

Reference Condition	Regulation	Interpretive Guidance	V-Tag
Infection Control	Infection Control	Direct care staff are observed and interviewed relative to infection control practices. Administrative and supervisory staff, as well as the Medical Director , may be interviewed to clarify issues.	V 110
	Require all clinical staff to report infection control issues to the dialysis facility's Medical Director and the quality improvement committee.	The nurse manager, administrator and Medical Director should each be able to describe the infection control program and reporting mechanisms	V 144
Water and Dialysate Quality	Maximum level of chemical contaminants in water: <i>chem analysis</i>	<p>The Medical Director is ultimately responsible for the safety and quality of the water used for patient treatments. Each product water chemical analysis must be within the parameters listed in Table 1 at V177. If any values are greater than those listed, facility staff must notify the Medical Director of the results, repeat testing, and take action to address any repeated high levels.</p> <p>The Medical Director must be knowledgeable of the water treatment system installed and assure that the system as installed will produce AAMI quality water.</p> <p>The use of water outside of AAMI standards should be extremely rare, considered only when no other option is available to provide desperately needed dialysis, and limited to one treatment per patient</p> <p>An emergency “plan” that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence the source water has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other</p>	V 177

		<p>contaminates known to be toxic to dialysis patients).</p> <p>The Medical Director is ultimately responsible for this decision; short term exposure to contaminants is limited to one treatment, rather than not receiving dialysis may be the optimal choice.</p>	
	Bacteriology of water: <i>max & action levels</i>	<p>Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL</p> <p>The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL.</p> <p>If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.</p> <p>Because this balance will almost certainly vary from circumstance to circumstance, the AAMI RDD Committee felt that there was insufficient data on which to base levels of bacteria and endotoxins above which dialysis should not be performed.</p> <p>The final decision of whether to discontinue dialysis rests with the Medical Director of a facility.</p>	V 178
	Bacteriology of conventional dialysate: <i>max & action limits</i>	<p>Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.</p> <p>The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action</p>	V 180

		<p>level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.</p> <p>“Promptly” would be met if action is taken within 48 hours of receiving the results of testing. Action might be repeating cultures, particularly in the case where one of several cultures are above the action level; or disinfecting the system and repeating cultures.</p> <p>Action would also include notifying the Medical Director of the results.</p>	
	<p>ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.2.5 Carbon adsorption: <i>two tanks/sample ports</i></p>	<p>If a facility has employed supplemental strategies for chlorine removal these must be in addition to the use of at least two carbon tanks.</p> <p>The Medical Director and the chief technician should be able to discuss the rationale for use of supplemental strategies. Facility records must document the systems in place protect patients from exposure to chlorine and chloramine and are monitored according to the manufacturer’s direction.</p>	V 192
	<p>ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.2.5 Carbon adsorption: <i>10 min EBCT</i></p>	<p>The empty bed contact time (EBCT) of the granulated activated carbon (GAC) system should be periodically calculated for the maximum water flow through the carbon tanks. Water flows may vary, altering the need for more or less GAC to achieve the 10 minutes total EBCT.</p> <p>If additional patient treatments or shifts are added, the resultant greater water demand should cause the Medical Director and technical staff to consider the need to add additional carbon in order to maintain the minimum EBCT. “Each adsorption bed” refers to the primary tank or tanks as one adsorption bed and the secondary tank or tanks as another adsorption bed.</p>	V 194

