

**MARYLAND COMMISSION ON KIDNEY DISEASE
OPEN SESSION MINUTES
Thursday April 29, 2004
4201 Patterson Avenue, Room 110**

Commission members present were: Drs. Jeffrey Fink, Joseph Eustace, Jose Almario, Kenneth Yim, Dean Taylor, and Tracey Mooney, CPA. **Staff present were:** Eva Schwartz, Executive Director, Joel Tornari, AAG, Commission Counsel, Carol Manning, KDP, Patricia Nowakowski, Medical Care Operations and Donna Adcock, RN, Commission Surveyor.

Guests present were:

Bill Frederick-Holy Cross
Karen Lambrecht-Amgen
Michelle Abbott- Gambro
Leslie Geary-Smith-Davita
Joan Rogers-IDF
Lori Ward- Peninsula Renal
Carisa Borji-Davita
Barry Tucker-Amgen
Jacquelline Walker-Amgen
Ron Stephens- Amgen
Karen Walker-Meadow
Dee Anderson-Porter
Francine Babineau-Porter
Sue Wessells- Deer's Head
Pearl Lewis- Patient Advocacy Group
Linda Schuler- Porter

Ellie Stewart, UMH Dialysis
Vanessa Ajay- Maryland General
Maria McDonough-Charing Cross Dialysis
TriDonna Brandford-Davita
Dorothy Dukes-Davita
Mary Keller- Davita
Susan Leon- Bon Secours
John Novello-Amgen
Sue Bautista-Amgen
Sherry Weaver-Snook-Meadow
Joe Ruger-Davita
Anne Phelan- Genzyme
Clifford Madden- Porter
Rachel Boro- Porter
Jim Straight- NKF/NCA

I. APPROVAL OF JANUARY 29, 2004 MINUTES

The Commission approved the Open Session minutes as submitted.

II. CHAIRMAN'S REPORT

Dr. Fink welcomed everyone. He discussed the Commission's efforts to protect the KDP formulary in light of budget cuts and new and expensive drugs. He invited everyone to participate in the meeting, which is an open forum for issues/questions.

III. EXECUTIVE DIRECTOR'S REPORT

Mrs. Schwartz discussed the need to review the role of the social worker in the dialysis facilities. She shared with the group articles from Nephrology News and Issues that relate to social work standards and the social workers' role in helping the staff deal with difficult and non-compliant patients in the facility. She reminded the guests that the social work task force is scheduled to present their findings regarding social work issues in Maryland at the July meeting.

Mrs. Schwartz notified the guests that the Commission will begin to update their Statutes. She invited anyone with comments to contact the Commission office.

IV. OLD BUSINESS

A. Medication List

Ms. Manning reported that a pharmacist for the Maryland Medicaid Program has reviewed Dr. Yim's List of Most Commonly Prescribed Meds. The pharmacist's comments were reviewed and discussion ensued. Dr. Yim will contact Ms. Manning to request a list of commonly prescribed medications from First Health. The revised list should contain a notice that it is not a comprehensive list of all the medications covered by KDP. The user-friendly list was generated at the request of renal social workers who routinely help patients with prescriptions.

- B. Updates on KPD Regulations regarding Co-payments
Ms. Manning reported that the KDP has proposed regulations that would eliminate the KDP's responsibility to cover the prescription copay for dually eligible full Medical Assistance patients. She noted that there have not been any comments thus far. The regulation will be printed in the Maryland Register on June 11, 2004 and will be effective June 21, 2004. Dr. Fink noted that the Commission has been negotiating with the Department to protect the needs of the patients at a time when monies are scarce and programs are being cut. Ms. Manning noted that patients cannot be denied prescriptions because they can't afford to pay the prescription copay.

V. NEW BUSINESS

A. KDP Statistics and Budget

Ms. Manning presented and discussed the KDP Budget, Statistics, and Expenditure Reports. She reported that the KDP budget for FY 2005 will be 10.8 million. The KDP is in compliance with the mandated 45 day processing period for applications. The KDP is currently processing applications within 43 days. Ms. Manning noted that the Electronic Claims Management System is set to go live in July. Applications and renewals will continue to be on paper. Ms. Manning reported that KDP is not requiring beneficiaries to apply for the new Medicare Drug Prescription Discount Card.

B. Changes in Reimbursement for Renagel

Ms. Manning read the Maryland Pharmacy Program's notice dated 4/26/2004. The notice introduces Step Therapy for the use of Renagel. The KDP will require all new recipients to try PhosLo prior to receiving Renagel. If Renagel is prescribed without following PhosLo it will require preauthorization. All patients with a history of Renagel use within the last 90 days will be grandfathered in and will not require preauthorization. This change will be effective 5/19/04.

Dr. Fink noted that the Commission deliberated on this issue and reported that Renagel is the most expensive drug on the KDP formulary. He noted that this requirement puts constraints on the nephrologists' practice however; he stated that this process is a small price to pay in order to keep Renagel on the formulary and keep the KDP budget solvent.

Ms. Schwartz noted that the preauthorizations will only be effective for one year. The Commission has some concerns about the annual preauthorizations for a drug that the patient may need for the rest of their life. The group decided to revisit the annual preauthorization requirement in the future if the need arises.

C. Sensipar Presentation

Dr. Barry Walker from Amgen presented information regarding Amgen's new drug Sensipar. A question and answer period followed the presentation. Amgen is requesting that Sensipar be added to the KDP formulary. Additional research and consultation with Joe Fine, Director of Pharmacy Services for DHMH, was recommended before the Commission would make a ruling.

