End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER
V100	***CfC: Compliance with Fed/State/Local Laws***
V101	Compliance with Fed/State/Local laws
V110	***CfC: Infection Control***
V111	IC: Sanitary environment
V112	IC: CDC MMWR 2001
V113	IC: Wear gloves/hand hygiene
V114	IC: Sinks available
V115	IC: Wear gowns, shields/masks; staff not eat/drink in tx area
V116	IC: Items taken to station disposed/dedicated or disinfected
V117	IC: Clean/dirty areas; med prep area; no common med carts
V118	IC: Single use vials
V119	IC: Supply cart distant/No supplies in pockets
V120	IC: Transducer protectors: not wetted/changed
V121	IC: Handling infectious waste
V122	IC: Clean,disinfect surfaces & equipment/written protocols
V124	IC: HBV: test all pts, review results/pt status known preadmit
V125	IC: HBV: seroconversion=investigation
V126	IC: HBV: vaccinate patients & staff
V127	IC: HBV: test pts/staff post last dose
V128	IC: HBV: isolation (existing facility)
V129	IC: HBV: isolation (new facility)
V130	IC: HBV: isolation of machines/equipment/supplies
V131	IC: HBV: isolation – staffing
V132	IC: Training and education
V142	IC: Oversight: Monitor activities & implement policies
V143	IC: Aseptic techniques for IV meds
V144	IC: Staff report IC issues
V145	IC: Report communicable diseases
V146	IC: Catheters; general
V147	IC: Staff education re catheters/catheter care
V148	IC: Monitor cath related BSI rates/surveillance
V175	***CfC: Water and Dialysate Quality***
V176	Water purity:ANSI/AAMI RD52:2004
V177	Max level of chemical contaminants in water/chem analysis
V178	Bacteriology of water-maximum and action levels
V179	Bacteriology of water-Medical Director responsible
V180	Bacteriology of conventional dialysate-max and action levels
V181	Bacteriology of ultrapure dialysate
V182	Equipment-general/back up plan
V184	Environment: secure and restricted
V185	Environment: access to ports/meters
V186	Environment: alarms in treatment area
V187	Environment: schematic diagrams/labels
V188	Sediment filters: config and monitoring
V189	Cartridge filters: config and monitoring
V190	Softeners: automatically regenerated/timers/salt/salt level
V191	Softeners: testing hardness/log
V192	Carbon adsorption: two tanks/sample ports
V193	Carbon adsorption: banks of tanks
V194	Carbon adsorption: Iodine #900/replacement
V195	Carbon adsorption: 10 minutes EBCT
V196	Carbon adsorption: monitoring, testing frequency
V197	Carbon adsorption: action if first test positive
V198	Chemical injection systems
V199	RO: meets AAMI/monitored, recorded on log
V200	RO: monitor/alarm/prevent use of unsafe water
V201	RO: chemical analysis: frequency
V202	DI: continuous monitoring resistivity/logged 2 x day
V203	DI: alarms/divert to drain
V204	DI: require carbon pre/UF post
V205	DI: polish or back up
V206	DI: chemical analysis: frequency
V207	Ultrafiltration: effective/opaque housing/monitoring
V208	Water storage and distribution: design
V209	Water storage tank: shape/vent/disinfected/filter post
V210	Water storage: monitoring
V211	Water distribution sys: continuous flow rates/no dead ends
V212	Water distribution systems: no added burden
V213	Dist sys: culture/LAL/sample sites/frequency(new)/log
V214	Bacterial control devices: ultraviolet irradiators
V215	Ultraviolet irradiators: filters post
V216	Ozone generators: system requirements/monitoring
V217	Hot water disinf sys: temp/time/follow DFU/piping
V218	Hot water disinfection systems: monitoring
V219	Bacterial control: disinfect monthly/disinfection dwell
V220	Bacterial control: machine supply line disinfected
V222	Acid bulk storage tanks: safety controls
V223	Concentrate preparation: materials compatibility
V224	Mixing systems: water/drain/electric
V225	Mixing systems: safe environment/PPE
V226	Mixing sys: follow DFU/monitor/PM/log/sanitization
V227	Mixing systems: self designed
V228	Mixing systems: labeling
V229	Mixing systems: permanent record/verification testing
