

New Conditions for Coverage

Andrew Lleras MPH, CHT, CBNT

President Elect –NANT

Administrator of Renal Services

The Terence Cardinal Cooke Health Care Center

New Conditions are divided into 4 sub parts

- General Provisions
- Patient Safety
- Patient Care
- Administration

Subpart A

General Provisions

Subpart A - General Provisions

- § 494.1 Basis & Scope
- § 494.10 Definitions
- § 494.20 Condition: Compliance with
Federal, State, and local laws and
regulations (V100)

Subpart A -General Provisions I

- **§494.1 Basis & Scope**

- Identifies the statutory authority of the new regulations
- Social Security Amendment of 1972 Sec. 2991
 - Extended Medicare coverage to ESRD patients
- Sec. 1861
 - (e)(9) Must meet all requirements in the interest of health & safety of individuals receiving services
 - (s)(2)(F) Inclusion of Home dialysis & self care supplies, recognition of role family members will play
- Sec. 1862
 - Exclusions of coverage
- Sec. 1881
 - Payment to approved facilities, transplant services, and the administration of ESAs (erythropoiesis-stimulating agents)
- Sec. 12 National Technology & Transfer Act
 - Requires federal agencies to use technical standards developed by standards bodies

Subpart A -General Provisions II

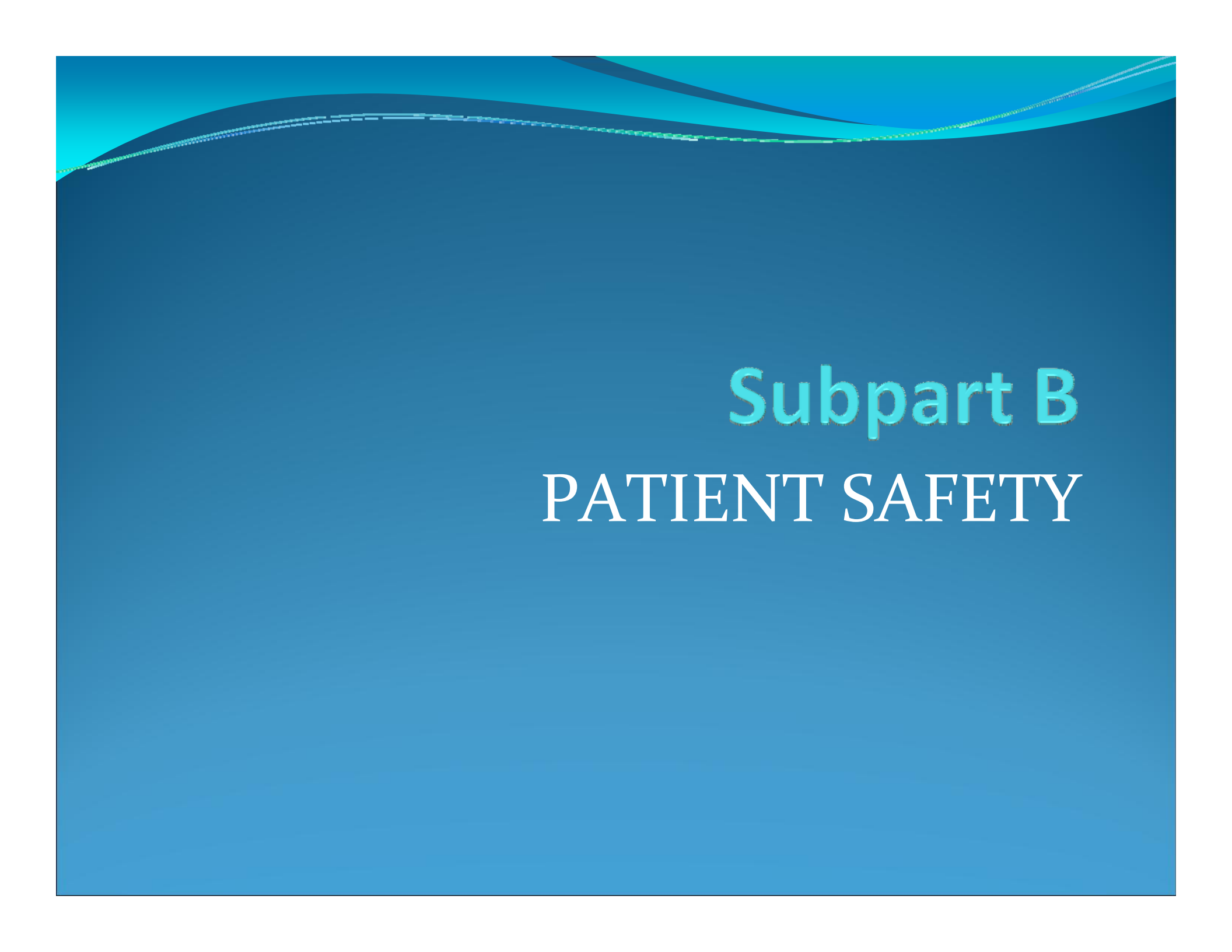
- **§494.10 Definitions**

- **Dialysis Unit** – entity that provides outpatient maintenance dialysis service.
- **Discharge** – termination of patient care services
- **Furnishes Directly** – services provided by the dialysis unit through staff or individuals under contract to furnish these services
- **Home dialysis** – dialysis performed at home by ESRD patient or caregiver
- **Self-dialysis** – dialysis performed with little or no professional assistance by the ESRD patient or caregiver
- **Transfer** – temporary or permanent move of a patient from one dialysis unit to another which requires medical record transmission

Subpart A-General Provisions III

- **§ 494.20 Conditions**

- **This Condition emphasizes Centers for Medicare & Medicaid Services' (CMS) role as a partner with State and local governments and with other Federal agencies. The purpose of this Condition is to affirm the principle that Medicare reimbursement should be distributed to ESRD facilities that comply with local, State and Federal laws and rules. This Condition is not intended to adjudicate laws and rules from state and local governmental agencies. This Condition should only be cited when a specific “deficient” practice has been completely settled with the appropriate entity, and a final decision of non-compliance with the other entity’s requirement has been reached. Facilities are expected to comply fully with investigations conducted by public health, regulatory, or law enforcement authorities.**



