

MARYLAND COMMISSION ON KIDNEY DISEASE
Thursday October 24, 2013
4201 Patterson Avenue
Room 108-109

MINUTES OF THE PUBLIC SESSION

The Public Meeting of the Commission on Kidney Disease was held on Thursday, October 24, 2013 at 4201 Patterson Avenue. Chairman, Dr. Luis Gimenez called the meeting to order at 2:08 P.M. In attendance, in addition to Chairman Gimenez, were Commissioners William Frederick, RN, Bernard Jaar, M.D., Edward Kraus, M.D., Paul Light, M.D., Belinda Lindsay, LGSW., Kulwant Modi, M.D., William Rayfield, M.D., Jim Stankovic, and Matthew Weir, M.D.

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

Commission Counsel present: Leslie Schulman, AAG

DHMH staff present: June Bowman, RN, Surveyor and Barbara Fagan, Program Manager from Office of Health Care Quality(OHCQ), and Carol Manning, Chief from Kidney Disease Program (KDP).

Guests present were:

Christine Wright, WMHC

Ivy Simmons, Good Samaritan

Eric Ruffcorn, DSI

Tezhina Bradley, Davita

Jodi Smith, DSI

Laura Conroy, JHH

Zarita Pearson, Advanced

Maria Tanzi-Samaan, Astrellas Pharma

Lori Hartle, Astrellas Pharma

Mary Whittaker, Good Samaritan

Pam Earll, Davita

Elaine Boyd, Davita

June O'Donnell, FMC

Chris Simon, IDF

Johny Niles, Holy Cross

**I. REVIEW AND APPROVAL OF THE MINUTES OF THE PUBLIC SESSION OF
July 25, 2013**

Dr. Weir motioned to approve the Public Minutes from the July 25th session; Dr. Modi seconded the motion and the Commission voted unanimously to approve the Minutes of the July 25, 2013 Public Session.

II. CHAIRMAN'S REPORT

Dr. Gimenez discussed the importance of patient nutrition in dialysis. He noted that some dialysis organizations are supplying patients with high protein supplements during dialysis treatments. Dr. Gimenez reported that in the future CMS may link nutrition levels to reimbursement. He noted that nutrition levels are strong predictors of patient morbidity and mortality.

Dr. Gimenez also reported that two of the leading categories for facility deficiency citations are infection control and personnel qualifications/staffing. He urged facilities to focus on patient quality by having their staffs adhere to policies and procedures for infection control, and to have their nurses assure that patients are receiving dialysis treatments in accordance with physician orders. Dr. Gimenez noted that facility nurses should be performing order rounds within the first 15-20 minutes of patient treatments.

Dr. Kraus voiced his concerns regarding the absence of Governance citations, and then discussed the importance of accountability of the Governing Body.

III. EXECUTIVE DIRECTOR'S REPORT

Mrs. Schwartz thanked everyone for coming to the meeting. She reiterated her concerns regarding the ongoing deficiency citations associated with infection control, personnel qualifications/staffing, governance, medical director responsibilities and accountability categories.

Dr. Gimenez also noted that the medical director is one of several nephrologists in the facility and that the medical director may not be aware of an issue or problem. However, it is the role of the medical director to provide leadership necessary to assure quality of care, as well as being held accountable for matters brought to the medical director's attention. Quality of care is a team effort.

Discussion ensued. Mrs. Schwartz suggested that the Commission consider writing a letter to each of the facility medical directors for the purpose of reminding them of their regulatory responsibilities vis a vis deficiencies cited by the surveyor in facilities with repetitive violations. The Chairman decided to table the Executive Director's recommendation at this time.

IV. NEW BUSINESS

A. Kidney Disease Program - Carol Manning

- **Stats and Budget**

Ms. Manning presented the KDP statistics and budget.

The Commission requested that in the future, Ms. Manning include the number of transplant patients in the report.

- **Request to add Astagraf XL (Tacrolimus extended-release capsules) to the KDP Formulary**

Maria Tanzi-Samaan, Clinical Pharmacist, Astellas Pharma US, presented clinical information on Astragraf XL and distinguished it from Prograf, the KDP formulary medication already approved. Both prescription medications are used with other medicines to help prevent organ rejection in people who have had kidney transplants. However, Ms. Tanzi-Samaan reported that Astragraf XL had a higher morbidity for women and its safety and efficacy for pediatrics transplant recipients has not been established.

Led by Dr. Kraus, an extensive discussion ensued. Upon questioning by the Commission, Ms. Hartel (Astellas representative) reported that Astragraf XL is not currently prescribed in Maryland.

The Commission moved to undertake further discussion in an Executive Session because of the request by Astellas Pharma US to retain confidentiality about their proprietary and financial information on the drug. The Minutes of the Executive Session will reflect the Commission's action, if any.

- **ICD 10 Code Review**

The physician members were distributed ICD9 codes with their corresponding ICD 10 code equivalents that are currently in use for KDP reimbursement. The codes will be reviewed independently by the Commissioners and returned with their comments.

B. Network Report

Mrs. Adcock directed the guests' attention to the Attachment C, included with the agenda, that outlines the project updates for Network 5.

C. ANNA/Commission Conference Rescheduled – January 28, 2014

Mrs. Adcock reported that the conference date for the American Nephrology Nurses' Association (ANNA) has been rescheduled due to low enrollment. She encouraged facilities to have staff attend and noted that the conference is a good opportunity for CEU credit, education and networking.

