

**Renal Disease Advisory Committee (RDAC) Meeting Minutes
October 24, 2008**

**Advisory Committee & Subcommittee
Members Present:**

**Robin Asick, MSW
Ruth Jeannerat R.N.
Bernard McGovern, R. Ph.
Dr. Lleras Samuels
Dr. Robert Gradzki
Marcy Saunders**

Members Absent:

**Denny Ebright, MSW
Dr. Kevin Ho
Dr. Akhtar Khan
Dr. Jose Bernardo
Tina Scipio, Pharm.D.**

Formulary:

Bernard McGovern, R.Ph. (chair)
Judith Dooley, R.Ph
Ruth Jeannerat R.N.
Lleras A. Samuels, M.D.
Tina Scipio, Pharm.D.

Strategic Planning:

Dennis Ebright, MSW
Bernard McGovern, R.Ph.
Robin Asick, MSW
Ruth Jeannerat, R.N.

Patient Services:

Robin Asick, MSW (chair)
Marcy Saunders
Cindy Paret
Jose F. Bernardo, M.D.

Medical Services:

Ruth Jeannerat, R.N. (chair)
Robert Gradzki, M.D.
Lleras Samuels, M.D.
Akhtar Khan, M.D.
Gail Flannery
Kevin Ho, M.D.

Department of Health Staff:

Janice Kopelman, Deputy Secretary for
Health Promotion and Disease
Prevention

Melita Jordan, Director
Bureau of Family Health

Carolyn Cass, Director
Division of Child & Adult Health Services

Kelly Holland, Public Health Program
Manager
Division of Child & Adult Health Services

Luann Cartwright, Renal Program
Administrator
Division of Child & Adult Health Services

Department of Aging:

No staff in attendance

First Health Services Staff:

Judith Dooley, R. Ph.

Public:

Lisa Glus, Genzyme
Tom Cella, Genzyme
Jen Mysel, Genzyme
Joanne Hollis, FMC
Barbara Henry,
R.N./BSN/Ed.Coordinator
Ben DeBrunner, DeBrunner &
Assoc./Baxter Healthcare
Mindy Soles, Pinnacle Health Hospital
Cindy Lynch Paret, RD, LPN/NEPA,
FMS

WELCOME AND INTRODUCTIONS

The meeting was called to order by Ms. Asick at 10:10 a.m. Introductions and affiliations of those present were made.

Deputy Secretary Kopelman announced Everette James as new acting Secretary of Health

Ms. Asick questioned if anyone from the RDAC joined the Pennsylvania Diabetes Action Partnership, and if not, she offered to become a member. No RDAC members indicated they had joined.

APPROVAL OF PRIOR MINUTES

There were no changes to the minutes from the July 25, 2008 RDAC meeting. Minutes were approved.

DEPARTMENTAL/BUREAU UPDATES

Online Application

At this time, the Department is not moving forward with the on-line application due to the cost. This will not be a hindrance to the patients applying to the Chronic Renal Disease Program (CRDP) or staff at centers who assist with the applications. Applications will still be able to be printed from the CRDP website.

Transportation

The new process for checking Medical Assistance Transportation Program (MATP) eligibility was explained. When an application is received for the Chronic Renal Disease Transportation Program, the application processors will check if the cardholder is eligible for the MATP. If the cardholder is MA eligible his/her application will be denied and the cardholder will be sent a letter advising him/her they should be using the MATP for their transportation needs. In addition, the invoice processors will be spot checking transportation invoices to see if any invoices are submitted for individuals who should be utilizing the MATP. If a cardholder should be using MATP instead of the renal transportation program the cardholder and provider will be sent a letter advising them they should be utilizing MATP. The cardholder will be given 60 days to apply for and start using MATP. After 60 days the cardholder will be removed from the Chronic Renal Disease Transportation Program. The RDAC felt the process was good and the timeframes were fair.

Ms. Asick suggested conducting audits on rides to make sure the Chronic Renal Disease Transportation Program is only paying for rides that were actually provided. Dr. Samuels agreed

that audits should be done, especially in Philadelphia because it is his experience that ambulance companies may be forging physician signatures. The RDAC agreed audits should be done but stated it is not realistic to ask physicians if they signed a prescription requiring an ambulance for transportation.

