Conditions of Coverage and Draft Interpretive Guidelines - What Nephrology RD’s Need to Know

September 18, 2008
Introduction, Background and Rationale for Change

Maria Karalis, MBA, RD, LDN
CRN Chair
Disclaimers

This presentation was created by the NKF Council on Renal Nutrition (CRN) to help inform and educate the dialysis community about the RD and nutritional aspects of the new Conditions of Coverage (CfC). The implementation and interpretation of the new CfC is anticipated to be a dynamic process. This presentation reflects the information available as of September 13, 2008.
Disclaimers

*Information provided by CRN is not intended to establish or replace policies and procedures provided by dialysis providers to their facilities.*

*Please check with your dialysis facility management before implementing any information provided here.*
Webinar Objectives

1. Review background & rationale for changes to CfC
2. Discuss major changes impacting the RD from the current to the new regulations
   - RD personnel requirements
   - CMPA
   - QAPI
3. Describe the interdisciplinary plan of care, which follows the CMPA
4. Apply ADA’s Nutrition Care Process (NCP) model and standardized language (SL) to the plan of care
   - NCP and SL is not mandated in CfC
5. “Just the facts”
   - FAQ Document pending to further provide guidance and implementation suggestions
History

- Since 1976, same conditions for coverage for dialysis facilities (CMS rules and regulations that dictate the practice of dialysis)
- 1970’s-1990’s: Technical Updates
- 1994: Community forum meeting convened to begin revisions to CfC
- 2005- Proposed updates to dialysis and transplant conditions
History

• 2007- CMS Community Forum about interpretive guidelines for the proposed CfC
• April 15, 2008 - New CfC published by the Department of Health and Human Services, Centers for Medicare & Medicaid Services
• Effective October 14, 2008 in every US and territory dialysis center
Reasons for Change to CfC

1. Move toward a *patient outcome-based system* that focuses on quality assessment & performance improvement
   - Needed to drive improvements in care
   - Critical if CMS moves to value-based pricing or P4P
   - Necessary as CMS moves to bundled reimbursement for ESRD care

2. Incorporation of the most recent medical and scientific guidelines and recommendations
   - NKF K/DOQI Guidelines
   - CDC Guidelines
   - Association for the Advancement of Medical Instrumentation (AAMI)
Reasons for Change to CfC

3. Modernize regulations and improve the availability of quality-of-care information
   - Changes in technology
     - Water treatment more complex
     - Changes in dialysis equipment
   - Differences in care delivery
     - 1970’s: few technicians; regulations were silent
     - 2008: technicians provide most direct care; public is demanding regulation
   - Electronic data submission required to keep pace with growing ESRD population & need for current data

4. To promote transparency
New Rules Posted April 15, 2008

Final Rule can be found:
http://www.cms.hhs.gov/center/esrd.asp
New Rules Require New Interpretive Guidance

• Interpretive Guidance (IG) is CMS’ interpretation of the Rule; provides clarification to surveyors & providers

• Community input was sought for this guidance:
  – Draft document posted on the web & emailed to 10,000 CMS listserv subscribers
  – Community Forum in December 2007 for patients, professionals (all disciplines), providers, suppliers, organizations

• CRN Participation: Karen Basinger, Paula Frost and Debbie Benner and Barbara Zebrowski
What’s Next?

- *Final Interpretive Guidelines* will come out soon
- New Conditions for Coverage will go into effect *October 14, 2008* in every U. S. (& territory) dialysis unit
- February 1, 2009: All units will have to electronically submit outcomes data to CMS
- At the same time, focus on Clinical Performance Measures (CPM’s)

  http://www.cms.hhs.gov/CPMProject/
**What are the Effective Dates for these Rules?**

<table>
<thead>
<tr>
<th>Rule Description</th>
<th>Effective Date</th>
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<tbody>
<tr>
<td>New Conditions for Coverage</td>
<td>6 months</td>
</tr>
<tr>
<td></td>
<td>10-14-08</td>
</tr>
<tr>
<td>Life Safety Code and Separate room for HBsAg+ patients</td>
<td>300 days</td>
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<tr>
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<td>2-9-09</td>
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<tr>
<td>Certification of technicians hired after 10-4-08</td>
<td>18 months</td>
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<td></td>
<td>from hire</td>
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<tr>
<td>Certification of existing technicians</td>
<td>24 months</td>
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<td></td>
<td>4-15-10</td>
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THESE WILL BE THE NEW DIALYSIS LAWS!
Remember- we are only talking about the RD and nutritional aspects of the conditions- there is lots more in the conditions!
Resources Used to Develop Webinar

• Final ESRD Conditions for Coverage (CfC)
• Draft ESRD Interpretive Guidelines (IGs)
  – Final IGs pending
  – Specific values from standards and guidelines have been deleted and MAT developed
• Measures Assessment Tool (MAT)
  – Separate from IGs so that it can be updated as community standards and guidelines change
• Clinical Performance Measures (CPM)
RD & Dietetic Technician Qualifications

Jane Greene, RD, CSR, LDN
CRN Region II Representative
Personnel Qualifications
494.140

• All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.
Dietitian Qualifications
494.140(c)(2)

- Requires a dietitian “have a minimum of one year’s professional work experience in clinical nutrition as a registered dietitian”

- A dietitian who only has foodservice professional experience would not qualify for a position as a dialysis dietitian
Dietitian Qualifications
494.140(c)(2)

• The one year of professional work experience in clinical nutrition is **AFTER** successful completion of the registration exam.

• Dietitians working in dialysis must have evidence of registration with the Commission on Dietetic Registration, the credentialing agency for the American Dietetic Association.
Dietetic Technicians

- Final rule requires an RD to be a member of the dialysis facility interdisciplinary team, perform patient assessments, and participate in patient care planning and the QAPI program. The RD may use a DTR to provide assistance under RD supervision, but it is the RD who must meet these conditions of coverage.
Competency

• All facility staff must be able to demonstrate competency required to serve the complex needs of dialysis patients and must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions. Each facility is expected to determine how each staff member will "demonstrate" competency.
Caseloads

• CMS has not defined a staff to dialysis patient ratio, and defers to state provisions that may have implemented ratios.

