

**Meeting of the  
PDL Implementation Advisory Committee  
600 East Broad Street, Suite 1300  
Richmond, Virginia  
November 2, 2004**

**DRAFT Minutes**

**Present:**

Cindi Jones, DMAS, Chair  
Madeline Abbitt, Generic Manufacturers Association  
Sheryl Garland, Virginia Hospital & Healthcare Association  
Jill Hanken, Virginia Poverty Law Center  
Hill Hopper, R.Ph., Virginia Health Care Association  
Anne Leigh Kerr, PhRMA  
David Markowitz Psychiatric Society of Virginia  
John Pezzoli, Virginia Association of Community Services Boards  
Matthew Sheffield, Boehringer-Ingelheim  
Becky Snead, Virginia Pharmacy Congress

**DMAS Staff:**

Cheryl Roberts  
Bryan Tomlinson  
Wayne Turnage  
Javier Menendez  
Kelly Gent  
Maryanne Paccione  
Katina Goodwyn

Guests: 12 guests attended

**Absent:**

James Evans, DMHMRSAS  
Valeria D. Thomas, Virginia Health Care Association  
Susan Umidi, Virginia League of Social Services Executives  
Mike Jurgenson, Medical Society of Virginia

**FHSC Staff:**

Donna Johnson  
Debra Moody

**Call to Order and Review of Minutes**

Cynthia B. Jones, Chief Deputy Director of the Department of Medical Assistance Services (DMAS), called the meeting to order. Ms. Jones thanked the Committee for their input in the development and implementation of the Preferred Drug List (PDL) program. The agenda for the meeting was reviewed. Ms. Jones asked if there were any comments on the minutes of the June 22, 2004 meeting. The Committee noted no changes to the minutes. Ms. Jones introduced Cheryl Roberts, Deputy Director of Programs and Operations, for her presentation on the status of the PDL program.

**Status of the PDL Program (See presentation attached)**

Cheryl Roberts noted that her presentation focused on initiatives related to brand drugs while Javier Menendez, Pharmacy Manager, will focus on generic drug initiatives. Ms. Roberts mentioned that there have been major changes in the Medicaid pharmacy program over the past year. She provided a handout to the committee with highlights of recent program initiatives including Phase III PDL implementation, annual review of Phase I drug classes, clinical edits, behavioral health medications included on the PDL and the annual General Assembly report.

**Phase III Implementation**

Eleven new therapeutic drug classes were added to the PDL program effective July 1, 2004 with soft edits (messaging only) and hard edits on August 2<sup>nd</sup> and August 9<sup>th</sup>. These classes included four ophthalmic classes, medications for ADD/ADHD, and six antibiotic classes. Postcards were mailed to remind providers that antibiotics would be fully implemented (with hard edits) on August 2<sup>nd</sup>. This was done based on the recommendation from Hill Hopper, a PDLIAG member.

The long acting narcotics drug class that was scheduled for Phase III implementation was held for further consideration by the P&T Committee. This class will now be implemented in January 2005 with designated clinical edits (see below).

### **Annual Review**

The annual review of PDL drug classes will occur in the fall (Phase I) and spring (Phases II and III). The P&T Committee conducted an annual review of the thirteen Phase I drug classes for January 2005 implementation during its meeting on September 20<sup>th</sup>. All classes were approved to continue as PDL eligible with minor changes. Additions to "Preferred" status included Hyzaar and Cozaar (Angiotensin Receptor Antagonist class) and Celebrex (Cox II Inhibitors class). Soft edits (message only) will be implemented for Bextra (COX II) on December 1<sup>st</sup>, as it is the only drug changing from preferred to non-preferred status.

A Medicaid Memo will be distributed in December addressing all the changes to the PDL Phase-I drug categories that will be effective as of January 1, 2005.

### **Clinical Edits**

In developing the prior authorization (PA) criteria for PDL drug classes, the P&T Committee decided to implement clinical edits for particular classes to ensure that drug therapy is managed appropriately based on various clinical considerations. These edits are often called step therapy.