D. Commission Newsletter

Ms. Adcock reported that the Commission's annual newsletter was mailed to all dialysis facilities in March 2004.

E. New Certifications

Ms. Adcock reported that the following facility has requested and received approval for certification:

- Holy Cross at Woodmore-1/29/04
11721 Woodmore Rd., Ste. 190
Mitchellville, MD 20721

F. Change of Ownership

Ms. Adcock reported that Bon Secours has decided to divest itself from their community based dialysis centers. The following facilities have changed ownership:

- Bon Secours North Charles and Bon Secours Chesapeake- Kidney Dialysis Centers (Dr. Victor Onyejiaka) 4/9/04
- Bon Secours Charing Cross- Drs. Moges, Beltran, Thomas and Liberty Dialysis 4/1/04

G. Facilities Closed

Ms. Adcock noted that the Commission has been notified that the following facilities are closed:

- GHC Whitesquare-PD 12/03
GHC Whitesquare obtained PD certification. All patients were transferred to that facility.
- Bon Secours-Liberty 3/15/04
All patients at the facility were transferred to another center. Most patients were absorbed by the Bon Secours's Baltimore facility.

H. Uncertified Facilities

Ms. Adcock reported that facilities not certified with the Commission have submitted KDP applications on behalf of their patients. These facilities are not eligible for reimbursement from the KDP. Ms. Adcock reminded the guests that KDP patients should not be admitted to uncertified facilities because there will be no reimbursement for services from the KDP until these facilities became certified. Ms. Mooney noted that obtaining a provider number from Medicare could take 6 – 9 months, which may explain why facilities do not apply for Commission certification immediately.

I. Complaints

Mrs. Schwartz reported that the Commission has received and investigated the following types of complaints since the last meeting:

Written

- Patient complaint regarding facility's eating policy
- Facility request to discharge patient for continuous noncompliance with attendance
- Patient complaint regarding infection control and machine issues

Verbal

- Facility complaint about a verbally abusive patient
- Anonymous complaint regarding facility staffing ratios
- Complaint regarding facility's social work staffing
- Hospital complaint regarding difficulty placing a patient
- Patient's wife complaint regarding patient's return to facility after hospitalization
- Patient complaint regarding facility's lack of response to a complaint
- Anonymous complaint regarding the water fountain at a facility
- Complaint regarding staff assigned at a facility

J. Citation Free Surveys

Mrs. Schwartz commended Davita Dulaney Towson and JHH Harriet Lane for having accomplished the status of "facility without deficiencies or citations".

K. Automated External Defibrillators (AED)

This agenda item was added at the request of Cliff Madden, Director of Nursing for Porter Dialysis. Mr. Madden reported that sudden cardiac death is the most common cause of death in adults. AEDs are designed to be user friendly even to lay people. The AEDs are located in airports, YMCAs and malls. He suggested that all dialysis facilities should consider having AEDs. The Commission discussed the concept and agreed that the devices would be appropriate for dialysis facilities; however they may be cost prohibitive. The Commission will work to create awareness of AEDs and recommend that each facility have an AED.

L. Commission Approval/Disapproval for KDP Transplant Reimbursement

The following Hospitals have been granted out of state transplant approvals:

Hospital	Granted	Refused
Washington Hospital Center	1	0
Inova Transplant Center @ Fairfax Hosp	0	0
Georgetown University Hospital	0	0

M. Surveys (17)

The Commissioners reviewed the results of the surveys and the deficiencies noted:

Deficiencies

Licensure/ State Laws	1
Governing Body	5
Reports/Incidents	0
Health Supervision	0
Inservice Education Programs	1
Patient Care Policies/Procedures	1
Medical Supervision	0
Long Term Program/Care Plan	12
Patient Rights/Responsibilities	1
Medical Records	5
Physical Environment	3
Preventive Maintenance Programs	1
Water Culture Reports/Water System	5
Contamination Prevention	3
Emergency Preparedness	1
Reuse of Hemodialyzers/Supplies	3
Affiliation Agreements	1
Director of Dialysis Center	1
Staff: RN Coverage	2
Laboratory Services	0
Dietetic Services	2
Social Services	3
Transplantation by Affiliation	2
Abusive and Dangerous Patients	0

Mrs. Adcock conveyed that Governing Bodies at facilities that have received repeat citations are being cited. The Governing Body is responsible for the overall operation of the facility and thus is responsible to assure that the facility complies with the submitted plan of correction.

N. Surveys Completed (17)

The following facilities have been surveyed since the last meeting:

GHC Howard Street	BMA Camp Springs
GHC Glen Burnie	JHH Harriet Lane
GHC Bel Air	Renal Care Bowie
GHC Oxon Hill	IDF Deaton
GHC Frederick	GHC Cottage City
BMA Rockville	Davita Dulaney Towson
Davita Bertha Sirk	FMC Washington
FMC Wheaton	Montgomery Renal
GHC Whitesquare	

It was concluded that the surveys were accepted as presented. If appropriate, follow up corrective action plans would be discussed in the closed session.

CLOSED SESSION: Pursuant to Maryland State Government Annotated "10-501 et seq., on a motion made by Dr. Jeffrey Fink and seconded by Tracey Mooney, the Commission unanimously voted to close its meeting on April 29, 2004 at 3:45 p.m., in room 110 for the purpose of complying with the Maryland Medical Practice Act that prevents public disclosures about particular proceedings or matters.