



Heartland Kidney Network 4/08 (Based on the proposed Conditions for Coverage)

**Proposed Conditions of Coverage Guide: Quick Locator**

Facilities are expected to become familiar with the Final Conditions for Coverage.

Red = QAPI

Blue = Relationship/responsibilities to the ESRD Network

Dk Blue = Outcomes

Brown = Patient rights/grievance/discharge

Green = Staffing

Pink = Emergency

ID# Range	Topic	Page	ID# & Comments
100 - 105	<b>Provisions of Proposed Part 494 Subpart A (General Provisions)</b> A. Basis and Scope (Proposed § 494.1) B. Definitions (Proposed § 494.10) C. Compliance with Federal, State, and Local Laws and Regulations (Proposed § 494.20)	1 2 4	100 - Compliance with Federal, State, and Local Laws 101 - Licensure 102 – Staff licensure & qualifications 103 - Fire safety: Equipment & building codes 104 – Drugs & medical devices 105 – OSHA & Civil Rights
110 – 140	<b>Provisions of Proposed Part 494 Subpart B (Patient Safety)</b> A. Infection Control (Proposed § 494.30)	4 -7  9 10  11  12  13 14  15  17 18	110 – Infection Control 111 – Follow CDC Guidelines 112 – Wear gloves when exposure to blood (touch machine/patient care.) 113 – Remove gloves & wash hands between patients or station 114 – Disposable items & non-disposables – single use and not returned to common area 115 – Multiple use vials – don’t carry station to station 116 – Common carts (treatment area) should not be used to prep or distribute medications 117 – Items in staff pockets (cross contamination) 118 – Use of medication trays (clean between patients) 119 – Clean & dirty areas designated 120 – External venous and arterial pressure transducers filters/protectors (What if wet?) 121 – Cleaning chair/supplies/area between patients 122 – Dialyzer and blood tubing reuse 123 – Transporting used dialyzers and tubing in leak-proof container to the reuse room 124 – HBV & HBC testing of patients; HIV 125 – HBV vaccination for patients and staff 126 - HBV vaccination follow up and revaccination if needed



