Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

FED - V0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition	Interpretive Guideline
	0

FED - V0100 - CFC-COMPLIANCE WITH FED/STATE/LOCAL LAWS

Title CFC-COMPLIANCE WITH FED/STATE/LOCAL LAWS

Type Condition

CFR 494.20

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

FED - V0101 - COMPLIANCE WITH FED/STATE/LOCAL LAWS

Title COMPLIANCE WITH FED/STATE/LOCAL LAWS

Type Standard

CFR 494.20

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Regulation Definition

The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Interpretive Guideline

Applicable laws and regulations of other Federal agencies which could be cited here include the Department of Health & Human Services' Office of Civil Rights (DHHS OCR) for the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA), the Department of Justice Civil Rights Division for Title III related to public accommodations under the Americans with Disabilities Act (ADA); the Occupational Safety and Health Administration (OSHA) for regulations related to employee safety; and the Food and Drug Administration (FDA) for regulations related to the safety of drugs and medical devices. If a drug or device may have caused or contributed to a serious injury or illness, the facility must notify the manufacturer and the FDA using FDA's User Facility reporting requirements. Clusters of adverse events (infectious or non-infectious) should also be reported to the appropriate State or local public health department, as required by those authorities. Because these other Federal laws are complex, surveyors are not expected to be their enforcement mechanism. If noncompliance with the laws or rules of another Federal agency is suspected or noted, contact your CMS Regional Office (RO) for guidance.

Compliance with reporting communicable diseases is addressed in the Condition for Infection control at V 145. Compliance with requirements for FDA reporting related to dialyzer/bloodline reuse is addressed in the Condition for Reuse at V383. Compliance with licensure and certification of facility staff is addressed in the Condition for Personnel qualifications at V681.

FED - V0110 - CFC-INFECTION CONTROL

Title CFC-INFECTION CONTROL

Type Condition

CFR 494.30

Regulation Definition

Interpretive Guideline

This Condition incorporates as regulation two documents from the Centers for Disease Control and Prevention (CDC) and also includes CMS-developed regulations. These infection control requirements apply to both the chronic dialysis in-center facility and any home dialysis program(s).

Survey of this Condition requires observations of care delivery, interviews with staff and patients, and review of medical records, facility logs, policies and procedures and quality assessment and performance improvement (QAPI) documentation. 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. Medical and administrative records must demonstrate recognition of any potential infection and actions taken to decrease the transmission of

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infection within the dialysis facility.

If deficient practices noted in infection control techniques are multiple, pervasive, or of an extent to present a risk to patient health and safety, Condition level non-compliance should be considered.

FED - V0111 - IC-SANITARY ENVIRONMENT

Title IC-SANITARY ENVIRONMENT

Type Standard

CFR 494.30

Regulation Definition

The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

Interpretive Guideline

The CDC defines a "sanitary environment" as an environment that meets the "Standard Precautions" for an inpatient hospital setting plus the more stringent precautions which are recommended for hemodialysis units because of the increased potential for contamination with blood and pathogenic microorganisms.

"Standard Precautions" apply to the care of all patients in any healthcare setting and include the use of gloves, gown, or mask whenever needed to prevent contact of the health-care worker with blood, secretions, excretions, or contaminated items.

Standard Precautions are the CDC's system of infection control precautions for all health care settings. Standard Precautions emerged from Universal Precautions and (UP) and Body Substance Isolation (BSI) and are based on the principle that all blood, body fluids, secretions, and excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents.

Dialysis facilities should adhere to Standard Precautions for all health care settings and the additional precautions recommended for hemodialysis facilities for infection control. Infection control requirements apply to both the chronic dialysis in-center facility and any home dialysis program(s).

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FED - V0112 - IC-CDC MMWR 2001

Title IC-CDC MMWR 2001

Type Standard

CFR 494.30(a)

Regulation Definition

The facility must demonstrate that it follows standard infection control precautions by implementing-

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients," developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.

The recommendation found under section header "HBV-Infected Patients", found on pages 27 and 28 of RR05 ("Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients"), concerning isolation rooms, must be complied with by February 9, 2009.

