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#### Executive Order 13563

- "Improving Regulations and Regulatory Review"
- Establish a plan for ongoing retrospective review of existing significant regulations, to identify those rules that can be eliminated as obsolete, unnecessary, burdensome or counterproductive or that can be modified to more effective, efficient, flexible and streamlined.

#### October 24, 2011

- Published a proposed rule that proposed reforms in CMS regulations that were identified as unnecessary, obsolete, or excessively burdensome to health care providers and beneficiaries.
- Final rule published May 16, 2012 and effective rule date: July 16, 2012

#### Two Changes

- Core Survey
- Limits mandatory compliance with the Life Safety Code to those End Stage Renal Disease facilities located adjacent to high hazardous occupancies and clarifies that the requirement for sprinklers in facilities housed in high rise buildings is intended to be applicable to those buildings constructed after January 1, 2008

CMS Efficiency & Effectiveness Initiatives-FY 2012 & Beyond

- Survey resources are limited, and may not improve
- Need to focus survey activities to achieve the most efficient use of survey resources to conduct an effective survey that:
  - Focuses on patient safety and quality
  - Utilizes facility data to focus
  - Supports a robust facility-based QAPI program

#### The Development Process

- Evaluated the data: citation frequency, patterns, research on outcomes
- Solicited input on which Vtags have the most impact on patient safety and quality care - These correlated!
- Looked to the patient & facility outcomes
  - Desired: clinical areas (e.g. adequacy, nutrition)
  - Adverse: infection control and technical areas (e.g. sepsis, chloramines breakthrough)
- Evaluated what facility structure and processes of care must be in place to facilitate the desired & prevent the adverse outcomes
- Determined what core survey actions could most efficiently validate the presence of those facility structures and processes

### The ESRD Core Survey

- The first in CMS Efficiency & Effectiveness Initiatives
- Pilot testing conducted in portions of 11 States in July, August, September, 2012
- National roll-out in FY 2013
- Transparency for all Core Survey manual materials/tools-will be posted at CMS ESRD Survey & Certification web site:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html

#### The ESRD Core Survey

- Streamlined, more concise reviews of what REALLY impacts patients
- Starts with "the basics", and expands to more detailed review if there is reason to
  - "Triggers" listed for each survey review indicate a problem or the need to look into something further
- Recognizes the major role direct care staff play in keeping patients safe and providing quality care

#### **Initial Results**

- Review up to 129 "tags" vs 381 mandatory "tags".
- 63% of surveyors trained
  - Washington, D.C., Puerto Rico, Wyoming, Oklahoma
- Technical reviews from 92 tags to 17
   Result 25% drop in survey time.

#### The "T's" of the Core Survey

- •Themes
- Threads
- •Tasks
- TriggersTools

### Themes of the Core Survey

#### • Data use

- Facility and patient-specific to focus reviews where improvement needed
- Infection control
  - Focus on methods for prevention, surveillance
     & control
- QAPI
  - Supporting 24/7/365 patient protection/quality care

#### Threads throughout the Core Survey

- Technical safety
  - Focus on elements critical to patient safety
- "Culture of Safety"
  - Supporting a facility-wide culture of open, non-judgmental communication, clarity of staff and patient expectations, and a proactive adverse occurrence reporting & investigation system
- Patients' voices
  - Ensuring staff are "listening" to patients' experience and point of view

### Tasks of the ESRD Core Survey

- Pre-survey prep
- Introductions
- Environmental "flash" tour
- Entrance conference
- Observations of HD care & infection control practices
- Patient sample selection
- Water treatment & dialysate review
- Dialyzer reuse & reprocessing review
- Dialysis equipment maintenance

- Home dialysis training & support review
- Patient interviews
- Medical record reviews
- Personnel interviews
- Personnel record reviews
- QAPI review
- Decision making
- Exit conference

