Meeting of the
Pharmacy and Therapeutics Committee
April 21, 2004
Minutes

Members Present:
Randy Axelrod, M.D., Chair
Roy Beveridge, M.D

Sue Cantrell, M.D.
Tim Garson, M.D.
Mariann Johnson, M.D.
Mark Oley, R.Ph.
James Reinhard, M.D.
Mark Szalwinski, Pharm.D. - Vice Chair
Renita Warren, Pharm.D.

Absent:
Gill Abernathy, M.S., R.Ph.
Avtar Dhillon, M.D.
Christine Tully, M.D.

A quorum was present

Guests:
Jane Woods, Secretary of Health and Human Resources
32 representatives from pharmaceutical companies, providers, advocates, associations, etc.
Manikoth Kurup, MD, Member, Board of Medical Assistance Services

DMAS Staff:
Patrick Finnerty, Agency Director
Cynthia Jones, Chief Deputy Director
Cheryl Roberts, Deputy Director of Programs and Operations
Paige Fitzgerald, Counsel to the Board, Office of the Attorney General
Adrienne Fegans, Program Operations Administrator
Javier Menendez, Pharmacy Manager
Bryan Tomlinson, Director, Division of Health Care Services
Katina Goodwyn, Pharmacy Contract Manager
Rachel Cain, Pharmacist Consultant
Maryanne Paccione, Pharmacy IT Consultant

First Health Staff:
Carol Perkins, Pharm.D, Clinical Manager
David Adams, Pharm.D., Rebate Support
Douglas Lipton, Esq.

WELCOME AND INTRODUCTIONS

Dr. Axelrod called the meeting to order. Nine P&T Committee members were in attendance.

COMMENTS FROM PATRICK FINNERTY, DMAS DIRECTOR

Mr. Finnerty welcomed those in attendance and provided an update on the status of the PDL implementation. He stated soft edits had started for the second phase on April 1st with no issues to date. Hard edits will start on May 3rd and May 10th for these classes. Things are going well with the First Health Call Center – the average speed of answer is very low and the average length of calls is minimal. The compliance rate for the first Phase of the PDL is greater than 95%. There have been no denials of any PA request – either the non-preferred agent was approved or the prescriber changed to a preferred product.

Wayne Turnage, Director of the Policy and Research Division, has assembled a PDL evaluation team to do a comprehensive review of the program. He has presented an initial report to the PDL Implementation Advisory Group. This initial report focused on the Call Center operations and the PA process. This presentation was included in the members' packets and is available on the DMAS internet site (www.dmas.state.va.us/downloads/pharm-pdl_interim_evaluation_report_3-16-04.ppt).

After discussions with First Health, DMAS has decided there is no need to include a fourth phase of medication classes in the PDL. The only exception would be the SSRIs and this decision is dependent on proposals pending with the General Assembly.

Mr. Finnerty states the program has received good reviews and he gave credit to the Committee for enabling this by determining the right classes and the right medications to include in the PDL.

COMMENTS FROM RANDY AXELROD, COMMITTEE CHAIR

Dr. Axelrod stated many written comments were received by the Committee and many of these related specifically to the COX2 class. These were included in the designated section for such comments in the members' packets. He noted this information is important to the decisions made by the Committee.

ACCEPTANCE OF MINUTES FROM JANUARY 6, 2004 MEETING

Dr. Axelrod asked if there were any corrections, additions or deletions to the minutes from the February 9th meeting. He noted two corrections/additions in the COX2 discussion forwarded by Dr. Daniel Paulson. In the second paragraph celecoxib was switched to rofecoxib and the comparator agents for the CLASS trial were ibuprofen and diclofenac. Upon request of the Chairman, the Committee voted on a motion and a second to approve the minutes of the February 9th meeting as amended. The Committee voted unanimously to approve the minutes as amended.

COX2 INHIBITOR CLINICAL CRITERIA

Dr Axelrod reminded the attendees that during the February 9th meeting there was a motion for the COX2 class to remain PDL eligible and to subject the class to some type of clinical edit or step therapy and this was unanimously approved at that meeting. Treatment failure with or a clinical contraindication to the NSAID class will be required before a COX2 medication prior authorization will be granted. The clinical criteria will be implemented along with a grandfathering provision. The criteria will apply to all patients less than 60 years of age with a new prescription for a COX2 medication. All patients on a COX2 as of June 30, 2004 will be grandfathered.

DMAS will complete a Medicaid Memo, which will be distributed to pharmacy providers and prescribers. Distribution will occur prior to the implementation of the new edit and the memo will explain the details of the clinical edit and the grandfathering rule.