Subpart B

PATIENT SAFETY

§ 494.30 Infection Control (V110 – 148)

- a) Standard: Procedures for infection control
 - “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients”
 - “Guidelines for the Prevention of Intravascular Catheters Infections”
- b) Standard: Oversight
 - Monitor and implement policies and activities
 - Clinical staff is compliant with aseptic technique
 - Staff to report
- c) Standard: Reporting – communicable diseases

Types of Infectious Diseases Seen in Dialysis:

- Hepatitis B
- Hepatitis C
- HIV
- TB
- MRSA/VRE
- Scabies



Procedures for infection control

- Washing hands / gloves– when touching pt or equipment
- PPE- potential for blood spurting
- Staff – no eating, drinking or drink in pt area
- Proper handling of equipment – disposal, disinfection, signal use
- Separate clean / dirty areas
- Medications – draw up in clean area, don't bring multi dose vials to pt, no medication carts, trays must be cleaned between pts., single dose vials punctured once.

Infection Control (cont.)

- Supply carts – common areas only (outside patient cubicle/treatment area)
- Transducers – must be used, changed when wet and between pts. Units should adopt a policy for the monitoring and “flagging” of machines should an potential exposure occur.
- Infectious waste – handling, storage, disposal; a “manifest” of all bio-hazardous waste must be maintained
- Cleaning of contaminated surfaces, equipment with approved surface disinfectant

Infection Control - Hepatitis

- Must have routine testing/screening - pt/staff
- Seroconversion
- Vaccination
- Isolation –
 - room/area
 - dedicated equipment/supplies
 - Staff – should not care for HepB susceptible pts.

Infection Control - Oversight

- Policies/procedures – implementation and monitoring
- Training and education of staff
- Reporting IC issues
- Catheters
 - Education/training
 - Many states – catheter is considered a central line and must only be accessed by a licensed nurse
 - Surveillance – site, infection, tracking, root cause
 - Antibiotic locking solution – don't use routinely

§494.40 Water and Dialysate quality

- Water purity
 - ANSI/AAMI RD52:2004
- Chemical analysis
- Bacteriology
- Ultrapure dialysate
- Corrective action plan / backup plan
- Adverse events
- In-center use of preconfigured hemodialysis systems

Water purification system

- Secure & restricted area
- Access to ports and meters
- Alarms in treatment area
- Schematic and label components
- Components of Water System
 - Sedimentation filters - configuration & monitoring
 - Cartridge filters - configuration & monitoring
 - Softners – regeneration, testing/documentation
 - Carbon adsorption – two tanks/sample ports, bank of tanks, CA media, monitoring, testing, frequency, and actions

Components of Water System (cont.)

