A WORD ON REGULATORY AND COMPLIANCE

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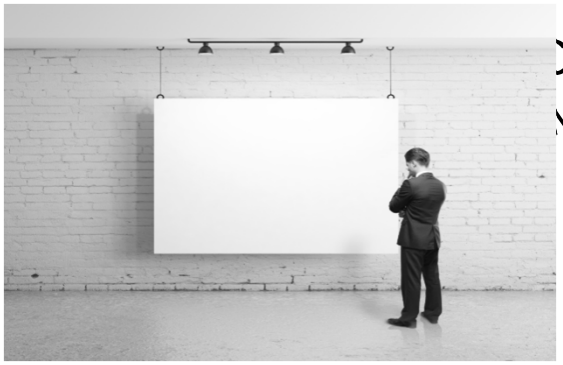
Introductions

Rules and Regulations



- The Regs We Share
- The Money Regs
- The Regs (Rules) We Break
- Plain Language

Objectives

At the end of the session the participant will be able to:

List three Emergency Preparedness responsibilities of ***every*** staff member in ***every*** setting

Identify three strategies for effective use of audits

Describe CMS expectations of interdisciplinary/multidisciplinary teams

Rules and Regulations

- **Emergency Preparedness Requirements for Medicare and Medicaid Providers and Suppliers**
  - Providers to implement by November 2017
- **Transplant Conditions for Participation**
  - Requirements for Approval and Reapproval
- **Dialysis Conditions for Coverage**
  - Basis for determining whether services will be covered by Medicare
- **Trade Preferences Extension Act**
  - Medicare Reimbursement for Acute Patients in Chronic Units
- **Policies and Procedures of clinic or hospital**
  - Providers guide for practice in specific workplace

THE *BURDEN* OF SURVEY

What does it add to the burden of managing complex patients?

What about areas where those patients are managed without special regulation?

Proposal to Reduce Burden

(CMS), HHS. ACTION: Proposed rule.

SUMMARY: This proposed rule would reform Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. This proposed rule would increase the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

Comments due by November 19, 2018 by 5PM

Emergency Preparedness

Emergency Preparedness Regulations

- Affect every provider type that participates in Medicare or Medicaid.

Transplant

- Not required to develop its own plan
- Must have representative(s) on group developing hospital plan
- Must have specific policies and procedures
- Requirement for "practices" is under review
- Competing forces: reduce burden, address increased medical challenges due to natural, and other, disasters

Emergency Preparedness Regulations

ESRD Centers

- Must develop individual facility plan for management in the event of an on site emergency:
  - Fire
  - Loss of power, water
  - Potential Violence
  - Potential threats identified by team
- Must conduct training in preparation and simulated emergency
- Must participate with other members of the community to clarify roles in broader emergency plan

Emergency Preparedness Regulations

Clinics

- Requirements Vary with location
  - Freestanding
  - Within another institution
- In all cases the clinic must have specific procedures for emergency response and designated responsible parties who understand and accept their responsibilities.
- Adequate training is provided to enable the staff to respond promptly and effectively to emergencies with highest likelihood of occurring at that site.

Emergency Preparedness Tasks

All providers

All staff, physicians, consultants and patients should:

- Understand THEIR role in those emergencies for which the provider identified potential risk and developed response plans.
- Share with management any concerns they have about the feasibility of the plan, especially any discomfort they have with performing their role.
- Share with management any potential risks they identify or think should be evaluated, for example: potential for violence, possible supply or staffing crises, other

Conditions of Participation: Transplant

General Requirements for Transplant Centers

- Special Requirements
- OPTN Membership
- Notification to CMS
- Pediatric transplants

Transplant Center Data Submission, Clinical Experience, Outcome Requirements

- Data Submission, Clinical Experience, Outcome Requirements: Initial
- Data Submission, Clinical Experience, Outcome Requirements: ReApproval

Conditions of Participation: Transplant

Transplant center Process requirements

- Patient and Living Donor Selection
- Organ Recovery and Receipt
- Patient and Living Donor Management
  - Multidisciplinary Care Team
- Quality Assessment and Performance Improvement
- Human Resources
- Organ procurement
- Patient and Living Donor Rights
- Additional Services Kidney Transplants

Conditions for Coverage Dialysis

1 Compliance	**19 Care at Home**
29 Infection Control	**15 QAPI**
91 Water and Dialysate	**7 Special Purpose Facilities**
73 Reuse	**1 Laboratory Services**
20 Physical Environment	**16 Personnel Qualifications**
20 Patients' Rights	**6 Medical Director**
20 Patient Assessment	**8 Medical Records**
22 Patient Plan of Care	**23 Governance**

272-291 rules

The Trade Preferences Extension Act 2015

Coverage

Section 1861 Social Security Act amended to include:

"Renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services to a patient with acute kidney injury."