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200 – 249	B. Water Quality (Proposed § 494.40)	<p>19</p> <p>20</p> <p>21</p> <p>24</p> <p>QAPI 26</p> <p>27</p> <p>QAPI 29</p> <p>QAPI 31</p> <p>32</p> <p>33</p> <p>33</p> <p>37</p> <p>40</p> <p>QAPI 45</p> <p>46</p> <p>47</p> <p>48</p> <p>49</p> <p>50</p> <p>51</p> <p>53</p> <p>55</p> <p>56</p> <p>57</p> <p>59</p> <p>60</p> <p>61</p>	<p>127 – HbsAg+ patients: Isolation</p> <p>128 - HbsAg+ patients: Isolation. Staff <u>can</u> care for both infected and <u>immune</u> pt on same shift.</p> <p>129 - HbsAg+ patients: Staff <u>shouldn't</u> care for both infected and <u>HBV susceptible</u> pt on same shift.</p> <p>130 - HbsAg+ Isolation room, equipment, etc. (Isolation/precaution P&amp;P for VRE, MRSA, etc.)</p> <p>131 – Handling, storage, and disposal of potentially infectious waste</p> <p>132 – Cleaning &amp; disinfecting contaminated surfaces, devices, and equipment</p> <p>133 – Biohazard oversight (log). Adverse events. Record station, machine #, staff, &amp; actions taken.</p> <p>134 – RN designated as infection control officer</p> <p>135 –CDC recommendation for multi-use vials</p> <p>136 – Reporting infection control issues to the UA and QI committee</p> <p>137 – Infection control training (staff &amp; patients) and improvements</p> <p>138 – Analyze, document, &amp; trend infections</p> <p>139 – Plan for reducing future infections</p> <p>140 – Reporting communicable diseases to the Health Department (FDA too if a device caused it)</p> <p>200 – Deficient practices for water testing, inadequate dialysate preparation etc.</p> <p>201 – Water purity statement AAMI</p> <p>202 – AAMI (water bacteriology, max levels chemical contaminants, water treatment equipment.)</p> <p>203 – Product water for facility use or reuse requirements</p> <p>204 – Water sample collection</p> <p>205 – Maximum chemical contaminants</p> <p>206 – Maximum chemical contaminants – testing &amp; sample collection</p> <p>207 – Water treatment equipment &amp; Med. Dir involvement</p> <p>208 – Materials compatibility non-toxicity of construction materials</p> <p>209 – Disinfection &amp; residuals</p> <p>210 – Water treatment system alarms: audio &amp; visual,</p> <p>211 – Time set for DI regeneration not during patient use</p> <p>212 – DI system set up and alarm</p> <p>213 – R/O – On line monitors, rejection rate</p> <p>214 – Sediment filters – opaque housing to prevent algae growth</p> <p>215 – Carbon beds- Two tanks and what happens with exhausted tanks</p> <p>216 – Water Softeners – timers &amp; salt</p> <p>217 – Storage tanks- rounded bottom and filters</p> <p>218 – Ultrafilters - opaque housing to prevent algae growth</p> <p>219 – Ultraviolet Irradiators – on line monitors</p> <p>220 – Hot water disinfection – heat resistant materials</p> <p>221 – Ozone disinfection – use in bicarb delivery system</p> <p>222 – Tempering valves – backflow preventers</p> <p>223 –Piping – loop configuration</p> <p>224 – Frequency of water testing</p>
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<p>300-392</p>	<p>C. Reuse of hemodialyzers and bloodlines (Proposed § 494.50)</p> <p>Maintaining the records is responsibility of MD</p> <p style="text-align: right;">QAPI</p>	<p>62 225 – Bacteria and endotoxin levels tested for monthly 226 – Bacteria and endotoxin levels tested for weekly in a newly installed system 227 –AAMI specifics <b>226– (Mis-numbered)</b> Water tested for microbials at least monthly 228 –Water sample sites – where culture samples and endotoxin samples are obtained 63 229 – Dialysate sample sites – from at least 2 machines monthly (each machine done yearly) 64 230 – Machine contamination – investigation and 3-month trends. Procedure for + machines. 65 231 – Repeat cultures for + machines &amp; water system. Repeat weekly until clear. 232 – Timing of sample is before disinfection of water system. 