Effective July 2004, patients under age 60 with a new prescription for any COX II Inhibitor are required to obtain a prior authorization for use of the drug. A grandfathering provision was implemented for patients under age 60 currently taking Cox IIs to avoid disruption of medications. Changes were also made to the PDL specific to the COX-II drug class as a result of Merck & Co. removing Vioxx from the market. DMAS, with the approval of the P&T Committee, took immediate action to allow the other 2 drugs (Celebrex and Bextra) in the Cox II drug class to be "preferred" drugs until December 31<sup>st</sup>. This was an interim step. At the P&T committee's October meeting, the decision was made that as of January 1, 2005, Celebrex will remain as the "Preferred" drug and Bextra will revert back to the "Non-Preferred" status. As mentioned previously, soft edits will begin on December 1<sup>st</sup> for Bextra to advise providers of the change.

The long-acting narcotics' clinical criteria were developed to manage these high-risk drugs and ensure that pain management decisions are made in an appropriate and safe manner, while maintaining access. This class was originally scheduled to be implemented with Phase III of the PDL. In January 2005, the clinical criteria will be applied for all long-acting narcotics requiring the attempt of two short-acting narcotics (average 4 hours) prior to the use of a long acting narcotic (average 8-12 hours). Prior authorization will be required if this clinical criteria are not met. The clinical criteria

will not apply to patients stabilized on long-acting narcotics. The criteria were developed with the advice of pain management specialists and consultants. The clinical criteria guidelines were distributed to members and are available on the DMAS web site. These guidelines will also assist with other DMAS program initiatives such as the CMM department initiatives and drug diversion programs.

### **Behavioral Health Medications**

The P&T Committee met on October 6<sup>th</sup> to conduct a clinical review the antidepressant and antianxiety drug classes as well as receive public comments from mental health advocates and other interested parties. The Committee also consulted with a board-certified psychiatric pharmacist who helped to review and discuss various clinical issues associated with these drug classes.

The Committee voted unanimously to include antidepressants and antianxiety medications as “PDL eligible” with the appropriate clinical criteria. This means that the Committee will review the financial information and clinical criteria for these classes to determine final drug inclusion on the PDL.

Patrick Finnerty, Director, completed a report on the status of antidepressant and antianxiety medications to the General Assembly on October 7, 2004. The report was distributed to PDLIAG members and is available on the DMAS web site. The report included the status of the P&T Committee decisions and next actions to be taken.

During its next meeting on December 8<sup>th</sup>, the P&T Committee will review financial and clinical information to determine the preferred status of drugs in these classes. First Health Services, DMAS’ PDL Contractor, will seek supplemental rebates from manufacturers of drugs in these classes. A final report on these classes will be provided to the General Assembly by January 1, 2005. The earliest these classes would be implemented would be July 1, 2005 with General Assembly approval. The General Assembly will review these recommendations during its 2005 legislative session to ensure it is agreeable with the Committee’s approach and make any changes it deems appropriate.

In addition, the Department is reviewing a Behavioral Health Management program with Eli Lilly and Comprehensive Neuroscience, Inc. (CNS) for antidepressant and atypical antipsychotics, which may be implemented in addition to these PDL classes. This is a quality program, which will be independent from PDL implementation of these classes. The Department is preparing for a data analysis to determine the feasibility of this program. The goal is to move forward with implementation of this program.

#### **Questions:**

Madeline Abbitt asked if a description of the CNS/ Lilly model is available.

- No, a description for the Virginia Medicaid is not available as the program has not been fully designed or implemented. Ron Hart, Eli Lilly representative, will be able to provide information on the program and the models currently used in Indiana, Ohio and Missouri. The information will be forwarded to the DMAS Pharmacy Manager who will pass along to members. There are approximately 30 states that are reviewing or actively participating in the program.

The Department is in the process of developing its 2004 PDL report to the General Assembly. This report will be completed within approximately 2-3 weeks.

Ms. Roberts acknowledged that the PDLIAG has been instrumental in the success of the PDL and other pharmacy initiatives. This committee model will be used with other Department program initiatives, e.g. dental.

Ann Leigh Kerr asked if the open issues, e.g., pediatric issues, related to antidepressants and anti-anxiety medications will be addressed at the December 8<sup>th</sup> P&T Committee meeting. She would like to advise manufacturers if they should attend to participate in or hear the clinical discussions around these classes. There is great interest in this topic.