• CMS does state - “Dialysis dietitian caseloads must not prevent RDs from providing care consistent with national standards of practice for dietitians”.
Adequate Staff

• The registered nurse, social worker, and dietitian members of the interdisciplinary team are available to meet patient clinical needs.
Adequate Staff

If a facility “shares” the social worker or dietitian with multiple clinics or requires professional staff to perform non-clinical tasks, it must NOT negatively impact the time available to provide the clinical interventions required to achieve the goals identified in the patient’s plan of care.
Adequate Staff
V758

- The facility CEO or administrator is responsible to assure the professional support staff members have sufficient time available in the facility to meet the clinical needs of in-center and home dialysis patients.
Adequate Staff
V758

• This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis.
• The dialysis facility may need to evaluate staffing levels as part of their action plan for the QAPI program.
Other Areas Affecting RD’s

Infection Control
Emergency Preparedness
Patient Safety
Infection Control

“We have strengthened infection control by making it a condition of coverage and expect that dialysis staff will comply with the hemodialysis infection control precautions developed by the CDC and required by this rule.”

*Federal Register pg 20379*
Infection Control 494.30

- CDC infection control precautions are mandatory and must be adhered to and demonstrated
- RDs must wear gown or lab coat in treatment area
- RDs must wear gloves and follow hand hygiene procedures
Infection Control

• Items taken into the dialysis station should be disposed of, dedicated for single patient use, or cleaned & disinfected before being taken to a common clean area or used with another patient.

• THINK- Patient education materials, videos, flip charts, etc.
Infection Control

- All staff must be able to demonstrate knowledge of infection control and annual training must be documented.
- All clinical staff are to report infection control issues to the dialysis facility’s medical director.
Emergency Preparedness

- The final rule requires that the staff be able to demonstrate the ability to manage emergencies that are likely to occur in the facilities geographic area.
- Patients must be educated on how to handle emergencies and must be able to describe what to do if they can’t get their treatment, including dietary precautions.
Patient Safety 494.6

- This final rule requires that dialysis facility patient care staff maintain current cardiopulmonary resuscitation (CPR) certification.
Comprehensive Multidisciplinary Patient Assessment (CMPA)

Karen Wiesen, MS, RD, LD
CRN Chair-Elect
Condition: Patient Assessment

V500 494.80

• The requirements in this Condition address the requirements for an interdisciplinary assessment of patients needs.

• The interdisciplinary team (IDT) consists of, at a minimum, the patient or patient’s designee, a registered nurse, a physician treating the patient for ESRD, a social worker and a dietitian.
Condition: Patient Assessment

- The IDT is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient’s treatment plan and expectations for care.

- Tags V502-515: contain standard assessment criteria that must be included for all disciplines.
Evaluation of Nutritional Status by a Dietitian

- Portions of the CMPA which correlate with the nutritional evaluation, such as fluid management or renal bone disease must be conducted by the RD or another team member.

- The evaluation of the patient’s nutritional status must be conducted by a qualified RD.

- The IDT must provide the necessary care & counseling services to achieve and sustain an effective nutritional status.
Evaluation of Nutritional Status by a Dietitian

- V502: Medical history/co-morbid conditions
- V504: Fluid management needs
- V505: Laboratory profile
- V506: Medication history
- V508: Factors associated with renal bone disease
- V510: Psychosocial factors
- V518: Adequacy
Minimum Criteria for Nutrition Assessment

Nutrition Assessment will include the following:

- Anthropometrics & recent change
- Diabetes Management
- Mineral and Bone Disorder Management
- Cultural Factors related to Diet
- Subjective Data related to appetite, dietary intake & nutritional status
- Objective Data related to nutritional status
Anthropometrics

- Height, weight, estimated dry weight, BMI
- Usual body wt and % usual body weight
- Recent weight change; frame size
- Reference weight, % reference weight with adjustment for obesity or amputation
- Nutrition related medications: vitamins, GI, stool softeners, other
- **Trigger**: Weight loss >5% in one month
Diabetes Management/Cultural Factors

**Diabetes Management**
- Diet, foot checks & frequency, dental hygiene
- Blood glucose monitoring frequency
- Hgb A1C, medications, education

**Cultural Factors**
- Religious and cultural food preferences
- Literacy/ language barriers, vision/hearing
- Social factors: cooking & shopping ability, food assistance
Bone and Mineral Metabolism Management

- Lab review: Ca, Phosphorus, PTH
- Trends: in goal, high, other
- Medication type and adherence
- Assessment of diet adherence and comprehension of diet.
- **Trigger:** usually high lab values
Subjective Data

- Appetite, food allergies, pica behavior
- Previous diet education and weight history
- Use of nutritional supplements including herbal
- **Triggers:** poor appetite, unplanned weight loss
Objective Data

- Albumin, nPCR, potassium, evaluation of protein & calorie intake
- Evaluation of nutritional status
- **Triggers:**
  - Inadequate protein or calorie intake
  - Pt assessed with mild, moderate or severe malnutrition
Frequency of Assessment

• Initial Comprehensive Assessment
  – Comprehensive multidisciplinary patient assessment (CMPA)
  – Completed within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first outpatient dialysis session
  – Conducted on all patients new to any outpatient facility
Frequency of Assessment

• Follow up CMPA
  – Must occur within 3 months after the completion of the initial CMPA
  – Re-evaluate: how well patients follow their treatment plan, their educational, rehabilitation, and nutritional needs, their adjustment to dialysis regimen
  – Re-evaluate the accuracy and appropriateness of patients’ plan of care
Patient Reassessment

• A comprehensive reassessment and a revision of the plan of care must be conducted annually on stable patients.

• Must be completed within 12 months of the 3 month reassessment after the patient’s admission to the facility.
Patient Reassessment Criteria V520

- Unstable patients must be assessed monthly.

- Minimum of 4 criteria for classifying patients as unstable. Each facility can develop further criteria based upon their patient population.

- While one discipline may trigger an unstable status, *all* disciplines must review and document whether their area was changed by the unstable status or remained unchanged.
Patient Reassessment Criteria v520

1. Extended or frequent hospitalizations defined as admissions longer than 8 days or more than 3 hospitalizations in a month. The reason for the admission may also result in the patient being classified as “unstable”.