It was suggested the transportation application have a space added to show how long the ambulance transportation will be medically necessary. It was also suggested that this be audited to verify ambulance transportation is not being used longer than prescribed. DOH staff will find out how many patients/claims are being submitted for ambulance rides and report that to the Patient Services Subcommittee. The Patient Services Subcommittee will re-visit the transportation application.

Age 21/Medical Assistance

A logic table, which provides clarification on how First Health reviews applications for patients 21 and under, was provided to the RDAC. See attachment 1.

Social Security

The Department's policy is that the CRDP be consistent with PACE (PACE counts Social Security as income) and in order to be under the same umbrella, the CRDP will count social security as income. Ms. Jordan stated she will ask Mr. Snedden to attend our next meeting to discuss this issue. Ms. Asick shared the Pennsylvania Bulletin that shows tax forms are required and if they are not available, other documentation must be submitted to determine eligibility for the CRDP. Ms. Jordan stated if the RDAC has different recommendations, they can vote to put it through the formal recommendation process.

Diagnosis Codes

The diagnosis codes are being reviewed by the Medical Services Subcommittee. The RDAC asked if the codes used are for primary diagnosis or secondary causes. Ms. Jeannerat brought the Federal list along which is used by Medicare and asked why the Federal list and the CRDP list do not match. It was stated this is why the Department started looking at the diagnosis codes. As discussed at previous meetings, the list used by CRDP is more generous than the Federal list. Ms. Asick state she did not feel this was an issue, since the centers fill out the application and most of them are using the Federal list. Ms. Dooley indicated there are two lists, a primary diagnosis list and a secondary diagnosis list. Ms. Dooley will provide the lists used by First Health and a meeting between First Health Staff, DOH staff and the Medical Services Subcommittee will be scheduled. A vote was taken and the RDAC voted to use the Medicare list. See attachment 2.

Other

Appeal Process – Ms. Asick asked for an overview of the appeal process. Ms. Cass explained that the appeal process is a 3 tier process, where First Health receives the first and second appeals. The third level appeal is reviewed by the DOH. (The appeal process was questioned by Ms. Asick due to an issue where an individual was told not to appeal the denial, it was not known at the time of the meeting who he had called). Ms. Cass will follow up with the social worker. Ms. Jordan stated that monthly roundtable meetings are held with the Department of Health, Department of Aging and First Health, and if these issues are brought to the Department's attention they can be discussed at these meetings.

Budget

Ms. Jordan stated that she had advised Ms. Matio that the RDAC would like her to come to the meetings on occasion.

For State Fiscal Year (SFY) 2008-09, the budget is \$5.5 million. Ms Jordan stated she knows it is a challenge to continue providing the same services. Decisions will have to be made on how to provide the same level of services with the reduced budget amounts. Prescription for PA addresses chronic conditions such as hypertension and diabetes which will help prevent getting

into the point where individuals need the CRDP. The 2009-2010 budget contains the same funding as 2008-2009. A request for additional funding for 2009-2010 was submitted; however, it will be a while until a final decision is received.

Ms. Dooley stated that \$1.38 million was spent in pharmaceuticals in the 1st quarter of this fiscal year (does not include rebates). This represents a 31.9% increase from the same quarter in 2007. Ms. Dooley also stated the CRDP only receives rebates if the CRDP is the primary payer and the rebates vary, and are not consistent or reliable from year to year. Ms. Dooley is doing research to see what is driving up the increase in utilization/costs. It was stated that an analysis should be done to look at how Part D affects the increased utilization/costs. Ms. Dooley stated all but 1,000 cardholders use Part D (4,500 cardholders have a Part D plan). Mr. McGovern asked could the difference be that Part D coverage begins in January and the state year begins in July, when people are already into the donut hole of Part D coverage. Ms. Dooley looked back to 2006 and everything has increased. She also has been reviewing the formulary and while the overall cost per claim has not increased due to utilization, the overall costs have increased. The CRDP is looking to the RDAC for suggestions to keep the budget in line and would like suggestions in the next two weeks. Ms. Asick stated she is not comfortable making a recommendation until it can be determined what is driving the increases. Members responded that in the past they have eliminated services, which they did not want to happen as it increases other costs such as hospitalization costs. Mr. McGovern didn't feel there were many options that were going to be effective other than changing eligibility guidelines, which the RDAC is not advocating. The Department stated they would provide the strategic planning subcommittee with information on budget expenditures for the past two fiscal years. The RDAC asked how likely is the possibility of additional funding if the community lobbies for more money. Ms. Cass outlined a process they could follow to discuss their opinions with members of the legislature. Ms. Cass shared an opinion from the Office of Legal Counsel related to activities the RDAC may engage in so far as "lobbying". She read the following statement: "Members of the RDAC are not prohibited from political activities such as contacting their representatives to advocate their point of view and identify themselves as members of the RDAC. The RDAC Chair may wish to sign any letters from the RDAC collectively and/or make any other desired communications to representatives on behalf of the entire RDAC." Ms. Asick handed out a document showing the Governor's contact information. A call will be scheduled with the strategic planning subcommittee for mid to late November to discuss the data.