	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.2.6 Chemical injection systems	<p>If the facility has designed its own system, the Medical Director should be cognizant of the risks and benefits of the system and is expected to have participated in the decision to install it.</p> <p>Verification of the function and the safety of a self-designed chemical injection system must be completed prior to placing the system online during an active patient treatment time</p>	V 198
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.2.7 Reverse osmosis: <i>meets AAMI/monitored/recorded on log</i>	<p>DFU = directions for use.</p> <p>The facility should have documentation of the RO manufacturer's DFU of feed water and monitoring, and facility procedures must reflect them. The RO parameters must be recorded and monitored each day the facility is operating.</p> <p>The Medical Director, nurse manager and chief technician must be able to describe how trends in the RO function are monitored to detect problems.</p>	V 199
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.2.7 Reverse osmosis: <i>alarm/prevent use of unsafe water</i>	<p>All manufacturers do not incorporate a preset limit which would activate an audible alarm when the quality of the product water diminishes, but all do offer a process for the user to follow in determining a limit to set.</p> <p>The Medical Director and the chief technician should be able to discuss how the set point was determined. The response should address the requirement that product water meet these requirements for chemical contaminants. Different criteria would apply if the RO is followed by DI polishing.</p>	V 200
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.3.3 Water distribution systems: <i>no added burden</i>	In the event a facility is using piping in the water distribution system which is not indicated as compatible with the disinfectant in use per Table 2, expect responsible staff (Medical Director , chief technician) to provide evidence that	V 212

		the disinfectant in use has been verified by the manufacturer of the disinfectant or the 510(k) licensed disinfection device as compatible with their distribution piping	
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.4.4.1 Mixing systems: <i>labeling</i>	<p>If multiple dialysate proportioning ratios are in use, applicable staff and the Medical Director must be able to describe safeguards in place to prevent mismatching dialysate components/machines.</p> <p>There should be no incidents of ratio mismatch, for example, 35X acid used with a machine set for 45X. Labels made by the facility are acceptable as long as the required information is included. Labels should be used to alert staff when bleach or ozone is in a tank or concentrate jug during disinfection. If a group of jugs are being disinfected at once, a process control (such as a label or sign marking the area in use) could be used rather than individual labels for each jug.</p>	V 228
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 6.5 Concentrate distribution: <i>bicarb monitoring initially</i>	<p>Whenever use of a new bicarbonate distribution system is initiated, weekly monitoring of dialysate should occur for at least four consecutive weekly reports of acceptable levels. Evaluation of positive culture or endotoxin reports should also consider the number of positives in relationship to the number of samples taken. For example, if one sample out of 10 has a count of 53, while the other 9 have no growth, doing a reculture of one or more sites may be the first action taken.</p> <p>The Medical Director must be involved in these decisions</p>	V 242
	ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a) 5.6 Dialysate proportioning: <i>match machine config w/ratio in use</i>	<p>The Medical Director and responsible staff must be knowledgeable of the mixing ratio the machines are set up to use and all dialysate supplies in the facility must match that ratio.</p> <p>Rarely, a facility may have machines set for different ratios; this is a risky practice, and would require very close monitoring to prevent mis-matching of supplies and machines. If machines are</p>	V 249

		<p>available for different ratios in the same facility, each machine must be clearly labeled for the applicable ratio, and supplies for the different ratios must be segregated and labeled clearly to avoid mis-match.</p> <p>The Medical Director must be aware of this practice, and be involved in quality control to avoid any patient consequence from potential mis-match of supplies and machines.</p>	
	<p>ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40 (a)</p> <p>7.2 Microbial monitoring methods:</p> <p>7.2.1 General: Dialysate</p>	<p>If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends.</p> <p>The Medical Director also should be notified.</p>	V 253
	<p><i>Ch/chl breakthrough: notify Medical Director</i></p> <p>(C) Immediately notify the Medical Director;</p>	<p>Policy and practice must demonstrate this requirement is met.</p> <p>Responsible staff should list notifying the Medical Director as an action they would take immediately in the event of a chlorine or chloramine breakthrough</p>	V 272
	<p><i>Water test results: deviations require corrective action plan</i></p>	<p><i>Corrective action plan.</i> Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.</p> <p>Water and dialysate monitoring must be reported in the QAPI materials and the Medical Director must to be involved in analyzing and addressing test results outside of expected parameters</p>	V 274
	<p><i>Standard: Adverse events. actions expected</i></p>	A dialysis facility must maintain active surveillance of patient	V 275

