

MARYLAND COMMISSION ON KIDNEY DISEASE
OPEN SESSION MEETING MINUTES
Thursday July 22, 2010
4201 Patterson Avenue, Room 108-109

The Open Session meeting of the Commission on Kidney Disease was held on Thursday, July 22, 2010 at 4201 Patterson Avenue in room 108-109. The Chairman, Dr. Jeffrey Fink called the meeting to order at 2:12 PM. Commission members present were: Drs. Edward Kraus, Matthew Weir, and Kulwant Modi and William Frederick, RN, Kim Sylvester, RN and James Stankovic. Commission staff present were: Eva Schwartz, Executive Director and Donna Adcock, RN, Surveyor. Commission counsel present: Leslie Schulman, AAG.

DHMH staff present: Carol Manning, Chief KDP, Barbara Fagan, Program Manager, Office of Health Care Quality.

Guests present were:

Debbie Ruppert, DHMH	Pat Machate, Davita
Robin Iacovelli, Norvartis	Brenda Redilla, Amgen
Jodi Zeleny, FMC	Monica White, Norvartis
Keisha Greene, RAI	Michael Przywara, Davita
Michael Walker, Davita	Danny McCrea, Davita
Katie Painter, FMC	Joyce Shannon, FMC
Katie Ingram, Davita	Casey Bazzano, Davita
Tracey Sease, WMHC	Christine Wright, WMHC
Steve Schell, Amgen	Anne Smith, RAI
Teresa Cerna, FMC	Debbie Ferguson, FMC
Pam Earll, Davita	Tracey Mooney, IDF
Juathawala Harris, Liberty	Jody Davis, Liberty
Felix Oloyede, FMC	Paula Hollinger, DHMH
Sharon Bloom, DHMH	Susanne Talbott, RAI
Dianna Burns, RAI	Jeanne Jendrek, Good Samaritan
Joan Rogers, IDF	Chris Simon, IDF

I. APPROVAL OF April 22, 2010 MINUTES

The minutes were approved as submitted.

II. CHAIRMAN'S REPORT

Dr. Fink welcomed everyone to the meeting. He discussed a news magazine's article about safety, how safety practices vary in the United States and the benefits of regulation and oversight. He noted that we must establish and maintain strict guidelines to avoid poor outcomes.

III. EXECUTIVE DIRECTOR'S REPORT

Mrs. Schwartz welcomed everyone and introduced Dr. Weir as a member of the Commission.

IV. OLD BUSINESS

A. Veterans Administration Update on Contacts – Dr. Jeffrey Fink

Dr. Fink reported that after the VA solicitation, local and national providers were selected to be providers for the VA. He noted that locally, Davita, FMC and IDF were chosen.

Ms. Mooney reported that the contract with the VA requires submission of care plans on VA patients to the VA.

B. Life Safety Code

Ms. Fagan reported that the Life Safety Code requirement for new and relocating dialysis facilities have been in effect since February 2009. In December 2010 the Office of Health Care Quality has been directed by CMS to survey dialysis facilities for Life Safety Codes when performing recertification surveys. Ms. Fagan stated that the 2000 NFPA guidelines would be utilized and that the State Fire Marshal would be conducting the Life Safety Code portion of the survey.

C. KDP Formulary Recommendations

Dr. Kraus reported on the work of the subcommittee regarding KDP Formulary recommendations. He noted that the subcommittee includes three expert pharmacists who have been reviewing the formulary for safe, appropriate, effective and affordable drugs. Dr. Kraus stated that he hopes the work will include an educational component for the dialysis facilities.

Mr. Simon inquired about the time frame for completion. Dr. Kraus noted that no specific time frame has been established and that the subcommittee's goals were evolving.

Dr. Fink stated that he would like to develop a timeline.

Mrs. Schwarz noted that the subcommittee was formed to proactively address any cuts that may be required of the KDP budget. While working on this task, the subcommittee has discovered that there should be changes made to the formulary to develop a safe and current list. She noted that the public would have an opportunity for comment on the proposed changes, if applicable.

V. NEW BUSINESS

A. Kidney Disease Program - Stats and Budget

Ms. Manning presented the KDP budget.

Dr. Fink inquired what the line item Physician/Special Projects included. Ms. Manning reported that that category includes dental work for pre-transplant work up, one time eyeglass provision, and special requests.

- **Removal of Alcon Drugs from the KDP Formulary**

Ms. Manning noted that the drugs identified below have been removed from the KDP formulary after the manufacturer, Alcon, decided not to provide the required rebate to the KDP. She noted that there are comparable medications on the formulary. The removed drugs are:

- Betoptic Eye Drops
- Carteolol Eye Drops
- Timolol Eye Drops and Gel Solution

B. Bill Cole, Norvartis, Request to Add Transplant Drug, Zortress, to the KDP Formulary

Monica White, pharmacist for Norvartis, presented information on Zortress. Information included risks and benefits of Norvartis' new immunosuppressant agent. Norvartis is requesting the addition of Zortress to the KDP formulary.

Ms. Iacovelli, representative from Norvartis, discussed patient assistance programs available for Zortress.

Dr. Fink inquired about the availability of therapeutic drug monitoring for Zortress. Ms. White noted that the therapeutic drug monitoring testing is not currently commercially available but that Norvartis was working with the transplant centers to identify ways to monitor the therapeutic drug levels.

