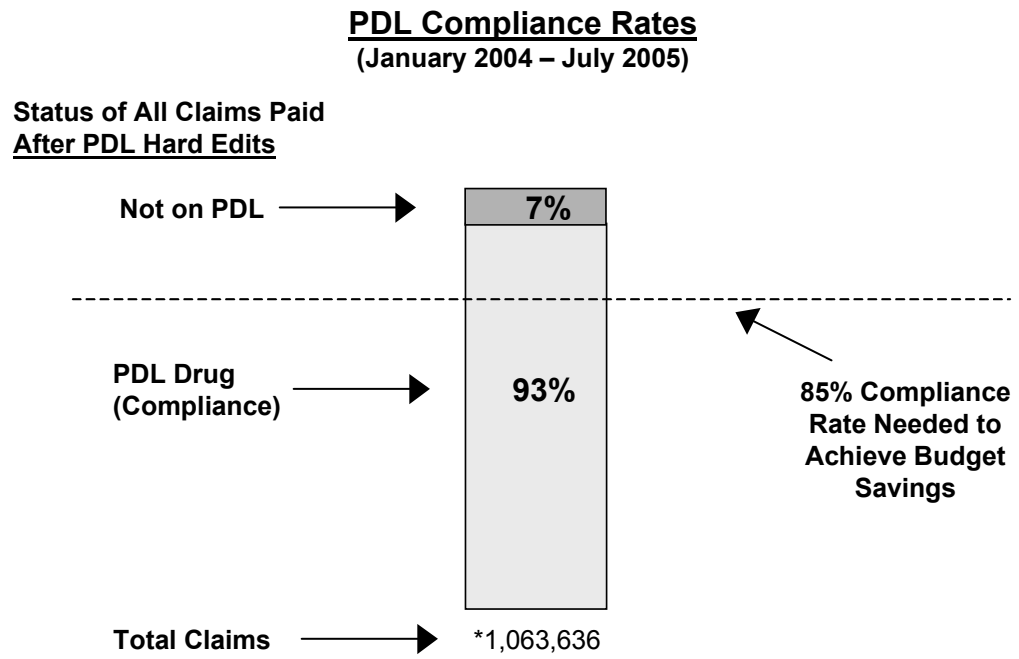
Figure 3 reports the compliance rate and shows that on average, 93 percent of all paid claims for PDL-eligible drugs were written for drugs on the PDL. In other words, slightly more than nine of every 10 prescriptions that could have been written for drugs on the PDL were actually paid from the PDL.

One concern expressed by many during the planning phase for the program was the issue of selective compliance. That is, it was believed that physicians would have no problem prescribing off of the PDL for drugs that treat less serious health problems but would be reluctant to do so for more complicated medical conditions. Accordingly, DMAS staff examined the compliance levels within selected drug classes to determine if the rates varied significantly.

As shown below, no significant differences were observed in the compliance rates across drug classes.

- Cardiac Medications (96 percent);
- Gastrointestinal Medications (93 percent)
- Asthma and Allergy Medications (91 percent)
- Anti-Biotics (94 percent)

Figure 3
PDL Compliance Rate For All Drug Claims Paid In The First 18 Months Of The Program



Source: DMAS staff analysis of Medicaid pharmacy claims data from January 2004 to August 2005.

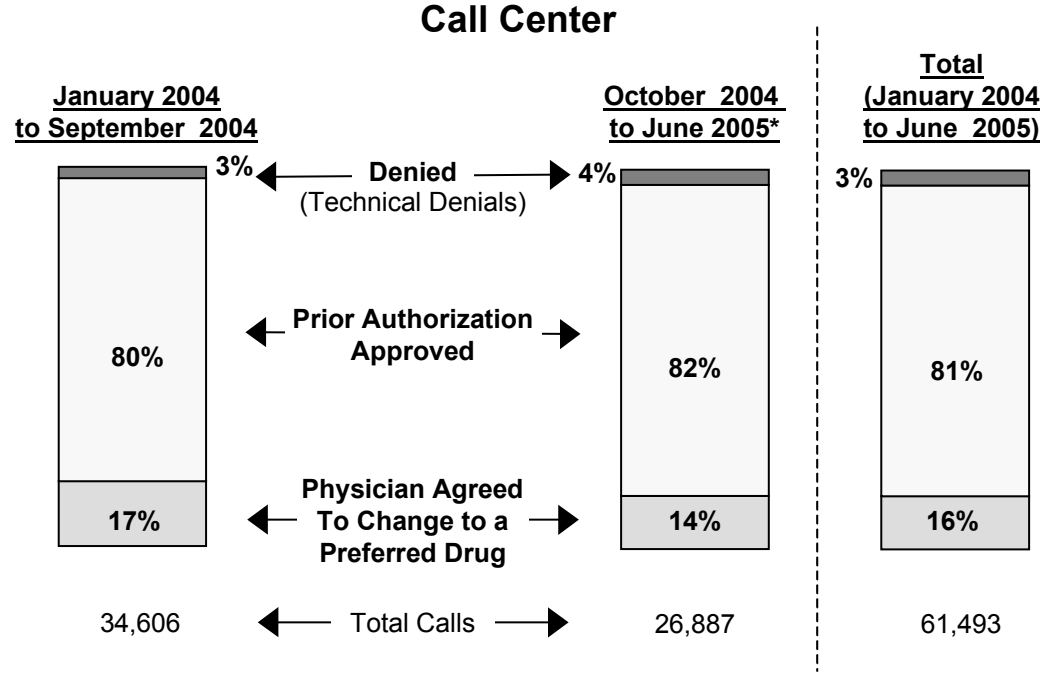
- Analgesics (89 percent)
- Diabetes Medications (98 percent).

