MARYLAND COMMISSION ON KIDNEY DISEASE

Thursday October 23, 2014 4201 Patterson Avenue Room 108-109

PUBLIC SESSION MEETING MINUTES

The Public Meeting of the Commission on Kidney Disease was held on Thursday, October 23, 2014 at 4201 Patterson Avenue. Chairman, Dr. Luis Gimenez called the meeting to order at 2:10 P.M. Commissioners' Dr. Kulwant Modi, Dr. Paul Light, Dr. Bernard Jaar, Dr. William Rayfield, Jim Stankovic and William Frederick were also present.

Commission staff present: Eva Schwartz, Executive Director and Donna Adcock, RN, Surveyor.

Commission Counsel present: Leslie Schulman, AAG

DHMH staff present: Roslyn Tyson, Coordinator and Barbara Fagan, Program Manager from DHMH's Office of Health Care Quality (OHCQ) and Carol Manning, Chief KDP.

Guests present were:

Lori Hartle, Astellas David Frushour, Davita Mary Whittaker, Medstar Kim Phillips-McNair, Davita

Chris Simon, IDF Julie Hoop, JHH

Joan Wise, IDF Terri Jenkins, Advanced Towanda Maker, NxStage Kristen Neville, DHMH

I. REVIEW AND APPROVAL OF THE MINUTES OF THE PUBLIC SESSION OF July 24, 2014

Dr. Modi motioned to approve the Public Minutes from the July 24, 2014 session. Dr. Jaar seconded the motion and the Commission voted unanimously to approve the Minutes of the July 24, 2014 Public Session.

II. REVIEW AND APPROVAL OF THE MINUTES OF THE EXECUTIVE SESSION OF July 24, 2014

Mrs. Adcock read the minutes. Dr. Modi motioned to approve the Executive Minutes from the July 24, 2014 session. Mr. Frederick seconded the motion and the Commission voted unanimously to approve the Minutes of the July 24, 2014 Executive Session.

III. CHAIRMAN'S REPORT

Dr. Gimenez discussed the threat of Ebola to our community. He described side effects which include bleeding, fluid loss and acute renal failure which may lead to the need for renal replacement therapy. Dr. Gimenez reported that there have been many discussions regarding how to consolidate care for these patients and the following regional centers have been designated: Medstar Washington Hospital Center in D.C, University of Maryland Center, and Johns Hopkins Hospital. He also requested that the facilities treating transients from the affected countries carefully screen the patients and refer them as necessary for further evaluation.

Dr. Gimenez noted that he is very pleased with the progress made in some of the citation categories this quarter.

IV. EXECUTIVE DIRECTOR'S REPORT

Mrs. Schwartz thanked everyone for coming to the meeting. She noted that infection control citations have improved but are still concerning. She requested that everyone focus on infection control practices in their facilities including, but not limited to, changing gloves, wearing personal protective equipment correctly, and increasing supervision of infection control practices.

V. OLD BUSINESS

• Draft Proposed Amendments to Chapters 01 and 02 Regulations

Dr. Gimenez directed everyone's attention to the comments received from a representative from Davita, Ms. Kasemeyer. After discussion, Dr. Modi motioned to promulgate the amendments, Dr. Light seconded the motion, and the Commission voted unanimously to promulgate amendments to Regulations .02, .03, and .11 under COMAR 10.30.01 General Regulations and Regulations .02—.04 under COMAR 10.30.02 Physical and Medical Standards; to adopt new Regulation .05 under COMAR 10.30.02 Physical and Medical Standards; and to recodify existing Regulations .05 and .06 to be Regulations .06 and .07 under COMAR 10.30.02 Physical and Medical Standards. The proposed action on regulations will be published in the Maryland Register and have an opportunity for public comment.

• Request to add Astragraf XL to the KDP Formulary

Ms. Hartle, Astellas representative reported that the cost and rebate provisions for Astragraf XL have been provided. She noted that at the University of Maryland approximately half of the transplant patients have KDP coverage and the KDP would be the payer of last resort. Discussion ensued. Dr. Gimenez noted that the addition of Astragraf XL should not have a large impact on the KDP budget. Dr. Light motioned to add Astragraf XL to the KDP formulary. Dr. Jaar seconded the motion and the Commission voted unanimously to add Astragraf XL to the KDP formulary, subject to Astellas supplying KDP with the NDC number, therapeutic class and labeler number. Ms. Hartle stated she would look into obtaining that information.

CMS Five Star Rating on Dialysis Facility Compare

Mrs. Adcock noted that this rating system is currently delayed until January 2015.

VI. NEW BUSINESS

A. Kidney Disease Program - Carol Manning

Stats and Budget

Ms. Manning presented the KDP statistics and budget.