PROCESS FOR REVIEW OF COMBINATION DRUG PRODUCTS

Single ingredient drug products will be reviewed during the scheduled annual review process. Mark Szalwinski recommended the combination products be reviewed during the regularly scheduled review time for the drug that is the major entity in the combination product. He offered an example of a new combination product containing an Angiotensin Receptor Blocker (ARB) and hydrochlorothiazide. This product would be reviewed with the ARBs. This motion was seconded and unanimously approved by the Committee.

ANNUAL DRUG REVIEW PROCESS

DMAS has discussed with First Health how the process of annual drug reviews could be accomplished. Mr. Finnerty made the following recommendation to the Committee. Contracts for Phase I will terminate on December 31, 2004. New contracts will be needed for January 2005. He proposed the Committee would meet in September to conduct the drug class reviews, to reassess if the drug classes would remain subject to the PDL, and hold the confidential session to discuss pricing issues at this same meeting. Contracts would be completed in November.

For Phase II classes, he recommended extending the current contracts to terminate on June 30, 2005 rather than March 31, 2005 (to coincide with the Phase III contracts). This would establish

a semi-annual schedule. A meeting with a similar structure to the September 2004 meeting would be conducted in March 2005. Contracts would be due in April for a July 2005 implementation. This would set up a schedule of two P&T Committee meetings per year. Any new products would be discussed during this annual review process, unless it is a new product that represents a significant breakthrough in therapy. A mechanism to handle this type of product was discussed at a previous meeting (http://www.dmas.state.va.us/downloads/pdfs/pharm-PDL_reviewing_new_drugs_01-08-04.pdf).
Depending on the outcomes of the issues with the SSRIs pending with the General Assembly, an additional meeting may be required to review this class.
A motion was made to have a semi-annual review – Phase I classes as one group and Phase II and Phase III combined. This motion was seconded and unanimously approved by the Committee. Cheryl Roberts, DMAS Deputy Director of Programs and Operations, noted the schedule would be posted on the DMAS web site in May.

CONFIDENTIAL SESSION

Paige Fitzgerald stated that under the Virginia Freedom of Information Act, specifically Virginia Code section 2.2-3711, a public body such as the P&T Committee, may go into a closed session for any of the 31 reasons listed in that statute. However, discussion of manufacturer and wholesaler prices is not one of the 31 reasons listed.

She stated the Attorney General strongly supports the principles of open government embodied by the FOIA and believes in the opportunity of the Commonwealth's citizens to witness the operation of government to the fullest extent.

Federal Law 42.U.S.C. section 1396r-8 requires such pricing information to be kept confidential. On this point federal law supercedes the Virginia FOIA. Since this pricing information must be discussed by the P&T Committee as part of its duties as charged by the General Assembly, a confidential meeting must occur pursuant to Federal Law. She cautioned only this confidential information should be discussed.

Vice-Chairman, Mark Szalwinski, made a motion for the P&T Committee to resume the meeting in another room to discuss this confidential information regarding prices charged by the manufacturers and wholesalers of the drugs previously certified in previous meetings on January 6, 2004 and February 9, 2004. This confidential meeting is authorized by Federal Law that requires this information to be kept confidential. This motion was seconded and unanimously approved by the Committee.
The meeting adjourned to an executive session.

P&T COMMITTEE DISCUSSION

The Committee reconvened and a motion was made that only such matters as were identified in the motion by which the confidential session was convened were heard or discussed in the confidential meeting of the P&T Committee. The motion was seconded and unanimously approved by the Committee.

THIRD GENERATION CEPHALOSPORINS
A motion was made to add Cedax®, Cedax® Suspension, Omnicef®, Omnicef® Suspension, Spectracef®, and Vantin® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee. A correction to the recording and reading of these listed drugs was noted; therefore, the motion was then amended to add Cedax®, Cedax® Suspension, Omnicef®, Omnicef® Suspension, and Spectracef® to the DMAS PDL. This amended motion was then seconded and unanimously approved by the Committee.