- Yes, the outstanding clinical issues will be addressed during the public meeting discussion (open session) at the December 8<sup>th</sup> meeting. Only financial issues will be discussed in the confidential meeting (closed session). Representatives from the Attorney General's office attend the confidential meeting and ensure that clinical information is not discussed in that forum.
- Interested parties may only present clinical information during the P&T Committee meeting on December 8<sup>th</sup>. Information can also be forwarded to provide to Committee members in advance of the meeting and include in their meeting packets. The deadline for submitting information has not been established but will be published with the agenda soon.

Madeline Abbitt asked how much information is provided to the Joint Commission on Health Care (JCHC) on the PDL program. Ms. Abbitt stated that some Commission members appeared to lack background information on the program to assist them with understanding PDL presentations at their last meeting.

- The October 7<sup>th</sup> Status Report on antidepressants and anti-anxiety medications was sent to the JCHC as well as the General Assembly. In addition, Kim Snead, Executive Director of Joint Commission on Health Care, has attended several of the P&T Committee meetings, which are open, public meetings. All of the PDL information is also readily available on the DMAS web site. The Department has invited all Committees of the Legislature to request individual or committee meeting presentations as needed on the PDL or other subjects. All information requested has been provided.
- Background information on the PDL has been provided to the JCHC in the past and a decision was made to not repeat this information in the most recent presentation; however, the Department recognizes that there may be a need to rehash this information due to Commission turnover and other changes. As the referenced PDL discussion was not on the agenda, the DMAS staff was not in attendance to support the presentation by Kim Snead in which some erroneous information was not corrected. Kim Snead attended the October 6<sup>th</sup> P&T Committee and should have been able to address the errors. For example, there was a quorum at the October 6<sup>th</sup> meeting, which was necessary for the P&T Committee to vote on the drug classes under discussion. There has never been a vote of the P&T Committee without a quorum. Typically, if there are questions following a P&T Committee meeting, Kim Snead will ask for clarification; however, none were directed to the Department following the October 6<sup>th</sup> meeting.

Becky Snead asked, in reference to long acting narcotics, what will happen at point of sale when a new prescription is needed for a short acting narcotic? How will emergency supplies (72-hour) of narcotics be managed?

- The process is being automated as much as possible. If two short acting narcotics are in the patient's medication history, the claim will pay immediately (automated) at point of sale. Also, if the patient has been stabilized on a long acting narcotic, shown through the use of long acting narcotics in the patient's medication history, the claim will also pay immediately (automated) at point of sale. This will only be an issue with new patients with long acting narcotic prescriptions in which a prior authorization is required. A 72-hour supply may be distributed until a new prescription is provided. This process will be described in the Medicaid Memo on this subject.

Becky Snead asked what type of notification is being sent to the provider community. There is a great deal of sensitivity and need for continuing education in the provider community related to proper management of the long acting narcotics drug class.

- The provider memo on long acting narcotics will be distributed prior to the Phase I annual review memo. The memo is currently under management review. The memo will be forwarded for review to Becky Snead before final DMAS review and distribution. (Becky Snead would like to forward to other pharmacy provider representatives as well due to potential issues in regards to record keeping with the long acting narcotics class.) She does not want patient care comprised due to these potential administrative issues. Becky Snead is the designated DMAS Medicaid Memo reviewer for pharmacy related initiatives.

Hill Hopper mentioned that the availability of long acting narcotics is a major issue for long-term care facilities. State regulations restrict long term care facilities in terms of what drugs may be offered for interim use which limit access to these medications, e.g., immediate release oral narcotics cannot be used in these facilities. Mr. Hopper stated that any additional notification, similar to what was done with antibiotics, would be beneficial.

### **Pharmacy Program Initiatives**

Javier Menendez, DMAS Pharmacy Manager, provided a presentation on recent pharmacy program initiatives including threshold, mandatory generic and maximum allowable cost (MAC) program. The presentation was distributed to PDLIAG members and is available on the Department's web site.

Questions:

Jill Hanken asked during the Coordination of Care program discussion if the 412 recipients, whose physicians received letters regarding their medication regimen, met the program criteria.

- Yes, all of the 412 recipients met the criteria (6 or more prescriptions, from 3 or more pharmacies that were written by 3 or more prescribers) based on August 2004 utilization data. All three criteria had to be met.

Jill Hanken asked who received the letters for the Threshold program.