2. Marked deterioration in health status
Patient Reassessment Criteria

3. Significant change in psychosocial needs. Includes any event which interferes with the patients ability to follow aspects of their treatment plan.

4. Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.
   - Refer to Measure Assessment Tool (MAT) which lists current professionally accepted clinical standards and current CMS Clinical Performance Measure.
CMPA

• Go to NKF website at www.kidney.org under Professionals to see a sample CMPA.
• May use entire form or incorporate sections into own facility document.
• CMPA must demonstrate integration of the evaluations completed by each team member. May be incorporated into 1 document or composed of sections developed by each team member as long as specific criteria from V502-514 are included.
Care Plans and Nutrition Care Process

Maureen McCarthy, MPH, RD, CSR, LD
CRN Secretary/Treasurer
Plan Of Care

CfC §494.90 Plan of Care

“The interdisciplinary team (IDT) must develop and implement a written, comprehensive plan of care that…”

- Specifies services needed
- Includes measurable and expected outcomes and estimated timetables
  - Outcomes must be consistent with evidence-based practice standards
Plan Of Care

- IDT – the same one as for CMPA
- Plan of care address “triggers” identified during CMPA
  - Plan of care is individualized (compared to QAPI, which addresses aggregate data)
- Required for all assessments
  - Initial
  - Follow-up—must address earlier targets that are not achieved or sustained
Plan Of Care

Nutrition is part of IDT

Components of IDT plan of care
- Dose of dialysis (PD or HD)
- Nutritional status (monitored monthly) v545
  - Address “triggers” identified in CMPA
- Mineral metabolism and renal bone disease (monitor q 3 mo)
- Anemia
- Vascular access
- Psychosocial status
- Modality—HD, PD, transplant status
- Rehabilitation status
The Nutrition Care Process and Model

Next Steps After CMPA

- Develop your care plan template
- Standardized language can help you describe
  - Diagnosis
  - Intervention (i.e., “services needed”)
  - Outcomes
    - Measurable
    - Include a timetable
    - Consistent with evidence-based practice
## Care Plan Template

### Problem or Diagnosis:
- Etiology:
- Signs/Symptoms:

### Nutrition Prescription/Recommendation
- **Intervention #1**
  - Goal (s)
- **Intervention #2**
  - Goal (s)
- **Intervention #3**
  - Goal (s)

### Monitoring & Evaluation
- **Outcome**

### Criteria/Timeline
- #1
- #2
- #3
NCP and SL

• In-depth tutorial in NCP and SL is beyond the scope of this webinar
• Go to www.eatright.org
  – Log in with userid and password
  – Select NCP from menu bar on left of screen
  – Select “Learn more” under Practitioners
  – Select “Learn more” under “How are you going to get there”
  – Select “NCP Introduction and Tutorial Modules” under presentations
    • Approved for CE credit
Step 2 in NCP: Nutrition Diagnosis

Before plan of care, you need a diagnosis

- Study Nutrition Diagnosis terms
- Audit chart notes to identify most frequently used diagnostic terms
Step 3 in NCP: Intervention

• First, define a goal
  – May have some general goals, such as “Adequate nutrition intake”, “Bone parameters WNL”
  – Or could be very patient-specific, as in case study to follow

• Review terminology for Intervention
  – Apply it in your Care Plan template
Step 4 in NCP: Monitoring and Evaluation

• Review monitoring and evaluation terms
  – These are “outcomes”

• Set criteria to measure success in reaching outcome
NCP or SL Not Required in CfC

• There is no mandate for using NCP or SL
• There is a mandate for a comprehensive multidisciplinary patient assessment, followed by a plan of care
• SL has some disadvantages
  – Large numbers of terms can be overwhelming
• SL has some advantages
  – Standard terms support quality improvement and research activities to evaluate impact of nutrition services/interventions on outcomes
# Care Plan Template

<table>
<thead>
<tr>
<th>Problem or Diagnosis:</th>
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<tbody>
<tr>
<td>Etiology:</td>
</tr>
<tr>
<td>Signs/Symptoms:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutrition Prescription/Recommendation</th>
<th>Intervention #1</th>
<th>Goal (s)</th>
</tr>
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<tbody>
<tr>
<td>Intervention #2</td>
<td>Goal (s)</td>
<td></td>
</tr>
<tr>
<td>Intervention #3</td>
<td>Goal (s)</td>
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<table>
<thead>
<tr>
<th>Monitoring &amp; Evaluation</th>
<th>Criteria/Timeline</th>
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<tbody>
<tr>
<td>Outcome #1</td>
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<tr>
<td>#2</td>
<td></td>
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<tr>
<td>#3</td>
<td></td>
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ASSESSMENT
57 yr old male with ESRD due to DM2

FOOD AND NUTRITION HISTORY: Previous education on low sodium, low phosphorus, low potassium, calorie controlled diet while in hospital. Some education at hemodialysis (HD) unit before starting PD. Reports good appetite, 3 meals/day with 1 snack; no nutrition supplements. He does most food shopping and preparation for his family. Eating out more than usual lately due to PD training, but usually eats most meals at home. Believes he follows 2 g sodium diet, but uses some salt at the table; also uses salt substitute.

ANTHRO: Height 184.8 cm; medium frame; target weight 115.6 kg; UBW* 127.8 kg (pt is 90% of UBW); SBW* 88 kg (pt is 131% of SBW); adjusted SBW (adj SBW) 109 kg. BMI = 34. Concerned about weight gain. Reports 18.2 kg wt loss in last 6 mo, and believes this was fluid weight.

