

Dialysis in Long Term Care

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State Agency



- Department of Licensing and Regulatory Affairs (LARA)
 - Bureau of Community and Health Systems
 - Federal Survey and Certification Division
- Federal Survey and Certification Division has two subsets
 - Long Term Care – surveys nursing homes
 - Non-Long Term Care (NLTC) – surveys various other providers including ESRD facilities

Federal Survey & Certification Division

- Two NLTC sections:
 - Specialized Health Services
 - DASH
- Dialysis, Ambulatory Surgery Center, & Hospitals (DASH) Section
 - Team of 10 surveyors
 - Cover entire State of Michigan



DASH Survey Team



Separate CMS Regulations

- The Centers for Medicare & Medicaid Services (CMS) have established a regulation set for nursing homes seeking federal certification
 - 42 CFR 483
- Separately, CMS has a regulation set for those seeking federal certification to provide dialysis for End Stage Renal Disease (ESRD) patients
 - 42 CFR Parts 405, 410, 413, 414, 488, and 494, Conditions for Coverage for End-Stage Renal Disease Facilities



ESRD Surveys

- ESRD recertification surveys are performed an average of 3.5 years unless otherwise indicated by CMS
 - CMS sets our workload using a Tier system
 - Initial certifications are Tier 3 (lowest priority)
- Complaint surveys



ESRD Surveys

- If the ESRD facility provides home dialysis services onsite in a LTC facility, the team must visit the LTC facility to conduct additional investigations (T. Hamilton, S&C:04-24, March 19, 2004)
- Applies to both recertification and complaint surveys



How to become certified to provide dialysis in LTC?

- At present there are two ways providers are seeking certification
 1. Home program
 2. Freestanding ESRD inside the nursing home
- Home Program is most common
- While an ESRD facility may only opt to provide one service, i.e., home dialysis training, the facility must comply with ALL applicable Conditions for Coverage (CfC), which include ALL ESRD CfCs with two exceptions
 - Renal transplant centers (405.2170 and 405.2171)
 - Special purpose dialysis facilities (405.2164)
 - Vacation camps (locations that serve ESRD patients temporarily)
 - Facilities established to serve ESRD patients under emergency circumstances



CFC 42 CFR
§494.100
Condition:
Care at Home

- Home dialysis is intended to be self-dialysis performed by the patient and/or with the assistance of other individuals (T. Hamilton, S&C:04-24, March 19, 2004)
 - Challenge to apply regulations for the home program to dialysis in the LTC setting
 - We have found that dialysis being performed in the nursing homes is similar to an In-Center Hemodialysis Clinic setting
 - Multiple patients/residents dialyze at the same time
 - ESRD provider have their staff onsite



Home Dialysis



In Center Hemodialysis



Physical Environment Requirements for LTC facility

- What facilities must be provided to perform dialysis in a Long Term Care Facility?



Public Health Code

Act 368 of 1978
Article 17
Part 201

- 333.20145 Construction permit; certificate of need as condition of issuance; rules; information required for project not requiring certificate of need; public information; review and approval of architectural plans and narrative; rules; waiver; fee; "capital expenditure" defined. Sec. 20145.
- (1) ***Before contracting for and initiating a construction project involving new construction, additions, modernizations, or conversions of a health facility or agency*** with a capital expenditure of \$1,000,000.00 or more, a person shall obtain a construction permit from the department. The department shall not issue the permit under this subsection unless the applicant holds a valid certificate of need if a certificate of need is required for the project under part 222.
- (2) To protect the public health, safety, and welfare, ***the department may promulgate rules to require construction permits for projects other than those described in subsection (1)*** and the submission of plans for other construction projects to expand or change service areas and services provided.



Minimum Design Standards

- 333.20145 Construction permit; certificate of need as condition of issuance; rules; information required for project not requiring certificate of need; public information; review and approval of architectural plans and narrative; rules; waiver; fee; "capital expenditure" defined.
- Sec. 20145. (6) The review and approval of architectural plans and narrative shall require that the proposed construction project is designed and constructed in accord with applicable statutory and other regulatory requirements. In performing a construction permit review for a health facility or agency under this section, ***the department shall, at a minimum, apply the standards contained in the document entitled "Minimum Design Standards for Health Care Facilities in Michigan" published by the department and dated July 2007.*** The standards are incorporated by reference for purposes of this subsection. The department may promulgate rules that are more stringent than the standards if necessary to protect the public health, safety, and welfare.