Payment

Section 1834 of Social Security Act amended to include

Payment for renal dialysis services for individuals with acute kidney injury

How Good Is Compliance with the Regs?

Top Ten Cited ESRD Deficiencies in 2017

IC - WEAR GLOVES/HAND HYGIENE	24.6%
IC - CLEAN, DISINFECT SURFACES & EQUIPMENT/WRITTEN PROTOCOLS	21.6%
PE - EQUIPMENT MAINTENANCE - MANUFACTURER'S DFU	14.4%
MANAGE VOLUME STATUS	14.1%
IC - ASEPTIC TECHNIQUES FOR IV MEDS	11.4%
IC - STAFF EDUCATION RE CATHETERS/CATHETER CARE	10.6%
APPROPRIATENESS OF DIALYSIS RX	10.2%
IC - CLEAN/DIRTY AREAS, MED PREP AREA, NO COMMON MED CARTS	10.0%
IC - SANITARY ENVIRONMENT	9.6%
IC - WEAR GOWNS, SHIELDS/MASKS; STAFF NOT EAT/DRINK IN TX AREA	9.5%

Is this important?

- Healthcare Acquired Infections (HAI) reportedly account for 1.7 million infections and 99,000 deaths annually.
- CDC, CMS, Agency for Healthcare Research and Quality (AHRQ), and HHS leadership prioritize and work collaboratively on this threat.
- Standardizing practices that reduce these infections has brought significant reductions in several infection categories.
- ***Do you track infections and conduct practice audits to prevent or reduce infections?***

Audits

- Measuring a clinical outcome or process against a defined standard
- Takes Time. Takes Team.
- Develop clear objective
- Collect, then analyze data
- Incorporate input from observed staff into analysis

Takes *TEAM?*

- Transplant regulations require multidisciplinary teams
- ESRD regulations require interdisciplinary teams
- Team members are expected by CMS:
  - Perform and Document Assessments, including "specials"
  - Activate necessary resources for patients as required
  - Collaborate in formation of Care Plans with Team
  - Communicate potential problems, as observed, or reported by patients, families and/or staff, to appropriate program management forum
  - Participate in performance improvement activities as a specialist and a active team member (QAPI mandatory for transplant and ESRD programs)

Care Plan Expectations, Simplified

- Specialized Assessment , Collaborative Plan
- Patient's voice central to the plan, even pre-verbally
- Patient's family's voice is heard in the plan, even routine plans
- Monitor, Recognize, and Address
- Repeat

Culture of Safety Theory

Based on the belief
that human errors are unavoidable,
and systems need to be built to create protective barriers

that every person at every level in the system has to be engaged in reducing errors and error trajectory

that a patient viewpoint, a new staff member viewpoint, a dietitian viewpoint, medical director viewpoint may be different; but errors happen at every level: all speak, all listen

that vigilance is important, encouraged, expected, appreciated at all levels: all speak, all listen

Different Management Question Today: Am I engaged?

Quality Assessment and Performance Improvement

- Are we GOOD?

How do we compare to community benchmarks in outcomes?

- Are we SAFE?

What do our errors, near misses, complaints and audits tell us about opportunities to reduce risk?

Are we READY?

Do we have clear, realistic plans to deal with foreseeable emergencies?

Quality Assessment and Performance Improvement

- All speak, all listen
- Your calendar is your friend, schedule as needed
- Every problem gets a plan
- Big challenges may need slicing and dicing
- The plan can be wait and see
- It can't be wait and see forever
- Plans need point people, depth, dates, and review
- Hold onto the rope
- Speak to the Good of the Order

Culture of Safety Action

Monitor:

- No news is no news
  - Ask
  - Provide non threatening avenues for input for careful processors
  - Listen for the meaning
  - Probe for meaningful details
  - Reward in all the ways that count
  - New eyes (company is coming)
  - Watch for canaries
  - This is not for surveyors

Culture of Safety Action

Recognize:

- If wishes were horses
  - If you must have an "excuse column" use it as a starting point, then click "hide"
  - Think 5 whys
  - Yours is not the only plate
  - A recognized risk cannot go plate-less
  - Don't wait till you have time to rationalize
  - Don't "continue to monitor" too long
  - You know how long is too long, teach the people you mentor
  - This is not for surveyors

Culture of Safety Action

Address:

- There is no "I" in TEAM, there is hope
- Don't fake it fix it
- If you can't fix it get help
- Once you do fix it, see that it stays fixed
- If you came up with a great fix, share
- This is not for surveyors

Does CMS want what Managers Want?

	CMS	YOU
Safer patients		
Increased patient perception of care		
Better health in the patient group		
Lower per capita cost of treatment		
Best practices identified and used		

Thank You

Wishing you serenity for all you do

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2018 ASPN MULTIDISCIPLINARY SYMPOSIUM

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