Major Changes to the Conditions for Coverage

Objective: Describe major changes in the new CMS regulations

- Turned upside down!
- Focus on Patient Safety First
- Focus on Outcomes
- Put in place regulations to address the changes just discussed:
  - Technicians providing care
  - QAPI paramount
  - Electronic data submission
  - And more!

Where Are Some of the Major Changes and Challenges?

- **Infection Control**
- **Water & Dialysate**
- **QAPI**
- **Personnel Qualifications**
- **Responsibilities of the Medical Director**
- **Governance**

New Condition: Infection Control

- From one tag to a Whole Condition!
  - With 29 separate tags
- Adopts as regulation
  - CDC's 2001 *Recommendations for Prevention of Infections in Hemodialysis* (RR05)
  - CDC's 2002 *Guidelines for the Prevention of Catheter-Related Infections* (RR10)

Infection Control

Regulations are very specific; as examples:

- Hand hygiene
- Changing gloves
- Distribution of supplies and medications
- Transducer protectors: changed when wet
- Gowns, not aprons for PPE

Must report infection control issues to Medical Director & QAPI

Hepatitis B

- Screening of all patients at admission
- Vaccine for patients and staff
- Existing facilities must have a separate room or area for HBV+ patients
- All new* facilities must have a separate isolation room (or a waiver)

Handout: Isolation Room Grid

Infection Control: Challenges

- Educating all staff regarding the new requirements
- Ensuring routine compliance with the requirements
- Developing easy to use systems to track, report, and trend all infections
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New Condition: Water & Dialysate Quality

- Was 4 tags under Physical Environment; now its own Condition with 92 tags
- Adopts AAMI RD52:2004 (which was written for the user) as regulation
- IG was developed with maximum community input and with the AAMI RD Committee
- Very detailed & thorough: most questions will now have a regulatory answer

Water Treatment

Specific requirements for each water treatment component:

- Includes requirements from another AAMI document (RD 62)
- Parameters & required monitoring detailed for each water treatment component
- All components listed are not required; those in place must meet these regulations

Water & Dialysate Quality

- First time to have specific regulations for dialysate
- Addresses acid & bicarbonate concentrates:
  - Labeling
  - Mixing
  - Distribution
  - Use

Monitoring Water & Dialysate Systems

- Chemical analysis: annually at a minimum
  - More frequent if seasonal changes are suspected
  - Repeated if rejection rate falls below 90%
- Microbial monitoring:
  - Frequency: weekly initially or if issues arise; routine = monthly
  - Before disinfection
  - Water and dialysate share:
    - Action levels: 50 cfu and 1 EU
    - Maximum levels : 200cfu and 2 EU

Suggestions to Meet These New Requirements

- Use RD 52:2004 to update your current policies in this area
- Be sure all your water and dialysate treatment/ mixing/ storing components are labeled
- Inservice staff on new procedures
- Do practice audits routinely

Water & Dialysate Quality: Challenges

- Staff turnover
- Being sure all staff responsible understand the “why” of tasks they are assigned to do
- Repetitive tasks = shortcuts
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Quality Assessment Performance Improvement (QAPI)

"The dialysis facility must develop, implement, maintain and evaluate an effective, data driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team."

ESRD Clinical Practice Standards: MAT

- The “Measures Assessment Tool” (MAT) provides a ready reference for standards for PA/POC and QAPI
- Standards developed by renal community:
  - National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) Guidelines
  - National Quality Forum (NQF): Clinical Performance Measures (CPM)
- Addresses management of complications of ESRD

QAPI Performance Measures*

Adequacy	Kt/V, URR
Nutrition	Albumin, body weight
Bone disease	PTH, Ca+, Phos
Anemia	Hgb, Ferritin
Vascular access	Fistula/catheter rate
Medical errors	↓Frequency of specific errors
Reuse	↓Adverse outcomes
Patient satisfaction	↑Survey scores
Infection control	↓Infections, ↑vaccinations

*See MAT for expected targets

It’s a MAT

Not a

Each Facility Must

- Continuously monitor its performance
- Take actions that result in improvement
- Track to assure improvements are sustained over time
- Immediately correct identified problems that threaten health & safety of patients

Require Immediate Correction

- Unsafe water or dialysate
- Defective clinical equipment
- Unsafe reprocessing of dialyzers
- Epidemiological risks
- Insufficient **number** of **competent** staff to perform scheduled treatments:
  - Preserve accesses
  - Monitor patients
  - Assure safe machine function

