

**MARYLAND COMMISSION ON KIDNEY DISEASE
OPEN SESSION MEETING MINUTES
Thursday October 27, 2011
4201 Patterson Avenue
Room 108-109**

The Open Session meeting of the Commission on Kidney Disease was held on Thursday, October 27, 2011 at 4201 Patterson Avenue. Chairman Dr. Luis Gimenez called the meeting to order at 2:05 P.M. Commissioner members present were: Drs. Bernard Jaar, Dr. Edward Kraus, Dr. William Rayfield, Dr. Kulwant Modi, Belinda Lindsay, LGSW, Bill Frederick, RN and Kim Sylvester, RN.

Commission staff present was Donna Adcock, RN, Surveyor and Eva Schwartz; Executive Director participated via conference call.

Commission Counsel present: Leslie Schulman, AAG

DHMH staff present: Barbara Fagan, Program Manager and Maria Krasnansky, RN, Surveyor from DHMH's Office of Health Care Quality, Carol Manning, Chief KDP, Chuck Lehman, Executive Director of Medicaid Systems Operation.

Guests present were:

Rhonda Witte, Deer's Head Hospital
Mary Wittaker, Good Samaritan
Tracey Mooney, IDF
David Kaplan, Davita
Barbara Galloway, Western MD Hospital
Robin Iacovelli, Novartis
Sheila Askins, Community Dialysis
Youaf Esmaili, Community Dialysis
Joan Guest, Davita
Kristen Neville, DHMH
Elena Balovlenkov, CMS
Lisa Lubomski, JHU
Anne Gaffney, FMC
Janine Arvaisis, IDF

Amy Lane, Davita
Chris Simon, IDF
Katie Ingram, Davita
Ivy Simmons, Good Samaritan
William Coll, Novartis
Naomi, Elcock, Community Dialysis
Monifa Kopano, Community Dialysis
Mary Keller, US Renal
Stuart Lessner, Union Memorial
Zarita Pearson, Advanced Dialysis
Alison Evans, Davita
Mila Carton, IDF
Teri Jenkins, Advanced Dialysis

I. REPORT OF THE EXECUTIVE SESSION OF July 28, 2011

Mrs. Adcock summarized the minutes of the July 28, 2011 Executive Session.

II. REVIEW AND APPROVAL OF THE MINUTES OF THE EXECUTIVE SESSION OF July 28, 2011

Dr. Jaar motioned to approve the Executive Minutes from the July 28th session; Dr. Modi seconded the motion and the Commission unanimously voted to approve the minutes of the July 28, 2011 Executive Session.

III. REVIEW AND APPROVAL OF THE MINUTES OF THE PUBLIC SESSION OF July 28, 2011

Dr. Jaar motioned to approve the Public Minutes from the July 28th session; Dr. Kraus seconded the motion and the Commission voted unanimously to approve the minutes of the July 28, 2011 Public Session.

IV. CHAIRMAN'S REPORT

Dr. Gimenez welcomed Dr. Rayfield, a newly appointed consumer member of the Commission. Dr. Rayfield stated that he is a Board Certified Pediatrician who had been on hemodialysis for 26 years, including 5 years in center and 21 years in home hemodialysis. He noted that he was transplanted in 2007.

Dr. Gimenez reported that the Commission's Infection Control Symposium held at Shepard Pratt's Conference Center on October 4th was successful, well attended and that the Commission has received a lot of positive feedback about the symposium. He noted that hopefully the information presented would make a difference in infection control practices and outcomes at the facilities.

V. EXECUTIVE DIRECTOR'S REPORT

No report given.

VI. OLD BUSINESS

A. Medical Orders for Life Sustaining Treatments (MOLST)

Dr. Gimenez reported that community members requested that the Department allow further public comment regarding the MOLST requirement with additional time for implementation of the MOLST forms. Ms. Fagan reported that the proposed regulations were published and open for public comment for 30 days beginning on September 23rd. More information is available online at <http://dhmh.maryland.gov/marylandmolst>.