		<p>reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—</p> <ul style="list-style-type: none"> • Obtain blood and dialysate cultures and endotoxin levels; • Evaluate the water purification system • Take corrective action. <p>The Medical Director must develop standard protocols which require blood and dialysate cultures and endotoxin levels be collected in the event of patient adverse reaction(s) during or following dialysis treatment.</p> <p>Responsible staff (i.e., the nurse manager, charge nurses, water treatment technicians, chief technician and Medical Director) must demonstrate recognition of the need to evaluate the water system in the event of patient adverse reaction(s) during or following dialysis treatment and to take indicated corrective action.</p>	
Reuse	<p>AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</p> <p>4 Records: <i>meet req for medical records</i></p>	<p>All records described in this recommended practice shall meet the requirements for medical records, including completeness, legibility, and security. A place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing procedure (i.e., the person performing preventive maintenance procedures, the person[s] investigating complaints, and the person[s] conducting quality assurance [QA] and quality control [QC] activities).</p> <p>Maintaining these records is the responsibility of the Medical Director.</p>	V 305
	<p>ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)</p> <p>5.2.2 Documentation: <i>includes med dir</i></p>	<p>Personnel files should include:</p> <ul style="list-style-type: none"> • Evidence the Medical Director/designee has certified each of the reprocessing personnel who have successfully completed the required training; 	V 309

	<i>certification</i>		
	ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 6 Patient considerations 6.1 Medical issues	Additional Guidance: Dialyzers of patients who are positive for Hepatitis B must not be reprocessed. Refer to V301. Facilities may also opt to exclude patients with other conditions from their reuse program. Facility reuse policies must specify which patients would be excluded. There should be evidence in policy or in the minutes of the governing body that the Medical Director has made the decision to reprocess dialyzers.	V 311
	ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 13.2.3 Recording: <i>adverse events dialyzer complaint log</i>	The facility must maintain a record of dialyzer complaints. Each complaint should be investigated, and any reuse incidents reported in the QAPI records with corrective actions as indicated. Responsible staff (e.g., the chief technician, area technical manager, nurse administrator, Medical Director) should consider if there have been any trends in complaints, and take indicated action. This information should be incorporated into the facility's QAPI program. Refer to V635. Facility staff must comply with the FDA's Medical Device User Reporting requirements. Refer to V383.	V 356
	ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 14 Quality assurance: <i>general/records/trend analysis</i>	A record of review, comments, trend analysis, and conclusions arising from QA practices serve as a foundation for future review and as documentation to external evaluation Additional Guidance: Reuse audits must be performed on the required schedule and reported in the QAPI activities. For many of the audits, there is a	V 360

		<p>two tier system of review required: the review of the process by the person assigned (i.e. reprocessing by the reuse technician), and oversight of that review by another person qualified to do so (i.e. the technical supervisor observing the reuse technician performing reprocessing).</p> <p>The criteria chosen as the internal standards of a facility shall be documented in its policy and/or procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff members should affirm, modify, or repeat these observations to confirm or improve the process. Clinical outcomes serve as the most important indicator of quality of all dialysis treatment practices including reuse. Final oversight is the responsibility of the Medical Director.</p>	
	ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1) 14.2 Schedule of quality assurance activities: Medical Director responsible	<p>High-volume tasks that are recognized as hazardous should have frequent (weekly or daily) oversight. Practices with little potential for harm may need critical scrutiny on only a quarterly or annual basis.</p> <p>Problems in a particular aspect of operations should be reviewed and tracked until a solution is in place and demonstrated to be effective. The Medical Director is responsible for scheduling review, endorsing findings, and, when appropriate, implementing changes.</p> <p>Additional Guidance: Reuse procedures/tasks/logs must be audited according to Table 2 (V360). The Medical Director is responsible to assure these audits are done, and may not routinely authorize less frequent audits than specified in this table.</p>	V 361
	ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42	<p>This regulation requires at least quarterly audits (observations) of the set-up for dialysis, including testing for presence of</p>	V 368