Call Center Activity. The final aspect of the DMAS' assessment of PDL implementation focused on FHSC management of its call center. In conducting this analysis, DMAS relied upon comprehensive reports that FHSC produces on its call center operations. These reports identify the total requests made to the center, the source and reason for the request, the length of the calls to the center, and the outcome of the request.

This information is useful in determining how the vendor for the program handles prior authorization requests by doctors for drugs that are not on the PDL. More important, the data can be used to determine whether recipients are being denied access to drugs if their physicians elect not to switch their prescriptions to drugs on the PDL.

Figure 4 summarizes some of the activity of the call center. As shown, since January 2004, FHSC has processed a total of 61,493 requests for drugs that were not on the PDL. In 81 percent of the cases -- four of every five requests

Figure 4
How Requests For Prior Authorization Are Processed At The Call Center



Notes: *There were also 5 reconsiderations (< 1 percent) in the October 2004 to June 2005 time period. Call data indicates that FH staff are answering phone calls within 28 seconds on average, the call lengths average two minutes and 27 seconds and they have average call abandonment rate of nearly zero .

-- the prior authorization requests for drugs that were not on the PDL was approved. For 16 percent of the requests, the physician agreed to change the prescription to drug on the PDL.

Approximately three percent of all prior authorization requests for drugs that were not on the PDL were denied. However, it is important to note that these were technical denials meaning that the patients were not actually denied their medications. These cases involve nursing homes that distribute medication in unit doses and then retrospectively request prior authorization for the drugs that they have already dispensed but which were not on the PDL. Because FHSC staff could find no justifiable reason for these requests, this permission was not granted. Subsequently, nursing homes were informed by DMAS that effective August 1 2005, the agency would no longer pay drug claims for medications not on the PDL, that are submitted retroactively, and not approved by the vendor.

In terms of call processing, DMAS determined that FHSC staff answered phone calls in an average of 28 seconds. Moreover, the call abandonment rate -- when the caller hangs up before the call is answered -- was practically zero.

Estimated Savings In The Medicaid Pharmacy Program

When the General Assembly passed the language authorizing DMAS to operate a PDL, specific savings for the program were assumed in the agency's budget. Overall, the General Assembly required DMAS to generate savings of $25.7 million in its pharmacy program with the expectation that the PDL program would produce $18 million of these savings.

Data comparing forecasted to actual pharmacy expenditures during the 18-months in which the PDL program has been implemented reveal that DMAS is spending $35.2 million less in its pharmacy program than the agency was predicted to expend without the PDL and other initiatives in place. Because DMAS implemented a number of pharmacy initiatives simultaneously, the precise amount of the savings occurring in the program that is due to the PDL could not be determined. However, as the agency's linchpin pharmacy initiative, the PDL is undoubtedly responsible for producing the majority of these savings.

Since Implementing The PDL DMAS Has Generated $35.2 Million In Savings For Its Pharmacy Program

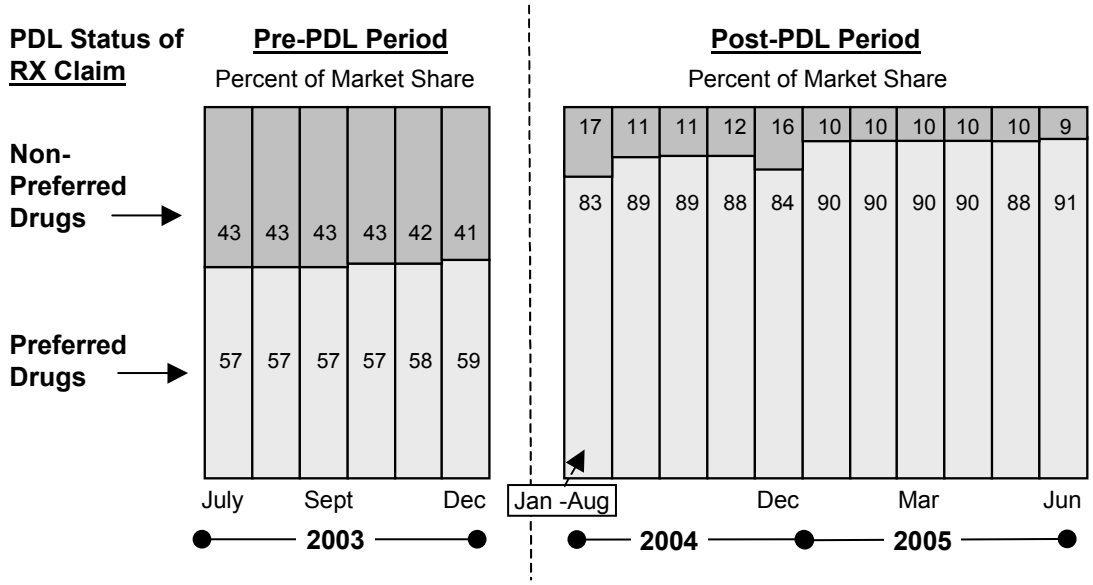
To determine the magnitude of the savings in the pharmacy program, DMAS staff conducted two separate but related analyses. Before estimating actual savings, DMAS staff determined if and how much of a shift has occurred in the share of the Medicaid drug market for preferred versus non-preferred drugs. Next, using the results from earlier forecast models, a comparison was made of the amount the agency was projected to spend on prescription drugs before the PDL initiative was established to the amount actually spent following the implementation of this program.