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<tr>
<th>BIOCHEMS</th>
<th>Results</th>
<th>Lab Norm</th>
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<tbody>
<tr>
<td>Potassium</td>
<td>5.0 mEq/L</td>
<td>3.5-5.5</td>
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<tr>
<td>CO2</td>
<td>24.0 mmol/L</td>
<td>23-29</td>
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<tr>
<td>BUN</td>
<td>49 mg/dL</td>
<td>6-20</td>
</tr>
<tr>
<td>Creatinine</td>
<td>12.3 mg/dL</td>
<td>0.7-1.5</td>
</tr>
<tr>
<td>Glucose</td>
<td>247 mg/dL</td>
<td>70-110</td>
</tr>
<tr>
<td>Albumin</td>
<td>4.0 g/dL</td>
<td>3.5-4.7</td>
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<thead>
<tr>
<th>BIOCHEMS</th>
<th>Results</th>
<th>Lab Norm</th>
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<tr>
<td>Calcium</td>
<td>9.4 mg/dL</td>
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<tr>
<td>Adj Calcium</td>
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<tr>
<td>Phosphorus</td>
<td>3.5 mEq/L</td>
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<td>Kt/V*</td>
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<tr>
<td>nPCR*</td>
<td>0.73</td>
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</tr>
<tr>
<td>Hgb A1c</td>
<td>8.3</td>
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PHYSICAL EXAM: No gastrointestinal complaints; patient not sure about urine output. No current exercise, but hopes to return to pre-dialysis routine of 30-45 minutes walking daily.

CLINICAL DATA: ESRD due to DM2; hyperlipidemia, hx triple-vessel coronary bypass graft (CABG). Checks capillary blood glucose (CBG) 4x/day before meals and at HS. Chronic ambulatory peritoneal dialysis (CAPD) prescription: 1 2.5% 2 Liter exchanger qd. Adjusting well to PD. Meds with nutrition significance: Humalog, Protonix, Tums, Promethazine, Nephrovite, Lantus q HS, Amaryl, Actos, Lipitor, furosemide, lisinopril.
DIAGNOSES (Problem—Etiology—Signs and Symptoms or PES)

**Problem (or Diagnosis):** Excessive carbohydrate intake related to
**Etiology:** lack of education to date regarding how to adjust for dextrose load of PD, as shown by
**Signs and symptoms:** elevated glucose and A1c since starting PD.

**Problem (or Diagnosis):** Excess dietary potassium due to
**Etiology:** knowledge deficit about potassium content of foods and seasonings as shown by
**Signs and symptoms:** stated use of high potassium salt sub while on “low potassium” diet.

INTERVENTION

**Nutrition Prescription:** 1.2-1.3 g pro/kg adj SBW or 130-140 g pro/day; 2 g Na, 2 g K, low phosphorus, constant CHO (5-6 carbs/meal with 15 g CHO per carb serving)

**Intervention 1:** Comprehensive nutrition education re: advanced topic
**Goal:** Patient will understand the concept of 15 gm dietary carbohydrate equal to 1 serving of “carbs” and will be able to evaluate carb content of some preferred meals.

**Intervention 2:** Comprehensive nutrition education re: skill development
**Goal:** Patient will be able to calculate carb servings from Nutrition Facts Panel information.

**Intervention 3:** Brief nutrition education re: survival information
**Goal:** Patient will stop using potassium-containing salt substitutes.

MONITORING AND EVALUATION

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<tr>
<th>Indicator</th>
<th>Criteria</th>
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<tr>
<td>Carbohydrate intake</td>
<td>Patient aware of carbs/meal and reaches goal of 5-6 carbs/meal.</td>
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<tr>
<td>Label reading skills</td>
<td>Patient able to calculate carbs/serving from nutrition label information.</td>
</tr>
<tr>
<td>HBGs and Hemoglobin A1c</td>
<td>Will meet goals set by primary care physician.</td>
</tr>
<tr>
<td>Serum potassium</td>
<td>Serum potassium will be in acceptable range for CAPD patient</td>
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Quality Assessment and Performance Improvement (QAPI)

Liz Kirk, RD, CDN
CRN Region I Representative
494.110 Condition: Quality Assessment and Performance Improvement (QAPI)

- This is a new Condition that looks at facility cumulative data and requires facility-based assessment and improvement of care.

- Compliance is determined by:
  - Review of clinical outcomes data
  - Records of the facility QAPI
  - Interviews of responsible staff including the medical director

- Non-compliance may be warranted if a pattern of deficient practices could impact patient health and safety is identified. Examples include, but are not limited to:
  - Absence of an effective QAPI program
  - Failure to recognize major problems
  - Failure to prioritize major problems
  - Failure to take action to address identified problems
Regulation – 494.110
Quality assessment and performance improvement

• The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven QAPI program with participation by the professional members of the IDT. The team must be lead by the medical director and there should be evidence that each member of the IDT participates in QAPI activities.

• The IDT must communicate effectively and must devote sufficient time and attention to produce effective QAPI activities which positively influence their patient’s outcomes.

• The QAPI program is expected to reflect the complexity of the dialysis facility’s organization and services and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.

• All services provided by the facility must be included (e.g. in-center, home hemodialysis, home peritoneal dialysis, reuse, central reprocessing, self-care).
Regulation – 494.110
Quality assessment and performance improvement

- The facility must maintain and demonstrate evidence of its QAPI for review by CMS. Records of activities must be available for review but do not need to be reported.

- There must be an operationalized, written plan describing the QAPI program scope, objectives, organization, responsibilities of all participants, and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving.

- Data on current professionally-accepted clinical practice standards must be used to track health outcomes. Efforts should be made to meet clinical practice guidelines or come as close as possible to meeting those guidelines for all patients.

- The QAPI program must allow for identification, prevention and reductions of medical errors, mortality and morbidities.

- Quality-oriented dialysis facilities that already have effective full-scale quality improvement programs will meet QAPI requirements
Regulation – 494.110
Quality assessment and performance improvement

• Data collected that relates to patient outcomes, complaints, adverse events, etc. should be used to identify problems and to improve care. Internal QAPI activities must evaluate the effectiveness of this program and make changes where indicated.

• It is expected that the facility undertake activities that will improve health outcomes, and prevent and reduce medical errors.

• Each facility has the flexibility to develop and implement QAPI via processes of their own choosing, as long as the efforts result in a multidisciplinary, data-driven QAPI program that achieves improvement and meets the criteria stated in 494.110.

• CMS does not intend for the implementation of facility-level clinical performance standards to negatively impact access to dialysis care and they do not hold facilities accountable beyond their control.
Regulation – 494.110

Quality assessment and performance improvement

- A facility whose treatment outcomes vary significantly from accepted standards must identify the reasons for poor outcomes and implement improvement projects to achieve expected outcomes.