V230	Mixing systems: cleaning
V231	Acid conc mixing sys: empty completely//prevent corrosion
V232	Bicarb mixing sys: empty/disinfect/prevent corrosion
V233	Bicarb mixing sys: storage/use time limits/min combine
V234	Bicarb mixing sys: not overmixed
V235	Additives: mixing spikes
V236	Additives: labeling spiked jugs/labeling if for specific pt
V237	Concentrate distribution: materials compatibility
V238	System configurations: elevated tanks
V239	Bicarb conc distribution: weekly disinfect/dwell times/conc
V240	Bicarb distribution systems: use of UV
V241	Bicarb distribution systems: ozone disinfection
V242	Concentrate distribution: Bicarb monitoring initially
V243	Bicarb jugs rinsed daily/stored dry
V244	Bicarb jug maintenance/disinfection
V245	Acid conc distribution: conc labeled & color-coded red
V246	Bicarb conc distribution: color coded blue & sealed
V247	Conc outlets: separate/labeled/connection safety
V248	Dialysate proportioning: match ratio: all conc/machine
V249	Dialysate proport: match machine config w/ratio in use
V250	Dialysate proportioning: monitor pH/conductivity
V252	Microbial monitoring: mo water samples/method
V253	Microbial monitoring: mo dialysate sample/collection/freq
V254	Microbial monitoring: sample before disinfect
V255	Microbial monitoring: repeat cultures
V256	Heterotrophic plate count: dip samplers require QC
V257	Heterotrophic plate count: refrig if delay >2 hrs/no calib loop
V258	Bacterial endotoxin test: LAL testing in house: how to
V259	Personnel : P&P
V260	Personnel: training program/periodic audits
V270	Ch/chl breakthrough: corrective action
V271	Ch/chl breakthrough: holding tank use
V272	Ch/chl breakthrough: notify Medical Director
V273	Ch/chl breakthrough: action = correction
V274	Water test results: deviations require corrective action plan
V275	Adverse events: actions expected
V276	I-C use of preconfigured HD systems: follow FDA labeling
V277	In-center preconfigured HD: meets AAMI RD52
V278	In-center preconfigured HD: quarterly cultures/LALs
V300	***CfC: Reuse of Hemodialyzers and Bloodlines***
V301	General requirements: no reuse for HBV+ pts
V303	Dialyzer must be labeled for multiple reuse per FDA
V304	Reprocessing requirements: meets AAMI RD47 2001/2002
V305	Records: meet req for med records
V306	Dialyzer reprocessing manual
V307	Personnel qualifications
V308	Training: curriculum
V309	Training documentation includes med dir certification
V310	Personnel health monitoring records
V311	Patient considerations: medical issues
V312	Patients informed regarding dialyzer reuse process
V313	Equipment: design/construction/function
V314	Water systems meet AAMI bacti/chem quality/monitoring
V315	Reprocessing systems: utility requirements
V316	Maintenance per DFU or semiannual/maintenance record
V317	Repairs by qualified personnel: fxn test before return to use
V318	Reprocessing area and ventilation
V319	Environmental safety regarding chemicals
V320	Personnel protective gear
V321	Storage area/segregation of dialyzers in process
V322	Reprocessing supplies: specifications and testing
V323	Inventory control
V324	Process control testing: methods established
V325	Process control testing: concentration of germicide
V326	Reprocessing record complete/available to patient
V327	Hemodialyzer labeling: unique to patient
V328	Time of labeling: before or at first use, updated p each use
V329	Label composition and placement
V330	Information recorded on label/similar name warning
V331	Reprocessing: transportation and handling
V332	Rinsing/cleaning: precleaning equipment/pressures
V333	Rinsing/cleaning: use AAMI quality water
V334	Dialyzer header cleaning and disinfection
V335	Rinsing/cleaning: chemicals used/rinse after each
V336	TCV measured after q use/original volume known
V337	Blood path integrity test after q use
V338	Germicide: sufficient for point of use
V339	Germicidal process high-level disinfection achieved