SECOND GENERATION CEPHALOSPORINS
A motion was made to add Cefaclor, Cefaclor ER, Ceftin® Suspension, Cefzil®, Cefzil® Supension, Cefuroxime, Lorabid®, and Lorabid® Suspension to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

THIRD GENERATION QUINOLONES
A motion was made to add Avelox® and Avelox ABC Pack® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

SECOND GENERATION QUINOLONES
A motion was made to add Cipro®, Cipro® Suspension and Cipro® XR to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

MACROLIDES – PEDIATRICS
A motion was made to add Biaxin® Suspension, Erythromycin ethylsuccinate, Erythromycin estolate and Zithromax® Suspension to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

MACROLIDES – ADULT
A motion was made to add Biaxin®, Biaxin® XL, erythrocin stearate, erythromycin base, erythromycin stearate, erythromycin with sulfisoxazole and Zithromax® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

PROSTAGLANDIN AGONISTS – OPHTHALMIC
A motion was made to add Lumigan®, Travatan®, and Xalatan® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

CARBONIC ANHYDRASE INHIBITORS – GLAUCOMA
A motion was made to add Azopt®, Cospot® and Trusopt® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

BETA BLOCKERS – GLAUCOMA
A motion was made to add Betoptic S, Levobunolol HCL, Betimol, Carteolol HCL, Metipranolol, Timolol Maleate, and Betaxolol HCL to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

ALPHA-2 ADRENERGIC AGENTS – GLAUCOMA
A motion was made to add Alphagan P®, bromonidine tartrate, and Iopidine® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

CNS STIMULANTS/ADHD MEDICATION
A motion was made to add Adderall XR®, Amphetamine salt combo, Concerta®, Dextroamphetamine sulfate capsule SA, Dextroamphetamine sulfate tablet, Dextrostat®, Focalin®, Metadate CD®, Metadate ER®, Methylin®, Methylin ER®, Methylphenidate, Methylphenidate HCL, Methylphenidate ER, Pemoline, Ritalin LA®, and Strattera® to the DMAS PDL. This motion was seconded and unanimously approved by the Committee.

LONG-ACTING NARCOTICS
A motion was made to add Avinza®, Duragesic, ® Morphine sulfate ER, Oramorph® SR and OxyContin® with limitations (*see OxyContin limitations under Narcotic Quantity Limits*) to the DMAS PDL. This motion was seconded.

DISCUSSION OF NARCOTIC QUANTITY LIMITS
Mark Oley made a motion for the limitations on OxyContin® to include limits on quantity and disease state. Dr. Axelrod reminded the Committee he sent a letter to the Board of Pharmacy on the behalf of the Committee asking for their recommendations and information on the handling of the long-acting narcotics. Mark Szalwinski stated the discussion at the Board of Pharmacy last week centered on the experience in other states and experience with the pilot Prescription Monitoring Program that is going on in southwestern Virginia. He stated the Board is more than happy to share the results of that prescription monitoring program with the Committee and to be as cooperative as possible, working both with the Medicaid Fraud Division as well as this Committee to make the work of these two groups synergistic. The Pharmacy Board discussed the issue of the usefulness and the applicability of the prior authorization process (primarily based on the experience of someone knowledgeable about the process in other states) and the Pharmacy Board was comfortable with the concept of a prior authorization process linked to disease states. They felt that the prior authorization could be good for a year for a patient with a chronic disease state or one that was related to cancer pain was appropriate and was not cumbersome to the pharmacies and is generally easily and expeditiously done and this does eliminate a segment of the fraud that is associated with OxyContin®.

Dr. Axelrod summarized that the Board of Pharmacy felt it was reasonable to put disease state limitations as well as a combination of potential quantity limits for OxyContin® in particular and that information can be/will be shared with particular prescribers for Board purposes. Mark Szalwinski concurred.

Dr. Axelrod also introduced the option of imposing limitations on Duragesic®. Dr. Beveridge stated he felt the abuse potential for Duragesic® was smaller and it is a widely used drug, particularly in oncology patients. He recommended against such an action. Dr. Axelrod asked if disease state limitations or quantity limits on strength could be considered. Dr. Beveridge recommended monitoring use over the next year to determine if there were problems with abuse.

Dr. Axelrod inquired about the option of limitations on Actiq®. He noted in the commercial side he has observed misuse with this product, particularly involving non-cancer diagnoses. Dr. Beveridge felt the abuse potential with Actiq® was very high and the delivery of fentanyl via the Duragesic® patch was more appropriate for this population.

Pat Finnerty noted that a clinical and operational discussion of these limitations would be helpful to ensure DMAS and First Health could operationally accomplish the recommendations. He

explained quantity limits could be accomplished with no concern – limits could be imposed on the number of tablets. He stated the information about a particular patient's diagnosis would have to be communicated to First Health (such as by fax or phone).