PDL-Generated Market Shift. In the year prior to the implementation of the PDL, approximately six of ten drugs paid for through the Medicaid pharmacy program were for drugs that would not have been on the PDL had the PDL been in place at that time. Thus, if the program were to have the desired fiscal impact, the share of the Medicaid market owned by manufacturers of drugs on the PDL would have to substantially increase.

DMAS staff examined changes in the trend by tracking market share from one year prior to PDL implementation through the 18-month period over which the program has been gradually phased in. As revealed in Figure 5, there has been a dramatic shift in market share brought about by the PDL program. Specifically, while the monthly market share for drugs on the PDL was around 57 percent in the year prior to the implementation of the program, following the start of the program, this figure steadily increased each month. By the end of June 2005, 91 percent of all PDL-eligible drugs paid for by the Medicaid program were for those on the PDL.

Figure 5

Trend In Market Share For Drugs On Virginia's PDL



Source: DMAS staff analysis of Medicaid pharmacy claims data

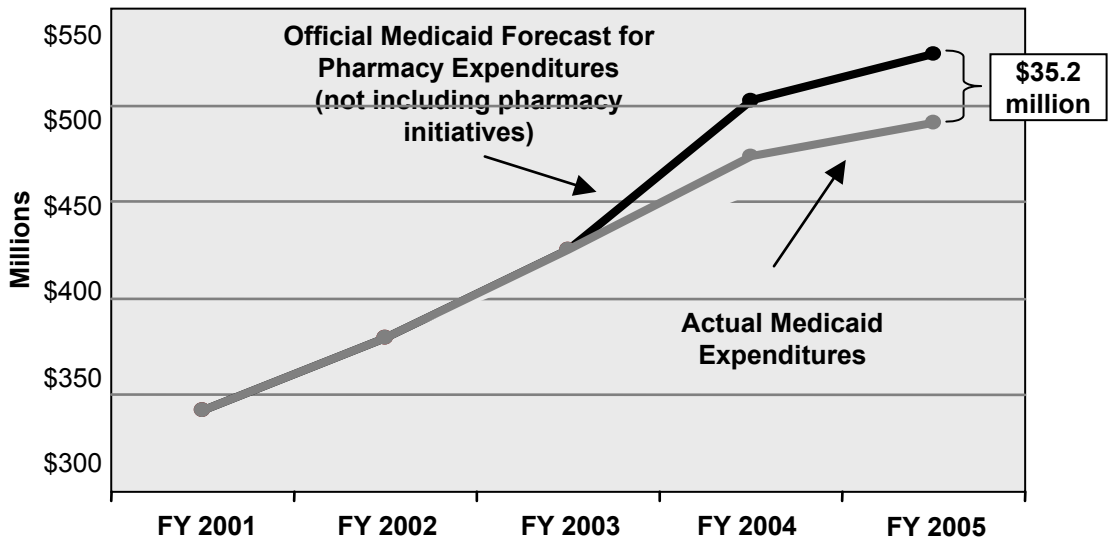
Estimated Medicaid Pharmacy Savings. To quantify the impact of this market shift in savings to the pharmacy program, DMAS staff compared the official Medicaid forecast for pharmacy expenditures to actual Medicaid expenditures at the end of FY 2005. The official forecast is produced using a time series forecasting technique called exponential smoothing. This statistical technique is a weighted moving average applied, in this case, to time series pharmacy expenditure data organized on a monthly basis. The moving average predicts the next monthly value in the time series using the average from previous observations. With moving averages, observations get less weight as the data points are predicted farther in the future.

Figure 6 illustrates the results from this comparison. As shown, in FY 2005, the official Medicaid forecast projected that DMAS would spend $526 million for pharmacy services without the PDL program and other pharmacy initiatives in place. This amount is net of the manufacturers' rebates that are collected by the federal government and passed along to the State.