Dr. Kraus voiced his concerns regarding the inability to monitor levels of this drug. Norvartis representatives were asked to keep the Commission informed when monitoring testing will be readily available and accessible to all those interested in using the drug in any setting.

C. Eligibility of ESRD Patients in Managed Care

Ms. Ruppert, Executive Director for the Office of Eligibility Services Medical Care Programs, reported on her office's outreach efforts to ESRD recipients who may be eligible for Medicare. She noted that her office would be sending letters to recipients and renal social workers to notify them of the requirement for the recipients to provide proof of application for Medicare. Ms. Ruppert also noted that as of August 1, 2010, Medicaid would not be paying the part B Medicare coinsurance or co-payments. A copy of a memo sent to providers regarding the elimination of the co-payments was provided to the group.

A discussion ensued.

D. Emergency Preparedness – Transportation Services

Chris Simon reported on the Emergency Preparedness and Response: Dialysis Clients, Medical Services and Transportation Services meetings. He noted that these meetings were initiated in response to the weather crisis last winter. The group is working to improve service to the dialysis patients during crisis. Mr. Simon noted that representatives are mostly from Baltimore City, Baltimore County and Anne Arundel County. He stated that the group is discussing Web Emergency Operations Center access for the dialysis providers. A demonstration is scheduled during the group’s next meeting on September 30th.

E. CMS Requirement – New Patient Nursing Assessments

Mrs. Adcock directed the group’s attention to the attachment from the CMS ESRD Regulations. She noted that the regulation requires that the Medical Director assure that dialysis orders are written and a specific nursing assessment is performed for new patients prior to the initiation of treatment in the outpatient facility.

F. Dialysis Access Clamp Usage Policy and Procedure

Mrs. Adcock noted that the Network has provided the Clamp Usage Policy and Procedure, which was developed in support of Fistula First. She noted that the policy prohibits the use of clamps on new or underdeveloped fistulas, only one clamp should be used at a time and that the presence of bruit/thrill must be monitored every 10 minutes while the clamp is in place.

G. New Facilities

The following new facilities have been certified by the Commission:

- Advanced Dialysis – Easton 1/6/10
- RAI- Clinton – 2/2/10
- Davita Calverton – 7/1/10

H. Change of Ownership

The following entity has notified the Commission of their acquisition by US Renal Care:

- Dialysis Corporation acquired by US Renal Care – June 3, 2010

I. Uncertified Facilities

The following facility has notified the Commission of the decision not to re-certify with the Commission:

- IDF Lions Manor – 7/1/10

J. Citation Free Surveys

The following facilities were commended for receiving citation free surveys:

- Good Samaritan Hospital Outpatient Dialysis
- WellBound Frederick

K. Complaints

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

Written

- o Facility complaint regarding patients who do not have secondary insurance coverage
- o Patient complaint about feeling that facility was attempting to transfer patient without her consent
- o Patient complaint regarding care at a facility

Verbal

- o Facility complaint regarding a non-compliant patient
- o Patient complaint regarding flying insects at a facility
- o Patient complaint regarding nursing care at a facility
- o Complaints regarding staffing at facilities
- o Complaint regarding care at a facility including lack of supplies and medications
- o Facility complaint regarding a potentially dangerous patient at the facility

L. Commission Approval/Disapproval for KDP Out of State Transplant Reimbursement

The following hospital has requested and been granted out of state transplant approvals:

Hospital	Granted	Refused
Washington Hospital Center	2	0

M. Surveys (23)

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

Citations

Compliance with Federal, State and Local Laws and Regulations	0
Infection Control	13
Water and Dialysate Quality	10
Reuse of Hemodialyzers/Bloodlines	1
Physical Environment	2
Patient Rights	1
Patient Assessment	0
Patient Plan of Care	6
Care at Home	0
Quality Assessment and Performance Improvement	4
Laboratory/Affiliation Guidelines	0
Personnel Qualifications/Staffing	13
Responsibilities of the Medical Director	0
Medical Records	1
Governance	2

Dr. Fink noted the significant increase of citations under Personnel Qualifications/Staffing.

Mrs. Adcock reported that some facilities are not staffed according to regulations and that she is finding that when reviewing treatment sheets patients are being discharged above and/or below goal weights and events during treatment such as saline administration following hypotensive episodes are not documented upon by the nurse.

N. Surveys Completed (23)

The following facilities have been surveyed since the last meeting:

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|-------------------------|--|
| WellBound Frederick | Davita Bertha Sirk |
| Davita Takoma Park | Davita Bel Air |
| ARA Ellicott City | Davita Harford Road |
| ARI Hyattsville | Davita Renal Care of Bowie |
| Davita Howard County | Artificial Kidney – Silver Spring |
| Good Samaritan Dialysis | Montgomery Renal |
| Davita Northwest | Renal Care Partners – Prince Frederick |
| Davita N. Rolling Rd. | FMC Ft. Washington |
| Davita Pasadena | Davita Rockville |
| Davita Aberdeen | Manor Care Dialysis |
| FMC Wheaton | Union Memorial |
| FMC Robinwood | |

CLOSED SESSION: Pursuant to Maryland State Government Annotated “10-508”, on a motion made by Dr. Jeffrey Fink, the Commission unanimously voted to close its meeting on July 22, 2010 at 4:15 p.m., for the purpose of complying with the Maryland Medical Practice Act that prevents public disclosures about particular proceedings or matters.