#### QAPI

- Expects a vigorous, comprehensive and pro-active QAPI program to protect patients 24/7/365
- Core Survey QAPI Review has 3 segments:
  - Monitoring ALL facility areas
    - Clinical & operational indicators
    - Oversight of technical areas
  - Performance Improvement activities
    - Mortality review/evaluation
    - Infection prevention & control program
    - Error/adverse event investigation system
    - Focus areas specific to your facility
  - Culture of Safety-facility-wide
    - Risk identification, reporting
    - Patient engagement
    - Staff engagement

#### Quality Assessment & Performance Improvement (QAPI)

- Verifying the QAPI program will protect and assure quality care for patients 24/7/365
- Review 6 months of QAPI documentation
- Interview responsible facility-based person
- 3 Segments of review
  - Monitoring care & facility operations
  - Performance improvement in critical priority areas & data-driven focuses and survey findings
  - Culture of Safety

#### Data Use

- Facility and patient-specific data is used to focus review where improvement is needed
- Starts with off-site preparation by review of the Dialysis Facility Reports
- At onset of survey, will ask for the current outcome data
  - Selects those areas that need improvement as
    - Basis for sampling patients for review
    - Focus area(s) for QAPI review

#### What is Facility "Culture"?

The values and behaviors that contribute to the unique social, psychological environment of an organization...It is based on shared attitudes, beliefs, customs, and written and unwritten rules that have been developed over time and are considered valid.

It is shown in:

- The ways it conducts it's business and treats it employees and customers
- The extent to which freedom is allowed in decision-making, developing new ideas, and personal expression
- how power and information flow through it's hierarchy
- How committed employees are towards collective objectives
- It affects the organization's performance, productivity...product quality and safety...is unique for every organization and one of the hardest things to change.

http://www.businessdictionary.com/definition/organizationalculture.html#ixzz2KnbZ5nC3

#### CMS Expects All Dialysis Facilities to Implement a True Culture of Safety! Not just in words or on paper

#### The Patient Safety Movement

- Institute of Medicine (IOM) reports-1999, 2001
  - $-\approx$ 100,000 patients die each year d/t preventable hospital medical errors!
- More recent suggestions of many more times this in outpatient settings
- Healthcare Associated Conditions (HAC)
   Healthcare Associated Infections (HAI)
- HUGE efforts and resources spent to study WHY

#### Patient Safety Lessons Learned

#### No one intends to harm patients

- Flaws in systems facilitate errors
- "Human factor": Nobody's perfect
- Comfort with a system will cause people to deviate from what they were taught to do with the belief they are acting safely

#### Patient Safety Lessons Learned

- The "blame/shame" culture of healthcare does not protect patients
  - When an error occurs, the person(s) responsible is sought out, blamed and punished
  - Fear of punishment causes staff to "clamp down"
  - Errors and "Near Misses" are under reported
  - Prevents meaningful investigation into WHY something happened or almost happened!

#### A Culture of Safety in Dialysis-the CORE of Patient Safety

## A facility-wide "Culture of Safety" will protect patients

- Everyone at the facility is committed to identifying and eliminating any risks to patients
  - Open, non-judgmental communication b/t all levels of personnel and patients-ALL share patient safety goal (no blame/shame)
  - Clear direction for staff of what is expected
    - Less reliance on memory
  - Robust system for reporting & investigating causal factors of ALL abnormal events, and near misses/close calls: NOT WHO, but WHAT and WHY did it happen?

# How the Core Survey Will Identify a Culture of Safety-You are the key!

Surveyors will ask YOU about:

- The facility system of communication
  - What is the facility system of communication like here?
  - How does the administration ask for your input?
  - Are you comfortable bringing issues and concerns to administration's attention? Do they listen to you?
  - How are you involved in the QAPI Program? How are QAPI plans for improvement communicated to you?

# How the Core Survey Will Identify a Culture of Safety-You are the key!

Surveyors will ask you about:

- Your involvement in investigating & problem-solving at the facility
  - What can someone in your position here do to prevent or reduce treatment errors?
  - What errors or near misses are you expected to report?
  - Do you feel comfortable reporting errors?
  - How and to whom would you report an error or near miss you observed or were involved in?
  - How would you expect the error or near miss to be addressed? What is your role in follow up?