66 233 – Chemical analysis of water at least annually 234 – Installation of a new system – chemical analysis needs to be done 235 –Membrane replacement (R/O) – when replaced, a water chemical analysis must be done 236 – Poor water quality (seasonal)- Flooding or draught can cause poor water quality 237 – R/O rejection rates – Monitored daily. If rejection falls below 90 water analysis is to be done 238 – R/O or DI – resistivity monitors 67 239 – Chlorine/chloramines – check at least daily 240 – 2 carbon tanks – primary and secondary method of chlorine/chloramine removal 241 – 1<sup>st</sup> carbon tank – the exit port is used to check before each patient shift or every 4 hours 242– 1<sup>st</sup> carbon tank &gt;0.50 mg/L for free chlorine and 0.10 mg/L for chloramine = use 2<sup>nd</sup> C. tank 243 – 2<sup>nd</sup> C. tank &gt;0.50 mg/L free chlorine and 0.10 mg/L chloramine = D/C dialysis, tell MD, action <b>QAPI</b> 68 <b>244 – Corrective action plan - deviation from AAMI standards</b> 245 –Adverse events- pyrogenic reactions (fever, chills, infection) 246– Blood cultures – obtain if suspected pyrogenic reaction 69 247 – Evaluation of water system if adverse patient reactions 248 – Corrective action – for adverse patient reactions related to potential water system 249 –Unused bicarbonate – once mixed use by the manufacturers specified timeframe</p> <p>69 <b>300- Reuse: failure to meet any requirements can = denial of payment &amp; termination from program</b> 301- Reuse of dialyzers and bloodlines (D&amp;B) OK except for Hepatitis B + patients 302- Reuse D&amp;B– use on same patient 70 303- Reuse D&amp;B – must be marked for multiple reuse on manufacturers label 304- Reuse D&amp;B – must meet AAMI standards 305- Reuse D&amp;B – Records ID of staff doing reuse; staff investigating c/o; staff doing QI. Reuse logs must be complete. MD can also be cited. 71 306 -Dialyzer reprocessing manual- manufacturers specs, P&amp;P, training, samples of forms/labels, 72 307-Reprocessing record – ID new dialyzer, date of each step, ID staff, tests for safety 308- Reuse equipment maintenance- Dates of PMs, testing, and results of testing, actions 309- Personnel health monitoring records – germicidal, MSDS, health records. OSHA 73 310-Complaint investigation log – patient/staff complaints, investigation, trends, actions 311-QA/QC – records, dates, results, staff ID</p>
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<p>Training program for reuse is responsibility of MD</p>	<p>74 75 76</p>	<p>312-Personnel qualification/training – competency and safety  313- Training &amp; curriculum – written steps, infection control, risks, hazards, toxic spills, PPE, emergency, principals of dialysis and how reuse affects them  314-Documentation – MD certification of staff, annual review, changes in program/equipment  315-Pt/medical issues – safe reuse staff protection, PPE, etc.  316-Informed consent- printed material for pt.  317- Equipment – Safety, QA, and QC.  318-Water systems – pressure and flow. Water sample for microbial and endotoxin tests monthly.  319-Utility requirements – drains, ventilation, electrical power.  320-Total cell volume tests  321- Process control tests- germicide concentration. Presence test verified. Heat disinfection.  322-Maintenance – routine PM and records  323- Repairs – Qualified person to do repair. Test functionality before used clinically.  324- Reprocessing area ventilation. Area clean and sanitary.  325- Reuse – storage: minimize deterioration, contamination, or breakage. (new &amp; used separate)  326- Reuse – lab area: testing for germicide done at unit.  327- Reuse personal protective equipment (PPE) – Eyewash, respirators, spill control measures.  328- Reuse: environmental safety: written procedures for safe storage and handling of chemicals.  329- Reuse: supplies meet written specification of manufacturer.  330- Reuse: inventory control. Use on first in /first out basis.  