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TAG	IDENTIFIER
V340	Dialyzer germicide = 90% conc/port caps disinfected
V341	Chemical germicidal concentration: verification testing
V342	Dialyzer exterior: low-level disinfection
V343	Dialyzer inspection after reprocessing: all aspects/aesthetics
V344	Disposition of rejected dialyzers
V345	Reprocessed dialyzer storage
V346	Prep for dialysis: written P&Ps for germicide testing
V347	Prep for dialysis: visual inspection: all aspects
V348	Verification of patient identification: 2 people
V349	Verification of germicidal contact
V350	Germicide presence test of each dialyzer
V351	Germicide presence: process control/sampling
V352	Dialyzer priming/rinsing the germicide
V353	Testing for residual germicide/max time rinsed to use
V354	Monitoring: dialysis/patient's clinical course
V355	Monitoring: fever/chills/other symptoms
V356	Recording adverse events/dialyzer complaint log
V357	Dialyzer failures/blood leaks recorded
V358	Monitoring: patient clinical results/Kt/V
V359	Ultrafiltration: monitoring patient's weight
V360	Quality assurance: general/Records/trend analysis
V361	Schedule of QA activities: medical director responsible
V362	QA audits: patient considerations annually
V363	QA audits: manuals and procedures annually & prn
V364	QA audits: physical plant/environmental safety annually
V365	QA audits: reprocessing supplies semiannually
V366	QA audits: hemodialyzer labeling quarterly
V367	QA audits: reprocessing procedures monthly; semiannually
V368	QA audits: preparation for dialysis quarterly
V378	Reprocess dialyzers and bloodlines by DFU
V379	Dialyzers not exposed to more than one germicide
V381	Blood/dialysate cultures for adverse patient reactions
V382	Cluster of adverse patient reactions=suspend reuse
V383	FDA reporting of adverse outcomes
V400	***CfC: Physical Environment***
V401	PE: Safe, functional, comfortable environment
V402	PE: Building: constructed/maintained to ensure safety
V403	PE: Equipment maintenance: manufacturer's DFU
V404	PE: Patient care environment: sufficient space
V405	PE: Comfortable temperature
V406	PE: Accommodations for patient privacy
V407	PE: Hemodialysis patients in view during treatments
V408	Emergency preparedness: procedures
V409	ER preparedness of staff: initial/annual/re informing patients
V410	Patient care staff: current CPR certification
V411	Nursing staff trained in emergency equip and meds
V412	Emergency preparedness: patients oriented/trained
V413	Emergency equipment: on premises: O2, AED, suction, etc.
V414	Emergency plans: EMS contact
V415	Annual evaluation of emergency/disaster plans
V416	Contact local disaster management agency annually
V417	Fire safety: Life Safety Code 2000
V418	LSC: sprinklers
V419	LSC: Waiver if state requirements meet Fed req
V420	LSC: waiver
V450	***CfC: Patients' Rights***
V451	Patients informed of rights when begin treatment
V452	Respect & dignity
V453	Receive information in an understandable way
V454	Privacy & confidentiality in treatment
V455	Privacy & confidentiality in records
V456	Participate in care; discontinue/refuse treatment
V457	Execute advance directives; facility policy re AD
V458	Informed: all modalities & settings
V459	Informed: patient care policies
V460	Informed: whether facility practices reuse; if so, options
V461	Informed: own medical status
V462	Informed: services & charges
V463	Receive services outlined in POC
V464	Informed: rules/expectations re patient conduct
V465	Informed: internal grievance process
V466	Informed: external grievance processes
V467	Informed: right to file int/ext grievance w/o risk/anon
V468	Informed: d/c & transfer policies inc involuntary dc
V469	Receive written notice 30 days before involuntary dc
V470	Rights posted with state /NW contact #s and addresses
V500	***CfC: Patient Assessment***
V501	Patient assessment: Interdisciplinary Team mbrs/resp.
V502	Assess current health status inc comorbids
V503	Appropriateness of dialysis Rx
V504	Assess B/P & fluid management needs
V505	Assess lab profile
V506	Immunization/medication history
V507	Assess anemia
V508	Assess renal bone disease
V509	RD: nutritional status
V510	MSW: psychosocial needs
V511	Dialysis access type & maintenance
V512	Eval for self care, modality & setting
V513	Transplantation referral
V514	Eval family /support systems
V515	Eval current physical activity level & voc/physical rehab
V516	Frequency: initial: 30 days/13 tx
V517	F/U reassessment: within 3 months of initial
V518	Assess HD adequacy monthly/PD adequacy q 4 months
V519	Frequency reassessment: stable = annual
V520	Frequency reassessment: unstable = monthly
V540	***CfC: Patient Plan of Care***
V541	Patient Plan of Care: Goals= evidence-based standards
V542	IDT develops plan of care
V543	Manage volume status
V544	Achieve adequate clearance
V545	Effective nutritional status
V546	Manage mineral metabolism
V547	Manage anemia/H/H measured monthly
V548	Home patient: eval safe ESA administration
V549	Monitor ESA response
V550	Vascular access: monitor /referrals
V551	VA monitor to prevent failure/stenosis
V552	Psychosocial counseling/referrals/assessment tool
V553	Home dialysis plan or why not
V554	Transplantation status plan or why not
V555	Rehab status addressed
V556	POC completed/signed by IDT & patient
V557	Initial POC implemented: 30 days/13 tx
V558	Implement updates of POC: 15 days p pt assessment
V559	Outcome not achieved: adjust POC
V560	Patients seen by med staff member monthly
V561	Track TP referrals/communicate with TP ctr annually & if Δ
V562	Patient/family education & training
V 580	***CfC: Care at Home***
V581	IDT resp = services equivalent to in-center patients
V582	IDT oversees home training
V583	Training provided by certified home training facility
V584	Training conducted by qualified RN
V585	Training content including emergency prep for home pts
V586	Pt/caregiver demonstrated comprehension of training
V587	Fac receive/review self monitoring data every 2 months
V588	Support services must be provided
V589	Monitor home adaptation; home visits = POC
V590	Coordination of care by member of IDT
V591	Home patient plan of care dev/updated
V592	Pt consultation with members of IDT as needed
V593	Monitor water/dialysate inc on site evaluation
V594	Preconfig HD sys: testing water/dialysate follow DFU/FDA
V595	Meet RD 52:2004
V596	Correct water/dialysate problem or arrange back-up dialysis
V597	Provide ordered supplies /equipment
V598	Plan for ER back-up dialysis
V599	Recordkeeping system
V625	***CfC: Quality Assessment & Performance Improvement***
V626	Covers scope of services/effective/IDT involved
V627	Ongoing ; uses indicators = improved health outcomes
V628	Measure, analyze and track quality indicators
V629	QAPI Indicator: Adequacy of dialysis
V630	QAPI Indicator: Nutritional status
V631	QAPI Indicator: Mineral metabolism/bone disease
V632	QAPI Indicator: Anemia management
V633	QAPI Indicator: Vascular access
V634	QAPI Indicator: Medical injuries/errors
V635	QAPI Indicator: HD reuse program
V636	QAPI Indicator: Pt. satisfaction & grievances
V637	QAPI Indicator: Infection control: trend/plan/act
V638	Continuously monitor/take action/track/sustain improve
V639	Prioritizing improvement activities
V640	Immediately correct any IJ issues