QAPI: Challenges

- Enlisting the support of the medical director
- Educating the IDT in the differences in care planning and QAPI
- Moving from data → information → knowledge→ wisdom
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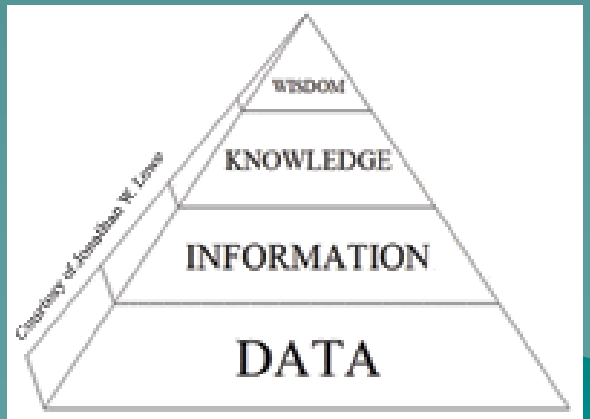

Questions?

CfC: Personnel Qualifications

- Individual Personnel Qualifications:
  - Medical director
  - Nurse manager; training nurse; charge nurse
  - Dietitian
  - Social worker
- Group Qualifications
  - Staff nurse
  - Patient care dialysis technicians
  - Water treatment system technicians

Personnel Qualifications Issues

- Medical director: “board-certified”
- Nurse manager: “full-time,” “employee”
- Self care training nurse: “responsible”
- LPN/LVN: “charge nurse”

More Personnel Issues

- Dietitian: 1 yr of “post-registration experience”
- Social worker: “specialization in clinical practice” and “grandfathered”

PCT Regulation

- Who is included?
  - "dialysis assistant"
  - "bio-med technician"
  - "machine technician"
  - "technician 1 or technician 2"
- "State certification programs"
- Timeline for compliance:
  - PCT's employed before 10/14/08=4/15/10
  - PCT's hired after 10/14/08 = 18 months from hire date

Challenges in Personnel Qualifications

- PCTs without HS diploma
- Turnover
- Availability of qualified RDs
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Condition: Responsibilities of Medical Director

- Lead QAPI program
- Assure staff education, training, & performance
- Develop policies and procedures
- Ensure all staff (including physicians) adhere to policies
- Initial assessment/orders
- Sign any order for involuntary discharge

Any Other Responsibilities?

- Infection Control: Informed of issues (V144)
- Water/dialysate: Responsible to ensure the design and use of water treatment system provides AAMI quality water (V179)
- Reuse: Responsible for program, training curriculum (V308), certifies techs successfully complete program(V309), and quality assurance (V361)

Challenges: CfC Responsibilities of the Medical Director

- Single Medical Director required: facility may “designate” “sub” directors for special programs (e.g., PD, home HD).
- Education of Medical Directors in effective QAPI
- Devoting sufficient time to these responsibilities
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Questions?

Condition: Governance

Addresses over-arching requirements:

- Overall management & accountability
- Staffing issues
- Resource issues: including staff & resources allocated for the QAPI program

- If the survey identifies outcomes related to these over-arching responsibilities of the Governing Body in other Conditions, this Condition could also be cited

Staffing Is Addressed Here

- Adequate number of qualified & trained staff
  - Patient/staff ratio appropriate to the level of care & meets the needs of the patients (V757)
  - RN, MSW, RD available to meet patient needs (V758)

Staffing Is Addressed Here

- RN present at all times in-center patients are being treated (V759)
- All staff have orientation to the facility & their work responsibilities (V760) & continuing education (V761)

Separate Standards within the Condition for Governance

- Identifiable governing body/designated person (CEO/Administrator) (V751-752)
- Medical staff appointments (V762)
- Internal grievance system in place (V765)
- Involuntary discharge process (V766-767)
- Emergency coverage (V768-770)
- Electronic data submission (V771)
- Relationship with the ESRD Network (V772)

Internal Grievance Process

- Each facility has an internal process to allow patients to file a grievance without reprisal or denial of services
- Must include:
  - Clearly explained procedure
  - Timelines for staff review of the grievance
  - Description of how the patient will be informed of steps taken to resolve the grievance

Involuntary Discharge (IVD)

Addressed under the Conditions of:

- Patients' rights
- Responsibilities of the Medical Director
- Governance

Patients' Rights: IVD

- Patients must be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services
- Patients must receive a 30-day written notice of an involuntary discharge
- Allows abbreviated discharge procedure in the case of immediate threats to the health and safety of others

Medical Director: IVD

- Responsible to assure that the interdisciplinary team adheres to discharge & transfer policies & procedures
- Under Governance, the Medical Director is required to co-sign any order for involuntary discharge

Governance: IVD

- Ensure staff follow discharge & transfer policies & procedures
- Medical director must ensure that no patient is discharged or transferred unless:
  - Patient/ payer no longer reimburses the facility for the ordered services;
  - Facility ceases to operate;
  - Facility can no longer meet the patient's documented medical needs; or if

Governance: IVD

- The facility has **reassessed** the patient and determined that the patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired.