	<p>CFR 494.50 (b)(1) 14.9 Preparation for dialysis: <i>audit quarterly</i></p>	<p>germicide, testing for residual germicide, and verification of the patient identity with the reprocessed dialyzer.</p> <p>Responsible staff (e.g., nurse manager, administrator, Medical Director) must be able to describe these audits, provide documentation the audits were accomplished, and provide evidence that any concerns identified were addressed.</p>	
	<p><i>Cluster of adverse patient reactions = suspend reuse</i></p>	<p>In this context, “cluster” refers to a group of hemodialysis patients suspected of having adverse reactions that could be clinically related to dialyzer reprocessing and/or reuse practices.</p> <p>Responsible staff (e.g., chief technician, area technical manager, Medical Director) must be able to describe actions to be taken if a group of patients experience adverse reactions potentially related to reprocessing/reuse.</p> <p>If a cluster of adverse patient reactions associated with reprocessing/reuse was identified, dialyzer reprocessing/reuse should have been suspended, pending investigation.</p>	V 382
Physical Environment	<p>Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs.</p>	<p>The minimum emergency equipment required is defined in V413. The emergency drugs to be kept onsite may be determined by the Medical Director and defined by facility policy.</p> <p>If the facility has chosen to use a defibrillator (rather than an Automated External Defibrillator [AED]), recognize that use of a defibrillator requires recognition of arrhythmias and knowledge of protocols to properly use the defibrillator. An AED can be used by any person with appropriate instruction.</p> <p>If a traditional defibrillator is present, written protocols approved by the Medical Director and a staff member trained and competent to use that equipment should be present</p>	V 411

		whenever patients are dialyzing in the facility.	
Patient Assessment	<i>Standard: Frequency of assessment for patients admitted to the dialysis facility.</i>	<p>Prior to the first dialysis treatment, an “initial assessment” must be completed.</p> <p>This initial assessment is addressed in the Condition for Medical Director at V715 and is different from the “initial comprehensive interdisciplinary” assessment.</p>	V 516
Patient Plan of Care	Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.	<p>In order for dialysis treatment to be initiated, each patient must have an initial dialysis prescription, orders for care, and baseline physical and nursing assessments before treatment is begun at the facility.</p> <p>See V715 under the Condition for Medical Director for this requirement</p>	V 557
Care at Home	The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.	<p>The Medical Director must review the results of all water and dialysate cultures and endotoxin levels, and analysis of source and product water for chemical contaminants of each home hemodialysis patient.</p> <p>The facility must maintain documentation of the Medical Director’s review, which should be incorporated as a part of the QAPI program review.</p> <p>Refer to the Condition for Water and dialysate quality at V178 and V180 for action and maximum allowable culture and endotoxin levels in water and dialysate.</p> <p>Results that are out of range require patient evaluation, notification of the patient’s physician/Medical Director, and action taken per facility policy. Documentation should include</p>	595

		culture/endotoxin results, physician and Medical Director notification of any abnormal levels, and a corrective action plan if results are out of range.	
	The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, .	<p>If the patient exhibits clinical symptoms associated with water and dialysate contamination that cannot be readily attributed to other causes, the facility must arrange for back-up dialysis until the problem is investigated and resolved.</p> <p>Clinical symptoms for water/dialysate contamination may include, but are not limited to, chills, shaking, fever, vomiting, headache, dizziness, muscle weakness, skin flushing, itching, diarrhea, hyper/hypotension, hemolysis and anemia.</p> <p>If such symptoms are present, the facility must notify the patient's physician/Medical Director to determine appropriate action (i.e., culture and treatment).</p>	V 596
Quality Assessment and Performance Improvement	Condition: Quality assessment and performance improvement.	<p>Compliance with this Condition is determined by review of clinical outcomes data and the records of the quality assessment performance improvement activities of the facility, and by interviews of responsible staff including the Medical Director. Non-compliance at the Condition level may be warranted if a pattern of deficient practices which could impact patient health and safety is identified. Examples include, but are not limited to:</p> <ul style="list-style-type: none"> • Absence of an effective QAPI program; • Failure to recognize and prioritize major problems that threaten the health and safety of patients; or • Failure to take action to address identified problems. 	V 625
	The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program	The professional members of the facility's "interdisciplinary team"(IDT) which must participate in the QAPI activities, must, minimally, consist of a physician, registered nurse, masters-prepared social worker, and registered dietitian.	V 626