# Your Role in Promoting a Culture of Safety

- Know what is expected in all of the care you givebe clear on HOW to best do things to protect patients and do it that way all the time
- Speak up about your work environment, issues, and concerns that may lead to problems with patient safety
- Report ALL abnormal events and close callsopenly give your POV of what and why
- Encourage patient engagement-don't take offense if they speak up-YOU are the professional
- Be open & honest with surveyors about your facility's "culture"! They can help improve things!

#### Dialysis Technicians are an Integral Part of the IDT

- Dialysis Technicians and other Direct care Staff **ARE THE CAREGIVERS**
- You have the most contact with the patients
  - You know them BEST-things the other IDT members do NOT know about them
- You have the greatest opportunity to establish rapport with the patients
- You are the primary members of the IDT that implement each patient's individualized plan of care

#### Be an Active Member of the IDT to Optimize Your Patients' Outcomes

- Dialysis Technicians and other Direct Care Staff are in the best position to "see" problems for patient outcomes first and communicate with the other IDT members to find solutions
- YOU can positively influence your patients' clinical outcomes by being an active IDT member, and bringing what YOU know about each patient to the team

### Why Is This Important?

- Because failing kidneys produce less or no erythropoietin (which stimulates red cell production)
- Because high fluid volume "dilutes" the blood & the dialysis process itself results in blood loss
- Because the IDT is expected to work with the patient to:
  - Identify, attain, and maintain the hemoglobin level that allows for desired function and QOL without S/S;
  - Use ESAs and iron appropriately to achieve that level respecting the patients risk/benefit choices;
  - Avoid transfusion

#### The ESRD Conditions for Coverage (CfC) Requirements for Clinical Management of Dialysis Patients

- Assess each patient's individual needs and plan and provide the care and services to meet those needs, using established clinical practice standards as the outcome goals
- The assessment and planning of care must include at least the members of the facility Interdisciplinary Team

#### Areas of Clinical Care in the CfC

- Anemia
- Dialysis adequacy and dialysis access
- Fluid and blood pressure
- Mineral and bone
- Nutrition
- Psychosocial and rehab

## Ways YOU can help improve your patients' anemia outcomes

- Watch patients for symptoms of increasing anemia and communicate this
  - Less energy, more shortness of breath, more pale, c/o chest pains
- Minimize blood loss from HD
  - Return as much blood as possible-report if dialyzer does not clear
  - Reduce heparin if prolonged or excessive bleeding (needs an order)

# Ways YOU can help improve patients' adequacy outcomes

- Deliver the patients' dialysis prescription accurately and consistently- communicate if you can't and why
  - Dialyzer type, BFR, DFR, dialysate, heparin, time
  - Make suggestions for improvement (e.g. 个BFR if access can support it)
- Monitor the vascular access
  - Follow your procedure, report when there are changes
- Draw post dialysis labs correctly (per procedure)
- Engage patients in improving their adequacy; encourage/support adherence ("It's great that you stayed for all 4 hours")

#### Ways YOU can improve outcomes in fluid and blood pressure

- Limit the fluid removal during an HD tx
  - Some studies suggest max 10-13mL/kg/hr
    - In 100kg. patient, no more than 1,000-1,300UFR
    - In 70kg. Patient, no more than 700-900UFR
- Be aware when your patient's blood pressure is not their "usual"-report too high or low
- Recognize that drops in BP ("crashes") and intradialytic symptoms of fluid depletion are detrimental to the patient and may shorten their life
- Engage patients in knowing why they should limit fluid & salt intake; Encourage/support adherence ("You only gained2 kg.-good work!")