It is important to note that the $35 million savings amount illustrated in Figure 6 cannot be attributed solely to the PDL. During the 18-month period over which these savings have been calculated, DMAS implemented other pharmacy initiatives that were designed to reduce expenditures on prescription drugs. In some cases, these initiatives and the PDL program have impacted the same drug claim. Attempts to decompose the savings into amounts due to the PDL

Figure 6

Estimated Savings in the Pharmacy Program Since Implementation of the PDL And Other Initiaitves



Source: DMAS staff analysis of monthly Medicaid pharmacy claims data

and other pharmacy initiatives were not successful. Accordingly, the savings reported here are total savings for the pharmacy program.

The Health Impacts Associated With Use of Preferred Drug List

The principal criticism leveled at PDL programs is that changing patients from non-preferred to preferred drugs destabilizes their medical conditions causing a number of adverse reactions. Proponents of this view contend that this destabilization can be seen in greater utilization of health care services and, in the case of Medicaid recipients, higher program cost. Under this scenario, it is argued that states that employ PDLs are pursuing short-term savings in their Medicaid drug programs at the expense of the health of its Medicaid recipients.

DMAS staff examined this issue by comparing Medicaid spending and healthcare utilization patterns for Medicaid recipients who were switched from non-preferred to preferred drugs with a control group of persons who were allowed to remain on their non-preferred drugs. Based on the results observed in this study, there is no evidence to support the view that Virginia's PDL program causes adverse health outcomes. Specifically, no differences could be found between these groups in total Medicaid spending, the degree and cost of inpatient hospitalizations, and the frequency of emergency room visits.

Virginia's PDL Program Does Not Produce Adverse Health Outcomes

Four research questions shaped DMAS' effort to assess the health impacts of the PDL program.

- Are there meaningful differences observed in the total amount of Medicaid spending for PDL members and the control group?
- Do differences exist in the Medicaid spending levels for hospital care for persons in the PDL and control groups?
- What, if any, differences are observed in the utilization of inpatient hospital care for PDL and control group members?
- Do PDL recipients utilize emergency departments for care at a higher rate than their counterparts in the control group?

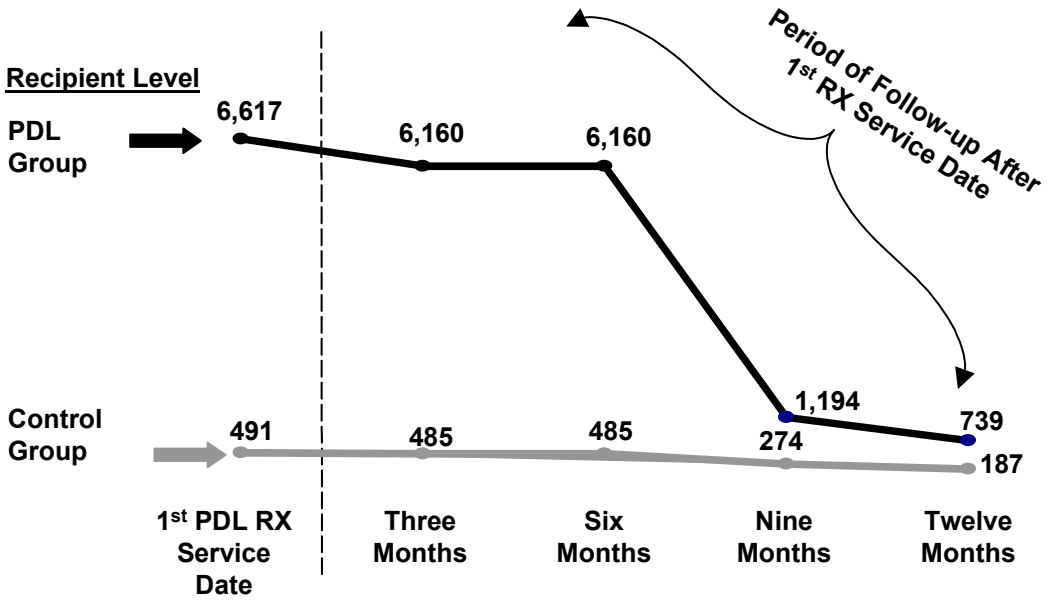
To address these questions, DMAS staff had to identify a PDL and control group of Medicaid recipients, establish the follow-up period that would be used to evaluate post-PDL Medicaid utilization patterns, and analyze the outcomes to determine if meaningful differences exist between the two study groups.

Identifying Study Groups. The first step in this analysis was the selection of the study groups. This was accomplished by identifying all recipients who could be classified into one of the following two groups:

- PDL Program Group. Medicaid recipients who were switched from non-preferred to preferred drugs after the PDL program started and who had no record of receiving any non-preferred drugs during the entire follow-up period.
- Control Group. Medicaid recipients who were allowed to remain on non-preferred drugs after the PDL program started and who had no record of receiving any drugs on the PDL during the follow-up period.

Establishing The Post-Program Follow-up Period. At the time this study was conducted, Medicaid claims were available through May 2005. Thus the post-program period for each recipient in the study began with the first date they received a PDL-eligible drug and ended in May 2005. Because there were no uniform start dates for the study, the length of the follow-up period varied considerably for some study members (Figure 7). Thus, based on these parameters, DMAS staff attempted to select the longest post-program period that could be used without losing an unacceptable number of study members. Accordingly, for this study, a nine-month period of follow-up was chosen.