B. Pilot Study to Reduce Bloodstream Infection in Hemodialysis Outpatients

Dr. Lubomski reported that her group is currently working with 30 Davita facilities on developing guidelines for the project. She noted that the Maryland Patient Safety Center has provided funding for an additional 30 dialysis facilities to participate. The contracts are being reviewed by legal representatives from Johns Hopkins and could be available by November 1, 2011. Dr. Lubomski stated that when the contracts are approved the group would solicit the additional 30 sites for participation. They will solicit participation through the Commission and the Maryland Patient Safety Center. The group will work with facilities for one year to improve infection outcomes.

C. Patient Discharge from Physician Practice

Dr. Gimenez reported that The Maryland Board of Physician's (BOP) responded to the Commission's request regarding nephrologists who involuntarily discharge patients from their practice cause issues for the facility providing dialysis for the patient. The Board of Physician's Opinion stated that there is nothing in Maryland law that requires the physician to accept or continue to treat a patient. They advise physicians to give patients at least 30 days written notice to avoid questions of abandonment.

Discussion ensued.

Mrs. Schwartz requested that Mrs. Schulman request clarification of "developing joint solutions" as stated in the BOP's Opinion statement from their Executive Director.

D. Infection Control Practices in the Dialysis Facility – Wrap Up

Reported in the Chairman's Report

VII. NEW BUSINESS

A. Kidney Disease Program (KDP) - Stats and Budget

Ms. Manning presented the KDP statistics and budget.

- **Request to add Zortress to the KDP Formulary**

Dr. Gimenez deferred to Dr. Kraus, who is a transplant nephrologist, regarding the approval of Zortress. Representatives from Novartis discussed the advantages of Zortress over Rapamune, which is a similar drug that is already on the KDP formulary. The representatives noted that there have been no "head to head" studies of the two drugs so comparison would be difficult. They noted that Zortress has a shorter half-life than Rapamune and may be better tolerated.

Ms. Manning noted that the drug manufactures must agree to provide the KDP with rebates before the drug could be added to the formulary.

Dr. Kraus stated that he does not believe that these drugs are widely used. Discussion ensued.

The discussion was tabled until more information regarding the current total KDP expenditures for Rapamune is obtained. The cost information would assist the Commissioners in determining the possible financial impact of adding Zortress to the formulary, as it is more expensive than Rapamune.

- **Request to add Phoslyra to the KDP Formulary**

The Commissioners discussed the request to add this medication to the formulary. Dr. Gimenez noted that the drug is a liquid preparation of Phos Lo. He reported that it may be better tolerated and more useful for some patients but that the liquid preparation is more expensive than the pill form.

Discussion ensued. The group felt that only a small population would benefit from the liquid formula and that it would not be widely used. Anne Gaffney, representing FMC, noted that the use of the liquid formula might increase patient compliance with phosphorus binders, decrease the pill burden, help with fluid restriction and benefit patients who have difficulty swallowing.

The discussion was tabled until pricing information regarding KDP costs for generic Calcium Acetate, Phos Lo and Renvella could be obtained. Ms. Manning will obtain this information.

B. Emergency/Disaster Preparedness

Mrs. Adcock reported that the earthquake and hurricanes this fall have tested most of the facilities emergency procedures. She noted that plans that did not work well this fall should be re-evaluated and revised. Information from the Texas Network and the Department was provided for information. She urged the facilities to prepare the patients, re-educate them on emergency procedures and give them handouts including phone numbers to call and emergency diets. Emergency phone numbers should not be to corporate offices that would be closed during an emergency. Ms. Adcock requested that facility staff check their answering systems to assure that they are operable and contain up to date information. She noted that facility's should consider agreements with companies that provide portable generators or enter into transfer agreements with facilities that have generators that are in close in proximity to their facility.

C. Water Quality Issues Post Hurricane Irene

Dr. Gimenez reported that the Commission's regulations require each facility to contact their water supplier in writing annually. The facility's location, contact information and needs during water service disruption should be identified in the letter. A copy should be kept at the facility for reference.

