

# WHAT DOES CMS MEAN TO ME AS A BIOMED TECH?

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# Objectives

- Become familiar with :
  - Medicare ESRD survey tasks related to the Biomed Tech role
  - What CMS surveyors are looking for during those survey tasks
  - The CMS expectation of the Biomed Department role in QAPI

# Have you been surveyed?

- Were you interviewed by the surveyor?
- Were their questions pertinent?
- What did they look at?
- What was your overall impression?



# Tips for survey success

- Know the “right” way to do things
  - do things that way daily
- Train your staff in the “right” way
  - monitor their practice frequently



- RELAX...Be polite and honest with the surveyor
- It's OK not to know an answer, but know where to find it
- NEVER make anything up!

# Background on CMS process

- ESRD Conditions for Coverage 2008
  - Focus on patient safety in technical areas
  - Adopts ANSI/AAMI RD 52:2004 w/corresponding parts of RD 62:2001 for water treatment & dialysate preparation/delivery
  - Adopts ANSI/AAMI RD 47:2002 for dialyzer reprocessing & reuse
- ESRD Survey Process
  - 16 survey “tasks” conducted on-site
  - Every 3-4 years-verifying compliance with CfC

## Most cited “Tech” tags in FY 2010

- **V403: Equipment Maintenance and Use**
  - #2 most frequently cited tag: 377 times
- **V401: Safe, Functional Environment**
  - #6 most frequent tag: 218 times
- **V402: Environment Maintained for Safety**
  - #8 most frequent tag: 206 times
- **V196: Carbon Adsorption Monitoring/testing**
  - #16 most frequent tag: 174 times
- **V250: Monitoring Dialysate pH/Conductivity**
  - #19 most frequent tag: 157 times

# What we'll be talking about

- In the 5 survey tasks most important to YOU:
    - Task 3: Tour and Observations of Care
    - Task 6: Water Treatment & Dialysate Preparation
    - Task 7: Reuse
    - Task 8: Machine Operation/Preventative Maintenance
    - Task 14: Quality Assessment and Performance Improvement
1. What surveyors are looking for/at?
  2. How to avoid survey citations...

# Task 3: Tour and Observations of HD Care

What surveyors are looking at/for:

- Patient treatment room
  - Condition of machines, chairs, equipment
  - **NO DUMMY DRIP CHAMBERS!!!**
  - Reprocessed dialyzers in use
  
- Water room
  - Condition of room & components: **3 required ones**
  - **Current chlorine/chloramine test & reagents**





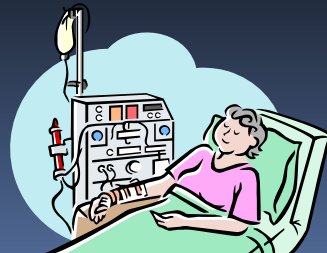
# Task 3: Tour and Observations of HD Care

- Dialysate preparation area
  - Mixing ratios of acid , bicarb and machines match
  - Equipment condition
    - watch the build up of concentrates!
- Reuse room
  - Equipment condition
  - Appearance/condition of stored dialyzers
  - Dirty dialyzers: at room temp or refrigerated?
  - Germicide odors



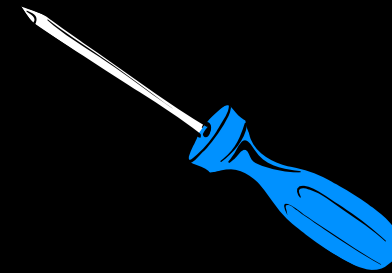
# Task 3: Tour and Observations of HD Care

- Machine maintenance area
  - Cleanliness
  - Machines being repaired clearly labeled
- Observation of HD patient care
  - Staff use of HD machines per DFU
  - Machine functions are intact
  - Dialysate pH/cond check w/independent method



# Task 3: Avoiding citations

- **Maintain ALL equipment**
  - Clean, functional
  - Replace worn, broken parts/components
  - Don't leave non-functional components in place
    - Ex: water treatment alarms, gauges
- **Keep non-patient areas clean, organized**
- **Train ALL staff in use of equipment per DFU**
  - Audit them periodically
- **Verify that ALL supplies are appropriate**
  - Ex: chl/chl reagents, concentrate proportioning ratios



## Task 6: Water Treatment & Dialysate Preparation

- What surveyors are looking at/for: Water
  - Carbon system w/sample port b/t; 10 min EBCT
  - RO w/ quality monitor
    - If DI is present-**automatic divert-to-drain required**
  - Water quality alarms in treatment area **working**
  - All other components set up/ monitored per RD52
  - All components, valves and flow direction labeled
    - Schematic/valve chart posted and **accurate**

# Task 6: Water Treatment & Dialysate Preparation

- What surveyors are looking at/for: Water
  - Will observe staff test for chlorine/chloramine
  - Will interview person responsible for daily monitoring of water treatment system
    - Assessing staff knowledge/competency (OK to read the component labels)
  - Will review water treatment logs
    - Daily system monitoring
    - Chlorine/chloramine testing
    - Microbial monitoring
    - Chemical analysis