Figure 7
Change In Size Of Study Group Based On Length Of Follow-up Period



Source: DMAS staff analysis of Medicaid pharmacy claims data

Comparison of Outcomes for the Two Study Groups. Once the follow-period was selected, DMAS staff compared outcomes for the PDL and control group using the following measures:

- Total Medicaid spending (excluding waiver and long-term care maintenance costs)
- Total hospital spending
- Number of inpatient hospitalizations
- Number of emergency room visits

As noted earlier, opponents of Virginia's PDL believe the savings which are generated by the program will be partially, if not completely offset, by higher Medicaid spending for PDL participants. They believe this higher spending will be manifest in more frequent visits to the emergency room and longer hospital stays for patients whose medical conditions will be aggravated by the sudden switch in their medications.

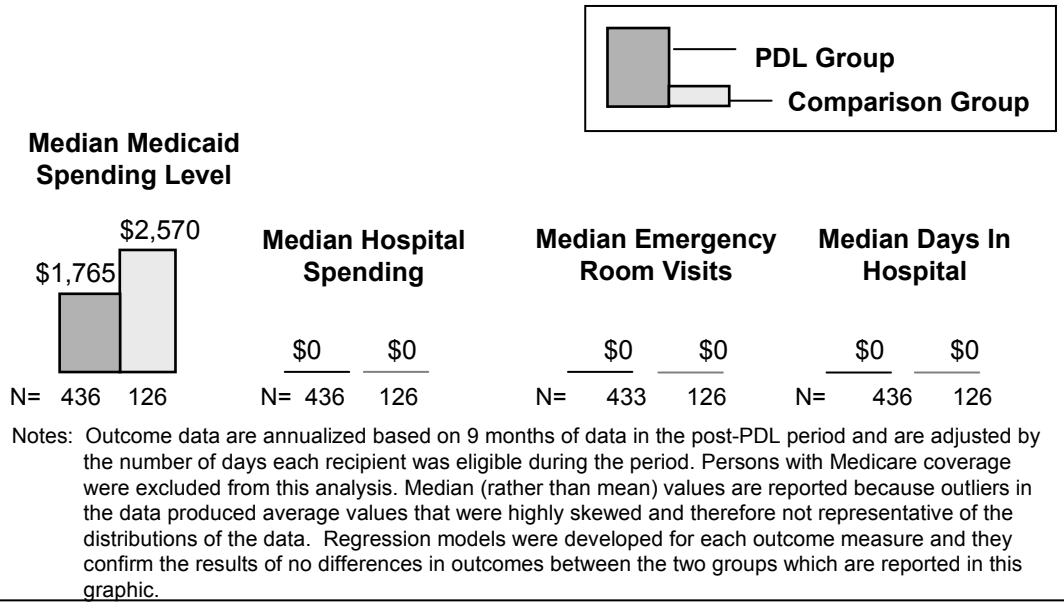
To test this theory, each of the outcome measures described on page 16 were annualized based on nine months of follow-up data. Further, to account for possible differences in the time recipients

actually spent on Medicaid, these outcomes were adjusted by the number of days each study member was covered by Medicaid during the post-program period.

In conducting the analysis, DMAS staff encountered recurring problems with outliers in the data for each outcome measure. Specifically, the average values were highly skewed and not representative of the distribution of the data for each outcome measure. As result, the median for each of the outcome measures was used as the basis for the analysis.

Figure 8 reports the results of this analysis. As shown, in the follow-up period, Medicaid recipients whose medications were switched from drugs that were not on the PDL to those that were on the PDL actually had a lower median amount of total Medicaid spending ($1,750) than the control group ($2,570). With regards to the other outcomes, there was no difference in the median values across the two study groups.

Figure 8
A Comparison Of Medicaid Spending And Healthcare Utilization For The PDL And Control Group



Notes: Outcome data are annualized based on 9 months of data in the post-PDL period and are adjusted by the number of days each recipient was eligible during the period. Persons with Medicare coverage were excluded from this analysis. Median (rather than mean) values are reported because outliers in the data produced average values that were highly skewed and therefore not representative of the distributions of the data. Regression models were developed for each outcome measure and they confirm the results of no differences in outcomes between the two groups which are reported in this graphic.

For inpatient hospital use – total spending and total days spent in the hospital -- and the number of emergency room visits, the results presented in Figure 8 indicate that the median values for these measures were zero for both the PDL and control group. This means that the typical Medicaid recipient in the PDL and control groups did not visit the emergency room or hospital in the nine-month period following the date they received their prescriptions for PDL-eligible drugs. Considered together these findings indicate that the PDL program does not produce adverse health consequences for its participants.