D. OHCQ Report – Barbara Fagan

Mrs. Fagan reviewed the CMS survey and certification memo, dated July 12, 2013 (Attachment D), concerning "Compliance with the Life Safety Code (LSC) in ESRD Facilities." This requirement affects those ESRD facilities that do not exit to the outside at grade level from the patient treatment area and those facilities that are located adjacent to high hazard occupancies. All ESED facilities are still required to comply with State and local fire codes and other safety standards. To claim an exemption to the National Fire

Protection Association Life Safety Code requirements, ESRD providers may submit an attestation to OHCQ if they are not located adjacent to high hazard occupancies and they do not provide exits at grade level from the patient treatment area level. Facilities that fail to do so will be considered non-exempt and surveyed for compliance. Mrs. Fagan also noted that OHCQ will send out a letter to all facilities summarizing the LSC requirements.

E. Mobility Certification Issues

Mrs. Schwartz brought to the Commission's attention that she has received complaints from the renal community concerning the adverse consequences that a change in Maryland Transportation Authority's (MTA) Mobility certification policy has had on patients in need of mobility services to dialysis treatment. She had requested a Mobility representative to attend today's public session, but was unable to persuade a representative to attend.

According to Ms. June O'Donnell, the representative for the Baltimore Council of Nephrology Social Workers, when the presumptive certification period ended the group was assured that patients would be able to get a Mobility certification appointment in 2 to 3 days. She noted that in the beginning they were able to acquire the appointment in that time frame but as of October 23, 2013, a patient requesting an appointment would have to wait until December 16th (almost 7 weeks) for their appointment. The patient would not have transportation in the interim. The group discussed the hardships this delay was causing patients, specifically how it hampers the patient's access to care.

Ms. Bradley, a Davita representative, also noted that patients who have Mobility certification are losing services.

The Commission requested further information from the social work group, including any specific examples and/or data of adverse consequences that have resulted from MTA's change in certification policy. When this information is received, Ms. Schwartz and the Commission will draft a letter to DHMH-Secretary Sharfstein with a cc to MTA-Secretary Smith outlining the adverse effects this new process has had on the health and safety, and access to care of the State's most vulnerable patient population.

F. Commission Committees

Mrs. Schwartz requested that Commissioners volunteer for Commission committees.

- **Physical and Medical Standards**
Volunteers: Drs. Gimenez, Jaar and Rayfield
- **Complaints**
Volunteers: Mr. Frederick, Ms. Lindsay, Drs. Kraus, Light and Weir
- **KDP Drug Formulary**
Volunteers: Drs. Modi and Kraus, and Ms. Sylvester

G. 2014 Commission Meeting Dates

Mrs. Adcock announced the following Commission public meeting dates for 2014:

- January 23, **April 17**, July 24 and October 23
- She noted that all but the April 17th date are the 4th Thursday of the month.

H. Citation Free Surveys

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

- Western MD Regional Dialysis
- IDF Allegany

I. New Facility

Dr. Gimenez reported the following newly certified facility:

- FMC – Odenton (August 22, 2013)

J. Closed Facility

Dr. Gimenez reported the following facility has notified the Commission of its closure:

- Davita Selim Downtown (July 24, 2013)

Patients from this facility were transferred to the newly relocated and expanded Davita Silver Spring facility.

K. Categories of Complaints

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

- Written
 - Facility complaint regarding patient behavior
- Verbal
 - Patient complaint regarding physician
 - Patient complaints regarding care at facilities (3)

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

Hospital	Granted	Refused
Georgetown University Hospital	2	0
Washington Hospital Center	6	0

The Commissioners discussed the request for out of state transplant approval from Rochester University Medical Center in New York. The Commissioners approved the request but requested that the transplant center be informed of KDP reimbursement policies.

M. Surveys (23)

For informational purposes, the Commission shared the results of their Survey Findings Deficiency Report for the past quarter. Dr. Gimenez noted that infection control and personnel qualifications/staffing categories continue to be the most cited areas of concern.

Citations

Compliance with Federal, State and Local Laws and Regulations	0
Infection Control	15
Water and Dialysate Quality	5
Reuse of Hemodialyzers/Bloodlines	0
Physical Environment	3
Patient Rights	0
Patient Assessment	1
Patient Plans of Care	5
Care at Home	2
Quality Assessment and Performance Improvement	3
Laboratory/Affiliation Guidelines	0
Personnel Qualifications/Staffing	16
Responsibilities of the Medical Director	0
Medical Records	1
Governance	2

N. Surveys Completed (23)

The following facilities have been surveyed since the last meeting:

- | | |
|--------------------|------------------------------|
| Davita Frederick | Bon Secours Dialysis |
| FMC Leonardtown | FMC LaPlata |
| Davita Catocin | Davita Mercy |
| Davita Largo | FMC Baltimore |
| Charing Cross | Davita Silver Spring |
| Davita Catonsville | FMC Springbrook |
| DSI Silver Hill | FMC Prince George |
| IDF Allegany | Western MD Regional Dialysis |
| IDF Garrett | JB Zachary |
| Davita Glen Burnie | Davita Glen Burnie Home |
| Davita Cambridge | Advanced Easton |
| Davita Easton | |

There being no further public business, upon motion made by Commissioner Jim Stankovic and seconded by William Frederick, the Commission unanimously voted to adjourn the Public Session 3:40 pm and move into Executive Session.