Nursing Home Licensing Rules

- **R 325.20213 Construction and major alterations of nursing homes.**
- Rule 213. (1) A home shall not contract for or initiate either of the following projects without first obtaining a construction permit from the department:
- (a) A project for which a construction permit is required by section 20145 of the code.
- (b) A project to expand or change service areas for services provided which involves major alterations.



Nursing Home Licensing Rules

- **Rule 213 (2) The owner or governing body of a home or proposed home shall submit plans.**
- for projects described in subrule (1) of this rule to the department for review and
- approval before contracting for and initiating such projects. The department shall
- approve the plans if it determines that the project is designed and constructed in accord
- with applicable statutory and regulatory requirements.



Nursing Home Licensing Rules

- Rule 213 (3) A major alteration is deemed to be any ***extensive structural alteration*** of an existing building area involving ***significant changes in the interior configurations or intended use*** by the moving of partitions of a number of rooms and involving an ***expenditure in an amount in excess of \$25,000.00***. Removal of a partition between 2 adjacent rooms to provide additional room space is not deemed to be a major alteration, unless it exceeds \$25,000.00 in cost or unless multiple changes are to be made for a changed use of an entire wing or area and extensive plumbing or electrical wiring changes are required.



Minimum Design Standards

Michigan Department of Community Health

**THE 2007 MINIMUM DESIGN STANDARDS
FOR
HEALTH CARE FACILITIES
IN MICHIGAN**



BRHS-PS-557 (Format Only Rev. 04/05/10)
Authority: P.A. 206 of 1976, as amended

The Michigan Department of Community Health will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability, or political beliefs. You may make your needs known to this agency under the Americans with Disabilities Act if you need assistance with reading, writing, hearing, etc.



7.14 Renal Dialysis Unit (Acute and Chronic)

Regulation Text (see Appendix A)