331- Reuse: labeling. Dialyzer for only one patient. Identify patient.  332- Reuse: time of labeling. Before the first use and updated after each use.  333- Reuse: composition of labeling. See blood path. Model and lot # and other details show.  334- Reuse: info needed. Name, # uses, date of last reuse. Similar name alerts.  335- Reuse: Begins with the labeling of the new dialyzer. (Process and records).  336- Reuse: Transportation/handling. Caps on, in bags, refrigerate if not done in 2 hours.  337- Reuse: Rinsing/cleaning. Pre-cleaning. Equipment design and maintenance.  338- Reuse: Rinsing/cleaning. Time limits for starting reprocessing.  339- Reuse: Rinsing/cleaning. Pre-cleaning done with AAMI water.  340- Reuse: Rinsing/cleaning. Done with diluted chemicals – rinse prior to additional chemicals.  341- Reuse: Performance Measurements. Verification of performance.  342- Reuse: Ultra-filtration. Pt. target weights not met. Does facility have QAPI on target weight?  343- Reuse: Blood path integrity. Pressure leak testing.  344- Reuse: germicide is filled in blood and dialysate compartments.  345- Reuse: germicide in blood and dialysate compartments. Minimum contact time of 24 hours.  346- no 346  347- Reuse: Dialyzer header cleaning and disinfection.  347 – (number issue) Reuse: germicide concentration at least 90% of prescribed concentration.  348- Reuse: water quality monitoring.  349- Reuse: germicide tested to verify concentration.</p>
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- 350- Reuse: exterior – cleaned of blood
- 351- Reuse: inspection – examined for damage
- 352- Reuse: inspection – jacket examined for blood
- 353- Reuse: inspection – jacket examined– no leaks, cracks
- 354- Reuse: inspection – jacket examined– no more than a few clotted fibers
- 355- Reuse: inspection – headers – free of all but small clots
- 356- Reuse: inspection – blood and Dialysate ports– capped with no leaks
- 357- Reuse: inspection – label properly filled out and legible
- 358- Reuse: disposition of rejected dialyzers – discard or additional testing
- 359- Reuse: storage – no longer than one month. Reprocess or discard after one month.
- 360- Reuse: prep for dialysis and testing for germicide residuals
- 361- Reuse: visual inspection – before use (several points of inspection)
- 362- Reuse: verification of patient identification. Before dialysis starts.
- 363- Reuse: Verification of germicidal contact
- 364- Reuse: presence test in each hemodialyzer
- 365- Reuse: process control and sampling
- 366- Reuse: process control
- 367- Reuse: Sampling for process verification
- 368- Reuse: Priming & rinsing the germicide
- 369- Reuse: Testing for residual germicide
- 370- Reuse: written procedure for test for germicide or other residues
- 371- Reuse: monitoring dialysis – patient observed for possible complication from new or used dialy.
- 372- Reuse: symptom – fever & chills
- 373- Reuse: other symptoms
- 374- Reuse: recording incidents- are these included in QAPI program?
- 375- Reuse: dialyzer failures
- 376- Reuse: clinical results (URR/Kt/V) QAPI program for adequacy?
- 377- Reuse: quality assurance audits in QAPI program?
- 378- Reuse: records – QAPI minutes review reuse?
- 379- Reuse: schedule of quality assurance activities
- 380- Reuse: patient considerations – audit to be sure to inform patient annually of reuse practices
- 381- Reuse: equipment – audits and annual review of P&P
- 382- Reuse: physical plant and environmental safety – audits
- 383- Reuse: reprocessing supplies audit
- 384- Reuse: hemodialyzer label audit
- 385- Reuse: audit and trend analysis
- 386- Reuse: preparation for dialysis audit
- 387- Reuse: hemodialyzers and blood lines – manufacturers recommendations
- 388- Reuse: hemodialyzers – don't expose it to more than one germicide
- 389- Reuse – monitoring evaluation, and reporting requirements for reuse of dialyzers and bloodlines