- Chemical injection systems
- Reverse osmosis – meets AAMI standards, monitoring, documentation, alarms, prevent unsafe water, chemical analysis frequency
- Deionization – continuous monitoring resistivity/logged 2x day, alarms/divert to drain, require carbon pre & UF post, polisher or backup, chemical analysis: frequency
- Ultrafiltration – effectiveness, opaque housing, monitoring,
- Water storage – general design, tank shape/vent/disinfection/filter post, monitoring
- Water distribution system – continuous flow rates/ no dead ends, no added burden, culture/LAL sample/sites/frequency /document

Bacteria Control Devices

- Ultraviolet irradiators – filters post
- Ozone generators – system requirements / monitoring
- Hot water disinfecting systems – time/temp/follow up/DFU/piping, monitoring
- Strategies – disinfection monthly/disinfection dwell, machine supply line disinfection

Concentration Preparation

- Bulk storage tanks – safety controls
- Mixing systems – water/drain/electric, safe environment/PPE, follow DFU/monitor/PM log/sanitization, self design, labeling, permanent record/verification testing, cleaning, empty completely/prevent corrosion
- Bicarbonate concentration mixing system – empty/prevent corrosion, storage/use time limits/minimize combine, not over mixed
- Additives – mixing spikes, labeling/additive/patient

Concentration Distribution

- System configuration – tanks elevated
- Bicarb distribution systems – weekly disinfection/dwell times/concentration, use of UV, ozone disinfection, labeled & color coded blue & sealed
- Concentration distribution – bicarb monitoring initially, bicarb jugs rinsed daily/stored dry/jug disinfection, outlets labeled separately (if more than 1)
- Acid concentration distribution system – labeled & color coded red
- Dialysate proportioning system – match ratio to machines, monitor ph/conductivity

Monitoring

- Monthly water samples
- Monthly dialysate samples
- Collected before disinfection
- Repeat cultures
- Heterotropic plate count (dip) – use with QC, procedure
- LAL testing
- P/P
- Training program/periodic audits

Monitoring – Cont.

- Chlorine/Chloramines
 - Free Chlorine 0.5mg/L or Chloramines 0.1 mg/L
 - Breakthrough – corrective action, holding tank, notify medical director, correction
- Water test results – deviation from norm – corrective action plan
- HD system – follow FDA labeling, meet AAMI standards, quarterly cultures/LAL

Condition: Reuse of hemodialyzers and bloodlines

- General requirements – no HepBAg+ pts, dialyzer labeled for reuse, medical records, reuse manual
- Reprocessing requirements
 - “Reuse of Hemodialyzers” third edition, ANSI/AAMI RD47:2002 and RD 47:2002/A1:2003
- Training & curriculum – medical director certification
- Personnel – PPE, medical records

Reuse:

- Patient issues - Physician order, Fully informed
- Equipment – design, maintenance, repairs by qualified personnel, retested after repairs, records,
- Water – meet AAMI bact/chem
- Physical environment – clean, sanitary, ventilated

Reprocessing

- Segregate dialyzers in process
- Use of supplies, testing of concentration
- Labeling & placement, similar name warning,
- Handling & transporting dialyzers
- Pre cleaning – use AAMI quality water
- Dialyzer header cleaning
- Rinsing/cleaning – chemical used
- Testing – volume, blood path integrity, germicide
- Inspection – clean, blood removed (only a few blood fibers), dialyzer case intact, no leaks, labeled

Prep for dialysis and monitoring

- Visual inspection
- Germicide confirmed
- Verification of patient – 2 people
- Priming the dialyzer and rinsing germicide
- Testing for residual germicide
- Dialysis treatment
 - Monitor pt during tx and dialyzer issues
 - Systems – fever, chills, other

Documentation

- Adverse events
- Dialyzer failure: Blood leaks, volume
- Clinical results – Kt/V, Ultrafiltration
- Quality Assurance
 - Annually
 - Pt considerations
 - Equipment manual & procedures
 - Physical plant & environmental safety
 - Semi annually – supplies
 - Quarterly – labeling, reprocessing, preparation for tx