#### Ways YOU can help patients adjust

## Create a Culture of Safety in your facility

- Maintain a professional attitude
  - It's not about us, it's about the patients
- Encourage patient engagement in their treatment plan
- Educate patients about dialysis and rationale for following their treatment plan
- Reinforce/support adherence (fluid, diet, etc.)
- Listen to the patients' "voices", and communicate with the other IDT members what you know about the patient

#### Infections: A Major Patient Safety Problem in Dialysis – 2<sup>nd</sup> Leading Cause Of Death



Approximately 15,000 dialysis patients die annually due to infections <sup>35</sup>

### IC Challenges in Dialysis

- Temporal and spatial issues
- Water and dialysate
- Staffing matrix

# Why Is Infection Prevention Such a Challenge in Dialysis?

The in-center hemodialysis patient treatment reality:



#### How Are Infections Spread in Dialysis?

Five main sources of pathogen transmission:

- On the hands of staff going between patients & between common areas and patients
- 2. From ineffectively disinfected equipment & environmental surfaces
- 3. From contaminated supplies & medications
- 4. From inadequate vascular access care
- From virulent pathogens (e.g. hepatitis
   B)

#### Dialysis Patient Infections Can Be Prevented by:

## Following good infection prevention and control practices

The Centers for Disease Control and Prevention (CDC) has guidelines for these practices in dialysis facilities

#### The CDC Guidelines

- Address general practices (wash hands, clean & disinfect equipment, etc.)
- •Do not include details for **application** of the guidelines (what parts of the equipment need to be disinfected, etc.)

#### Remember the lesson from the Patient Safety Movement...

## Staff need clear directions in what is expected of them in their duties...

### NOTICE!

#### <u>National Opportunity To</u> Improve Infection Control In <u>E</u>SRD

The NOTICE Initiative is funded by the Department of Health and Human Services to support the renal community in improving infection control

Initiation of Dialysis with Central Venous Catheter #1
<u>Notes</u> : Patient should wear a mask whenever CVC is accessed; Staff PPE must be gown, mask and eye protection, gloves
Bring supplies needed for that patient to station (no common cart/tray)
Hand hygiene, don clean gloves
Place clean field under CVC ports
Close CVC clamps: Disinfect exterior or interior of CVC hubs with appropriate antiseptic (exterior disinfection=wipe hubs before removing; interior disinfection=remove caps, wipe threads and top of open hub to remove residual blood/residue; closed connector devices=wipe outside connecting surfaces)
Connect sterile syringes aseptically to each port to remove indwelling solutions and/or flush with sterile saline; initiate treatment
Remove gloves; hand hygiene
<u>Note</u> : If troubleshooting or manipulation of catheter or dialysis lines occurs during the dialysis treatment, then PPE, hand hygiene, gloves and external disinfection of the CVC hub procedure should be performed as above with each manipulation.

Discontinuation of Dialysis with Central Venous Catheter #3
<u>Notes</u> : Patient should wear a mask whenever CVC is accessed;
Staff PPE must be gown, mask, eye protection, and gloves
Bring supplies needed for that patient to station (no common cart/tray)
Hand hygiene, don clean gloves
Place clean field under CVC ports
Reinfuse extracorporeal circuit
Remove gloves; hand hygiene; don clean gloves
Close CVC clamps: Disinfect connections with appropriate antiseptic (exterior disinfection=wipe exterior connection before disconnecting blood lines; open hub disinfection=wipe threads and top of open hub after disconnecting blood lines, removing any residue/blood; closed connector devices=wipe exterior of connections before disconnecting blood lines)
Disconnect blood lines aseptically
Apply sterile port caps aseptically after post-treatment protocol (applicable to closed connector devices when changed)
Discard unused supplies or dedicate to that patient-no supplies returned to common supplies
Remove gloves; hand hygiene

	CVC Exit Site Care
	Notes: Patient should wear a mask whenever CVC is accessed;
	Staff PPE must be gown, mask and gloves
	No common supply cart/tray brought to station (supplies for only that patient brought to station)
$\longrightarrow$	Hand hygiene, don clean gloves
	Remove old dressing & discard
	Remove gloves; hand hygiene; done clean gloves
	Cleanse area around CVC exit site with antiseptic; allow to dry before applying dressing
	Apply sterile dressing to CVC exit site may apply antimicrobial ointment if not contraindicated or chlorhexidine-impregnated dressing if no sensitivity
	Remove gloves; hand hygiene