Mrs. Schulman noted that the Maryland Department of the Environment would be meeting with representatives from the Department to discuss water quality concerns.

D. RPA Guidance on Providing Dialysis to Acute Kidney Injury Patients

Tracey Mooney reported on The Renal Physicians Association's published guidance on providing dialysis to Acute Kidney Injury (AKI) Patients. She noted that the CMS 2728 form requires attending physician to certify the patient has renal impairment that appears irreversible and permanent. These forms should not be completed for patients who clearly have AKI. The guidance notes that AKI is not covered under the Medicare entitlement regardless of the patient's age.

Discussion ensued. The group concluded that hospitals might have difficulty discharging AKI patients, as the payment mechanism is not clear for these patients. Facilities may enter into single payer agreements with the hospital.

E. MARC - Webex Series Professional Responsibility & Palliative Care: Case Studies on Shared Decision Making in Dialysis

Mrs. Adcock directed the guests' attention to the informational attachment regarding a webex sponsored by the Mid Atlantic Renal Coalition on November 3rd. The registration deadline is October 28th.

F. MARC Letter Regarding Facility Participation in National Healthcare Safety Network (NHSN)

Mrs. Adcock noted that CMS has proposed that in January 2012 all dialysis facilities be required to report Healthcare Associated Infections through the National Healthcare Safety Network platform. The final rule is due November 1, 2011. The Network is available to assist facilities with enrollment and preparation for the submission of the data.

G. 2012 Commission Meeting Dates

Dr. Gimenez reported that the Commission will meet on the following dates next year:

- January 26
- April 26
- July 26
- October 25.

H. Categories of Complaints

Dr. Gimenez reported that the Commission has received the following types of complaints since the last meeting:

- **Written**

- Facility complaints regarding threatening and dangerous patients
- Facility complaint regarding lack of follow up from a home patient
- Patient complaint regarding discharge from a facility
- Facility complaint regarding a disruptive patient
- Anonymous complaint regarding a facility's environment

- **Verbal**

- Facility complaints regarding threatening and dangerous patients
- Physician/Facility complaint regarding non-compliant patient
- Facility complaints regarding non-payment from patients
- Patient complaint regarding noise level and comfort of chairs at facility
- Hospital complaint regarding facility refusing to take patient back after incarceration

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

The following hospitals have requested and been granted out of state transplant approvals:

Hospital	Granted	Refused
Inova Fairfax	1	0
Christiana Hospital	1	0
Washington Hospital Center	2	0

J. Surveys (19)

The Commissioners reviewed the results of the surveys and the deficiencies.

Citations

Compliance with Federal, State and Local Laws and Regulations	0
Infection Control	10
Water and Dialysate Quality	4
Reuse of Hemodialyzers/Bloodlines	0
Physical Environment	1
Patient Rights	0
Patient Assessment	1
Patient Plan of Care	8
Care at Home	1
Quality Assessment and Performance Improvement	1
Laboratory/Affiliation Guidelines	0
Personnel Qualifications/Staffing	11
Responsibilities of the Medical Director	1
Medical Records	0
Governance	2

Dr. Gimenez commented that infection control and personnel qualification/staffing remain the top two areas of deficiency.

K. Surveys Completed (19)

The following facilities have been surveyed since the last meeting:

Davita N. Rolling Road
Davita Bertha Sirk
FMC Rockville
FMC Hagerstown
Davita Aberdeen
FMC Washington
Davita BelAir
Community Dialysis
Davita Howard County
RAI Hyattsville

Davita Chestertown
WellBound Frederick
Davita Falls Road
Western MD Hospital Dialysis
Davita Pasadena
Davita Harbor
Davita Harford Road
Davita Northwest
Manor Care Dialysis

On motion made by Commissioner Bernard Jaar, M.D. and seconded by Commissioner Kulwant Modi, M.D., the Commission, at the direction of Chairman Luis Gimenez, voted unanimously to move into closed session, pursuant to State Government Article, Section 10-508 (a)(12), to discuss confidential complaints and investigatory matters.

There being no further public business, the Open Session Meeting was adjourned at 3:37 P.M.