- As the QAPI program is an internal facility function, facilities may use their own risk adjustors and include incident and/or prevalent patient designators within their programs. However, both adjusted and unadjusted QAPI data must be available for review but QAPI requires the use of aggregate patient data to evaluate the facility patient outcomes.

- It is recognized that patient adherence to the treatment plan can be a factor in meeting facility QAPI goals. It is possible that during prioritization of improvement activities that patient compliance trends need to be addressed within the QAPI program.

- CMS has not included minimum facility-level clinical standards. Setting thresholds below established performance levels could serve to undercut current performance levels. i.e currently 91% of HD patients achieve dialysis adequacy target and 81-84% of patients have a hemoglobin of ≥11.

- The Measures Assessment Tool (MAT) lists the expected outcomes based on these standards and CMS Clinical Performance Measures (CPMs).
Regulation – (a) Standard: Program scope

• QAPI must include, but not be limited to:
  – An ongoing program which continuously looks at indicators as they are available, trends outcomes and develops an improvement plan when indicated
  – Achievement of measurable improvement in health outcomes and reduction of medical errors
  – Use of indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors

• The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations
Regulation – (a) Standard: Program Scope

- Generally this would require at least monthly review of indicators, since prescribed patient indicators are typically evaluated with laboratory results monthly and this serves as a functional time frame for trending of data within the facility.

- “Indicators” or “performance measures” include at least those specified in this Condition as well as measures of water and dialysate quality and safety, and safe machine maintenance.

- Performance expectations are based on current professionally-accepted clinical practice standards:
  - Refer to the Measures Assessment Tool (MAT) which lists current professionally accepted and the CMS Clinical Performance Measures (CPMs).
Regulation – (a) Standard: Program Scope

• CMS-generated data reports, including the Dialysis Facility Reports (DFR) and other CROWNWeb provided data reports are to assist facilities to help them focus the QAPI program. Each facility should compare their performance with other facilities in their State, Network and the U.S. and strive to improve their outcomes where needed. Surveyors will use these data reports to focus their survey activities.

• HD and PD patients should be reviewed separately since factors affecting their clinical outcomes may be different.

• Data related to patient outcomes, complaints, medical injuries and medical errors should be used to identify potential problems and to identify opportunities for improving care. The IDT is expected to discuss areas which need improvement and develop, implement, and evaluate a plan for such improvement.
Regulation – (a) Standard: Program Scope

• The facility must use broadly accepted, community developed standards (e.g., CMS CPMs, NKF KDOQI, AAMI) as performance measures.

• Where minimum outcome values have been determined, facilities are expected to provide care directed at achievement of at least the minimum outcome value by all patients.

• Facilities may add topics to their QAPI program as needed to meet the unique needs of their facility.

• The IDT must work with individual patients who do not reach the target and must be reflected in the patient’s plan of care for that outcome.

• CMS may update QAPI topics as needed in future revisions of the ESRD CfC.
Regulation – (ii) Nutritional Status

- Serum albumin is a valid and useful measure of protein-energy nutritional status in maintenance dialysis patients. Serum albumin levels are commonly and extensively used to evaluate the nutritional status of ESRD patients. Low albumin levels are highly predictive of mortality risk.

- Serum albumin is affected by inflammation and other factors as well as by diet. The IDT may not be able to have a majority of its patients achieve the desired goal for this area, but should be actively intervening on actionable factors.

Measures Assessment Tool (MAT)
- Nutritional values measure not identified (albumin assumed)

- Values – Increase % in target range
Regulation – (iii) Mineral Metabolism and Renal Bone Disease

• The intent of QAPI is to address management of mineral metabolism and renal bone disease is to maximize the number of patients who achieve the goals for this area

• Since this area is heavily influenced by patient diet, it is critical that patient education, encouragement and support be included in improvement plans for this indicator

• If the facility uses a standardized mineral metabolism protocol or algorithm, the efficacy of this tool must be evaluated if facility QAPI goals in this area are not achieved over consecutive evaluation periods

Measures Assessment Tool (MAT)

• Measure
  – Calcium
  – Phosphorus

• Increase % in target range monthly
Additional QAPI Regulations

- Vascular access
- Anemia Management
- Adequacy
- Medical injuries and medical errors identification
- Hemodialyzer reuse program (if reuse is used)
- Patient satisfaction and grievances
- Infection control
- Vaccinations
- Patient (treatment options) education measured annually
- Physical and mental functioning
- Patient survival

- Facilities are encouraged to include social services and other suggested QAPI topics when appropriate, but are not requiring additional topics

- It is expected that the facilities devote the needed resources to their QAPI programs, based on prioritization of facility needs
Regulation – (b) Standard: Monitoring Performance Improvement

- The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

- Outcome data, achievement of treatment goals, adverse events, infections, falls, errors, etc. must be monitored as this data is available or as these events occur. Tracking and trending, analysis of root causes, development of improvement plans, implementation of those plans, evaluation of the success of the plan, and revision of the plan must occur as indicated.

- Once improvement is made, there must be a mechanism to ensure that improvement is sustained.

- The medical director must communicate with the governing body about the status of QAPI activities and be demonstrated in the minutes.
Regulation – (c) Standard: Prioritizing Improvement Activities

• The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.

• The facility must incorporate CMS-generated data reports, along with data reports that the facility produces to identify all areas needing improvement and to prioritize these, ranking those which have potential to affect patient health and safety as more urgent than those that do not have such potential.

• In setting priorities, prevalence and severity of the identified problems must be considered.
Regulation – (c) Standard: Prioritizing Improvement Activities

• The facility must immediately correct any identified problems that threaten the health and safety of patients
• Examples of conditions which could pose a threat to the health and safety of dialysis patients and require immediate correction include but are not limited to:
  – Dangerous levels of water contaminants
  – Unsafe levels of dialysate electrolytes
  – Failure to provide adequate observation of patient, vascular access, equipment
  – Defective clinical equipment
  – Failure to adequately disinfect reprocessed dialyzers
  – Failure to reduce residual germicides in reprocessed dialyzers to safe levels
  – Lack of qualified staff to perform crucial tests or meet critical patient needs
  – Evidence that staff are not competent
  – Potential for cross-contamination between infected and non-infected patients
  – Failure to use machine-provided safety devices
  – The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety
Q & A

From your screen, type in your question in the appropriate box
Frequently Asked Questions

Q: The regulations specify assessments must be done on all patients new to a dialysis unit followed by a 3 month assessment. What about currently established patients?