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Initiation of Dialysis with AV Fistula or Graft
Notes: Staff PPE must be gown, face shield or mask/eye protection, and gloves
Bring supplies needed for that patient to station (no common cart/tray)
Patient or staff wash skin over access with soap and water or antibacterial scrub Note: Patients should be instructed to wash their access sites upon entering facility and staff verbally confirm with patient that it was done; for dependent patients, staff must do this before proceeding with skin antisepsis
Evaluate access; locate/palpate cannulation sites
Hand hygiene (remove gloves, if worn); don clean gloves
Apply antiseptic to skin over cannulation sites and allowed to dry; sites not touched again after skin antisepsis without repeating skin antisepsis
Insert cannulation needles; tape in place; initiate treatment
Remove gloves; hand hygiene
Note: This checklist is not intended for use with buttonhole cannulation technique

Discontinuation of Dialysis and Post Dialysis Access Care of AV Fistula or Graft
<u>Notes</u> : Staff PPE must be gown, face shield or mask/eye protection, and gloves
No common supply cart/tray brought to station (supplies for only that patient brought to station)
Hand hygiene, don clean gloves
Reinfuse extracorporeal circuit, disconnect bloodlines aseptically
Remove gloves; hand hygiene; don clean gloves
Remove needles aseptically; discard needles in Sharps container at point of use Needle sites held with clean bandage or gauze using clean, gloved hands (patient, staff, other) or disinfected clamps
Remove gloves; hand hygiene
When hemostasis is achieved: Hand hygiene; don clean gloves; replace blood-soiled bandage or gauze to needle sites Ensure the bandage or gauze on each needle site is clean and dry before discharge
Discard unused supplies or dedicate to that patient-no supplies returned to common supplies
Remove gloves; hand hygiene Patient or visitor who held sites remove gloves, hand hygiene

Cleaning and Disinfection of the Dialysis Station #6 <u>Notes</u> : All items listed below must be disinfected using an EPA-registered hospital disinfectant prepared and used per manufacturer's instructions for us Staff PPE must be gown, face shield or mask/eye protection, and gloves	
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	se;
Remove all bloodlines & disposable equipment & discard in biohazardous waste; dialyzer for reprocessing cap all ports; transport dialyzer and bloodlines in a manner to prevent contamination of other surfaces	
Empty prime waste receptacle, if present on machine	
Remove gloves; hand hygiene; don clean gloves	
Use disinfectant cloth/wipe to visibly wet all machine top, front and side surfaces, dialysate hoses, Hansen connectors, and outside surfaces of concentrate containers	
□ Wipe wet all internal and external surfaces of prime waste container & allow to dry (prime waste container must be disinfected before used to prepare for another patient treatment)	V ľs
When chair is vacated, remove and discard disposable supplies or dedicate to that patient-not returned to common supplies	e
Recline chair fully, use a fresh disinfectant cloth/wipe to visibly wet all external front-facing and side chair surfaces, including along sides of seat cushion and side tables	$\langle$
Apply disinfectant to all non-disposable items: BP cuff and tubing, TV controls, call button, data entry station & counters around station	
If clamps were used, cleaned of visible blood and disinfected	
Discard cloths/wipes	
Remove gloves; hand hygiene	

**Note:** It is **not required** that the patient has vacated the dialysis station before disinfection and preparation of the machine can be conducted.

If the patient remains in the chair during disinfection, strictly adhere to separation b/t the patient and the disinfected/prepared machine.

#### **Checklist:** Dialysis Station Routine Disinfection

This list can be used if there is no visible soil on surfaces at the dialysis station. If visible blood or other soil is present, surfaces must be cleaned prior to disinfection. The proper steps for cleaning and disinfecting surfaces that have visible soil on them are not described herein. Additional or different steps might be warranted in an outbreak situation. Consider gathering necessary supplies<sup>1</sup> prior to Part A.