- The letters are sent to the prescribing physicians of recipients that meet the Threshold program criteria. For recipients in long-term care, the letters are sent to the pharmacy consultant.

Ann Leigh Kerr asked if duplicate therapy were identified through the Threshold program, would letters be sent to both physicians?

- Yes, letters will be sent to both physicians.

Matt Sheffield asked if the Mandatory Generic program applied to both PDL and non-PDL brands.

- Yes, the program applies to both PDL and non-PDL brand drugs; however if a brand drug is preferred it will not be subject to the mandatory generic edit.

Madeline Abbitt asked if any cost savings figures were available at this time for Mandatory Generic program.

- No, cost savings information is not currently available for the mandatory generic program. Total pharmacy program savings has been calculated and will be presented with Wayne Turnage's presentation. These savings are attributed to multiple pharmacy savings initiatives. The mandatory generic program was implemented in September 2004.

Becky Snead stated that the majority of states require a prior authorization or Medwatch form be completed to use a brand name if there is generic available. In these states, writing "brand medically necessary" is not sufficient to have the prescription filled when a mandatory generic program is in place. She asked if Virginia Medicaid had considered these practices.

- The Department has not evaluated these practices from a policy perspective; however, they have been successful in other states. These practices ensure that generic utilization is increased, quality is maintained and savings are achieved.

Matt Sheffield asked if most of the pharmacy claims were paid with the FUL rate, does the Department review the FUL to compare with retail purchasing prices? There are typically disputes when there are discrepancies in purchasing price vs. FUL rate.

- Yes, there is a dispute resolution process included in the MAC program which will allow pharmacy providers to dispute any payment rates that are below their purchasing price.

Jill Hanken asked how often the pharmaceutical prices changed.

- The market prices of drugs may change daily; however, the MAC list is updated on a monthly basis, which is the standard among most state Medicaid programs.

Jill Hanken asked is there is any variation in MAC pricing around the state of Virginia.

- There is no variation around the state of Virginia. This MAC list would apply to all pharmacy providers offering services to Virginia Medicaid recipients.

Becky Snead stated that the generic utilization percentage should be monitored closely. The current MAC list has been reviewed and is acceptable; however, if providers begin to become unable to cover their costs for generics, they will begin to work with prescribers to have brand name drugs

dispersed that will provide a more reasonable reimbursement rate. This may have a negative affect on the generic utilization rate going forward. To encourage use of generics, the reimbursement rates based on the MAC list must be fair.

In addition to the pharmacy initiatives mentioned in the presentation, the pharmacy department also conducted four training sessions in September and October. These sessions were held throughout the state – Northern Virginia, Roanoke, Tidewater and Richmond.

Jill Hanken asked if the procedure related to physicians’ use of “brand medically necessary” on prescriptions was being changed.

- No. Becky Snead mentioned that most other states require that a prior authorization or Medwatch form (FDA form) to be completed to fill a “brand medically necessary” prescription. Ms. Snead asked that Virginia Medicaid consider these policies used by other states for additional justification. No action has been taken by the Department to implement this policy. This policy would be more cumbersome for both the pharmacy providers and prescribers. This is mainly an issue for drug classes that are not subject to the PDL; however, the policy would offer incentive to increase generic utilization.

#### **Update on the Evaluation of the PDL Program (See presentation attached)**

Wayne Turnage, Director for the Division Policy and Research, provided a presentation and handouts on the evaluation of Virginia’s preferred drug list: fourth quarter interim report. The handout will be available on the Department’s web site. Mr. Turnage stated that the Department’s analysis of the PDL program was completed based on a directive from the Director. Budget staff, the Pharmacy staff, and First Health Services’ staff provided support in the development of the analysis. Mr. Turnage acknowledged the work of Kelly Gent in developing the report.

The presentation included components of evaluation, movement of prescriptions through the PDL process, the prior authorization process, preliminary budget savings, review of study group vs. comparison group, and conclusions of study results. The savings projections provided were based on the total pharmacy program including all initiatives, not specific to the PDL. The study conclusions include:

Study results of the early implementation of PDL in Virginia continue to be favorable:

**Compliance --** The PDL compliance rate, measured as the percent of patients being prescribed “preferred” drugs, remains high. While the compliance rate varies among the different drug classes, the overall compliance rate across all drug classes is 92%. This rate exceeds the compliance level (85%) needed to achieve the necessary budget savings.