Governance: IVD

If an IVD is necessary, the medical director ensures that the IDT:

- Documents reassessments, ongoing problem(s), and efforts to resolve the problem(s);
- Provides the patient & the ESRD Network a 30-day notice of the planned discharge;

Governance: IVD

- Obtains a written physician's order signed by both the medical director & patient's attending physician agreeing to discharge or transfer;
- Contacts another facility, attempts to place patient; and
- Notifies the State survey agency of the IVD

Governance: IVD

- In cases of immediate severe threats to health & safety of others, the facility may use an abbreviated discharge procedure

Standard: Emergency Prep

Related requirements under the Condition for Physical Environment:

- Staff training/knowledge (V409 & V411)
- Staff CPR certification (V410)
- Patient orientation & training (V412)

Emergency Coverage

- Emergency preparedness – Implement processes & procedures to manage medical & non-medical emergencies (V408)
- Staff & patient training – Training & orientation, including what to do, where to go, & who to contact (V409)
- Emergency plans – Evaluate/update annually, make contact with local Emergency Management (V416)

Governance: Emergency Coverage

- V768: Written instructions to patients & staff for obtaining emergency medical care
- V769: Roster of physicians
- V770: Agreement with a hospital that provides inpatient dialysis (Separate certification for “ESRD” for the hospital is NOT required)

Resource: Kidney Community Emergency Response (KCER) Coalition

- **Mission**: Collaboratively develop, disseminate, implement & maintain a coordinated preparedness & response framework for the kidney community in the event of any type of emergency or disaster.
- **Vision**: KCER is the leading authority on emergency preparedness & response for the kidney community by providing organization & guidance that seamlessly bridges emergency management stakeholders & the ESRD community nationwide.

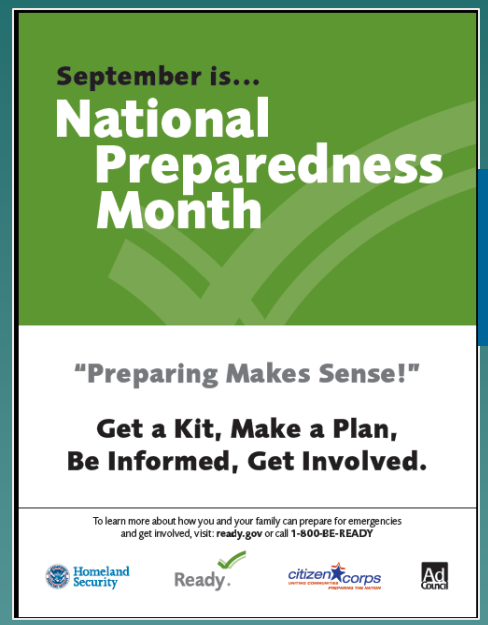
KCER Coalition

- Initiated in 2005
- >125 individuals representing the kidney community: nurses, dietitians, technicians, social workers, physicians, patients, ESRD Networks, government agencies, industry representatives
- Eight Response Teams focus on specific areas:

Communications	**Facility operations**
Patient assistance	**Coordination of staff & volunteers**
Federal response	**Physician's assistance**
Facility/patient tracking	**Pandemic preparedness**

KCER Tools & Resources

- www.kcercoalition.com
- Response Team Pages
  - Information & education
- Drills & education
- Helpful links
  - ESRD & disaster-related information
  - www.kidney.org/help



Emergency Management Institute

CROWNWeb

Consolidated Renal Operations in a Web Enabled Network

Each facility must submit data electronically effective Feb 1, 2009

Data to include:

- Cost reports
- ESRD administrative forms
- Patient survival information
- Existing ESRD clinical performance standards (see MAT)

Network Relationship

- Receive and act upon NW recommendations
- Participate in NW activities and pursue NW goals
  - Improve the quality & safety of services
  - Improve independence, QOL, rehab for all patients
  - Encourage activities to ensure achievement of these goals
  - Improve the collection, reliability, timeliness and use of data

Challenges: CfC Governance

- RN present at all times patients are being treated
- Sufficient resources for effective QAPI
- Reducing involuntary discharges (IVD)
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