# Task 6: Water Treatment & Dialysate Preparation

- What surveyors are looking at/for: Dialysate
  - All proportioning ratios match machines
  - What mixing and distribution systems are in place
  - All equipment used per DFU
  - Central delivery outlets labeled
  - Will interview staff doing mixing/testing
  - May observe mixing/testing
  - Will review mixing & disinfection logs



## Task 6: Avoiding Citations

- Get your water treatment and dialysate systems **RIGHT** and keep them that way
- Train, train, and re-train staff
  - Audit/monitor staff frequently
  - Download CMS interview guides (will ease anxiety)
- Review logs frequently
  - Address problems promptly
  - Encourage staff honesty in reporting by not “coming down” on them-use problem resolving solutions
  - **NEVER create missing records-surveyors can spot this!**

# Task 7: Reuse



- What are surveyors looking at/for:
  - Reprocessing equipment setup, used, maintained/DFU
    - Water pressures at pre-rinse sink
  - Environmental safety w/germicides
  - Will observe entire reprocessing and reuse process
    - Staff w/germicide tests, priming, patient ID
    - Transporting dialyzers to reprocessing location
    - Reprocessing and labeling for 2-3 dialyzers
      - Header cleaning per RD 47
      - All reprocessed dialyzers preprocessed & labeled b4 1<sup>st</sup> use
  - Interview w/Reuse Tech-assess knowledge/competency



# Task 7: Reuse



- What surveyors are looking for/at:
  - Will inspect stored reprocessed dialyzers
    - Labeling, similar names warning, storage times
  - Will review reuse logs:
    - Reprocessing logs for some patients
    - Maintenance and repair of equipment
    - Microbial monitoring in reuse room
    - Germicide air level testing
    - **QA AUDITS!**

# Task 7: Avoiding Citations

- Maintain the reprocessing equipment
- Train, train and re-train **ALL** staff
  - **Directly audit ALL staff procedures for QA! Record the audits**
  - Download CMS interview guides (ease anxiety)
- Review reuse logs routinely
  - Also required in Reuse QA audits



# Task 8: Machine Operation/Preventative Maintenance

- What are surveyors looking for/at:
  - HD machines & other equip maintained per DFU
  - Will interview Machine Tech-**assess knowledge**
  - Will review PM/repair logs of 25% HD machines
    - **Tracking operating hours & calendar months b/t PMs**
    - Repairs documented-trends addressed
  - Will review dialysate/machine cultures
    - **Each machine at least annually (2 per month)**
  - Will review ancillary equip maintenance logs
    - AED, scales, pH/cond meters, infusion pumps, eyewash stations, glucose meters, etc.

# Task 8: Avoiding Citations

- **Know** the HD machine manufacturer DFU for PM and **stick to it**
- Have a master calendar for PM and cultures
- **Keep good PM records-use manufacturer forms,** if available
- Include ancillary equipment in program
- Train, train and re-train staff (no CMS interview guide yet, but look for one soon)



# Task 14: Quality Assessment and Performance Improvement

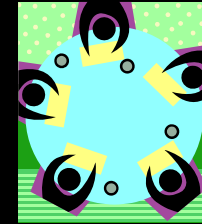
You are an important part of the QAPI program

□ Patient safety is the primary goal!



- Keep your logs/records organized
- Attend the QAPI meetings
- Report problems-**opportunities for improvement**
- Be actively involved in action plans & follow up

# Task 14: Quality Assessment and Performance Improvement



- What are surveyors looking for/at:
  - Will review QAPI meeting minutes and materials
    - Participation of Biomed staff
    - Water analysis & water/dialysate cultures reported
    - Reuse QA audits completed
    - Equipment maintenance and repair discussed
    - All adverse occurrences & environmental issues discussed
  - Any areas of concern addressed w/action plans and follow up monitoring

# In Summary

**The Biomed Department is the cornerstone  
for patient safety!**

You have a vital role in how well a survey will go

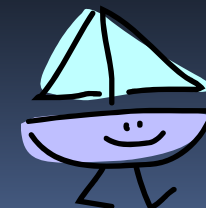
So...

Know the “right” way to do your job

Make it your daily practice,

and

**You will CRUISE through a survey!**



# CMS Resources

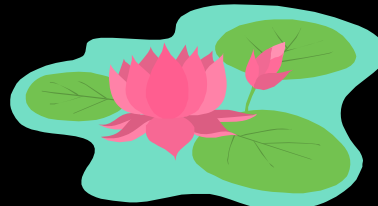
- CMS ESRD Survey and Certification Web site:  
[http://www.cms.gov/GuidanceforLawsAndRegulations/05\\_Dialysis.asp](http://www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp)  
for all survey tools, interview guides, etc.

CMS ESRD mailbox for survey-related  
questions:

[ESRDSurvey@cms.hhs.gov](mailto:ESRDSurvey@cms.hhs.gov)



Thank you!



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