• Discussion – Additional Coverage for OTCs and Supplements

Mrs. Schwartz queried Mrs. Manning regarding the KDP budget including the funds left over from last year and how the bills paid will impact the new fiscal year. She questioned whether a defined small number of over the counter medications or supplements could be added to the KDP formulary. Ms. Manning reported that the Department is looking into cuts to the Medical Assistance Program and warned that this may not be a good to time to request additional funding for KDP. Mrs. Schwartz noted that she may bring the additions up after the budget is passed.

Request to add Belatacept

Dr. Gimenez reported that the Commission has received a request to add Belatacept to the KDP formulary from Dr. Leeser, Chief of Kidney and Pancreas Transplantation at the University of Maryland. He noted that the Commission would need more information including the cost and the number of patients being prescribed the drug in order to consider the request. Dr. Gimenez and Mrs. Schwartz will respond to Dr. Leeser in writing and will request additional information.

B. Network Update

Mrs. Adcock reviewed the submitted report. She noted that the report includes the number of Network grievances, involuntary discharges, failure to place, Health Care Associated Infection Learning and Action Network, and the new website for Dialysis Facility Compare.

Mrs. Schwartz reminded everyone to keep the Commission in the loop when considering whether to involuntarily discharge a patient. Commission regulations require that prior to discharge documentation should be sent to the Commission's office for review and approval.

C. UNOS Ruling – Kidney Transplant Wait List

Julie Hoop, Laboratory Manager for the Immunogenic Laboratory at the Johns Hopkins School of Medicine, reported that in November 2013 UNOS changed the kidney allocation system. The new system will be in effect December 4, 2014. She noted that the goal is to increase the number of life years after the transplant. Ms. Hoop reported that, under the new rules, the wait time for dialysis patients will be determined by the patient's dialysis start date. She presented the details for recipient and donor scoring under the new system and then discussion ensued.

D. Request for Nominations to Serve on the Commission

Mrs. Schwartz reported that three members of the Commission's terms are expiring; one physician, one healthcare provider and one renal administrator. She requested input from everyone regarding new appointments. She noted that anyone interested in serving should send her an email.

E. Policy for Facilities Responding to Survey Reports

Mrs. Schwartz reported that she is very concerned with how facilities address monitoring and compliance matters in corrective action plans. She noted that most facilities respond by designating their facility administrator as the person responsible for compliance, rather than specifying the person(s) who will monitor for compliance. Mrs. Schwartz requested that the facilities provide a more specific delineation of persons responsible for specific action items.

F. Commission Meetings for 2015:

Dr. Gimenez reported that the scheduled Commission meeting dates for 2015 will be:

- January 22
- April 23
- July 23
- October 22

G. Citation Free Surveys

Dr. Gimenez commended the following facilities for achieving citation free surveys:

- Johns Hopkins Harriet Lane Kidney Center
- USRC Prince Frederick
- Davita Washington County
- FMC Hagerstown

H. Categories of Complaints

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

Written

- Facility complaint regarding patient who refuses certain aspects of her prescribed care
- Facility complaint regarding a threatening/dangerous patient

Verbal

- Hospital complaint regarding difficulty placing a bariatric patient
- Facility complaint regarding KDP issue
- Complaint regarding gnats in a facility

Commission Approval/Disapproval for KDP Out of State Transplant Reimbursement Dr. Gimenez noted that in the past quarter, the following hospitals have requested and been granted out of state transplant approvals:

Hospital	Granted	Refused
Washington Hospital Center	1	0
Georgetown University Hospital	1	0

J. Surveys

For informational purposes, the Commission shared the results of their Survey Findings Deficiency Report for the past quarter. Dr. Gimenez noted improvement in the number of Infection Control and Personnel Qualification citations which were both 17 last quarter.

Surveys (22) Citations

Surveys (22)	Citations
Compliance with Federal, State and Local	0
Laws and Regulations	
Infection Control	10
Water and Dialysate Quality	3
Reuse of Hemodialyzers/Bloodlines	2
Physical Environment	4
Patient Rights	0
Patient Assessment	0
Patient Plans of Care	1
Care at Home	1
Quality Assessment and Performance	0
Improvement	
Laboratory/Affiliation Guidelines	0
Personnel Qualifications/Staffing	13
Responsibilities of the Medical Director	1
Medical Records	2
Governance	2

K. Surveys Completed (22)

The following facilities have been surveyed since the last meeting:

Davita Carroll County IDF Parkview Davita Chestertown FMC Odenton

Davita Rockville JHH Harriet Lane Kidney Center

FMC Hyattsville

FMC Greater Baltimore

Davita Catonsville

USRC Prince Frederick

Davita Seton Drive

Good Samaritan – Cromwell

FMC Dundalk

Davita Greenspring

FMC Robinwood

FMC Hagerstown Davita – Washington County
Good Samaritan Outpatient Dialysis
Union Memorial Outpatient Dialysis

There being no further public business, upon motion made by Commissioner Modi and seconded by Commissioner Frederick, the Commission unanimously voted to adjourn the Public Session 3:30 pm.