Other considerations

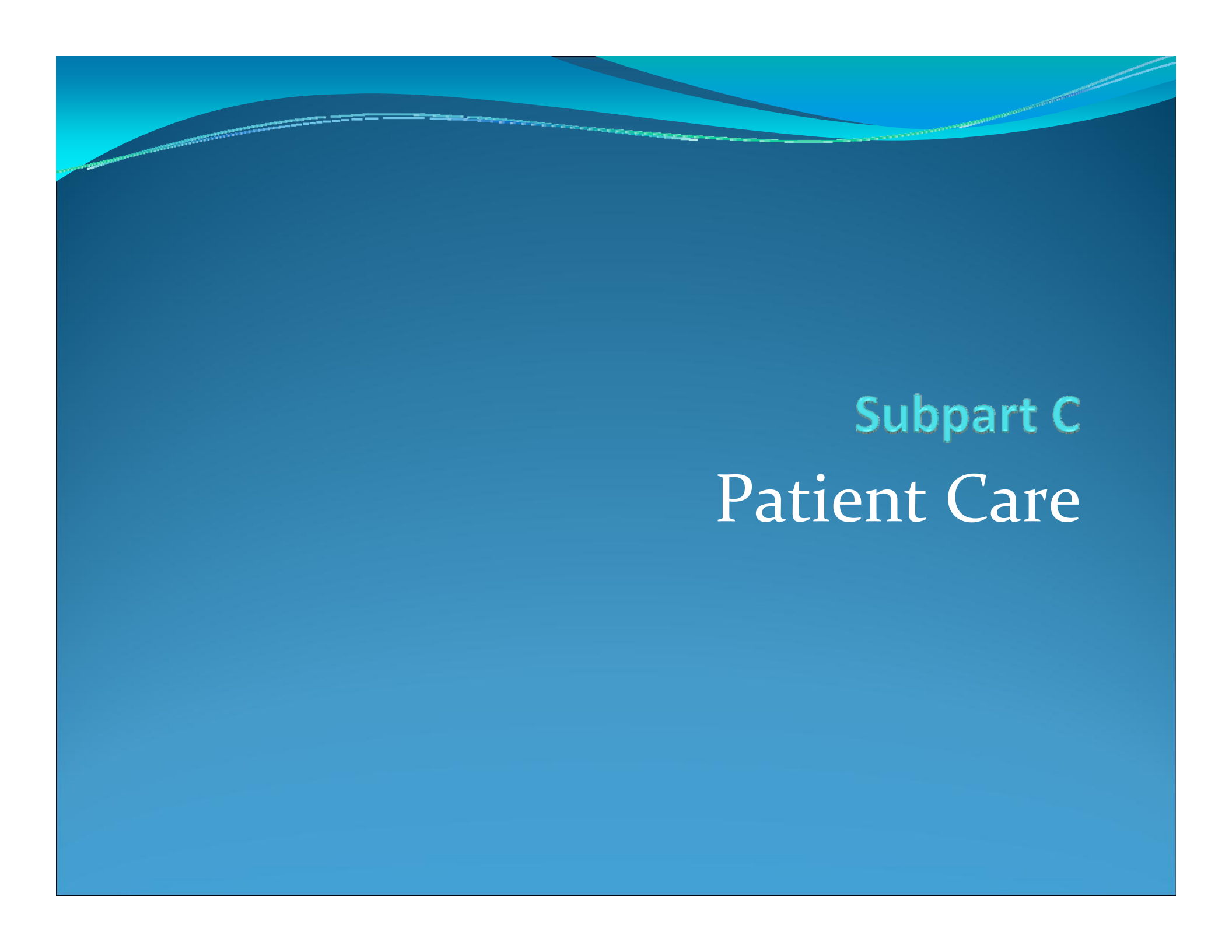
- Only 1 chemical/dialyzer
- Adverse reactions
 - Blood/dialysate cultures
 - Cluster of reactions – suspend reuse
 - Report to FDA, Federal, State, and Local government as required

§ 494.60 Physical Environment

- Building –constructed and maintained safe for pt, staff & public
- Equipment maintenance – operable by manufacturers recommendations
- Patient care environment – space, reasonable temp (pt not comfortable), pt privacy for exams, pt in view of staff during tx (no video surveillance)

Physical environment cont.