Interpretive Guideline

The CDC "Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients" (MMWR, Vol. 50/No. RR-5), pages 18 to 28, including the "Recommended Infection Control Practices for Hemodialysis Units at a Glance," is incorporated by reference and has the authority of regulation. For purposes of these Conditions for Coverage, the portions of the CDC infection control recommendations which are incorporated by reference are mandatory and must be adhered to and demonstrated within the dialysis facility. When serving as Regulation text, the words of the CDC document are excerpted exactly as written. When serving as a part of the Interpretive Guidance, the language incorporated from these documents has been edited for clarity, brevity, and to eliminate redundant requirements. The entire CDC document includes background information and rationale for the CDC recommended practices and can be used as an informational resource.

According to the CDC, "preventing transmission among chronic hemodialysis patients of bloodborne viruses and pathogenic bacteria from both recognized and unrecognized sources of infection requires implementation of a comprehensive infection control program. The components of such a program include infection control practices specifically designed for the hemodialysis setting, including routine serologic testing and immunization, surveillance, training and education."

CDC's components of a comprehensive infection control program to prevent transmission of infections among chronic hemodialysis patients include:

- o Infection control practices for hemodialysis units
  - Infection control precautions specifically designed to prevent transmission of bloodborne viruses and pathogenic bacteria among patients.
  - Routine serologic testing for hepatitis B virus infections.
  - Vaccination of susceptible patients against hepatitis B.
  - Isolation of patients who test positive for hepatitis B surface antigen.
- o Surveillance for infections and other adverse events.
- o Infection control training and education.

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The infection control practices recommended by CDC for hemodialysis units will reduce opportunities for patient-to-patient transmission of infectious agents, directly or indirectly through contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel. These practices should be carried out routinely for all patients in the chronic hemodialysis setting because of the increased potential for blood contamination during hemodialysis and because many patients are colonized or infected with pathogenic bacteria. Those infection control practices include additional measures to prevent Hepatitis B Virus (HBV) transmission because of the high titer of HBV in each milliliter of infected blood and its ability to survive on environmental surfaces.

According to the CDC, for patients at increased risk for transmission of pathogenic bacteria, including antimicrobial-resistant strains, additional precautions might also be necessary. Patients with either an infected skin wound with drainage uncontrolled by dressings or uncontrolled fecal incontinence or diarrhea should be dialyzed at a station with as few adjacent stations as possible. Staff members treating the patient should wear a separate gown for the care of the patient, and supplies and equipment (such as blood pressure cuffs) should not be shared between patients who have uncontrolled draining wounds.

Surveillance for infections and other adverse events is required to monitor the effectiveness of infection control practices, as well as training and education of both staff members and patients to ensure that appropriate infection control behaviors and techniques are carried out.

FED - V0113 - IC-WEAR GLOVES/HAND HYGIENE

Title IC-WEAR GLOVES/HAND HYGIENE

Type Standard

CFR 494.30(a)(1)

Regulation Definition

Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.

Interpretive Guideline

According to the CDC, handwashing is the most important measure to prevent contaminant transmission.

Because exposure to blood and potentially contaminated items can be routinely anticipated during hemodialysis, gloves are required whenever caring for a patient or touching the patient's equipment. To facilitate glove use, a supply of clean nonsterile gloves and waste receptacles should be readily accessible to each dialysis station and work area. Gloves should be changed frequently during patient care.

Examples of when gloves should be worn:
o Staff members should wear gloves while performing procedures which have the potential for exposure to blood,

dialysate and other potentially infectious substances. This includes procedures such as caring for patients' vascular accesses or catheters, setting up reprocessed dialyzers pre dialysis treatment, inserting or removing the vascular access needles, connecting the dialysis blood lines to the vascular access needle lines or catheter lines, touching the dialysis blood lines, dialyzer, or machine during or after a dialysis treatment, administering intravenous medications, handling blood lines, dialyzers, dialysate tubing and machines post dialysis treatment, and cleaning and disinfecting the dialysis machine and chair post dialysis treatment.
o Gloves must be provided to patients and visitors if these individuals assist with procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis.
o Chair-side computer keyboards/screens can easily become contaminated because of their proximity to the patient station. Hand hygiene is imperative after contact with the chair-side computer and before contact with the patient, regardless of whether contact with the computer occurred through gloved or ungloved hands.