Website

The CRDP website has been updated. Ms. Asick noted there were a few errors on the RDAC members' information. The corrections were noted and will be made by the Department.

Dr. Ho's Presentation

Dr. Ho was not able to attend the meeting, however, it was stated that Network 4 is having a conference in Hershey in May. They would like to have a session on Chronic Kidney Disease and Network 4 would like someone from the CRDP/RDAC to work with them in the development of the session. The session would be an educational day for family physicians. We could also work through the American Academy of Pediatrics (AAP) thus encouraging family practices to be involved in the training. It was agreed that the Department will work with Network 4 on this training session. It was suggested the CRDP send "Save the Date" cards as soon as possible. The Committee again discussed the possibility of having multi-disciplinary symposiums across the state. Also, the RDAC suggested getting the Governor to write a proclamation declaring a National Kidney Day. Ms. Saunders suggested having a "community day" at dialysis centers to educate people about kidney disease. Ms. Jeannerat said this is what the National Kidney Foundation does under their "KEEP" Program. This could also be done at civic centers, etc. Speakers and participants could be recruited from several disciplines including Chronic Kidney Disease, Diabetes, and Cardio-vascular specialties.

2009 Meeting Dates

A calendar was provided to RDAC members and the 2009 meeting dates will be January 23, April 24, July 24, and October 23 in room 327 of the Health & Welfare Building. The time will be 10 am to 2 pm. Members are asked to please let Ms. Cartwright know if they will not be attending.

Election of Chair

There was a call for nominations for a Committee Chair. Robin Asick and Dr. Samuels were nominated. It was agreed that since all committee members were not present, biographies would be sent to the committee members via email with a week for additional nominations to be submitted. After the nominations are received, the Department will put out a vote by e-mail. It was stated if RDAC members had a new biography they wanted to use, it should be sent to Ms. Cartwright.

RDAC SUBCOMMITTEE REPORTS

Patient Services Subcommittee

Ms. Asick asked if the social workers had been sent a flyer letting them know the Nutritional Supplement Toolkit was available on the Department's website. The Department stated the flyer had not been sent at this time as they are still working on compiling a current list of social workers. The RDAC suggested the Department check the ESRD website for a list of social workers. The RDAC asked that the toolkit also be sent to the nutritionists. The subcommittee asked if they could recommend additional supplements. Ms. Dooley stated this is already done through the formulary subcommittee.

Medical Services Subcommittee

The Sub-Committee is working on the services manual. Ms. Jeannerat found the fee schedule has procedure codes that are no longer valid. She asked if a formal recommendation is needed to correct the codes. The Department stated the invalid codes can be corrected. A formal recommendation is not needed.

Strategic Planning Subcommittee

No report.

Formulary Subcommittee

The process for submitting a recommendation was discussed. It was stated that after the RDAC voted to make a recommendation, the Department would write the recommendation and submit it through the appropriate channels. The RDAC would like to review current supplements and see if some of the items can be traded to have different types of supplements (i.e. bars, cookies) on the fee schedule.

The subcommittee recommended Renagel® be replaced with Renvela on the CRDP medical exception process with the same criteria as Renagel®, a calcium phosphate product greater than or equal to 70. The subcommittee would also like to send a letter to physicians informing them that the CRDP recognizes the KDOQI guideline for calcium phosphate being 55, but that the CRDP needs to be fiscally responsible. It was stated a vote and formal recommendation was not required to send the letter. The letter will be sent to the RDAC for review.