- Emergency – fire, power failure, care related emerg., water supply interruption, natural disasters.
- Emergency preparedness of staff: training, pt care staff – CPR, nsg- emergency equip & drugs
- Emergency preparedness patient training
- Emergence equipment – Oxygen, airways, suction, AED, and drugs
- Emergency plans – annual review & notify OEM
- Fire safety – “2000 edition of the Life Safety Code of the National Fire Protection Ass.; sprinkler required if built after 1/2008; wavier may be applied for



Subpart C
Patient Care

§494.70 Patients' Rights

- Inform pt of rights and responsibilities when they begin their tx.
- Must protect and provide for exercise of rights
- Right to be informed of facility's discharge and transfer policy – 494.180(f)(4).
- Posting of rights

§494.80 Patient Assessment

- Interdisciplinary team – pt or designee, RN, physician, SW, dietitian.
- Individualized and comprehensive to meet the pt's needs
- Used to develop plan of care
- Assessment Criteria

- **Current health status & medical condition including comorbid conditions**

- **Appropriateness of dialysis prescription**

- **Blood pressure & fluid management**

- **Lab profile**

- **Immunization & medical history**

- **Anemia**

- **Renal bone disease**

- **Nutritional status**

- **Psychosocial needs**

- **Vascular access**

- **Pt's involvement in care, choice of modality, expectations of outcomes**

- **Evaluation for transplant**

- **Support systems**

- **Physical activity level**

Patient Assessment (cont.)

- Frequency of assessment
 - Initial – latter of 30 calendar days or 13 txs
 - Follow up reassessment – within 3 months of initial assessment
- Assessment of treatment prescription – HD monthly, PD 4 months
- Patient reassessment –
 - annually for stable pts;
 - monthly for unstable
 - extended or freq. hosp,
 - deterioration in health,
 - changes in psychosocial needs, or
 - poor nutritional status, unmanaged anemia and inadequate dialysis.

§494.90 Patient plan of care

- Written, individualized comprehensive PoC based on pt's needs and identified in comprehensive assessment
- Development of patient PoC by IDT–
 - dose of dialysis, nutritional status, mineral metabolism, anemia, VA, psychosocial status, modality, transplant status and rehabilitation
- Implementation of PoC –
 - w/in 30 days or 13 txs, w/in 15 days of updates
 - If unable to achieve goals – must update, state reason
 - Seen monthly by phy, NP, CN specialist, or PA evidenced by note
- Transplantation referral tracking – track resolute of referral, status of pt, communicate w/transplant center at least annually.
- Patient education and training – dialysis management, infection control, personal care, tx modalities, quality of life, rehabilitation, vascular access

§494.100 Care at Home

- Approved to provide home services
- Services must be equivalent to in-center services
- Training – conducted by RN, overseen by IDT
 - ESRD management, procedures, complications, support resources, handling of emergencies, monitoring & documentation, infection control procedures, waste handling and disposal
- Home dialysis monitoring – document training, retrieval & review of monitoring records & placement in medical record
- Support services – emergency back up care, home visits, maintenance of equipment, H2O

§494.110 Quality assessment and performance improvement

- Develop, implement, maintain, and evaluate an effective data driven, quality assessment and performance improvement program w/ participation by the professional members of the ID team
- Program scope
 - improve health outcomes and reduction of errors
 - Measure, analyze and track quality indicators
 - Include: adequacy of dialysis, nutrition, mineral metabolism and renal bone disease, anemia, VA, medical injuries and errors, hemodialysis reuse, pt satisfaction & grievances, and infection control.