		<p>This facility-based team is led by the Medical Director, who may also serve as the physician representative of the IDT.</p> <p>The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p>	
	Infection control	<p>Responsible staff must review and</p> <ul style="list-style-type: none"> Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; Develop recommendations and action plans to minimize infection transmission, promote immunization; Take actions to reduce future incidents <p>Results of all routine and diagnostic testing are reviewed (including culture and serology) upon receipt and ensure that the Medical Director periodically reviews recorded episodes of bacteremia, vascular access infections, soft tissue infections, and other communicable diseases to aid in tracking, trending, and prompt identification of potential environmental/staff practices issues or infection outbreaks among patients.</p>	V 637
	<i>Standard: Monitoring performance improvement.</i>	<p>The dialysis facility must continuously monitor its performance and take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.</p> <p>The Medical Director should continuously communicate with the governing body about the status of QAPI activities, particularly when resources are required to address program improvements. See V756.</p>	V 638

		<p>If the Medical Director is a part of the governing body, there should be some evidence he/she provides information to members who do not participate in the QAPI meetings.</p> <p>The minutes of the governing body or the minutes of the QAPI committee should demonstrate communication between the governing body and the Medical Director</p>	
Special Purpose Dialysis Facility	<p><i>Standard: Physician contact.</i></p> <p>The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care</p>	<p>The facility must contact the patient's physician prior to initiating care in the SPDF to update that physician on the status of the patient and to coordinate the patient's plan of treatment. In the event of a natural disaster, the facility must make every effort to contact the patient's physician; however when it is impossible to contact or communicate with that physician, emergency dialysis care must be provided.</p> <p>In this case, the SPDF should have standard orders for dialysis, diet/fluids, and medications that the Medical Director of the SPDF could prescribe until he/she communicates with the patient's attending physician.</p>	V 666
Personnel Qualifications	<p><i>Standard: Medical Director.</i></p>	<p>The Medical Director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.</p> <p>The facility is expected to maintain verification of the Medical Director's board certification and documentation that he/she has completed a board-approved training program in nephrology or pediatric nephrology and has the required experience.</p> <p>A Medical Director may maintain current certification in</p>	V 682

		<p>nephrology or pediatric nephrology or current certification in internal medicine or general pediatrics.</p> <p>CMS accepts the position of the ABIM and ABP and accepts current board certification in internal medicine, pediatrics, nephrology, or pediatric nephrology as meeting this requirement.</p> <p>Completion of a “board-approved training program” means the physician has completed a two-year nephrology fellowship, which would serve as evidence of the required 12-months of nephrology experience.</p>	
	If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.	If the facility is using a physician as Medical Director who does not meet the requirement at § 494.140(a)(1), there must be documentation available that the Secretary of DHHS approved the facility’s use of the physician as Medical Director	V 683
	Personnel Qualifications: Patient Care Technician Training Program (paraphrased)	<p>There must be a training program for patient care dialysis technicians, approved by the Medical Director and governing body and directed by a registered nurse.</p> <p>The training program may be conducted at the facility or at another location. Community or corporate-based programs are acceptable if the required components are included; the program is under the direction of a registered nurse; and the program has been approved by the Medical Director and governing body.</p> <p>All patient care (dialysis) technicians (PCT) who are not yet certified must have successfully completed the approved training program before independently providing patient care. “Successfully completed” means the PCT will have completed all didactic portions of the course and demonstrated competency in the knowledge and skills provided by the training</p>	V 693