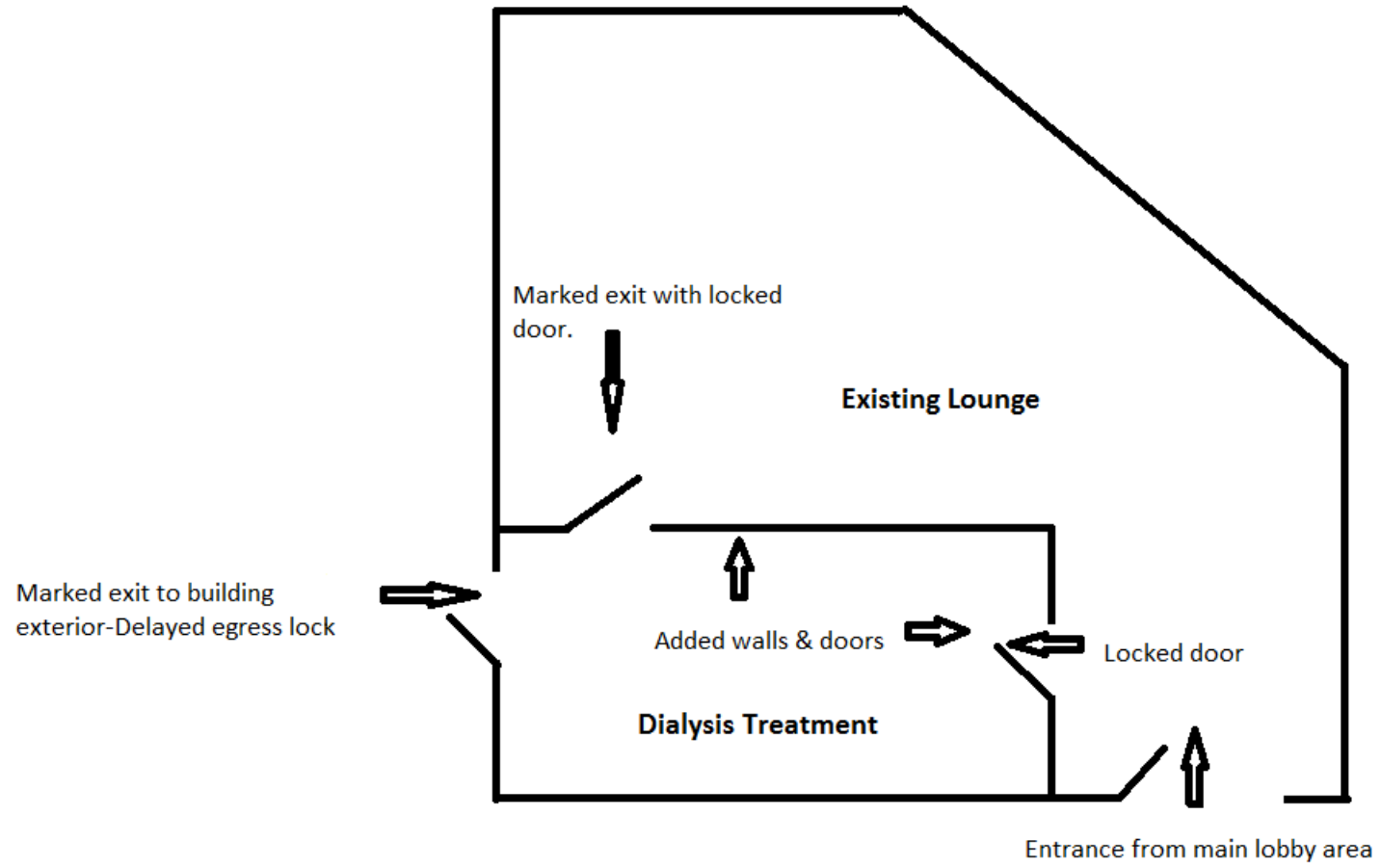
- **A.7.14** *The unit should comply with the guidelines of the Association for Advancement of Medical Instrumentation (AAMI) and the requirements of the CMS as found in 42 CFR section 405.2102 and following for End Stage Renal Disease (ESRD).*
- **A.7.14.A2** *The location should offer convenient access for outpatients. Accessibility to the unit from parking and public transportation should be a consideration.*
- **A.7.14.A3** *Space and equipment should be provided as necessary to accommodate the operational narrative, which may include acute (inpatient services) and chronic cases, home treatment and kidney reuse facilities. Inpatient services (acute) may be performed in critical care and designated areas in the hospital, with appropriate utilities.*