**Prior Authorization --** There have been no denials of medications as a result of the PDL prior authorization process. Since the beginning of the program, 76% of all requests for prior authorization have been granted; for the remaining 24%, the prescribing physician voluntarily switched to the preferred drug. There have only been technical denials for retrospective payments to long-term care facilities that have already dispensed the medication but did not comply with the appropriate PDL processes. Therefore, there is no

evidence that any patient has been denied access to their medications as a result of this program.

**Call Center Operations** -- The PDL call center, managed by First Health Services, has been operating efficiently. The Call Center is responsible for receiving and evaluating prior authorizations as well as responding to other program inquiries. As of September 2004, Call Center activity has leveled off with an average of 894 calls per week and an average of 1,755 issues addressed each week. Physicians make the majority of calls and most calls involve requests for prior authorization. The Call Center staff continues to manage these calls promptly. As of September 2004, calls were being answered within 16 seconds and the average call length was less than two and one-half minutes.

**Market Shift** -- Market share of PDL drug classes has significantly shifted as a result of the program. In September 2004, preferred drugs accounted for 89% of all claims in PDL drug classes compared to 61% in January 2004 (prior to the PDL Program). This market shift indicates an acceptance among providers of the drugs available as “preferred,” and supports the achievement of program savings.

**Cost Savings** – Evaluation results show the average cost per prescription has decreased below the projected amount since PDL implementation. In addition, the actual pharmacy expenditures are significantly below the Department’s official forecast. While the final savings estimates have not been completed, these comparisons of actual versus forecasted expenditures indicate the program is meeting the targeted level of savings required in the Appropriations Act. These savings are driven principally by a supplemental rebate process that has worked very well (overall, manufacturers have provided competitive pricing) and the high PDL compliance rate (92%).

Questions:

Hill Hopper asked if the saving projections for the Threshold program, based on the Appropriations Act, were revised with the General Assembly subsequent to the implementation of the program.

- No, it was not revised. The Department will be reviewing overall pharmacy program savings given the number of changes over the past year. The original savings were set as \$9 million, which was not reasonable given that it is primarily a quality initiative.

Ann Leigh Kerr asked if the Department would be able to share with the General Assembly specific savings for the PDL.

- It is possible but it will be very difficult to segregate PDL savings specifically because several initiatives may affect each pharmacy claim. First Health, the Department’s PDL contractor, will conduct a separate analysis of PDL savings. The General Assembly will be concerned that \$18 million was saved in the pharmacy program and this can be accomplished. The Department will continue to attempt to tease out the affect of each new pharmacy initiative in the most reliable manner possible.

Madeline Abbitt asked if complaints by drug class are available.

- No, the complaints are not separated by drug class. There are very few complaints overall. There were no complaints in recent weeks and majority of complaints relate to being unable to contact the DMAS call center.

Ann Leigh Kerr asked if we know which drug class have most of the drugs within the class as “preferred”? If the class is more restrictive, you may expect to see a less favorable compliance rate.

- The data have been analyzed to determine if, controlling for the number of drugs within the class, there would be variation. These analyses did not show variation among classes with differing numbers of preferred drugs. The data will continue to be monitored for any effects.

During the discussion of prior authorization denials received to date, Jill Hanken asked if all the denials were for 72-hour emergency requests. She asked how many were prospective 72-hour requests vs. retrospective long term care claims for reimbursement.

- Yes, all of the denials were retrospective requests from long-term care facilities. This is a billing issue rather than the provision of medication to the patient. The reimbursement is not denied until the second or third claim is submitted without the appropriate prior authorization in place. Because these are retrospective requests, the patients were not left without medication.

Madeline Abbitt stated that there was large decline from January 2004 to September 2004 in the number of physicians agreeing to change to a preferred drug.

- This decline is mainly due to increased knowledge of the program. As physicians become more aware of the PDL, there are fewer requests for prior authorizations (preferred drug used automatically), which creates a decline in the number of physicians changing following their initial requests.

Becky Snead asked if additional physician and provider education has been conducted.

- There has been no additional education necessary. Providers and physicians received Medicaid Memos with the implementation of each phase of the PDL. In addition, the Pharmacy staff has recently completed pharmacy training sessions throughout the state. There have been no complaints specifically about the program design, which would warrant further education.