	Personnel Qualifications: Water Technician (paraphrased)	<p>Any staff member who operates the water treatment system must complete a training program approved by the Medical Director and the governing body prior to independently performing water treatment system tasks.</p> <p>Refer to V260 in the Condition for Water and dialysate quality for additional requirements related to training for the persons operating the water/dialysate systems.</p>	V 696
	Condition: Responsibilities of the Medical Director.	<p>This Condition defines the role the facility Medical Director is expected to assume to ensure the delivery of quality patient care and clinical outcomes. Most deficient practices identified in the delivery of quality patient care and patient clinical outcomes are most appropriately cited under the Conditions pertinent to the practice (e.g., infection control practices, lack of patient assessment or plan of care implementation). Citation of these standards or this Condition should be considered when deficient practices are pervasive, the results of the deficient practices are egregious, or the deficient practice identified is not covered under other Conditions</p> <p>Determine compliance with this Condition by patient and staff interviews, review of clinical and QAPI records and review of survey findings related to care delivery, patient assessments and plans of care, water and dialysate quality, reuse, and QAPI.</p> <p>Examples of Condition level non-compliance include, but are not limited to:</p> <ul style="list-style-type: none"> • Serious and/or pervasive problems/trends identified in the quality of care delivery, quality assurance and performance improvement activities; • Significant deficient practices in patient care policy and procedure development or implementation in which a lack of involvement and oversight by the Medical Director was a contributing factor. 	V 710

	<p>Medical Director Qualifications (paraphrased)</p>	<p>Each dialysis facility must have a single Medical Director who meets the qualifications under the Condition for Personnel at V682 identified as responsible for carrying out the duties of this position.</p> <p>The position of Medical Director may not be shared by several physicians.</p> <p>The governing body and Medical Director may designate other physicians to direct different program components in that facility (e.g., home hemodialysis program, home peritoneal program), as long as all components ultimately report to the facility Medical Director and are under the same QAPI and governing body oversight.</p> <p>These regulations do not preclude the Medical Director from also serving as the chief executive officer/administrator of the facility (refer to V752), as long as the responsibilities of both positions are fulfilled.</p> <p>The Medical Director is expected to be actively involved in the oversight of the facility patient care delivery and outcomes (e.g., to attend and contribute during interdisciplinary meetings for his/her patients, to participate in performance improvement plans, and to be involved in the education of staff).</p> <p>The Medical Director should devote sufficient time to fulfilling these responsibilities. As a guideline, the financial cost report each facility must file annually with CMS considers the Medical Director position to reflect a 0.25 FTE.</p> <p>Refer to the Conditions for Infection control (V144); Water and dialysate quality (V177, V179); Reuse of hemodialyzers and bloodlines (V305, V309, V311, V361); and Governance (V766, V767) for Medical Director oversight responsibilities specific</p>	V 711

		to those areas. Generally, unless they are serious or pervasive, findings in those areas should be cited at the more specific tags rather than at this tag	
	Medical Director Responsibilities	<p>While these regulations charge the facility governing body with the responsibility for allocating necessary staff and resources for the QAPI program (refer to V756), the Medical Director is assigned operational responsibility for:</p> <ul style="list-style-type: none"> • Facility QAPI program. <ul style="list-style-type: none"> ○ Operational responsibility review of quality indicators related to <ul style="list-style-type: none"> ▪ improved patient health outcomes and monitoring this data on a continual basis as is required by the Condition for QAPI; ▪ education of facility and medical staff in the QAPI objectives; ▪ reviewing the method of prioritizing the importance of improvement projects; ▪ inclusion/encouragement of all staff in participating towards achievement of QAPI goals; ▪ communication with the governing body regarding the needs identified by QAPI; ▪ participating in the evaluation of the effectiveness of performance improvement plans/activities. <p>Materials documenting the QAPI program should include evidence of active participation and oversight by the Medical Director (e.g., discussion of issues, guidance and contribution to the development of performance improvement plans, assessment of the effectiveness of those plans</p>	V 712
	Staff education, training, and performance	The Medical Director is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities.	V 713