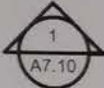
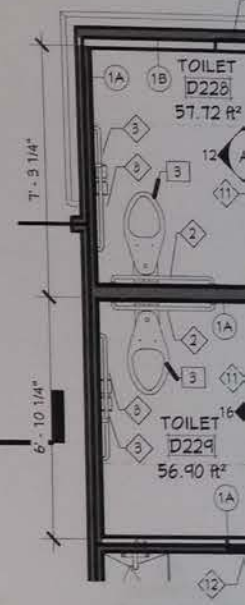
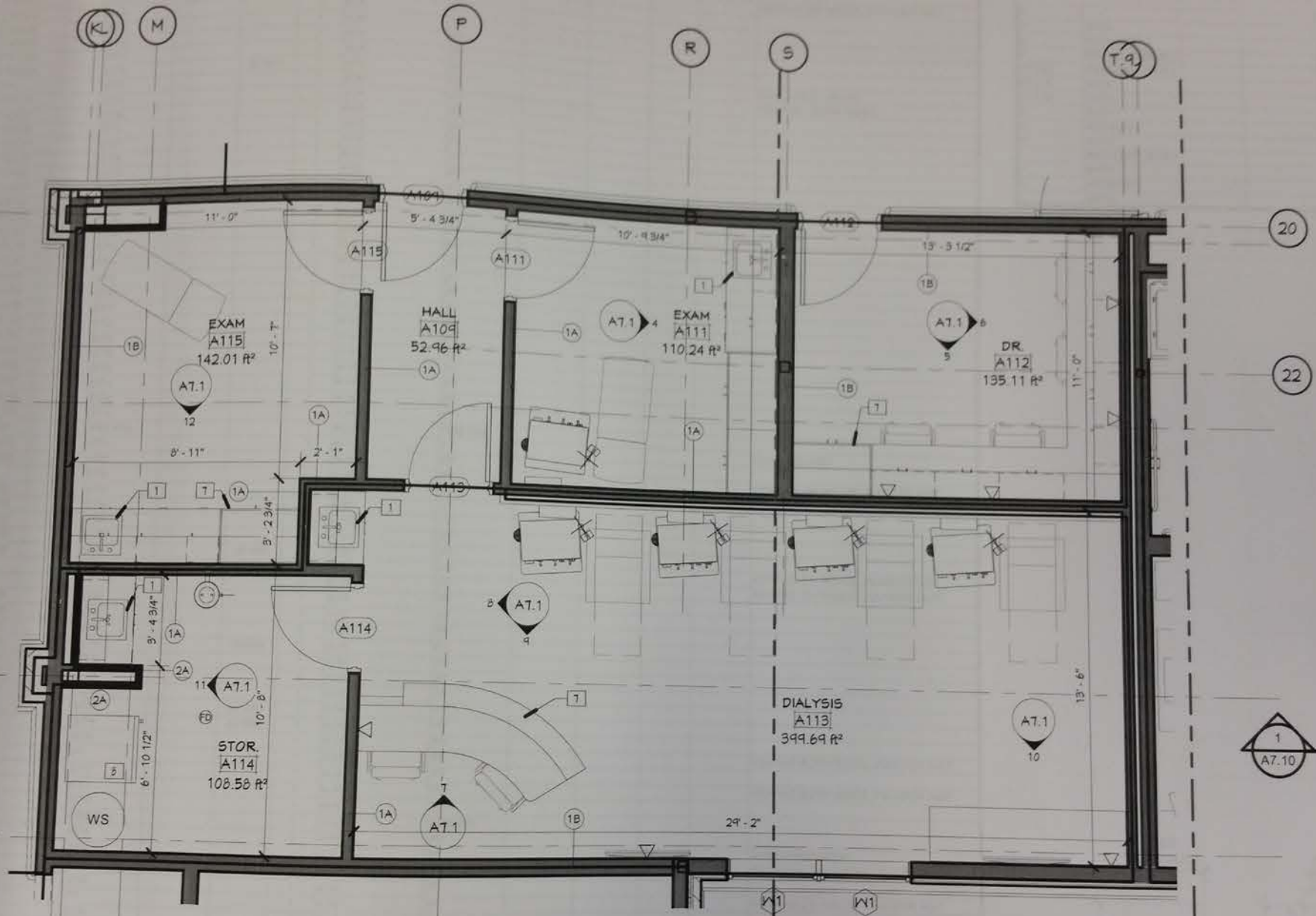


Life Safety Concerns

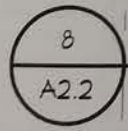
- Blocked or Locked Exits
- No Audible or Visible Alarm
- Storage within 18 inches of sprinkler heads