Dr. Cantrell asked for clarification that if OxyContin® was listed as preferred, normally a preferred drug would not require any extra communication in order to be filled. How would this process work – the diagnosis or other specific information noted in the chart was not always communicated to DMAS for any other preferred drug. Dr. Axelrod noted this was a unique drug – it has an incredible capacity for tolerance and that applying a strict quantity limit in some instances is incorrect and not putting it in on in other instances would be incorrect. He wants to ensure how it is used is consistent with medical guidelines and that it is being used in the most appropriate fashion. Dr. Cantrell stated she felt it should be a PA drug, otherwise there needed to be some other process to communicate the necessary information. Utilization numbers for twice daily and more frequent dosing of OxyContin® for a six month period were provided to the Committee. Javier Menendez, Pharmacy Manager, stated there were 2,900 patients with twice daily dosing, 1,100 patients with three times a day dosing and it significantly declined after this point with less than 600 patients with four tablets a day, 200 patients with six tablets a day and less than 100 patients with eight tables a day. Dr. Axelrod said he assumed the dosing more frequent than two to three times daily would be largely for oncology patients. Dr. Beveridge concurred. Javier Menendez noted this information was from a six month time period and the majority of the patients were at twice daily dosing. Dosing outside this level would hopefully be opiod tolerant patients with an oncology diagnosis and those are the ones that would also unfortunately fall to patients who may have potential for abuse. He added the issue of primary importance is the number of pills that get into the community and this would be a way to curtail this and yet provide appropriate use for oncology patients.

Twice daily dosing is recommended by the manufacturer. It was clarified that a set quantity limit could be implemented without obtaining additional information about the patient. Dr. Garson suggested the option of imposing the quantity limits at this time and developing the methodology within the next year to implement limitations based on disease state. Mark Szalwinski expressed concern about the inappropriate use of OxyContin® for acute situations such as post-surgery. Mr. Finnerty explained disease state limitations could be imposed, but this would be part of the PA process, communication of the patient-specific information to First Health would be necessary. Dr. Beveridge advocated setting up a fairly broad guideline for now and this could be evaluated in future meetings to allow the development of inclusive, yet fair, guidelines.

Secretary Woods asked for clarification, that for cancer patients would a PA be required only once for per year and how much of a burden would this be. Dr. Beveridge did not feel this would be an onerous process – that there are a fairly small number of oncologists that take care of a large number of patients. If you include the number of pain specialists, this is still a small number of prescribers impacted. He had no problems with a prior authorization process for OxyContin® for oncology patients given its abuse potential. He said there are other patient groups such as Sickle Cell patients, with ongoing pain where this would also apply. Dr. Cantrell suggested making the PA process as broad as possible to include these patients, but not to move away from this process.

Dr. Axelrod stated the motion was now not to have OxyContin® listed as preferred, but to have it subject to the PA process and to have quantity limits associated with this process. Dr. Beveridge

suggested the PA process be very liberal with the doses and also use this as a mechanism to collect data. Dr. Cantrell added this would be a way to deal with clearly inappropriate use. Dr. Axelrod referred the Committee to the draft OxyContin® quantity limit criteria included in the notebooks. He stated the changes to this would include the length of the authorization, the maximum daily quantity would be decreased down to twice daily dosing and exceptions would be made for Sickle Cell patients, pain associated with end-stage HIV/AIDs, cancer pain and intractable pain. He questioned if intractable pain should be included since it was so broad a category. Dr. Beveridge recommended keeping the diagnoses very broad at this time and evaluating the data at six and twelve months. If it is then determined that a large percentage of the use is for intractable pain then this could be evaluated further.

Dr. Axelrod stated there would be a limitation of twice daily dosing across all strengths and the diagnoses would include intractable pain at this time. Mark Szalwinski also agreed intractable pain should be included at this time and be reconsidered in the future after data is gathered. Dr. Beveridge asked for clarification if the limits would be placed on all strengths. The proposed criteria did not include limits on the 80 mg strength. Dr. Axelrod clarified there would be no quantity limits on the 80 mg strength.

Dr. Axelrod requested the motion be amended to reflect the Committee's discussion. Mark Oley restated the motion to include Avinza®, Duragesic®, Morphine sulfate ER, Oramorph® as preferred under the PDL. This motion was seconded and unanimously approved by the Committee.

Mark Oley made motion to consider OxyContin® as a non-preferred drug with a quantity limit of one tablet twice a day for the 10 mg, 20 mg and 40 mg strengths, no quantity limits on the 80 mg strength, with a diagnosis of Sickle Cell pain, intractable pain, pain associated with end-stage HIV/AIDs, and cancer pain. Mark Szalwinski stated for clarification it should be "or cancer pain" not "and cancer pain." This motion was seconded and unanimously approved by the Committee.