Examples of when gloves should be changed:
o When soiled (e.g., with blood, dialysate or other body fluids);
o When going from a "dirty" area or task to a "clean" area or task. The CDC defines a "dirty" area as an area where there is a potential for contamination with blood or body fluids and areas where contaminated or "used" supplies, equipment, blood supplies or biohazard containers are stored or handled. A "clean" area is an area designated only for clean and unused equipment and supplies and medications;
o When moving from a contaminated body site to a clean body site of the same patient; and
o After touching one patient or their machine and before arriving to care for another patient or touch another patient's machine.

In addition, a new pair of clean gloves must be used each time for access site care, vascular access cannulation, administration of parenteral medications or to perform invasive procedures. The intention is to ensure that clean gloves which have not previously touched potentially contaminated surfaces are in use whenever there is a risk for cross contamination to a patient's blood stream to occur.

"Hand hygiene" includes either washing hands with soap and water, or using a waterless alcohol-based antiseptic hand rub with 60-90% alcohol content. Hands should be washed with soap and water if visibly soiled. If not visibly soiled, hand hygiene with alcohol-based hand rub may be used. The CDC recommends that hand washing incorporate rubbing hands together "vigorously" for 15 seconds, and that the use of alcohol-based rubs incorporate covering all surfaces of hands and fingers, until hands are dry. According to the CDC, even with glove use, hand hygiene is necessary after glove removal because hands can become contaminated through small defects in gloves and from the outer surface of gloves during glove removal.

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Examples of when hand hygiene should be performed:
o After touching blood, body fluids, secretions, excretions, and potentially contaminated items;
o Before and after direct contact with patients;
o Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications;
o Immediately after gloves are removed;
o After contact with inanimate objects, including medical equipment or environmental surfaces at the patient station;
o Before entering and on exiting the patient treatment areas; and
o When moving from a contaminated body site to a clean body site of the same patient.

The CDC document, "Prevention of Intravascular Catheter-Related Infections," ("RR-10" which is adopted as regulation in this section), states that staff should wear clean or sterile gloves when changing the dressing on intravascular catheters. Staff must observe hand hygiene before and after palpating catheter insertion sites, as well as before and after accessing or dressing an intravascular catheter.

Hand hygiene is required after every direct contact with a patient and between patient contacts, even if the contact is casual. Gloves are not necessary for casual social contact with a patient, for example, staff members may touch the patient's shoulder, take his/her arm, or shake hands without wearing gloves. However, gloves should always be worn anytime contact with blood or body fluids is anticipated.

Physicians and non-physician practitioners functioning in lieu of physicians (i.e., advanced practice registered nurses and physician assistants), social workers and dietitians must follow these same requirements for glove use and hand hygiene.

FED - V0114 - IC-SINKS AVAILABLE

Title IC-SINKS AVAILABLE

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.

Interpretive Guideline

A "sufficient number" means that sinks are easily accessible and readily available in the patient treatment area and in other appropriate areas such as the reuse room, medication area, home training room, and isolation area/room to meet the needs of the staff and patients. Sinks must be plumbed with both hot and cold water; if the flow of water is started through motion detection, adjustments to the system must assure that warm water is available to encourage staff to

wash their hands according to CDC recommendations (see V113).

Handwashing sinks should be dedicated only for handwashing purposes and should remain clean. Avoid placing, cleaning, or draining used items in handwashing sinks. Used or contaminated items should be handled in designated utility sinks. The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. This sink may also be used by staff for handwashing. Soap and a supply of paper towels protected from contamination must be available at each sink.

FED - V0115 - IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK

Title IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.