The clinical effectiveness of Sensipar® in lowering the parathyroid hormone level as well as the calcium level was discussed. Sensipar® can lower the calcium levels to a point where the patient can actually use a less expensive phosphate binder, such as PhosLo®. It was suggested a letter be sent to physicians regarding the use of Sensipar® as first line therapy with the addition of a phosphate binder based on the calcium level after Sensipar® therapy has been initiated. A vote is not necessary, and the letter can be drafted. The committee will review the letter prior to mailing.

Ms. Dooley also provided information on Actos® vs Avandia®: Due to recent concerns in medical literature regarding cardiovascular complications noted with the use of thiazolidinediones, in particular the brand name product Avandia® in contrast to the only other agents in this class, Actos®, a step therapy approach to the use of these agents is proposed for CRDP. The steps are as follows:

1. Prior to as yet to be determined start date all CRDP patients currently using Actos® or Avandia® will be pre-approved to continue this therapy.
2. Following that start date, new prescriptions for Avandia® or Actos® will be denied if the patient has not currently maximized the use of either Metformin, a sulfonylurea or insulin as per the latest American Diabetes Association guidelines. If the patient has tried one of these agents first, only prescriptions for Actos® will be approved for reimbursement. New prescriptions for Avandia® will be denied with the message that the preferred thiazolidinedione for use in the CRDP program is Actos® due to cardiovascular side effect concerns.

A motion was made by Ms. Jeannerat to replace Renagel with Renvela, replace Actose with Avandia; Ms. Saunders seconded the motion; approved as all in favor. Next steps are to prepare recommendations for the Secretary, from the Division of Child and Adult Health Services to the Deputy Secretary and budget office. Ms. Cass stated the recommendations will probably not be acted on until the budget projections are completed.

FORMULARY UTILIZATION REPORT

Ms. Dooley distributed the CRDP utilization report for the third quarter of 2008.

PUBLIC COMMENTS

The Department was thanked for making the CRDP website more user friendly. Mr. DeBrunner requested that RDAC meeting minutes be posted to the website.

NEXT MEETING

Scheduled for January 24, 2009 at 10:00 AM, Health and Welfare Building, Room 327.

Adjournment

**FIRST HEALTH PROCESS TO DETERMINE ELIGIBILITY FOR UNDER 21'S
(Both new enrollments and renewal applications)**

IF:

Applicant is under 21, receiving dialysis, lives with parents and parents' claims applicant on their income tax return as a dependent

THEN:

First Health requests proof of MA denial (letter from OMAP that also explains reason for denial) before processing, count total number of dependents on tax form for exemptions and obtain documents to substantiate all incomes.

If the applicant does not respond within 30 days, the application is denied and forwarded to DOH for referral to the MA Program.

IF:

A. Applicant is under 21, receiving dialysis, lives with parents but parents do not claim applicant on their income tax return as a dependent, and doesn't include copy of MA card, MA denial, or discontinuance notice

THEN:

First Health requests proof of MA denial before processing. If applicant does not respond within 30 days, the application is denied and forwarded to DOH for referral to MA Program.

B. Applicant is under 21, receiving dialysis, does not live with parents and does not include a copy of the MA card, denial letter or discontinuance notice

First Health requests proof of MA denial before processing. If applicant does not respond within 30 days, the application is denied and forwarded to DOH for referral to MA Program.

IF:

Applicant is under 21, a transplant patient, lives with parents and parents claim applicant as a dependent on their income tax return

THEN:

Count total number of dependent on tax form for exemptions and obtain documents to substantiate incomes of applicant and parents.

IF:

Applicant is under 18, a transplant patient, lives with parents but parents do not claim applicant as a dependent on their tax return

THEN:

Count one exemption, obtain documentation of "emancipated minor" and income documents for applicant only. If applicant does not respond within 30 days, the application is denied and forwarded to DOH for referral to MA Program.

IF:

Applicant is age 18-21, a transplant patient, lives with parents but parents do not claim applicant as a dependent on their tax return

THEN:

Count as one exemption and obtain income documents for applicant only.

CHRONIC RENAL DISEASE PROGRAM LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary.