A: The regulations do not address this, however, since all stable patients will now require an annual assessment, each facility should consider working out their own schedule for assessing currently stable patients. That way anniversary dates for future assessments can be established. This schedule can be kept on file should any state surveyors request it.
Frequently Asked Questions

Q: What nutrition indicators do I need to be assessing that might trigger a plan of care?

A: The regulations state that albumin, body weight and trends in body weight be measured monthly. Significant changes in body weight or a decline in albumin to below accepted targets would trigger an unstable condition. "Additional evidence-based professionally accepted nutrition indicators may be monitored as appropriate” per the draft interpretative guidelines.

MAT references the NKF/KDOQI Nutrition Guidelines, published in 2000, as one of the evidence-based references.
Frequently Asked Questions

Q: Are there RD staffing ratios mandated in the CfC?

A: No. Although it was a concern to many commenters, there was discontent related to how this provision would be interpreted and enforced if a ratio was provided. The rule does define adequate staff which applies to RD’s: “staffing must be sufficient so that quality of care is provided to dialysis patients that is consistent with the patient plan of care and professional practice standards”.

The dialysis facility may need to evaluate staffing standard levels as part of their action plan for the QAPI program.

See page 20434 for more information
Frequently Asked Questions

Q: If a dietitian does not have all the experience required by the new rule, will that dietitian lose their job?

A: The rule and interpretive guidelines do not make that clear at this time, but it would certainly apply to new hires, and would most probably be incorporated in dialysis company policies.

It is also important to note that the rules specifically recognize that the RD’s work is “specialized”.
Frequently Asked Questions

Q: PTH is part of the requirement for the plan of care but not part of QAPI in the Measures Assessment Tool (MAT)? Why?

A: MAT (*in its draft form*) has only established calcium and phosphorus indicators at this point since calcium and phosphorus (and not PTH) are professionally-accepted clinical practice standards.

The NKF/CRN has already provided comments to CMS on this issue. CRN feels that Ca, P *and PTH* are integral in the management of bone and mineral metabolism.
Frequently Asked Questions

**Q:** Is it mandatory to use the NCP and SL?

**A:** Essentially ADA cannot mandate the application of the NCP or the specific terms in the SL. ADA members can access a well-written discussion of this question among FAQs on the NCP pages of ADA’s web site (go to http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/home_13910_ENU_HTML.htm Accessed 9-14-08).

However, there are advantages to using SL. These include describing what dietitians do in standard terms that will support quality improvement audits and research projects to define clearly

1. How dietitians assess patients (assessment terms)
2. What problems or diagnoses we treat (diagnosis terms)
3. What services we provide to patients with particular diagnoses (intervention terms) and
4. What outcomes our patients/clients enjoy (monitoring and evaluation terms)

The mandates in the CfC are for CMPA and for plan of care developed for each individual patient. Neither CMS or NKF mandates the application of the NCP or its SL.
Frequently Asked Questions

**Q:** How can RDs apply ADA’s Nutrition Care Process (NCP) in the CMPA?

**A:** The CMPA is just the first quadrant of the NPC—the assessment quadrant. CMPA templates, and the policies and procedures about how to use them, will have to be developed at the unit level, the regional level or the corporate level. The CMPA drafted by the NKF and ANNA does not use ADA’s standardized language (SL) of the NCP, and that may be unavoidable since it is multidisciplinary. But it will help the care team to assess patients and to identify problems that require attention.

There is an opportunity to apply the NCP and its major tool, the SL, for the plan of care that follows the CMPA. A nutrition diagnosis can build a bridge from the CMPA to describing services (see SL for the intervention quadrant of the NCP) and outcomes (refer to the monitoring and evaluation terms for the NCP). ADA members can find more information about the NCP and SL on the ADA web page (www.eatright.org). Follow links on from the “Nutrition Care Process” menu button on the left edge of the ADA home page.
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Thank You

• This webinar presentation has been audiotaped and will be available soon on the CRN web page for National CRN members only
  – Download slides and listen at your convenience

• Check your email for more information regarding “CfC FAQ Document” - coming soon
How to best stay informed about the new conditions and future changes?

CRN National Membership

How do you join?

Go to www.kidney.org

or

Call (800) 622-9010
Appendix A - QAPI
Regulation – (iv) Anemia management

- For anemia management, factors which should be tracked for the facility patient population as a whole include:
  - laboratory values (hemoglobin, hematocrit, transferrin saturation (TSAT), ferritin levels and other iron indices)
  - erythropoietin stimulating agent (ESA) doses and dose response
  - evidence of blood loss, such as repeated episodes of insufficient rinseback of red blood cells or prolonged bleeding post treatment

Measures Assessment Tool
- **Measure**
  - Serum ferritin and transferrin saturation or CHr
  - Mean hemoglobin > 3 mo
  - Mean hematocrit
- **Values**
  - Increase % in target range for 3 mo (in-center HD) or 6 mo (PD or home HD)
  - Increase % with mean 10-12 g/dL for 3 mo
  - Increase % with mean 30-36% for 3 mo
Regulation – (i) Adequacy of dialysis

- The intent of QAPI in addressing adequacy of dialysis is to maximize the number of patients who achieve the goals for this area.