End Stage Renal Disease Facilities V-Tags & Identifiers

TAG	IDENTIFIER
V660	***CfC: Special Purpose Renal Dialysis Facilities***
V661	Special Purpose: two categories
V662	Approval period: 8 months
V663	Service limitations
V666	Physician contact
V667	Records transferred within 30 days
V675	***CfC: Laboratory Services***
V676	CLIA labs/meet needs of patients
V680	***CfC: Personnel Qualifications***
V681	Staff licensed as req/qualified/demonstrate competencies
V682	Medical Director: BC + 12 mo dialysis exp
V683	Medical Director exception (CMS approval)
V684	Nurse manager: 12 mo RN + 6 mo dialysis
V685	Self care/home training nurse: 12 mo RN + 3 mo modality
V686	Charge nurse: 12 mo nursing + 3 mo dialysis
V687	RN/LPN Charge supervision
V688	Staff nurse: meet state requirements
V689	Dietitian: RD
V690	Dietitian: 1 year experience
V691	Social worker: MSW; grandfather only if hired before 1976
V692	PCT: state requirements & HS diploma
V693	PCT: complete training program
V694	PCT training program content
V695	PCT certified
V696	Water treatment system techs training
V710	***CfC: Responsibilities of the Medical Director***
V711	Medical director qualified/accountable to Governing Body
V712	MD resp: QAPI Program
V713	MD resp: Staff ed, training & performance
V714	MD resp: Develop, review& approve P&P
V715	MD resp: Ensure all adhere to P&P
V716	MD resp: Ensure involuntary discharge P&P followed
V725	***CfC: Medical Records***
V726	Medical Records: complete, accurate, accessible
V727	MR: Protect patient records from loss/keep confidential
V728	MR: Obtain written permission for release
V729	MR: Complete records promptly
V730	MR: Centralize all info; each member of IDT has access
V731	MR: Maintain home patient records
V732	MR: Retain all records 6 years from discharge/death
V733	MR: Transfer requested records within 1 working day
V750	***CfC: Governance***
V751	Identifiable Governing Body w/full authority/responsibility
V752	Appoint CEO/Administrator
V753	Adm resp for staff appointments
V754	Adm resp for fiscal operations
V755	Adm resp for relationship with ESRD NW
V756	Adm resp for resources for QAPI
V757	Staff # & ratio meet patient needs
V758	RN, MSW, & RD available to meet patient needs
V759	RN present at all times
V760	GB: responsible for staff oriented to facility & resp
V761	Staff have access to continuing education
V762	GB: responsible for medical staff credentialing
V763	GB: Informs medical staff of P&P and QAPI program
V764	Services furnished on the main premises
V765	Internal grievance process components & implemented
V766	GB & med dir ensure all staff follow disch/transfer P&P
V767	Involuntary discharge process requirements
V768	GB: provide pts/staff direction re emergency med care
V769	Physician roster available
V770	Transfer agreement with hospital for inpatient care
V771	Electronic data submission required for program adm
V772	Responds to NW requests/works toward goals
V773	Disclosure of ownership