Interpretive Guideline

Staff should wear personal protective equipment (PPE) appropriate to the anticipated potential exposure. Staff should wear PPE during the initiation and termination of dialysis treatment, manipulation of access needles or catheters, administration of medications through the extracorporeal circuit or by subcutaneous injection, the reprocessing of dialyzers, and cleaning and disinfecting of patient care supplies and equipment. Protective clothing or gear must be changed if it becomes soiled with blood, body fluids (including dialysate), secretions, or excretions.

Street clothes, scrub suits, or uniforms are sufficient attire within the dialysis unit, except for times when the spurting or spattering of blood, body fluids, potentially-contaminated substances, or chemicals might occur. At those times a cover garment which provides an impervious barrier to fluids must be worn. This could be a lab coat, a gown, or an apron which incorporates sleeves. The garment may open to the back or front, but must be closed in front during use for patient care. The protective garment should fully cover the arms and torso from the neck area to the thigh/knee area. Aprons without sleeves are not sufficient PPE for procedures which may result in spurting or spattering of blood.

Physicians, advanced practice registered nurses, physician assistants, social workers and dietitians must wear a cover garment which provides an impervious barrier to fluids if they are providing service to any patient in the treatment area during a time of high risk for spurting or spattering of blood, as, for example, during initiation or termination of dialysis. The garment should be changed if it becomes soiled. Visitors must be provided impervious cover garments if they are in the treatment area during initiation or termination of dialysis.

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Home patients do not have to wear gowns when they are caring for themselves. The partner or caregiver of a home patient should wear appropriate PPE, including gloves, and practice appropriate hand hygiene.

Separate PPE (gown, face shield, etc.) should be used in the isolation area/room and removed before leaving the isolation area/room. If a patient's family member or other visitors are allowed in the isolation area, staff should provide these individuals barrier PPE, to be worn during the visit and removed when leaving.

The "treatment area" includes the reuse room and home training area. Staff must avoid any other activity which would allow self-contamination, such as applying lip balm or handling/inserting contact lenses in the treatment area. Patients may eat and drink at their dialysis stations, depending on facility policies. If non-disposable dishes are provided by the facility, they should be cleaned in the usual manner; no special care of these items is needed

FED - V0116 - IC-IF TO STATION=DISP/DEDICATE OR DISINFECT

Title IC-IF TO STATION=DISP/DEDICATE OR DISINFECT

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
-- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.
-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.

Interpretive Guideline

According to the CDC, any item taken to a patient's dialysis station could become contaminated with blood and other body fluids and serve as a vehicle of transmission to other patients either directly or by contamination from the hands of personnel. Items taken to a patient's dialysis station include those items placed on the top or sides (in baskets) of dialysis machines and on dialysis chairs.

After use, all equipment and supplies must be considered as potentially blood contaminated, and should be separated, handled with caution, and either disinfected or discarded. If provided, linens should be removed after use, separated from clean items and laundered. If blood pressure cuffs are used for multiple patients, the coverings must be disposable or able to be adequately disinfected.

If the facility provides linens or blankets for patient use, these items should be considered as potentially contaminated with blood. If patients bring their own blankets, pillows, etc. patients should be instructed about washing the linen they bring to treatment and using bleach to remove blood stains.

If the facility provides portable or cellular phones, remote controls, or individual televisions for patient use during treatment, these need to be cleaned if shared among patients.

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FED - V0117 - IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS

Title IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.

When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.

Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

Interpretive Guideline

According to the CDC, measures to prevent contamination of clean or sterile items include a) preparing medications in a clean room or area separated or away from the patient treatment area and designated only for medications; b) not handling, cleaning, or storing potentially contaminated (i.e., used) supplies, equipment, blood samples, or biohazard containers in areas where medications and clean (i.e., unused) equipment and supplies are handled; and c) delivering medications separately to each patient: common medication carts must not be used to deliver medications.

It is acceptable for the medication prep area to be within the treatment area, but the space should be away from individual patient stations and a clean area must be provided. Medications used in the home training area may be prepared in the same room where home training is conducted; a clean area should be provided for this activity.