Quality assessment and performance improvement II

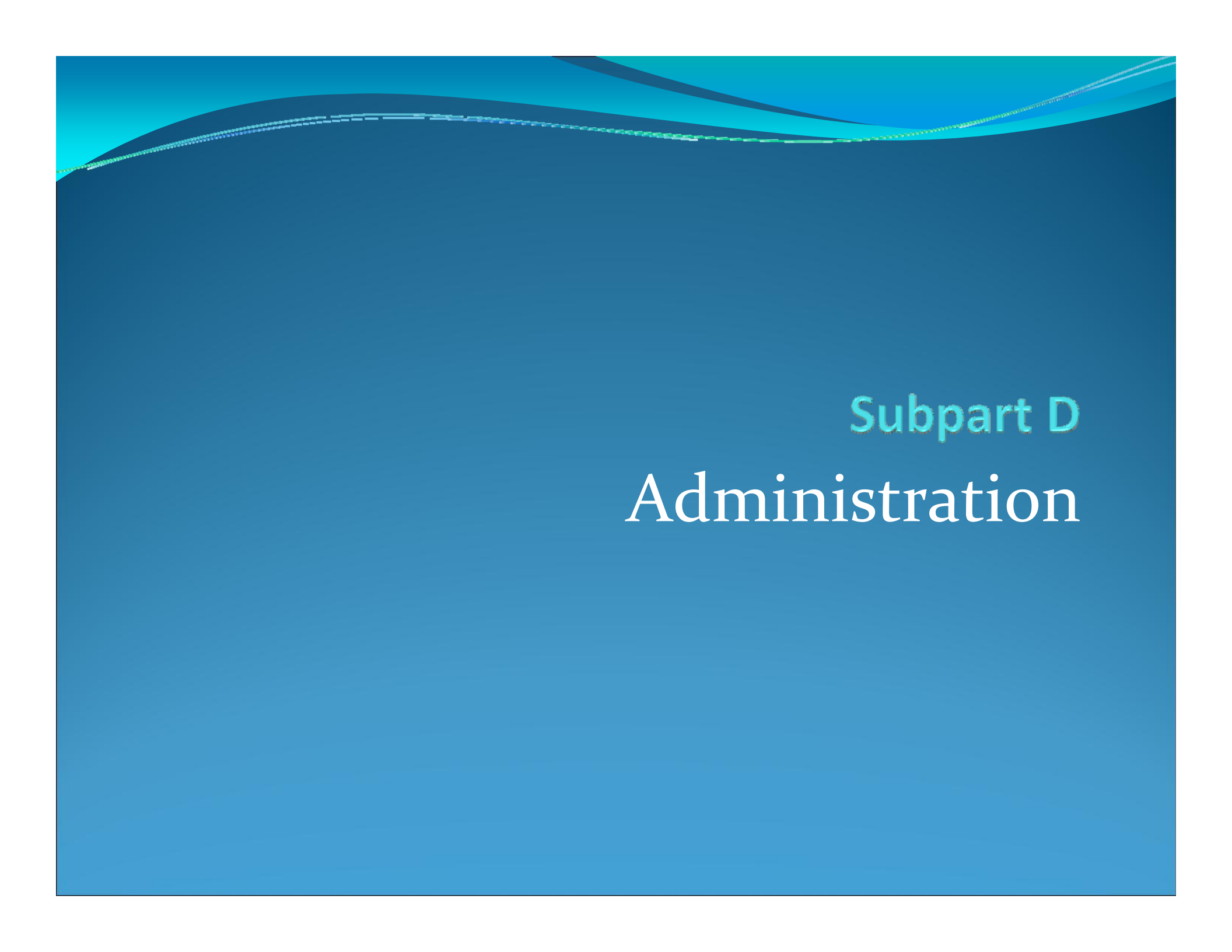
- Monitoring performance improvement – take action & track to maintain & sustain over time
- Prioritizing improvement activities
- Immediately take action that threatens pt health & safety

§494.120 Special purpose renal dialysis facilities

- Approved to provide dialysis on a short term basis at special locations (dialysis camps or to provide emergency services)
- Approval period – no more than 8 months in a 12 month period
- Service limitation in area
- Scope of requirements – operate under direction of a certified renal dialysis facility and comply w/ CfC
- Documentation – sent to pt's facility w/in 30 days.