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	<p>D. Physical Environment (Proposed § 494.60)</p>	<p>135</p>	<p>390- Reuse – after adverse reaction – get blood cultures          391- Reuse – after adverse reaction – evaluate reuse and water purification. No reuse until safe.          392- Reuse – after adverse reaction – report to state, FDA, CDC, etc.</p> <p>400 - Facility and equipment &amp; building provide comfort and safety for patient and staff.          401 – Building constructed and maintained to ensure safety of patient, staff, and public.          402 – Equipment maintenance – all maintained in accordance with manufacturers recommendations.          403 – Patient care environment -space sufficient          404 - Facility must maintain temp comfortable for patients          405 - Emergency – must have P&amp;P in place to manage medical and no medical disaster/emergency          406 – Emergency prep for staff          407 – Staff inform patients where to go, what to do, who to contact, how to disconnect from mach.          408 – staff know CPR          409 – Nurses trained in emergency use drugs and emergency equipment          410 – Emergency training for patients.          411- Emergency equipment list          412 – Have a plan to obtain emergency medical system assistance when needed (911)          413 – Update emergency and disaster plans at least annually          414 – Fire safety –meet 2000 edition of Life Safety Code of the National Fire Protection Association          415 – Fire safety – <u>Chapter 5</u> of the 2000 edition Life Safety Code doesn't apply to a dialysis facility          416 – Fire safety – State law might supersede the Life Safety Code (up to CMS)          417 - Fire safety – CMS might wave for a period of time certain parts of Life Safety Code              Fire safety – waiver would not affect safety of patients          418 - Fire safety – rigid application of specific provisions in LSC would result in unreasonable hardship for unit</p>
	<p><b>Provisions of Proposed Part 494 Subpart C (Patient Care)</b>          A. Patients' Rights (Proposed § 494.70)</p>	<p>143</p>	<p>450 – Inform patients of rights and responsibilities on beginning treatment &amp; must protect rights.          451 – Right to respect, dignity, personal needs, psychological needs, ability to cope with ESRD          452 – Receive information in a way he/she can understand.          453 – Privacy and confidentiality in all aspects of treatments (access uncovered)          454 – (nothing listed here)          455 - Privacy and confidentiality in personal medical records          456 – be informed about all aspects of care, advance directives, refuse treatment, refuse research          457 – informed about treatment modalities, transplant, home treatments          458 – informed about P&amp;P including isolation          459 – informed about P&amp;P reuse of supplies          460 – informed by physician about medical status unless contraindicated</p>