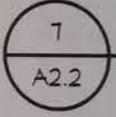


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ENLARGED DIALYSIS PLAN

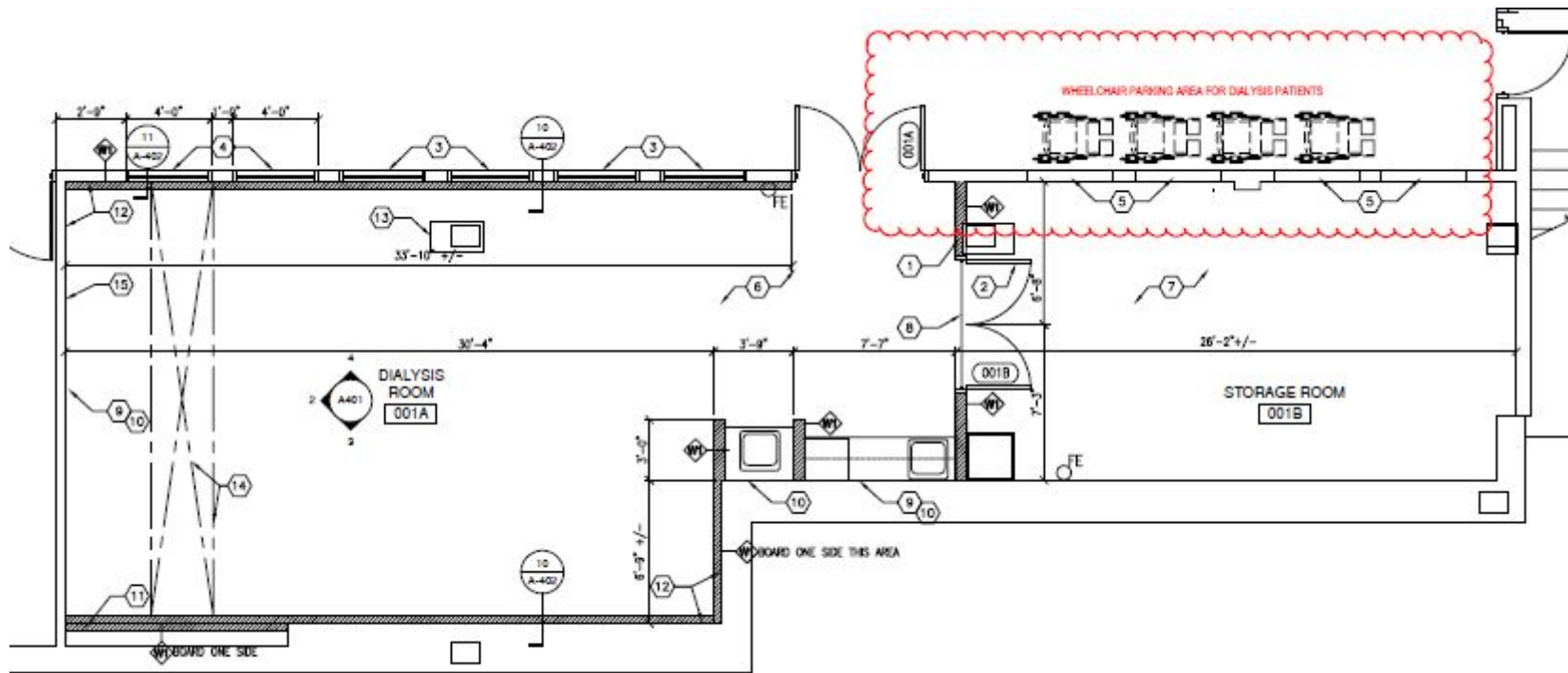
1/4" = 1'-0"



REST

1/4" = 1'-0"





LSC Requirements – K 22

- On February 17, 2016 at approximately 1:20 AM, the following observation was made and witnessed by the Maintenance Director that the rear door from the Dialysis Treatment Room/Lounge did not have a sign installed indicating that it was a 15 second delayed egress door. The sign shall be readily visible, durable sign letters not less than 1 inch high and not less than 1/8 inch in stroke width on a contrasting background that reads as follows: **PUSH UNTIL ALARM SOUNDS DOOR CAN BE OPENED IN 15 SECONDS.**



LSC Requirements – K 38

- 3. Observed that the secondary exit door from the Lounge leading through the Dialysis Treatment Room had a key lock installed on the door from the exit egress side.



LSC Requirements – K 51

- Based on observation and interview, the facility failed to provide fire alarm system in accordance with LSC Sections 19.3.4 and 9.6. This deficient practice could potentially affect 6 occupants of the facility in the event of a fire where detection or notification were delayed.
- Findings Include:
- On February 17, 2016, 2015 at approximately 1:17 PM, the following observation was made and witnessed by the Maintenance Director that the Dialysis Treatment Room located in the 1st floor Lounge did not have a required fire alarm notification device installed.



ESRD Survey Process for LTC visit

- Surveyor(s) will present onsite to LTC location(s) where the ESRD facility has patients
- Will need a workspace
- Will need to immediately begin observations of dialysis being performed



ESRD Survey Process

- Primary focus of surveyors is to assess compliance with CfCs for ESRD provider
- Perform observations of patients/residents undergoing dialysis
- Information to provide the ESRD surveyor:
 - The contractual arrangements (written coordination agreement) between the ESRD facility, the LTC facility, and the Durable Medical Equipment (DME) supplier



ESRD Survey Process cont.