The patient treatment area should have designated "clean" and "dirty" areas. The CDC defines a "dirty" area as an area where there is a potential for contamination with blood or body fluids and areas where contaminated or "used" supplies, equipment, blood supplies or biohazard containers are stored or handled. A "clean" area is an area designated only for clean and unused equipment and supplies and medications. Staff must remain aware of the separation of clean and dirty areas to prevent cross-contamination.

Recognize that smaller, older facilities may face challenges in achieving separate areas for clean and dirty equipment or tasks; the key is protection of clean areas and items from cross contamination.

FED - V0118 - IC-SINGLE USE VIALS

Title IC-SINGLE USE VIALS

Type Standard

CFR 494.30(a)(1)(i)

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Regulation Definition

Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once.

Interpretive Guideline

According to the CDC, once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial.

Single use vials/ampules must be used for only one patient, should not be entered more than once, and if entered, may not be stored for future use.

Staff should only enter vials with a new sterile syringe and needle. If both vials are single use and are discarded after the single entry into each, the same syringe may be used. If either vial is multi-use, a different syringe must be used for entry into each vial.

FED - V0119 - IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS

Title IC-SUPPLY CART DISTANT/NO SUPPLIES IN POCKETS

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.

Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.

Interpretive Guideline

According to the CDC, if a common supply cart is used, it must be kept in a designated area away from any areas where the spurting or spattering of blood or fluid may occur, and the cart should not travel between stations.

Medication vials, patient care items including gloves, or other dialysis supplies should not be in pockets, inside fanny packs, etc.

Supplies of gloves should be strategically placed so that staff has adequate access for both routine and emergency use.

FED - V0120 - IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED

Title IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED

Type Standard

CFR 494.30(a)(1)(i)

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Regulation Definition

Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.

If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.

Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.

Interpretive Guideline

Recognize that some bloodlines do not have external transducer protectors; this requirement would not apply in those cases, except for changing the bloodlines between patients.

According to the CDC, external transducer protectors, [which provide a protective barrier between dialysis bloodlines and the dialysis machine], should not be reused. "Wet" ("wet with blood or other fluid") external transducer protectors must be changed immediately and the side of the external transducer protector that faces the machine should be inspected for visible fluid. If the external transducers are wetted with blood, the staff should inspect the wetted transducer to see if fluid has passed through. If fluid or blood is visible on the side of the transducer protector that faces the machine, the machine must be opened by qualified personnel after the dialysis treatment to allow the internal transducer to be inspected for contamination, including inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. Frequent blood line pressure alarms or frequent requirements for adjustment of the blood level in the drip chamber can be indicators of contamination of the internal transducer filter.

FED - V0121 - IC-HANDLING INFECTIOUS WASTE

Title IC-HANDLING INFECTIOUS WASTE

Type Standard

CFR 494.30(a)(4)(i)

Regulation Definition

[The facility must demonstrate that it follows standard infection control precautions by implementing-]
(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-
(i) Handling, storage and disposal of potentially infectious

Interpretive Guideline

Potentially-infectious waste and soiled laundry should be removed from the patient treatment area throughout the day as the containers are filled in order to maintain an environment that enhances safe patient care. All disposable items should be placed in bags thick enough to prevent leakage.

Any wastes contaminated with blood should be considered "infectious" and handled according to local, State, and Federal regulations governing medical waste disposal.

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waste;

Biohazardous waste containers should be clearly labeled and sealed prior to being full. Biohazardous waste should be stored in an area that is protected from casual access and from the ability to contaminate the water supply.

FED - V0122 - IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL

Title IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL

Type Standard

CFR 494.30(a)(4)(ii)

Regulation Definition

[The facility must demonstrate that it follows standard infection control precautions by implementing-
(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]
(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

Interpretive Guideline

A facility should establish written protocols for cleaning and disinfecting surfaces and equipment, including careful mechanical cleaning before any disinfection process. Refer to CDC RR 5 Table 2 included below for guidance.

Any manufacturer's guidance for sterilization or disinfection of an item should be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time.