- To identify opportunities for improvement and track progress in adequacy of dialysis for its HD and PD population the IDT must:
  - Review aggregate patient data
  - Identify any commonalities among patients who do not reach the minimum expected targets
  - Develop a plan to address those causes
  - Implement the plan
  - Monitor the effectiveness of the plan
  - Adjust portions of the plan that are not successful

- The IDT must use current professionally-accepted clinical practice standards as target values (refer to MAT)
Regulation – (i) Adequacy of dialysis

• If a data report shows that the facility’s ranking for HD adequacy is below the expected average, the facility must demonstrate QAPI review of global factors that might affect adequacy (e.g., missed/shortened treatments, less efficient dialyzers, ordered blood flow rates not achieved)

Measures Assessment Tool (MAT)
• HD adequacy measured monthly
• PD adequacy measured every 4 months
• Measure
  – HD: Adult > 3 mo
  – PD: Adult
• Values
  – % with SpKt/V > 1.2 or URR > 65% (conventional 3 times/week dialysis)
  – % with weekly Kt/Vurea > 1.7 (dialysis + RKF)
Appendix B – Nutrition Diagnosis
Diagnostic/Problem Labels

- Currently 60
- Clustered into 3 Domains
  - Intake
  - Clinical
  - Behavioral/Environmental
- Each domain represents unique characteristics contributing to nutrition status
- Within each domain are classes/sub-classes
Intake Domain

• Problems related to intake of energy, nutrients, fluids, bioactive substances through oral diet or nutrition support
• 5 classes
  – Caloric/energy balance
  – Oral or nutrition support intake
  – Fluid intake
  – Bioactive substance balance (not vit, min, PFC)
  – Nutrient balance – sub-categories for vitamins, minerals
Clinical Domain

- Nutrition findings/problems identified that relate to medical or physical conditions
- 3 classes
  - Functional
  - Biochemical
  - Weight
Behavioral Domain

- Nutritional findings/problems identified that relate to knowledge, attitudes/beliefs, physical environment, access to food, and food safety
- 3 classes
  - Knowledge and beliefs
  - Physical activity and function
  - Food safety and access
Nutrition Prescription

What can the Nutrition Prescription include, what should it address?
• Energy? Specific foods/ nutrients?
• Route of nutrition?
• Physical activity?
• Education needs?
• Access to food, resources?

It is NOT a diet order!
May include as much or as little detail as needed.
Nutrition Prescription

What can the Nutrition Prescription include, what should it address?
• Energy? Specific foods/ nutrients?
• Route of nutrition?
• Physical activity?
• Education needs?
• Access to food, resources?

It is NOT a diet order!
May include as much or as little detail as needed.
Nutrition Intervention Domains

See page 182 of IDNT Manual for superbill of Intervention terms.

• 4 Domains
  – Food and/or Nutrient Delivery
  – Nutrition Education
  – Nutrition Counseling
  – Coordination of Nutrition Care

• Also, see definitions, worksheets—just like nutrition dx terms
Food and/or Nutrient Delivery

8 Classes

- Meals and Snacks (3 terms)
- Enteral & Parenteral Nutrition (6 terms)
- Medical Food Supplement (4 terms)
- Vitamin and Mineral Supplement (15 terms)
- Bioactive Substance Supplement (5 terms)
- Feeding Assistance (6 terms)
- Feeding Environment (7 terms)
- Nutrition Related Medication Management (5 terms)
Nutrition Education

2 Classes

• **Initial/Brief Nutrition Education**
  – Purpose of nutrition education
  – Priority modifications
  – Survival skills

• **Comprehensive Nutrition Education**
  – Purpose
  – Recommended modifications
  – Advanced or related topics
  – Result interpretation
  – Skill development
  – Other
Nutrition Counseling

2 Aspects:

- Theory or Approach
- Strategies
Nutrition Counseling (cont’d)

Theory or Approach
- Cognitive-behavioral theory
- Health belief model
- Social learning theory
- Trans-theoretical/ stages of change
- Other

....All well described in Manual, p 203-216
Nutrition Counseling (cont’d)

2nd Aspect of Nutrition Counseling: Strategy
• Motivational interviewing
• Goal setting
• Self-monitoring
• Problem solving
• Social support
• Stress management
• Stimulus control
• Cognitive restructuring
• Relapse prevention
• Rewards/ contingency management
• Other
Nutrition Counseling Strategies

• Refer to IDNT Manual worksheets
  – Pages 217-224
Coordination of Care

2 Classes

- Coordination of other care during nutrition care
  - Team meeting
  - Referral to RD with different expertise
  - Collaborate/refer to other providers
  - Referral to community agencies/programs

- Discharge and transfer of nutrition care to another setting or provider
  - Collaboration
  - Referral to community agencies/programs
Monitoring and Evaluation

- 4th phase of NCP
- Purpose: Determine and quantify progress towards goals and expected outcomes; are goals being met?
- Tracks outcomes relevant to nutrition intervention plans and goals
- Defines outcomes (desired results of nutrition care)
  - Identifies specific indicators that can be compared to reference standards or norms
    - e.g., Suggested Guidelines, evidence-based guidelines
Activities in M&E

- **Measuring**
  - Data collected (initial or subsequent encounter)
    - Patient or RD/DTR

- **Monitoring**
  - Review of data at regular intervals

- **Evaluating**
  - Systemic comparison of current findings with previous status, intervention goals, and/or with a reference standard
  - Overall effectiveness of nutrition care
Nutrition Outcome Indicators

Outcome terms are defined for M&E

For each outcome term, the reference page includes potential indicators that could be used to measure effectiveness of nutrition care

2 criteria to consider:

• Nutrition Rx or Goal/expected outcome
• Reference standard (e.g., national, institutional and/or regulatory standards)
Types of Outcomes

• “Physician-centric” or “institution-centric”
  – Morbidity and mortality
  – Length of stay

• Nutrition-centric
  – Weight change
  – Changes in biochemical indicators
  – Diet parameters: energy, gm protein, mg K, etc
  – SGA score
Monitoring & Evaluation

2 Major Categories

• Nutrition Care Domains--represent dietetics clinician’s contribution to care
  – Nutrition-related behavioral and environmental outcomes
  – Food and nutrient intake outcomes
  – Nutrition-related physical sign and symptom outcomes
  – Nutrition-related patient/client-centered outcomes
Monitoring & Evaluation

(2 major categories, cont’d)

- Health care domains (not nutrition specific—defined elsewhere)---outcomes of interest to providers, systems, payors, policy-makers not on superbill
  - Clinical outcomes (changes in health status)
  - Cost outcomes
  - Patient/client outcomes (functional and quality of life [QOL])