- The number of residents who are dialyzing
 - Are they dialyzing as a skilled nursing facility's (SNF) or nursing facility's (NF) resident?
 - How long have they been residents of the LTC facility?
 - Are they on hemodialysis or peritoneal dialysis?
 - What DME supplier is used (if applicable)?
- Where and when are the residents dialyzing
 - In a common room or bedroom
 - Days/hours dialysis is performed
- Have all of this information ready in a binder
 - "Survey Ready" binder
 - Update monthly

ESRD Survey Process cont.

- Written Coordination Agreement
 - Signed by both ESRD facility and LTC facility
 - Must be reviewed annually
 - Must include information on financial aspects and patient care responsibilities among the ESRD facility, the LTC facility, and the DME supplier (if applicable).



ESRD Survey Process cont.

- Written Coordination Agreement (Cont)
 - Delineates respective responsibilities and accountability for:
 - Routine & emergency care
 - Where will patients be sent in event of emergency
 - Care planning
 - Communication
 - ESRD facility staff communicates patient care issues with LTC staff
- Clear lines of responsibility and accountability between ESRD and LTC facilities that safeguard the health and safety of the patients

ESRD Survey Process cont.

- In addition to infection control observations look for evidence of collaboration between ESRD and LTC facilities to investigate, control, and prevent infections
- LTC facility's infection control policies are to be reviewed by the Medical Director of the ESRD facility
- Staff providing dialysis follow appropriate hand hygiene, use of gloves
- Items used for dialysis are dedicated to single use or appropriately cleaned and disinfected



ESRD Survey Process cont.

- ESRD provider must ensure one or more licensed health care professional experienced in dialysis is on duty to oversee ESRD patient care whenever patients are undergoing dialysis
 - Experienced in or trained by the ESRD facility to
 - Perform assessments
 - Observe patients pre and post treatment
 - Respond to emergency situations relative to dialysis treatments
 - Administer any necessary intravenous, intradialytic, and intramuscular medications in accordance with all Federal and State requirements
- If LTC facility has contracted staff to the ESRD facility please be prepared to provide documentation related to training as indicated above



ESRD Survey Process cont.

- Medical Records
- Patient records must be maintained at both the ESRD facility and the ESRD's LTC location
- Must contain a multidisciplinary, written, individualized care plan that is updated as required
- The LTC staff and ESRD facility staff communicates and coordinates the development and implementation of the care plan



LTC Survey

- Home dialysis occurring onsite – Please provide
 - Resident's names
 - Room numbers
 - Name of ESRD assigned caregiver/technician – is this a staff member of the ESRD facility, the DME supplier, or LTC facility?
 - Days and times when each resident will receive dialysis treatment
 - Provide copy of agreement between Nursing Home and ESRD provider



LTC Survey Cont.

- LTC Surveyors will perform:
 - Observations of dialysis treatment areas
 - Observations of storage locations of dialysis equipment
 - Interviews with residents &/or family
 - Interviews with staff members
 - Record/Document reviews



LTC Survey Cont.

- Record/Document Review
 - Evidence of sufficient staffing
 - Evidence that LTC staff and ESRD facility staff coordinate the assessment and care planning
 - Ensure home dialysis is appropriate for patient
 - Ensure patient was educated and given the choice for this modality
 - Care plans are developed, updated and individualized to the patient's needs
 - LTC staff communicates nutritional or psychosocial concerns to ESRD dietician or social worker
 - Resident's response to dialysis treatment
 - Problems identified with dialysis treatment and care are reported to Quality Program



Similarities

- Both the ESRD surveyors and the Long Term Care are looking at the collaboration between the two facilities
- LTC surveyors will communicate concerns identified to the complaint intake unit which could generate a complaint survey by the ESRD surveyors



Resources: Links to S&C memos related to ESRD in LTC

- CMS released two Survey and Certification memorandums pertaining to dialysis in the long term care setting: S&C: 04-24 and S&C: 04-37. Links to the respective memos are provided below
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS022981.html>
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS023004.html>



Resources:
ESRD CORE
survey
documents

- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/ESRD-Core-Survey-Field-Manual.pdf>



***THANK
YOU for
LISTENING***

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APPENDIX – A

7.14 Renal Dialysis Unit (Acute and Chronic)

- A.7.14 The unit should comply with the guidelines of the Association for Advancement of Medical Instrumentation (AAMI) and the requirements of the CMS as found in 42 CFR section 405.2102 and following for End Stage Renal Disease (ESRD).
- 7.14.A General