		<p>“Performance” refers to the responsibility of the Medical Director to assure that staff members are competent to carry out their assigned duties (e.g., to adequately monitor the patient and the dialysis process, to provide needed social services), and follow facility policy regarding expected performance.</p> <p>Refer to other Conditions in these regulations for specific requirements for staff education, training and/or competency:</p> <ul style="list-style-type: none"> • V132 in Infection control; • V260 in Water and dialysate quality; • V308, 309 in Reuse; • V409, V410, V411 in Physical environment; • V693, V694, V696 in Personnel qualifications; and • V760 in Governance. <p>Generally, these more specific tags should be used rather than this tag if the problem identified in staff education, training or in the performance of assigned responsibilities is related to one of these areas.</p>	
	Policies and procedures.	<p>The Medical Director must— participate in the development, periodic review and approval of a “patient care policies and procedures manual” for the facility;</p> <p>Written patient care policies and procedures are an essential reference for clinical staff and should reflect current practice at the facility. The patient care policies and procedures should address all areas of patient assessment and care delivery for the dialysis modalities provided, and the policies and procedures should reflect these regulations as well as current practice standards and adherence to equipment manufacturers’ instructions for use.</p> <p>There must be evidence that the Medical Director reviewed and approved the patient care policies and procedures and any</p>	V 714

		<p>revisions as they are made. Corporate-owned or corporate-managed facilities may use standard policies and procedures developed by the corporation.</p> <p>There should be a mechanism for the facility Medical Director to have input into the policies and procedures and to have some authority to individualize corporate policies to address unique facility situations.</p> <p>Policies are expected to be adequate, accurate and up to date</p>	
	Ensure	<p>The Medical Director that— all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers</p> <p>This includes holding medical staff accountable for complying with facility policies and procedures, e.g., updating plans of care, signing verbal orders, being knowledgeable of the QAPI targets and working to achieve those targets in their patients.</p> <p>In reviewing the performance of the medical staff, the Medical Director should consider using currently-available methods, such as practitioner profiles, to review and evaluate performance.</p> <p>The Medical Director is responsible for ensuring that the facility has an established policy regarding admissions to the facility</p> <p>Policies relative to patient admission must address the expectation for an initial assessment by a member of the medical staff (i.e., physician, APRN or PA) before the initiation of the patient's first dialysis treatment in the facility, in order to develop the admission treatment orders and to provide for</p>	V 715

		<p>prompt recognition and action to address urgent patient medical needs (e.g., anemia with Hgb <10 gm/dL, fluid overload, hyperkalemia) prior to completion of the comprehensive patient assessment. This evaluation could be accomplished by review of medical records and consultation with the referring physician, and is not intended to require the medical staff member to “see” the patient in the facility prior to this first treatment.</p> <p>Orders for treatment must be in place prior to the initial treatment, as well as a patient evaluation by a registered nurse for any immediate needs. At the time of publishing these regulations, according to the American Nephrology Nurses’ Association, the minimal nursing evaluation prior to initiating treatment for a patient new to the facility should include:</p> <ul style="list-style-type: none"> • Neurologic: level of alertness/mental status, orientation, identification of sensory deficits • Subjective Complaints • Rest and comfort: pain status • Activity: ambulation status, support needs, fall risk • Access: assessment • Respiratory: respirations description, lung sounds • Cardiovascular: heart rate and rhythm; presence and location of edema • Fluid gains, blood pressure and temperature pre-treatment • Integumentary: skin color, temperature and as needed, type/location of wounds <p>Note that other parts of these regulations address adherence to policies and procedures as applicable to specific Conditions, e.g., Infection control at V142, Water and dialysate quality at V259, Reuse at V306, and Physical environment at V408. Generally, these more specific tags should be used for deficient practices identified in those areas.</p>	
	The interdisciplinary team adheres to the	The Medical Director must monitor and review each	V 716