Maximum Allowable Cost Program
Reimbursement Methodology for Generic Drugs

Department of Medical Assistance Services

January 1, 2005

Introduction

The 2004 General Assembly adopted language in the 2004 – 2006 Appropriation Act directing the Virginia Department of Medical Assistance Services (DMAS) to modify the methodology used to reimburse pharmacies for providing generic drugs to Medicaid recipients. The mandate (Appendix A) requires DMAS to amend the State Plan to replace an existing pricing methodology, known as the Virginia Maximum Allowable Cost (VMAC) program, with a new pricing methodology referred to simply as Maximum Allowable Cost (MAC). The Appropriation Act also requires DMAS to report to the General Assembly by January 1 of each year on the savings achieved through the new MAC program.

This is the program's first annual program status and cost savings report. It provides a brief overview of state pharmaceutical reimbursement policies and discusses both the previous and new reimbursement methodologies, and reviews the potential impact the revised methodology may have on the State's pharmacy community. Because the new MAC program began in December 2004, the actual cost savings achieved through the program will not be measurable until the next cost savings report, which will be presented in January 2006.

An Overview of State Pharmaceutical Reimbursement Policies

Federal law allows states to provide prescription drug benefits to their Medicaid recipients as an optional benefit. This service provides individuals who otherwise may be unable to obtain necessary but expensive drug therapy, with access to a broad range of prescription drugs. All states have chosen to cover prescription drugs, though some place limits on either eligibility groups or types of drugs covered. For example, Virginia does not cover prescription drugs used for fertility or cosmetic purposes.

Medicaid prescription drug coverage is becoming one of the fastest growing health care expenditures in the United States. For example, Medicaid drug spending increased nationally 194 percent from $48.2 billion to $141.8 billion between 1992 and 2001. Many states have become concerned about escalating drug costs due to resulting pressures on their budgets. In response, the Centers for Medicaid and Medicare Services (CMS), which is the federal agency within the Department of Health and Human Services that is responsible for directing the Medicaid and Medicare programs, established guidelines allowing states to implement certain drug cost reduction strategies. Examples of these strategies include authorizing states to limit reimbursement payments to pharmacies for providing prescription drugs to Medicaid recipients, and allowing states to require pharmacies to provide recipients with less costly generic drugs instead of brand name drugs.

A brand name drug is an innovator drug that holds a patent to prevent other manufactures from copying the product. It is usually available from a single manufacturer. A multiple-source generic drug is a copy of a brand name drug that contains the same active ingredients, but is usually made by several companies and marketed at less expensive prices. In Virginia, Medicaid requires that prescriptions for multiple-source drugs be filled with a generic unless the physician indicates that the brand name product is necessary.

Under federal Medicaid guidelines, CMS is responsible for establishing maximum prices that pharmacies receive as reimbursement for providing prescription drugs to Medicaid recipients. The maximum prices are known as federal upper limits (FUL). The FUL represents the maximum amount that Medicaid may reimburse pharmacies for certain multiple-source generic drugs, and it is equal to 150 percent of the lowest priced version of the drug product. For a drug to receive a FUL, a sufficient number of therapeutically equivalent versions must be available from at least three manufacturers.

Federal guidelines allow states to reimburse pharmacies for certain drugs at rates lower than the federal upper limits. However, because not all drugs have FULs, states may establish reimbursement limits for non-FUL drugs using certain pricing methodologies. Examples of pricing methodologies that many states may use include average wholesale acquisition price (AWP) minus a percentage discount, the usual and customary charge, and the maximum allowable cost (MAC). A description of each methodology is shown below:

- The average wholesale price (AWP) is a manufacturer's published price for a drug product. Because pharmacies often purchase drugs at a percentage discount (price minus a percentage discount), states that use this methodology establish reimbursement rates by estimating a percentage discount and subtracting that number from the drug's AWP.

- The usual and customary charge represents the actual price that pharmacies charge cash-paying customers for prescription drugs.

- The Maximum Allowable Cost (MAC) methodology resembles the FUL methodology in that it establishes maximum reimbursement amounts for equivalent groups of multiple-source generic drugs. While basing reimbursement payments off the FUL can save states money, they can achieve additional savings by implementing a MAC program because: 1) they can include more drugs in these programs than are covered under the FUL program, and 2) they can set reimbursement rates for drugs that are lower than the FUL rates. Forty-five states currently have MAC programs. According to the U.S. Department of Health and Human Services, states can achieve substantial savings by implementing MAC programs.

The Previous Virginia Maximum Allowable Cost Reimbursement Program

Prior to December 1, 2004, DMAS reimbursed pharmacies based on the lowest of the following pricing methodologies:

- Federal Upper Limit (FUL);
- Virginia Maximum Allowable Cost (VMAC);
- Average Wholesale Price (AWP) minus 10.25 percent; and
- Pharmacy's usual and customary charge.