Ann Leigh Kerr asked if the savings shown were from 2003 when the program began.

- The pharmacy program expenditures and savings are shown from fiscal year 2003 through fiscal year 2004. The PDL program started in the middle of fiscal year 2004 so savings were not fully realized during that fiscal year. In addition, there were several other cost-saving pharmacy program initiatives implemented during this time period.

Matt Sheffield stated that if First Health has advised that an 85% compliance rate must be achieved to reach program savings, is it safe to say that at the current 92% compliance rate, the savings have been met?

- Yes, this is correct; however, the equation cannot be simplified in that manner because all of the drug classes originally proposed for the PDL were not implemented. There are several other factors to consider as well, i.e., savings shown do not reflect Phase III drug classes implemented in July 2004 or the upcoming antidepressant and antianxiety drug classes.

Ann Leigh Kerr asked if the savings shown were net on the contract expenditures for the PDL Contractor, First Health Services. Are there separate contracts for the PDL, Threshold and MAC programs?

- No, these expenditures were not factored into the savings analysis; however, it is relatively a small figure. In addition, it is an administrative services contract vs. medical services. The savings analysis is based on medical expenditures only.
- There are contracts with First Health for PDL, Threshold, Coordination of Care, clinical edits and ProDUR. There are both pharmacy services and systems contracts with First Health. The vendor for the MAC program is Sentara Health Plan (Optima) under a separate contract.

Jill Hanken asked if the health quality study piece of the report included actual recipients who may not stay in the Medicaid program and if new recipients will be excluded from the study.

- Yes, these are simply factors, which must be addressed through the analysis going forward. Any outcomes measure reported will be adjusted/standardized for the number of days the recipient is in Medicaid. This makes the measure comparable for recipients with different periods of utilization. Controls for age differences will also be reviewed in the future.

### **Other Issues**

Matt Sheffield stated that, based on savings shown to date with the program, he does not feel additional classes need to be added to the PDL, including the antidepressants and antianxiety classes scheduled to be implemented in July 2005. He added that his company does have interest in behavioral health medications. He asked that PDLIAG members, Drs. David Markowitz and James Evans, provide their input to the Committee in the future. Cheryl Roberts responded that the Department does not make decisions in regards to the drug classes included on the PDL. This is the responsibility of the P&T Committee. The Department only implements based on General Assembly and P&T Committee's decisions. Mr. Sheffield asked that his comments be documented. Ms. Roberts stated that no additional classes are being considered for the PDL at this time; however, this may change due to new clinical considerations or market factors. The majority of the high volume classes have already been considered for inclusion or exclusion in the PDL.

Patrick Finnerty clarified that antipsychotic drugs are not being considered for the PDL; they were excluded from consideration during the early stages of PDL implementation. The P&T Committee has only approved antidepressants and antianxiety medications for the PDL.

Matt Sheffield asked Mr. Finnerty to inform the group of information provided to the Joint Commission on Health Care (JCHC) related to the legislative inquiry about multi-state purchasing pool. Mr. Finnerty stated that he advised the JCHC that DMAS is not actively pursuing participation in the multi-state purchasing pool. This does not preclude the Department from participating in the future; however, at this time the Department is doing well with rebates negotiated by its PDL contractor, First Health Services (who is also the contractor for the multi-state purchasing pool).

DMAS did not join the pool at the outset because when the decision was being made the pool did not have CMS approval. At that time, DMAS did not want to proceed with implementation using the pool and then determine that the mechanism being used for manufacturer rebates was null and void at the federal level.

Ann Leigh Kerr stated that she would like to see more work on the budget savings figures related to the PDL, as this information must be provided to the General Assembly. It would be helpful to clearly state the current status of savings related specifically to the PDL program.

No other issues were addressed.

### **Schedule Next Meeting**

Cindi Jones stated that the Department is interested in having the PDLIAG continue to meet, although the PDL has been fully implemented. The PDLIAG has been useful to the Department and if the group would like to meet periodically to receive updates on the status of the program and offer additional input, it would be appreciated. The group agreed that they would like to continue meet, especially following the General Assembly session.

The next meeting has been tentatively scheduled for May or June of 2005. The exact date will be scheduled in the future.

### **Adjournment**

There being no further business, the meeting was adjourned.