Failures in environmental cleaning and disinfection have led to transmission of bloodborne pathogens (e.g., hepatitis B virus) and other infections from one patient to another in hemodialysis units. Correct cleaning and disinfection of environmental surfaces (including patient chair or bed surfaces, dialysis equipment surfaces, adjacent tables and work surfaces) must be performed between patient uses to prevent transmission of dangerous pathogens.

In hemodialysis units, cleaning and disinfection procedures during patient changeover are particularly prone to error and contribute to risk of cross-contamination if correct procedures are not observed. At the end of each dialysis treatment, all surfaces without visible blood should be cleaned following the low level disinfection protocol using soap, detergent or detergent germicide. For visible blood, the intermediate-level disinfection protocol must be followed, which requires the area be immediately cleaned with a cloth soaked with tuberculocidal disinfectant or 1:100 dilution of bleach (300-600 mg/L free chlorine), following the manufacturer's direction for contact time. Gloves must be worn, and the used cloth placed into a leak proof container. After cleaning up all visible blood, a disinfectant must be applied a second time using a new cloth or towel. No patient should be at the station during this time.

For each "station" (i.e., the machine, the purified water connection, dialysate concentrate container(s) or connection(s), and the treatment chair), the completion of one patient's treatment and post-dialysis care must be separated by enough time from the initiation of the next patient's care to allow correct disinfection. If the previous patient remains in the treatment chair while the machine is prepared for the next patient, extreme caution must be

employed to prevent cross-contamination.

CDC Table 2. Disinfection procedures recommended for commonly used items or surfaces in hemodialysis units

Item or Surface	Low-Level Disinfection*	Intermediate-Level Disinfection*
Gross blood spills or items contaminated with visible blood		X
Hemodialyzer port caps		X
Interior pathways of dialysis machine		X
Water treatment and distribution system	X	X+
Scissors, hemostats, clamps, blood pressure cuffs, stethoscopes	X	X§
Environmental surfaces, including exterior surfaces of hemodialysis machines	X	

*Careful mechanical cleaning to remove debris should always be done before disinfection

+Water treatment and distribution systems of dialysis fluid concentrates require more extensive disinfection if significant biofilm is present within the system

§ If item is visibly contaminated with blood, use a tuberculocidal disinfectant

Blood spills in the treatment area and other areas, such as the waiting room and patient bathroom, need to be cleaned effectively and immediately, or as soon as possible given the patient care situation. If a blood spill occurs, staff must

clean it up immediately [or as soon as possible] with a cloth soaked with a tuberculocidal disinfectant or a 1:100 or stronger dilution of bleach (300-600 mg/L free chlorine) (i.e., intermediate-level disinfection). After all visible blood is cleaned, staff should use a new cloth or towel to apply disinfectant a second time.

"Intermediate-level disinfection" means disinfection that kills bacteria and most viruses and is accomplished by using a tuberculocidal "hospital disinfectant" or a 1:100 dilution of bleach (300-600 mg/L free chlorine). "Low-level disinfection" means disinfection that kills most bacteria and is accomplished by using general purpose disinfectants.

At the end of each patient treatment, the staff should clean and disinfect the dialysis station. Special attention should be given to cleaning control panels on the dialysis machines, the treatment chairs and other surfaces that are frequently touched and potentially contaminated with patients' blood. The staff should discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment.

After each treatment, the staff needs to clean and disinfect medical devices and equipment. Items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs need to be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant must be used.

Staff must appropriately clean and disinfect the internal circuits of the dialysis machines. Single-pass machines may be rinsed and disinfected at the beginning or end of each day, while batch recirculating machines must be drained, rinsed and disinfected after each use. If a blood leak occurs, the manufacturer's recommendations for additional disinfection should be followed.

A facility should document procedures for the dialysis machine disinfection, including testing for residual disinfectant.