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	<p>B. Patient Assessment (Proposed § 494.80)</p>	<p>156</p>	<p>461 – informed of services available in facility and those not covered by Medicare  462 – receive the necessary services outlined in the patient plan of care  463 – informed of rules and expectations of facility for patient conduct and responsibilities  464 – informed of facility’s internal grievance process  465 – informed of grievance process like ESRD NW and State Agency and how to contact them  466 – informed of right to file internal or external grievance without reprisal or denial of services  467 – informed may file int. or ext. grievance personally, anonymously or via a representative.  468 –informed of facility discharge, transfer, and discontinuation of service policies  469 –Written notice 30 days before terminating care. Credible threat may =shorter discharge procedure.  470 –Posting of rights: prominently display patient rights and how to contact SA and NW easily read  475 – Interdisciplinary team pt (or designee), RN, Phys, SW, RD. Comp. assess. to dev. care plan  476 –Comp. assess. Includes current health status, medical conditions including co-morbid.  477 –Evaluation of dialysis prescription, blood pressure, and fluid management  478 – Lab profile and medication history  479 – anemia management and EPO  480- bone disease  481 – nutritional status  482- evaluation of psychosocial needs  483 – evaluation of dialysis access type and maintenance (few catheters)  484 – Patient interest and capacity for self care  485 – Suitability for transplantation referral  486 – evaluation of family and other support system  487 –evaluation of current physical activity level.  488 – Evaluation of vocational and physical rehabilitation status and potential  489 – Initial Comp. assess. within 20 calendar days after first treatment.  490 – follow-up comp. assess. within 3 months of initial to adjust plan of care.  491 – assessment of treatment prescription (adequacy evaluation ongoing)  492 – HD patient: monthly by Kt/V or equivalent method  493 – PD patient: at least every 4 months by delivered weekly Kt/V or equivalent method  494 – Reassessment and revision of care plan at least annually for stable patient  495 - Reassessment and revision of care plan At least monthly for unstable patient</p>
	<p>C. Patient Plan of Care (Proposed § 494.90)  1. Development of the Patient Plan of Care (Proposed § 494.90(a))  a. Dose of Dialysis (Proposed § 494.90(a)(1))</p>	<p>166</p>	<p>500 – Team develops and implements written comp plan of care  <b>501 –Measurable &amp; expected outcomes &amp; est. timetables to achieve outcomes.</b>  502- Team develops comp plan of care  503 - Plan of care: provide care, services to achieve and sustain prescribed dose of dialysis  504 - Plan of care: provide care, services to achieve and sustain effective nutritional status (monthly)</p>