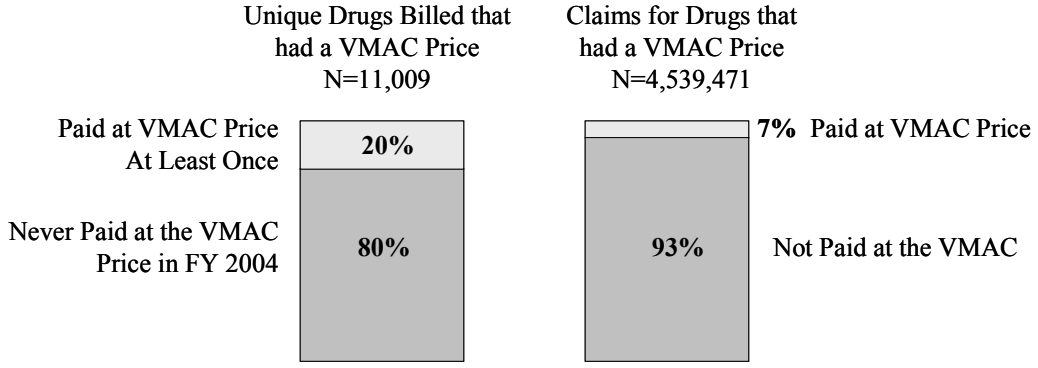
The purpose of using the lowest of multiple methodologies was to ensure that DMAS functioned as a prudent purchaser of prescription drugs. Often, however, DMAS reimbursed pharmacies at much higher rates due to limitations with the VMAC program.

VMAC, which was established in 1993 as a cost saving measure, calculated reimbursement rates for generic drugs that were lower than the FUL rates. VMAC was based on a methodology developed by the Virginia Department of Health, which established reimbursement amounts separately for "unit" and "non-unit" dose drugs, which are distinctions related to how a drug is packaged. A unit dose is the prescribed amount of each dose in a separate package. For example, a sealed package containing two Tylenol capsules represents a unit dose. These are most often distributed in nursing homes and long-term care facilities. Non-unit dose drugs are those packaged in larger containers. For example, a pill bottle containing 250 Tylenol capsules is a non-unit dose.

The VMAC methodology established the price for unit dose drugs at the 60th percentile and the price for non-unit dose drugs at the 75th percentile. However, the VMAC prices did not represent the lowest reimbursement rates because the methodology did not have a point of reference that set the price at a competitive point. Moreover, the generic market is extremely dynamic and requires daily monitoring for changes and adjustments. As a result, the VMAC rates were often higher than the FUL rates. For example, the VMAC rate for Trimox 125mg (a non-unit dose antibiotic) was $0.03640, which is higher than its FUL rate of $0.02010.

Figure 1

Drugs Paid at the VMAC Prices in FY 2004



Source: DMAS staff analysis of claims data.

Figure 1 illustrates that the VMAC rates were rarely used to reimburse claims. As shown, in FY 2004, DMAS received claims for 11,009 unique drugs that had a VMAC price on file. Of those drugs, 20 percent were paid at least once during that year at the VMAC price. Looking more specifically at the claims, only seven percent of the 4.5 million claims for drugs that had a VMAC price were paid at that price during FY 2004. The remaining 93 percent were paid using one of the other pricing methodologies described above, such as the FUL rate. Had the VMAC rates been more competitive, they would have been lower than the other rates, and DMAS would have experienced cost savings from paying at the lower rate.

The Revised Maximum Allowable Cost Program

To address this issue, the 2004 General Assembly directed DMAS to revise the VMAC methodology through Item 326 WW (1) of the 2004-2006 Appropriation Act. The revised methodology is now known simply as the Maximum Allowable Cost (MAC) program. DMAS contracted with Sentara-Optima in the fall of 2004 through a procurement process to revise the MAC methodology and to administer the MAC program. The State Plan amendment has been approved by CMS and the emergency regulations have been approved. The revised program became operational on December 1, 2004.

The revised MAC price for any given generic drug shall be no less than 110 percent of the lowest-published wholesale acquisition cost (WAC) for products widely available for purchase in Virginia and included in national pricing compendia. The MAC prices will be established based on market prices for each drug in accordance with the following parameters:

1. There must be at least three different suppliers that are able to supply the drug and from which pharmacies can purchase sufficient quantities of the product. The drugs that are considered must be listed as therapeutically and pharmaceutically equivalent on the FDA's most recent version of the "Orange Book," which is a list of approved drug products.

2. If the drug has a FUL, the pricing methodology will determine whether the MAC rate is lower than the drug's FUL rate. If the MAC rate is higher, then the lower price will be paid.

3. The list of MAC rates will be available to pharmacies via the DMAS website at www.dmas.virginia.gov under the "Pharmacy Services" section. The MAC list will be updated monthly and will contain a column with the effective MAC price dates.

4. DMAS will publish the factors used to set MAC reimbursement rates, including:

    - the identity of the reference product used to set the MAC rate;
    - the generic code number (GCN) of the reference product;
    - the difference by which the MAC rate exceeds the reference product price, which will be no less than 110 percent of the lowest-published wholesale acquisition cost (WAC); and
    - the identity and date of the published compendia used to determine the reference product and set the MAC rates.