ICD-9 NARRATIVE

DIABETES

- 25040 Diabetes with renal manifestations Type 2
- 25041 Diabetes with renal manifestations Type 1

GLOMERULONEPHRITIS

- 5829 Glomerulonephritis (GN)
(histologically not examined)
- 5821 Focal glomerulosclerosis, focal sclerosing GN
- 5831 Membranous nephropathy
- 58321 Membranoproliferative GN type 1, diffuse MPGN
- 58322 Dense deposit disease, MPGN type 2
- 58381 IgA nephropathy, Berger's disease
(proven by immunofluorescence)
- 58382 IgM nephropathy (proven by immunofluorescence)
- 5834 With lesion of rapidly progressive GN
- 5800 Post infectious GN, SBE
- 5820 Other proliferative GN

SECONDARY GN/VASCULITIS

- 7100 Lupus erythematosus, (SLE nephritis)
- 2870 Henoch-Schonlein syndrome
- 7101 Scleroderma
- 28311 Hemolytic uremic syndrome
- 4460 Polyarteritis
- 4464 Wegener's granulomatosis
- 58392 Nephropathy due to heroin abuse and related drugs
- 44620 Other Vasculitis and its derivatives
- 44621 Goodpasture's syndrome
- 58391 Secondary GN, other

INTERSTITIAL NEPHRITIS/PYELONEPHRITIS

- 9659 Analgesic abuse
- 5830 Radiation nephritis
- 9849 Lead nephropathy
- 5909 Nephropathy caused by other agents
- 27410 Gouty nephropathy
- 5920 Nephrolithiasis
- 5996 Acquired obstructive uropathy
- 5900 Chronic pyelonephritis, reflux nephropathy
- 58389 Chronic interstitial nephritis
- 58089 Acute interstitial nephritis
- 5929 Urolithiasis
- 27549 Other disorders of calcium metabolism

HYPERTENSION/LARGE VESSEL DISEASE

- 40391 Unspecified with renal failure
- 4401 Renal artery stenosis
- 59381 Renal artery occlusion
- 59383 Cholesterol emboli, renal emboli

ICD-9 NARRATIVE

CYSTIC/HEREDITARY/CONGENITAL DISEASES

- 75313 Polycystic kidneys, adult type (dominant)
- 75314 Polycystic, infantile (recessive)
- 75316 Medullary cystic disease, including nephronophthisis
- 7595 Tuberosus sclerosis
- 7598 Hereditary nephritis, Alport's syndrome
- 2700 Cystinosis
- 2718 Primary oxalosis
- 2727 Fabry's disease
- 7533 Congenital nephrotic syndrome
- 5839 Drash syndrome, mesangial sclerosis
- 75321 Congenital obstruction of ureteropelvic junction
- 75322 Congenital obstruction of ureterovesical junction
- 75329 Other Congenital obstructive uropathy
- 7530 Renal hypoplasia, dysplasia, oligonephronia
- 75671 Prune belly syndrome
- 75989 Other (congenital malformation syndromes)

NEOPLASMS/TUMORS

- 1890 Renal tumor (malignant)
- 1899 Urinary tract tumor (malignant)
- 2230 Renal tumor (benign)
- 2239 Urinary tract tumor (benign)
- 23951 Renal tumor (unspecified)
- 23952 Urinary tract tumor (unspecified)
- 20280 Lymphoma of kidneys
- 20300 Multiple myeloma
- 20308 Other immuno proliferative neoplasms
(including light chain nephropathy)
- 2773 Amyloidosis
- 99680 Complications of transplanted organ unspecified
- 99681 Complications of transplanted kidney
- 99682 Complications of transplanted liver
- 99683 Complications of transplanted heart
- 99684 Complications of transplanted lung
- 99685 Complications of transplanted bone marrow
- 99686 Complications of transplanted pancreas
- 99687 Complications of transplanted intestine
- 99689 Complications of other specified transplanted organ

MISCELLANEOUS CONDITIONS

- 28260 Sickle cell disease/anemia
- 28269 Sickle cell trait and other sickle cell (HbS/Hb other)
- 64620 Post partum renal failure
- 042 AIDS nephropathy
- 8660 Traumatic or surgical loss of kidney(s)
- 5724 Hepatorenal syndrome
- 5836 Tubular necrosis (no recovery)
- 59389 Other renal disorders
- 7999 Etiology uncertain