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	<ul style="list-style-type: none"> <li>b. Nutritional Status (Proposed § 494.90(a)(2))</li> <li>c. Anemia (Proposed § 494.90(a)(3))</li> <li>d. Vascular Access (Proposed § 494.90(a)(4))</li> <li>e. Transplantation Status (Proposed § 494.90(a)(5))</li> <li>f. Rehabilitation Status (Proposed § 494.90(a)(6))</li> <li>g. Social Services</li> </ul> <ol style="list-style-type: none"> <li>2. Implementation of the Patient Plan of Care (Proposed § 494.90(b))</li> <li>3. Transplantation Referral (Proposed § 494.90(c))</li> <li>4. Patient Education and Training (Proposed § 494.90(d))</li> </ol> <p>D. Care at Home (Proposed § 494.100)</p> <ol style="list-style-type: none"> <li>1. Dialysis of ESRD Patient in the Home Setting</li> <li>2. Dialysis of ESRD Patient in Nursing Facilities and Skilled Nursing Facilities             <ul style="list-style-type: none"> <li>a. Delineation of Responsibility</li> <li>b. Applicable ESRD Conditions for Coverage</li> <li>c. Nursing Coverage</li> <li>d. Training</li> <li>e. Monitoring</li> </ul> </li> </ol>	<p>174</p>	<p>505- Plan of care: provide care, services to achieve and sustain expected Hgb and Hct</p> <p>506 - Hemoglobin and hematocrit must be measured at least monthly</p> <p>507 – home HD patient: Can patient administer and store EPO</p> <p>508 - If Hgb &lt; 11 or Hct &lt; 33% must check if patient is candidate for EPO</p> <p>509 –Patient response to EPO including BP and iron stores monitored routinely</p> <p>510 – vascular access – team provides care and services to achieve and sustain vascular access</p> <p>511- HD patient evaluated for appropriate VA type (consider co-morbid)</p> <p>512- VA must be monitored to prevent access failure: AVG and AVF for stenosis.</p> <p>513 – Transplant status: if patient is a candidate team develops plan for t-plant</p> <p>514 – Develop a plan for transplant if patient is interested in being referred for transplant</p> <p>515 – Document if a patient has chosen not to be a transplant candidate</p> <p>516 - Document rationale for non-referral for transplantation.</p> <p>517- Rehabilitation: team provide care and services to achieve and sustain productive activity</p> <p>518- Plan of care implemented by the team</p> <p>519 – Must be signed by the patient or designee</p> <p>520 –Implementation of care plan must begin within 10 calendar days after patient assessment.</p> <p>521- Expected outcome: if not achieved – team readjust care of plan to achieve goal</p> <p>522 – In-center patients are seen by a physician at least monthly.</p> <p>523 – Team tracks results of transplant referral and monitors status of patient on transplant list.</p> <p>524- Team communicates with transplant center regarding transplant status at least quarterly</p> <p>525- Patient education for dialysis experience/management, quality of life, transplant, &amp; rehab.</p> <p>530 – Home patient have equivalent services of in-center patients.</p> <p>531 – Team trains home patient, caregiver, or self-dialysis patient prior to home dialysis or self care.</p> <p>532 – Training by facility certified to provide home dialysis services.</p> <p>533 – Training: Self care conducted by RN meeting requirements (12 mth nursing &amp; 3 mth modality)</p> <p>534 – Training individualized</p> <p>535 – Training on management of ESRD</p> <p><b>536 – Complete training in use of dialysis supplies and equipment to achieve outcomes</b></p> <p>537 – Implement nutritional care plan</p> <p>538 – How to achieve and maintain emotional and social wellbeing</p> <p>539 – How to detect, report and manage dialysis complications</p> <p>540 – Availability of support resources and how to access and use resources</p> <p>541 – How to self monitor health status and record and report health status information</p> <p>542 – How to handle medical and non-medical emergencies</p> <p>543 – Infection control precautions</p> <p>544 - Proper waste storage and disposal procedures</p> <p>545 – Home dialysis: document in medical record that adequate comprehension of training</p> <p>546 – Retrieve and review complete self-monitoring data from patients at least every 2 months</p> <p>547 – Maintain information in patient medical record.</p>
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<b>Provisions of Proposed Part 494</b> <b>Subpart D (Administration)</b>		
<p>A. Personnel Qualifications (Proposed § 494.140)</p> <ol style="list-style-type: none"> <li>1. Medical Director (Proposed § 494.140(a))</li> <li>2. Nursing Services (Proposed § 494.140(b))</li> <li>3. Dietitian (Proposed § 494.140(c))</li> <li>4. Social Worker (Proposed § 494.140(d))</li> <li>5. Patient Care Dialysis Technicians (Proposed § 494.140(e))</li> <li>6. Other Personnel Issues</li> </ol>	<p>196</p>	<p>610 – Dialysis staff meet qualifications and be competent with skills          611 – Medical Director (MD)- physician completed board training in nephrology -at least 1 yr of exp.          612 – If physician not available to direct facility another physician may -Secretary approval needed.          613 – Nurse manager – FTE of facility cant be a contract/agency nurse.          614 - Nurse manager – RN meets state requirements.          615 - Nurse manager – 12 months experience clinical nursing with 6 months dialysis experience.          616- Self-care training nurse - RN meets state requirements.          617- Self-care training nurse – 1 yr exp clinical nursing with 3-mth self-care specific training modality.          618- Charge nurse - RN or LPN meets state requirements.          619 - Charge nurse – 12 months experience clinical nursing with 6 months dialysis experience.          620 – Staff Nurse - RN or LPN meets state requirements.          621 – Dietitian – Be a RD with the Commission on Dietetic Registration.          622 - Dietitian –Meet requirement of the state          623 - Dietitian –Minimum of 1 year experience as RD after registration as RD          624 –Social Worker – Masters degree in SW from school of SW accredited by Council on SW Edu          625 – Social Worker –Meet requirement of the state          626 – PCT - Meet requirement of the state          627 – PCT – High School graduate or equivalency          628 – PCT – 3 mth exp following training, under direct supervision or RN          629 – Water Treatment Tech – Completed training approved by MD and gov. body</p>
<p>B. Responsibilities of the Medical Director (Proposed § 494.150)</p> <p style="text-align: right;">QAPI QAPI</p>	<p>203</p>	<p>635 – Resp. of MD – Facility must have qualified MD responsible for delivery of pt care &amp; outcomes  <b>636 - Resp. of MD – QA/QI program (QAPI) ensure facility achieves: adequacy, nutrition, anemia, VA, medical injuries &amp; med error ID, reuse, patient satisfaction, grievance, etc...</b>          637 - Resp. of MD – staff education, training, and performance (monitor pt and water system)          638 - Resp. of MD – Develop, review, and approve patient care P&amp;P manual          639 - Resp. of MD – Assuring that attending physicians and non-physicians adhere to P&amp;P          640 - Resp. of MD – Assuring that team adheres to discharge &amp; transfer P&amp;P of M. regulations</p>
<p>C. Relationship with the ESRD Network (Proposed § 494.160)</p>	<p>207</p>	<p><b>641- Unit must cooperate with the ESRD Network (signed agreement) and compliance w/goals</b>  <b>642- Unit cooperates in fulfilling the terms of the NW current statement of work.</b>          650- Complete, accurate, and assessable records for all patients (home too)          651- Safeguard records against loss, destruction, or unauthorized use.          652 – Keep confidential records (except transfer, 3<sup>rd</sup> party payer, law, patient OK, authorized agents)          653 – Written authorization from patient or legal representative before releasing information          654 – Current records and those of discharged patients must be completed promptly.          655 – Clinical information contained centrally in the record.          656 – Home patient records – maintain and monitor including receipt of supplies and equipment.          657 – Medical record retention as per state law (more specifics included)</p>
<p>D. Medical Records (Proposed § 494.170)</p>		