Figure 2 provides an example of how MAC prices are established. Sentara-Optima first identifies multiple-source generic drugs that are available from at least three manufacturers. Once the products have been identified, Sentara-Optima selects the drug with the lowest WAC and multiples that price by 1.1. To give pharmacies the ability to purchase drugs from multiple vendors, Sentara-Optima also selects the WAC with the second lowest price and multiplies it by 1.06. This addresses situations where the lowest priced product has a large gap between the

second lowest priced product and gives pharmacies more choices in product selection. It then sets the MAC for the generic drug based on the higher of the two rates derived from this process. There are 29,642 drugs that currently have MAC prices.

Figure 2

Example of How a MAC Price is Established for a Multiple Source Generic Drug

Ibuprofen 800 mg Tablet	WAC Rate				MAC Rate
Version with Lowest WAC*	**$0.04312**	X	110%	=	**$0.04743**
Version with 2nd Lowest WAC	**$0.05210**	X	106%	=	**$0.05523**

The MAC rate for this drug is set at $0.05523, which is the highest of the two possible reimbursement rates.

* WAC rate for the lowest WAC was unavailable so .04312 is an example of what it could be.

Impact of the Revised MAC Program on Virginia's Pharmacy Community

The intent of the MAC program is to reduce overall Medicaid drug expenditures, while reimbursing pharmacies fairly based on accurate generic drug costs. The implementation of the revised MAC program may reduce profits for pharmacies that sell a substantial amount of generic and multiple-source drugs. Thus, the pharmacy community may express some concerns about the MAC program.

As a result, DMAS has established a dispute resolution process to allow pharmacy providers the opportunity to challenge inaccurate MAC prices. In an effort to be as proactive as possible, the dispute resolution process was implemented on November 1, 2004 – one month prior to the start of the program. A MAC Medicaid Memo was also distributed to pharmacy providers 45 days prior to the start of the program to inform them about the new pricing methodology and to allow them the opportunity to comment.

The dispute resolution process consists of three methods to handle disputes. Pharmacists can either use a Fax Form, Call or email Sentara-Optima. Pharmacists will be notified of the receipt of their dispute resolution within one business day, and a decision will be made within three business days. The pharmacy provider will either receive notice stating that the drug product can be obtained from a manufacturer at or below the MAC price, or the provider will be reimbursed accordingly based on the results of the review. The key to DMAS maintaining a positive relationship with the State's pharmacy community is to maintain a fair, expeditious, and equitable process for resolving reimbursement disputes.

In addition, the DMAS Pharmacy unit has worked proactively with the Virginia Pharmacists Association (VPhA) to address specific pricing issues with the current MAC list. For example, VPhA sent a proposed MAC list to selected providers in the independent, chain, and nursing home settings for feedback on the appropriateness of the established prices. Of the approximately 800 drugs on the proposed list, providers challenged MAC prices for 17 drugs. Of these, 10 drugs were found to have unfair prices, which were subsequently revised.

Savings Attributable to the Revised Virginia Maximum Allowable Cost Program

The 2004-2006 Appropriation Act requires DMAS to report to the General Assembly by January 1 of each year on the savings achieved by the revised MAC program. However, because the program only became operational in December 2004, DMAS has not yet been able to measure savings attributable to the program. Once DMAS has collected 12 months worth of claims data from the revised MAC program, staff will calculate the program's actual annual savings and report this information to the General Assembly in the second annual report on January 1, 2006.

APPENDIX A

2004 – 2006 Virginia Acts of the Assembly

WW.1. The Department of Medical Assistance Services shall amend the State Plan for Medical Assistance to modify the reimbursement methodology used to reimburse for generic drug products. The new methodology shall reimburse for the product cost based on a Maximum Allowable Cost list to be established by the Department. Such amendments shall be effective within 280 days or less from the enactment of this act.

2. In developing the maximum allowable cost (MAC) reimbursement rate for generic pharmaceuticals, the Department shall: (i) publish the factors used to set state MAC rates, including the identity of the reference product used to set the MAC rate; the GCN number of the reference product; the factor by which the MAC rate exceeds the reference product price, which shall be not less than 110 percent of the lowest-published wholesale acquisition cost for products widely available for purchase in the state, and included in national pricing compendia; and the identity and date of the published compendia used to determine the reference product and set the MAC rate; (ii) identify three different suppliers that are able to supply the product and from whom pharmacies are able to purchase sufficient quantities of the drug. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the FDA's most recent version of the "Orange Book"; (iii) identify that the use of a MAC rate is lower than the Federal Upper Limit (FUL) for the drug, or the development of a MAC rate that does not have a FUL will not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program; and (iv) distribute the list of state MAC rates to pharmacy providers in a timely manner prior to the implementation of MAC rates and subsequent modifications.

3. The Department shall: (i) review and update the list of MAC rates at least quarterly; (ii) implement and maintain a procedure to eliminate products from the list, or modify MAC rates, consistent with changes in the marketplace; and (iii) provide an administrative appeals procedure to allow a dispensing provider to contest a listed MAC rate.

4. The Department shall report on savings achieved through the implementation of MAC rates in the Medicaid pharmacy program to the Chairmen of the House Appropriations and Senate Finance Committees, and the Joint Commission on Health Care by January 1 of each year.