V100: § 494.20 Condition: Compliance with Federal, State, and Local Laws and Regulations: Emphasizes the Centers for Medicare & Medicaid Services' (CMS) role as a partner with State and local governments and with other Federal agencies. The purpose of this Condition is to affirm the principle that Medicare reimbursement should be distributed to ESRD facilities that comply with local, State and Federal laws and rules. This Condition is not intended to adjudicate laws and rules from other governmental agencies. Therefore, this Condition should only be cited when a specific "deficient" practice has been adjudicated with the appropriate entity, and a final decision of non-compliance with the other entity's requirement has been reached. Facilities are expected to comply fully with investigations conducted by public health, regulatory, or law enforcement authorities.

V110: § 494.30 Condition: Infection Control: Incorporates as regulation two documents from the Centers for Disease Control and Prevention (CDC), along with CMS developed regulations. These infection control requirements apply to both the chronic dialysis facility's in-center dialysis and any home dialysis program(s).

V175: § 494.40 Condition: Water and Dialysate Quality: Incorporates by reference the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," 2004 and has the authority of regulation. This AAMI document references portions of their "American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD62:2001) as the specifications for various water treatment components. The referenced portions of RD62:2001 are also incorporated by reference, and have the authority of regulation.

V300: § 494.50 Condition: Reuse of Hemodialyzers and Bloodlines: Applies only if the facility reuses hemodialyzers or bloodlines. The AAMI "Reuse of Hemodialyzers" Third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference as regulation as part of this Condition (V304-V368).

V400: § 494.60 Condition: Physical Environment: Addresses the requirements related to the building and equipment of the facility and incorporates by reference the ambulatory health care occupancy provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. This Condition also includes requirements for emergency preparedness for medical and non-medical issues.

V450: § 494.70 Condition: Patients' Rights: Requires the facility to provide respect, privacy, information, and appropriate services for their patients, as well as an internal grievance mechanism and information about external grievance mechanisms.

V500: § 494.80 Condition: Patient Assessment: Addresses the requirements for an interdisciplinary assessment of patient needs; the requirements related to meeting those needs are contained in the Condition of Patient plan of care at 494.90.

V540: § 494.90 Condition: Patient Plan of Care: Directly related to the Condition of Patient assessment, as the plan of care is built upon the patient assessment. The individual plan of care is revised after each patient assessment, and portions of the plan of care must be updated if the target goals for each area are not achieved or not sustained.

V580: § 494.100 Condition: Care at Home: Applies to those facilities that provide training and support services for any type of home dialysis. This Condition focuses on items that are unique to the home dialysis modality. All of the ESRD Conditions must be met regardless of whether the setting is in-center or at home.

V625: § 494.110 Condition: Quality Assessment and Performance Improvement: Looks at facility aggregate data and requires facility-based assessment and improvement of care, while the Plan of care Condition expects patient-based improvement of care.

V660: § 494.120 Condition: Special Purpose Renal Dialysis Facilities: Outlines the requirements for dialysis facilities that provide care to patients who need dialysis on a short-term basis because of emergency conditions or because they are staying at remote vacation camps. These "special purpose renal dialysis facilities" (SPDF) require a special certification. This certification may not exceed 8 months in any 12-month period of time.

V675: § 494.130 Condition: Laboratory Services: Describes the requirements for clinical laboratory services required to meet the needs of ESRD patients.

V680: § 494.140 Condition: Personnel Qualifications: Defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs.

V710: § 494.150 Condition: Responsibilities of the Medical Director: 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.

V725: § 494.170 Condition: Medical Records: Requires the facility to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records.

V750: § 494.180 Condition: Governance: Addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process and decreasing the potential for involuntary discharge of patients; for emergency coverage and backup; for electronic data submission; and the relationship of the facility to the ESRD Network.