FED - V0124 - IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT

Title IC: HBV: TEST ALL,REV RESULTS/STATUS B4 ADMIT

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition	Interpretive Guideline
Routine Testing for Hepatitis B	Clarification of terminology: "HBsAg positive" is used synonymously with "HBV+" meaning that the person has tested positive for the presence of Hepatitis B surface antigen. "HBsAg negative" is used synonymously with "HBV-"

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The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit.

Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus]. Promptly review results, and ensure that patients are managed appropriately based on their testing results.

meaning that the person does not have the Hepatitis B surface antigen. "HBV susceptible" means that the person does not have sufficient Hepatitis B surface antibody levels to achieve immunity to the virus. "HBV immune" means the person has sufficient Hepatitis B surface antibodies to achieve immunity to the virus.

According to CDC, although the incidence of HBV infection is low among chronic hemodialysis patients, preventing transmission depends on timely detection of patients converting from HBsAg negative to HBsAg positive and rapid implementation of isolation procedures before cross-contamination can occur.

In order to prevent the transmission of Hepatitis B among ESRD patients, all new patients should be tested and their HBV serologic status (i.e., HBsAg, total anti-HBc, and anti-HBs results) should be known prior to admission for treatment. If the results of this testing are not known at admission because of an emergency situation, the patient should be tested immediately upon intake and results known within 7 days of admission.

CDC ' s schedule for Hepatitis B testing is below:

Schedule for Routine Testing for Hepatitis B Virus (HBV) Infections

Patient Status	On Admission	Monthly	Semi-annual	Annual
All patients	HBsAg,* Anti-HBc* (total), Anti-HBs,*			
HBV-susceptible, including nonresponders to vaccine		HBsAg		
Anti-HBs positive (=10 mIU/mL), anti-HBc negative				Anti-HBs

Anti-HBs and anti-HBc positive	No additional HBV testing needed

* Results of HBV testing should be known before the patient begins dialysis.
+ HBsAg = hepatitis B surface antigen; Anti-HBc = antibody to hepatitis B core antigen; Anti-HBs = antibody to hepatitis B surface antigen.

HBV-Susceptible Patients.
Susceptible patients should begin receipt of hepatitis B vaccine immediately upon admission. Test susceptible patients monthly for HBsAg, including those who a) have not yet received hepatitis B vaccine, b) are in the process of being vaccinated, or c) have not adequately responded to vaccination. Note that, while the patient's anti-HBs is <10 mIU/mL, he/she is considered susceptible to hepatitis B, and should be tested for HBsAg monthly.

Follow-Up of Vaccine Responders.
Retest patients who respond to the vaccine annually for anti-HBs.

HBV-Infected Patient.
Chronically infected patients do not require any routine follow-up testing for purposes of infection control. Annual testing for HBsAg is reasonable to detect the small percentage of HBV-infected patients who might lose their HBsAg.

HBV-Immune Patients.
Annual anti-HBs testing of patients who are positive for anti-HBs (>10 mIU/mL) and negative for anti-HBc determines the need for booster doses of vaccine to ensure that protective levels of antibody are maintained. Follow-up testing after booster doses of vaccine are given is not recommended, nor is routine follow-up testing necessary for patients who are positive for both anti-HBs and anti-HBc.

A facility should have systems in place for communicating these test results to other units or hospitals when patients are transferred for care.

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FED - V0125 - IC-HBV-SEROCONVERSION=INVESTIGATION

Title IC-HBV-SEROCONVERSION=INVESTIGATION

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Routine Testing for Hepatitis B: seroconversion

When a seroconversion occurs, review all patients' routine laboratory test results to identify additional cases. Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit, including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures.

Interpretive Guideline

According to the CDC, in patients newly infected with HBV, HBsAg often is the only serologic marker initially detected. HBsAg-positive seroconversions must be reported to the State or local health department as required by law or regulation. Patients with a positive HBsAg must be isolated. Patients newly identified with a positive HBsAg should be evaluated for the need for counseling, medical evaluation, and vaccination of contacts. Repeat HBsAg testing should be conducted and patient should be tested for anti-HBc (including IgM anti-HBc) 1-2 months later. Six months later, the facility should repeat HBsAg testing and test for anti-HBs to determine clinical outcome and need for counseling, medical evaluation, and referral of contacts for vaccination. Patients who become HBsAg negative are no longer infectious and can be removed from isolation.