Acute care dialysis may occur at patient bedside in critical care units and elsewhere. In these cases, dedicated utilities (water and water drain) shall be provided. Section 7.14 shall apply to chronic outpatient (ESRD) facilities or dedicated inpatient units in hospital and nursing facilities.
- 7.14.A1 (Not Used)
- 7.14.A2 (Not Used)
- A.7.14.A2 The location should offer convenient access for outpatients. Accessibility to the unit from parking and public transportation should be a consideration.
- 7.14.A3 (Not Used)
- A.7.14.A3 Space and equipment should be provided as necessary to accommodate the operational narrative, which may include acute (inpatient services) and chronic cases, home treatment and kidney reuse facilities. Inpatient services (acute) may be performed in critical care and designated areas in the hospital, with appropriate utilities.
- 7.14.B Treatment Area
- 7.14.B1 The treatment area shall be separate from administrative and waiting areas.
- 7.14.B2 Nurse's station(s) shall be located within the dialysis treatment area and designed to provide visual observation of all patient stations.
- 7.14.B3 A minimum of 100 square feet of clear floor area shall be provided per bed/stretcher treatment station. A minimum of 80 square feet of clear floor area shall be provided per chair treatment station. A minimum of 4 feet clearance shall be provided between chairs/beds/stretchers, between the side of chair/beds/stretchers and walls, and beyond the foot of the station as an aisle for access to each station. Provide a minimum head wall width of 8 feet for treatment stations. Handwashing facilities shall be provided consistent with Section 2.1.A.
- 7.14.B4 (Not Used)
- 7.14.B5 The unit shall be designed to provide privacy for each patient.
- 7.14.B6 The number of and need for required airborne infection isolation rooms shall be determined by an infection control risk assessment. When required, the airborne infection isolation room(s) shall be consistent with the requirements of Section 7.2.C., except that toilet rooms and bathing facilities are not required.
- 7.14.B7 Service areas shall be provided consistent with the requirements of 2.7 and the operational narrative.



APPENDIX - A

7.14 Renal Dialysis Unit (Acute and Chronic)

- 7.14.B12 If dialyzers are reused, a reprocessing room is required. It shall be sized to perform the functions required. The reprocessing room shall be designed to provide work flow from soiled to clean.
- 7.14.B13 (Not Used)
- 7.14.B14 The housekeeping room shall be for the exclusive use of the unit.
- 7.14.B15 If required by the operational narrative, an equipment repair and breakdown room shall be provided. It shall be equipped with a hand wash sink, work counter and storage cabinet.
- 7.14.B16 (Not Used)
- 7.14.B17 (Not Used)
- 7.14.B18 (Not Used)
- 7.14.B19 Each facility shall provide a separate room for storage of bulk materials, equipment used in preparation and clean-up of jugs used for providing dialysis solutions consistent with the operational narrative. This room can be used for water treatment or other bulk storage functions.
- 7.14.B20 The water treatment equipment shall be located in an enclosed room.
- 7.14.B21 Provide a patient toilet room convenient to the treatment area.
- **7.14.C** Ancillary Facilities
- 7.14.C1 Staff clothing change areas. Appropriate areas shall be provided for male and female personnel (orderlies, technicians, nurses, and doctors) working within the unit. The areas shall contain lockers, water closets, handwashing facilities, and space for changing clothes.
- 7.14.C2 Storage for patients' belongings shall be provided.
- 7.14.C3 A waiting room, toilet room, drinking fountain, access to a public telephone, and seating accommodations shall be available or accessible to the dialysis unit.
- A.7.14.C3 Before the proliferation of cellular telephones, pay phones were more ubiquitous and the minimum design standards required that public telephones be provided in or near renal dialysis units. The wording has been changed to require "access to" a public telephone, which would permit the facility the option to simply allow patients to use a staff telephone in the area. If a pay phone is not provided, the phone designated for patient use should be identified with a sign. If the phone is not located in a public area, the sign should indicate how a patient might obtain access to the phone.
- 7.14.C4 Office and clinical work space shall be available for administrative services.