Units of measure, scales to be developed
Nutrition-Related Behavioral and Environmental Outcomes Domain

4 Classes:

- Knowledge and beliefs--BE 1...
  - Beliefs and attitudes (7 terms)
  - Food and nutrition knowledge (2 terms)

- Behavior (10 terms)--BE 2...
  The terms include: ability to plan meals/snacks; ability to select healthful food/meals; ability to prepare food/meals; adherence; goal setting; portion control; self-care management; self-monitoring; social support; stimulus control
Nutrition-Related Behavioral and Environmental Outcomes Domain

4 classes (cont’d)
• Access--BE 3...
• Physical Activity and Function--BE 4...
  – Breastfeeding success, nutrition-related ADLs, physical activity,
Food and Nutrient Intake Outcomes Domain--6 classes

- **Energy--FI 1** (1 term)
- **Food and Beverage--FI 2**...
  - Fluid/beverage; food intake
- **Enteral and parenteral--FI 3**...
  - Access, formula/solution, discontinuation, initiation, rate/schedule
- **Bioactive substances--FI 4**...
  - Alcohol intake, bioactive substance intake, caffeine intake
- **Macronutrients--FI 5**...
  - Fat and cholesterol, protein, CHO, fiber (22 terms total)
- **Micronutrients--FI 6**...
  - Vitamin, mineral (20 terms)
Nutrition-Related Physical Sign and Symptom Outcomes Domain--3 classes

- Anthropometrics--S 1...
  - Body composition (12 terms)
- Biochemical and medical tests--S 2
  - (80 terms)
  - Acid-base, electrolyte and renal, essential fatty acids, GI (including fecal fat), glucose, lipid, mineral, nutritional anemia, protein, RQ, urine, vitamin
- Physical examination--S 3....
  - CV-pulmonary, extremities and musculoskeletal, GI, head and neck, neurological, skin, vital signs
Nutrition-Related Patient/Client-Centered Outcomes Domain--2 classes

- Nutrition quality of life--PC 1...
  - Food impact; physical state; psychological factors; self-image; self-efficacy; social/interpersonal factors; nutrition quality of life score
- Satisfaction--PC 2 to be developed
Appendix C

CRN Membership Benefits
CRN Benefits at a Glance

- RenalRD Listserv
- Free or Discounted Publications & Journals
- Online CE Programs
- Online Professional Resources
- Fact Sheets
- Research Grants and Educational Stipends
- Discounted Fees for Clinical Meetings
- Access to the JobMart Career Center
RenalRD Listserv

International Discussion & Mentoring Group

1300+ Members Worldwide

- Post a question and get answers overnight!
- Find resources & educational supports
- Share ideas, projects, and concerns
- Connect with Renal Dietitians
Free Publications

The Journal of Renal Nutrition

Bimonthly since 2007:
Issues in January, March, May, July, September & November

- CPE Program based on journal articles offers up to 12 CE credits per year
- January issue publishes papers from ISRNM meeting
  - RenaLink

National Kidney Foundation

130
Reduced Subscriptions & Savings

- Pocket Guide for Nutritional Assessment of the Adult Renal Patient
  - 4th Edition Coming and will be free to all CRN Members!

- American Journal of Kidney Disease

- Advances in Chronic Kidney Disease

- 15% savings when you purchase any title or electronic product
  www.wiley.com
Online Resources

✓ Online Pocket Guide to Nutritional Assessment of the Patient with Chronic Kidney Disease 3rd Edition – free to members!
✓ Patient Education Nutrition Brochures – downloadable at no charge.
✓ CRN Research Bulletin Board
✓ Renal RD Orientation & Training checklist
✓ Online Membership Database

and more…
Facts Sheets

CRN Fact Sheets are patient oriented and available for download in either English or Spanish.

Variety of nutrition topics:
✓ Carbohydrate Counting with CKD
✓ Cholesterol and CKD
✓ Dietary Guidelines for Adults Starting on Hemodialysis
✓ Emergency Meal Planning
✓ Nutrition for Children with Chronic Kidney Disease
✓ Phosphorus and Your CKD Diet
✓ Potassium and Your CKD Diet
✓ Sodium and Your CKD Diet: How to Spice Up Your Cooking
✓ Use of Herbal Supplements in CKD
✓ Vitamins and Minerals in Kidney Disease
✓ Your Guide to the New Food Label

and many more…
JobMart Career Center

JobMart Career Center (careers.kidney.org.) is the National Kidney Foundation’s interactive job board, with a focus on companies and professionals in the field of renal health.

• Benefits for Job Seekers Using JobMart Career Center
  – FREE and confidential resume posting
  – Make your resume available to employers
  – Job search control
  – Easy job application
  – Saved jobs capability

• Benefits for Employers & Recruiters Using the JobMart Career Center
  – Post jobs online
  – Increase company’s awareness
  – Significantly reduce costs and time-to-hire
  – Search for qualified candidates
  – Create an online resume agent to e-mail qualified candidates daily
  – Benefit from online reporting that provides job activity statistics
  – Receive discounts on posting packages for being NKF members
Research Grants & Educational Stipends

• Apply for funding for your research project
  – October: Letter of intent due to NKF
  – December: Grant Proposal due to NKF
  – January/February: Review by CRN Research Grants Committee
  – March: Awards announced
  – July: Approved project begins operation and continues until June 30th of the following year

• Obtain stipends to attend the NKF Clinical Meetings.

  PLUS:

  Discounted Registration Fees for Spring Clinical Meetings
Other CRN Professional Activities

• Standards of Practice and Standards of Professional Performance for RDs in Nephrology Care with ADA/RPG - Coming Soon!
• FDA Food Labeling Petition
• Nutrition Care Process – standardized language
• IDPN Guideline development with ASPEN
• CMS Assessment Tool
• MedPAC Improving the Nutritional Status of Dialysis Patients
• National Disaster Coalition
Future Spring Clinical Meeting Dates

- March 24-28, 2009
  Gaylord Opryland
  Nashville, TN

- April 7-11, 2010
  Walt Disney World Swan and Dolphin
  Orlando, FL