#### Part A: Before Beginning Routine Disinfection of the Dialysis Station

Discard tubing and dialyzers in a leak-proof container<sup>2</sup>.

Check that there is no visible soil or blood on surfaces.

Ensure that the priming bucket has been emptied<sup>3</sup>.

Ensure that the patient has left the dialysis station<sup>4</sup>.

Discard all single-use supplies. Move any reusable supplies to an area where they will be cleaned and disinfected before being stored or returned to a dialysis station<sup>5</sup>.

Remove gloves and perform hand hygiene.

#### PART B: Routine Disinfection of the Dialysis Station - AFTER patient has left station

Wear clean gloves.
Apply disinfectant <sup>§</sup> to all surfaces <sup><math>Z</math></sup> in the dialysis station using a wiping motion (with friction)
Ensure surfaces are visibly wet with disinfectant. Allow surfaces to air-dry $^{\underline{8}}$
Disinfect all surfaces of the emptied priming bucket <sup>3</sup> . Allow the bucket to air-dry before reconnection or reuse
Keep used or potentially contaminated items away from the disinfected surfaces
Remove gloves and perform hand hygiene.

Do not bring patient or clean supplies to station until these steps have been completed.



Making dialysis safer for patients



Centers for Disease Control and Prevention National Center for Emerging and Zoonotic Infectious Diseases

Dialysis Supply Management & Contamination Prevention
Supplies are stored and kept in designated clean areas, sufficient distance from dialysis stations to prevent contamination from potentially infectious materials/substances
□ Supplies for next patient are not brought to the station before the prior patient's treatment is discontinued and applicable equipment (machine, chair) cleaned/disinfected (supplies for the next patient are not placed on or near the machine until it has been stripped, cleaned and surface disinfected)
Carts or trays containing supplies are not taken to or moved between dialysis stations
Staff do not keep patient care supplies in pockets or on their person
Non-disposable equipment (e.g. thermometer, pH/conductivity meter, access flow device, O <sub>2</sub> saturation meter, blood glucose meter, stethoscope diaphragm/bell end) brought to the dialysis station is cleaned and disinfected before being returned to a common area or taken to another dialysis station. Disinfection=all surfaces wiped with EPA-registered hospital disinfectant and allowed to dry
Medication vials are not taken to the dialysis station
Disposable supplies taken to the dialysis station and not used for the patient are discarded or dedicated to the individual patient & not returned to common supplies

Parenteral I	Medication	Preparation	and
Administrat	tion		

#8

<u>Notes</u>: Medications must be prepared in a clean area on a clean surface away from dialysis stations. The exception to this is drawing saline syringes from the patient's saline bag at the station following aseptic technique after wiping port with disinfectant prior to aspirating.

#### Hand hygiene

Γ	Single dose	vials used	for one patie	nt only and	discarded
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Multiple dose vials entered with ONLY a new, empty, sterile syringe and needle (label with date opened and discard within 28 days or by manufacturer instructions)

Wipe stopper with alcohol or other antiseptic

Withdraw medication into sterile syringe; label syringe if medication not immediately administered Note: May prepare meds for multiple patients at one time, but administration must be to one patient at a time, leaving the remainder of drawn meds in the clean

preparation area

Take only individual patient's medications to their dialysis station

Hand hygiene; don clean gloves (other PPE as indicated by potential exposure)

Wipe injection port with disinfectant; inject medication

Discard syringe into Sharps container (exception if using needless system with no attached needle, disposal in Sharps not necessary)

Remove gloves; hand hygiene

### In Summary

#### **Dialysis Technicians:**

- Are in the best position to know what is going on with the dialysis patients
- Are integral to the facility Interdisciplinary Team
- Can positively influence patients' clinical outcomes
- Are vital to the implementation of a "Culture of Safety" in the dialysis facility
- Are vital in reducing HAI