Dr. Axelrod noted there was a suggestion by DMAS to review Duragesic® for a quantity limit, and referred to the proposed draft criteria in the packet. He asked if after review of these criteria, if the decision would be reconsidered – the length of authorization could be changed. Dr. Cantrell asked for clarification if there were any current quantity limits on Duragesic® – currently there are no such limits. Dr. Beveridge asked if the department of Pharmacy felt there were any abuse issues with Duragesic® patches at this time. Mark Szalwinski noted there could be abuse potential for all methods of narcotic delivery, but the patch system represents less potential than oral tablets. He stated there have been reports of attempts to extract the fentanyl from the patches as well as inappropriate use has been seen. Dr. Cantrell offered the example of Duragesic® patches being used for post-operative pain. Mark Oley noted there is less potential for abuse with Duragesic® than for OxyContin®. He asked Dr. Beveridge, as an oncologist would he want to see a limitation placed on Duragesic®. Dr. Beveridge said that not personally, nor in a large practice, nor a hospital has he seen any abuse with Duragesic®. He stated if there was evidence there was an abuse problem he would be willing to change. Otherwise, he felt it was more reasonable to keep it a fairly open system until we realize there are problems, noting again he was in favor of gathering data and evaluating in six months. Utilization data for Duragesic® claims with quantities over ten per month were provided to the Committee. Javier Menendez, Pharmacy Manager, stated there were 367 claims over a six-month period for

quantities of greater than ten per month. Total utilization of Duragesic® was approximately 10,000 claims over six months.

Dr. Beveridge did not feel the data available at this time indicated a significant problem. Dr. Cantrell noted she has seen some abuse in southwest Virginia, in terms of inappropriate use and also trying to extract the fentanyl from the patch. She felt comfortable not placing a limitation on Duragesic® at this time, but also noted the need to monitor utilization to determine if limitations placed on one drug, caused patients to shift to another drug.

Dr. Axelrod referred to the Actiq® criteria, again noting the abuse he has observed on the commercial side. Mark Szalwinski questioned if the medication had to be covered at all. It was clarified Actiq® had to be covered under Medicaid. Mark Szalwinski stated he would like to add to the criteria that the patient would have to fail every other opiod available and have a diagnosis of cancer. Dr. Beveridge asked about the omission of methadone from the list of long-acting narcotics – it is an inexpensive option and is being used more often, especially in hospice patients. It was clarified a quantity limit could be placed on a product, without a PDL clinical review. Dr. Axelrod stated with the issue of Actiq®, there is a block box warning willingly placed there by the manufacturer that this medication is intended for use in cancer patients and has specific precautions about keeping away from children. Dr. Beveridge stated it was appropriate to follow that which it has been approved for and set up reasonable quantity limits. Dr. Axelrod stated the intention was to abide by the manufacturer's packaging in regards to its clinical criteria. It was clarified limitations on Actiq® are separate from the PDL, this is a clinical edit.

A motion was made to accept the criteria as written with the exception that the patient must have a diagnosis of cancer "and" have tried all other opiods. This motion was seconded and unanimously approved by the Committee.

Dr. Beveridge raised the issue of methadone again. He would like to see it added as a preferred agent under the long-acting agent. It was clarified that there were no current PA requirements on methadone and since it was not listed as non-preferred on the PDL, no such restrictions would be implemented.

DISCUSSION OF DRAFT PDL CRITERIA FOR THIRD PHASE (JULY) IMPLEMENTATION

Proposed PDL criteria for the Phase III medication classes were provided to the Committee members in their packets. The criteria included a list of the medications within each class. Dr. Axelrod asked if the medication lists would be divided and categorized as preferred versus non-preferred. Carol Perkins (FHSC) clarified the medication lists would be updated to reflect the decisions made at today's meeting. A motion was made to approve the criteria for all of the classes included as presented; with the expectation the drug lists would be updated to specify each medication as preferred or non-preferred. This motion was seconded and unanimously approved by the Committee.

Mr. Finnerty thanked the Committee for their expertise they bring to the process. He also thanked the staff from DMAS and the staff from First Health for their efforts towards the preparation required for the meeting.

OPEN ISSUES

The next meeting is tentatively scheduled for May 17th at 1:00 PM in the DMAS Board Room. This meeting will only be necessary if there will a fourth phase of the PDL. This decision is pending decisions on the SSRI class by the General Assembly. If this meeting is not required, the next meeting will be scheduled for September. Updates will be posted on the DMAS web site (http://www.dmas.state.va.us/pharm-home.htm).

{Please note a correction to the meeting discussion. The actual tentative meeting date is May 18, 2004.}

Chairman Axelrod adjourned the meeting.