§ 494.130 Laboratory services

- Dialysis facility must provide or make available lab services to meet the needs of ESRD patient
- Meet requirements of laboratory services



Subpart D
Administration

§494.140 Personnel qualifications

- Medical director – board certified in internal medicine or pediatric and board approved training in nephrology, 12 months exp in nephrology providing care
- Nursing services
 - Nurse Manager – FT, RN, 12 mos nsg exp + 6 mos exp in dialysis
 - Self care and home dialysis training nurse – RN, 12 mos nsg exp + 3 mos exp in specific dialysis area of training
 - Charge nurse – resp for each shift, RN, LPN or VN, 12 mos nsg exp + 3 mos exp in dialysis, if LPN must be supervised by RN
 - Staff nurse – RN or LPN

Personnel qualifications II

- **Dietitian** – RD with the Commission on Dietetic Registration, 1 year work exp
- **Social Worker** – Master in SW w/ specialization in clinical practice from school of SW accredited by the council on social work education or has served at least 2 yrs as SW, 1 yr prior to 9/1/76 and has relationship with SW who qualifies

Personnel qualifications III

- **Dialysis technician**
 - Meets state requirements,
 - HS diploma or equivalency,
 - Training
 - approved by Med Dir or governing body,
 - under direction of RN
 - Include: principles of dialysis, care of pt w/ESRD, interpersonal skills, dialysis procedures & complications, water treatment & dialysis preparation, infection control, safety & dialysis reprocessing
 - Certified w/in 18 months
 - Water treatment system techs – must complete approved program by medical director

§494.150 Responsibilities of the Medical Director

- Responsible for delivery of pt care and outcomes
- Accountable to governing body quality of medical care to patients
- Responsibilities –
 - quality assessment and performance improvement program
 - Staff education, training and performance
 - P/P – development and review and r/t pt admissions, pt care, infection control and safety, staff adhere to p/p
 - IDT adheres to discharge and transfer p/p

§494.170 Medical Record

- Maintain complete, accurate and accessible records on all pts. Including home pts
- Protection of records – against loss, destruction or unauthorized use and to keep info confidential
- Written authorization for release of MR
- Completion of patient records promptly and centralization of clinical information including advance directives
- Record retention and preservation – 6 mos of d/c, transfer or death
- Transfer of patient record information – w/in 1 working day of transfer

§494.180 Governance

- Under control of a governing body w/full legal authority and responsibility of the operation of the facility
 - Adapts rules for the health & safety of the pts, their personal & property rights, & operation of facility
- Designating a chief executive officer or administrator – manage facility and provision of all dialysis services – staff appointments, fiscal operations, relationship with ESRD Networks & allocation of staff for QA&IP program
- Adequate # of qualified personnel –
 - RN present during txs
 - RN, SW, dietitian available to meet pt needs
 - All staff have appropriate orientation & opportunity for CE

Governance II

- Medical staff appointments – physicians, physicians assistant, nurse practitioner, clinical nurse specialist
- Informed of p/p & QA&IP
- Communicates expectations improving the quality of care
- Furnishing services on premise
- Internal grievance process - explanation to file a grievance, timeline to review, how pt will be notified of resolution

Governance III

- Involuntary discharge and transfer policies and procedures must be clearly defined and available to all patients upon admission
 - Non payment
 - Facility ceases to operate
 - Facility can't meet the needs of the pt
 - Pt 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 IV

- Emergency coverage
 - Provide pt & staff w/ written instructions for emergency medical care
 - Names of physicians and contact info
 - Agreement w/ hosp for 24/7 care
- Furnishing data and information for ESRD program – as of February 1, 2009
 - Be submitted at intervals specified by the Secretary
 - Be submitted electronically in the format specified
 - Include but not limited to: cost reports, ESRD administrative forms, patient survival information and existing and future ESRD clinical performance measures

Governance V

- Relationship w/ ESRD Network
 - Governing body receives and acts upon recommendations from the NW
 - Dialysis facility must cooperate with the NW in fulfilling the terms of the NW's current SOW
 - Must participate in ESRD NW activities and pursue NW goals.
- Must disclosure of ownership interest of 5% or more to state authorities

What are the Effective Dates for These Rules?

New Conditions for Coverage	10-14-08
Electronic reporting of data	2-1-09
Life Safety Code Separate room for HBsAg+ patients	2-9-09
Certification of technicians hired after 10-14-08	18 months from hire
Certification of existing technicians	4-15-10

Acknowledgements

- Ms. Carol Lyden,
 - Quality Improvement Coordinator
 - ESRD Network II – IPRO
- Ms. Karen Evans, RN, MSN, CHT, CBNT
 - President NANT 2008 – 2009
- Center for Medicaid & State Operations
 - Survey Certification Group – End Stage Renal Disease Program Interpretive Guidance (Version 1.1)

Questions????