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	<p>E. Governance (Proposed § 494.180)</p> <ol style="list-style-type: none"> <li>1. Existing Requirements for Governing Bodies</li> <li>2. Overview of the Proposed Governance Requirements</li> <li>3. Governance Condition (Proposed § 494.180)</li> <li>4. Designating a Chief Executive Officer or Administrator (Proposed § 494.180(a))</li> <li>5. Adequate Number of Qualified and Trained Staff (Proposed § 494.180(b))</li> <li>6. Medical Staff appointments (Proposed § 494.180(c))</li> <li>7. Furnishing Services (Proposed § 494.180(d))</li> <li>8. Internal Grievance Process (Proposed § 494.180(e))</li> <li>9. Discharge and Transfer Policies and Procedures (Proposed § 494.180(f))</li> <li>10. Emergency Coverage (Proposed § 494.180(g))</li> <li>11. Furnishing Data and Information for ESRD Program Administration (Proposed § 494.180(h))</li> </ol> <p>Disclosure of Ownership (Proposed § 494.180(i))</p>	<p>210</p> <p>216</p> <p>217</p>	<p>658 – Transfer of patient record within one working day.</p> <p>660 – Facility under control of identifiable governing body and acts on recommendations of NW.</p> <p>661 – CEO is a designated person and has responsibility for the management &amp; oversight of the unit</p> <p>662 – Staff appointments appointment of medical staff and ancillary personnel</p> <p>663 – Fiscal operations (Missed meds, deterioration of unit attributable to mismanagement)</p> <p>664 – Relationship with ESRD NW. Signed contract and NW goals.</p> <p>665 – Allocation of staff, time, or resources for QAPI program</p> <p>666 – Adequate # of trained staff.</p> <p>667 – RN must be present in the facility at all times that patients are being treated.</p> <p>668 – All employees have appropriate orientation and responsibilities upon employment.</p> <p>669 – all employees have opportunity for continuing education and related development activities.</p> <p>670 – Approved written training program specific to dialysis technicians (more specifics)</p> <p>671 – Medical staff appointments &amp; credentialing (attending physicians NP, PA)</p> <p>672 – all medical staff informed of P&amp;P including QAPI.</p> <p>673 – Services are rendered on main premises</p> <p>674 – Internal grievance process – inform patients of grievance procedure (no reprisals)</p> <p>675 - Internal grievance process – clearly state procedure for submission of grievances</p> <p>676 - Internal grievance process – clearly defined timeframe for investigation.</p> <p>677 - Internal grievance process – description of how patient will be informed of the steps to resolve</p> <p>678 – All staff follow the units patient discharge and transfer P&amp;P</p> <p>679 – Medical Director insures that no patient is discharged or transferred <u>unless</u> (more specifics)</p> <p>680 – Documents the reassessment, ongoing problems, and documents in the patient medical rec.</p> <p>681 – Written order signed by Medical Director and physician concurring with discharge or t-fer.</p> <p>682 – Document the attempts to place patient in another facility.</p> <p>683 – Notify the SA and ESRD NW <u>prior to</u> the involuntary transfer or discharge.</p> <p>684 – Patients and staff have written instructions for getting emergency medical care. (On-call MD)</p> <p>685 – At nursing station: roster of MDs to be called in emergency and how to reach them.</p> <p>686 – Agreement with a hospital for inpatient care and acute dialysis services.</p> <p>687 – Unit must furnish data &amp; information electronically to CMS</p> <p>688 - Unit must furnish data &amp; information to CMS at intervals as specified by the Secretary.</p> <p>689 - Data &amp; information submitted to CMS electronically in format as specified by the Secretary.</p> <p>690 – including cost reports</p> <p>691 – ESRD administrative forms such as the Annual Facility Survey</p> <p>692 – Patient survival information</p> <p>693 – Clinical performance measures (and future ones)</p> <p>694 – Full and complete information about ownership to the SA</p>
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