	discharge and transfer policies and procedures	<p>involuntary patient discharge to ensure that the facility interdisciplinary team follows the discharge and transfer policies and completes the steps required under the Condition for Governance at V766 and V767.</p> <p>The records of any patients who have been involuntarily discharged must show evidence of compliance with each of the requirements detailed at V767, including evidence that the Medical Director as well as the patient's attending physician, signed the order for involuntary discharge.</p>	
Governance	Designating a chief executive officer or administrator.	<p>The qualifications for this position are not specified in these regulations, but should be defined in facility policy, and include sufficient educational and practical experience to fulfill the responsibilities listed in this section.</p> <p>The governing body or its designee must appoint the selected individual to this role. This position may be held by a member of the staff who is holding a different role, e.g., nurse manager, the Medical Director, as long as the duties of each role are accomplished</p>	V 752
	Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program	<p>Under QAPI (at V626) requirements for the minimum professional membership in the QAPI process are delineated. If those professional members are not given enough time or support to participate in QAPI activities, this tag should be considered.</p> <p>There must be communication between the Medical Director and the governing body regarding QAPI. The governing body must provide resources (time, staff or funding) for QAPI audits, staff education, refurbishing, etc. as needed to support correction of identified problems. The governing body must review information related to significant problems</p>	V 756

	All staff, including the Medical Director , have appropriate orientation to the facility and their work responsibilities;	The CEO or administrator is responsible to ensure that each member of the staff receives an orientation to the facility, his/her job duties, and how to do the work assigned. While the orientation of employees should be documented in their personnel files, the orientation of physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician assistants) should be documented in their credential files and include evidence of understanding of and agreement to medical staff bylaws, policies and procedures, and responsibilities related to QAPI	V 760
	Ensures that all medical staff	<p>The governing body must inform members of the medical staff of all aspects of the facility's QAPI program, including the requirement to participate in efforts to improve the quality of medical care to their patients.</p> <p>These efforts must be reflected both in documentation of the QAPI program and in the medical records of individual patients. It is not required that all members of the medical staff attend all the QAPI meetings.</p> <p>Examples of the lack of medical staff adherence to facility policies or goals would include physician(s) not participating in the development of the plan of care, or not addressing poor patient outcomes with a change in the plan of care. Medical staff "not informed" indicates this requirement is not met. For medical staff "not compliant," refer to V715 under the Condition for Medical Director.</p>	V 763
	Involuntary discharge and transfer policies and procedures.	<p>The Medical Director ensures that no patient is discharged or transferred from the facility unless –</p> <ul style="list-style-type: none"> • The patient or payer no longer reimburses the facility for the ordered services; • The facility ceases to operate; • The transfer is necessary for the patient's welfare because the facility can no longer meet the patient's documented 	V 766

		<p>medical needs;</p> <p>In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure the Medical Director must be informed of and approve any involuntary discharge or transfer of a patient.</p> <p>A facility may involuntarily discharge or transfer a patient only for those reasons listed here and at V767.</p> <p>The Medical Director must ensure that the reasons for any involuntary discharge or transfer are consistent with this requirement.</p>	
	Involuntary Patient Discharge: Reassessment (paraphrased)	<p>The facility has reassessed the patient and determined that the patient's 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, in which case the Medical Director ensures that the patient's interdisciplinary team:</p> <ul style="list-style-type: none"> • Documents the reassessments, ongoing problems(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record; • Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge; • Obtains a written physician's order that must be signed by both the Medical Director and the patient's attending physician concurring with the patient's discharge or transfer from the facility; • Contacts another facility, attempts to place the patient there, • Notifies the State survey agency of the involuntary transfer or discharge. <p>In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure there must be a written order in the</p>	V 767

		<p>patient's medical record, signed by the attending physician and the Medical Director for the facility to involuntarily discharge or transfer a patient</p> <p>An "immediate severe threat" is considered to be a threat of physical harm. For example, if a patient has a gun or a knife or is making credible threats of physical harm, this would be considered an "immediate severe threat." An angry verbal outburst or verbal abuse is not considered to be an immediate severe threat. In instances of an immediate severe threat, facility staff may utilize "abbreviated" involuntary discharge or transfer procedures. These abbreviated procedures may include taking immediate protective actions, such as calling "911" and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and other patients are safe, staff must notify the patient's physician and the Medical Director of these events, notify the State agency and ESRD Network of the involuntary discharge, and document this contact and the exact nature of the "immediate severe threat" in the applicable patient's medical record.</p>	
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