If there have been any seroconversions since last survey, there should be documentation of actions taken in response. Recognize that seroconversions should be relatively rare, and each seroconversion should be carefully analyzed for any potential that transmission occurred within the dialysis unit.

FED - V0126 - IC-HBV-VACCINATE PTS/STAFF

Title IC-HBV-VACCINATE PTS/STAFF

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Hepatitis B Vaccination

Vaccinate all susceptible patients and staff members against hepatitis B.

Interpretive Guideline

According to the CDC, hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients and staff members, whether or not the facility accepts HBV+ patients. OSHA mandates that each facility provide HBV vaccine to all susceptible staff members. Hepatitis B vaccination is also recommended for Stage 1-5 chronic kidney disease patients not yet on dialysis and peritoneal dialysis (PD) and home hemodialysis (home HD) patients because they might require in-center hemodialysis. While not a requirement, best practice would suggest that the home

training nurse advise anyone who assists in the home hemodialysis treatment of an HBV+ patient to ask their physician to vaccinate them against hepatitis B.

The patient's physician should refer to the CDC recommendations or the vaccine literature for guidance in dosing. Higher doses of the vaccine are recommended for hemodialysis patients due to their immuno-compromised state.

Since patients and staff have the right to refuse a vaccination, this rule is interpreted to mean that all susceptible patients and staff are "offered" an appropriate Hepatitis B vaccination schedule in an appropriate timeframe. "Appropriate timeframe" means that vaccinations should be offered and initiated at hire for employees and upon admission or earlier for patients, and the course completed according to the timeline suggested by the manufacturer of the vaccine.

Personnel files should demonstrate compliance with this regulation: OSHA requires facilities to maintain a record of their employee's Hepatitis B immunization history and to contact past employers to obtain records of vaccination, if applicable. OSHA requires these records be maintained for 30 years after the person leaves employment. If the employee states he/she has been vaccinated, but the records are not obtainable, the personnel record should include a statement attesting to the employee having received the vaccine with dates (or approximate dates) signed by the employee.

Patient medical and personnel records respectively must show whether susceptible patients and staff are offered hepatitis B vaccination. There must be a system in place to track vaccination administration to assure completion of the ordered course.

FED - V0127 - IC-HBV-TEST PTS/STAFF POST LAST DOSE

Title IC-HBV-TEST PTS/STAFF POST LAST DOSE

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Hepatitis B Screening: Patients and Staff

Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose.
-- If anti-HBs is <10 mIU/mL, consider patient or staff

Interpretive Guideline

According to the CDC, all vaccinees (patients and staff) must be tested for anti-HBs 1-2 months after the last primary vaccine dose to determine their response to the vaccine. Patients and staff members who do not respond to the primary vaccine series should be revaccinated with a full course of vaccine and retested for response. No additional doses of vaccine are warranted for those who do not respond to the second series. Patients who require a booster dose of the HBV vaccine should not be assigned to a staff member concurrently caring for HBV+ positive patients.

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member susceptible, revaccinate with an additional three doses, and retest for anti-HBs.
-- If anti-HBs are =10 mIU/mL, consider immune, and retest patients annually.
-- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually.

The CDC defines an adequate response to vaccination as a laboratory result of =10 mIU/mL anti-HBs. The laboratory performing the testing for anti-HBs must be able to define a 10 mIU/mL concentration. Results should be reported as a numeric value; a result of "positive" or "negative" is not sufficient. Some manufacturers of anti-HBs assays consider a level of anti-HBs that is slightly higher than 10mIU/mL to be protective. For these assays, the higher level of titer considered to be protective by the manufacturer of the kit should be used to determine whether or not the patient or staff member is immune.

Primary nonresponders to vaccination who are HBsAg negative should be considered susceptible to HBV infection.

Patients who respond to the vaccine should be retested annually for anti-HBs. If anti-HBs declines to <10 mIU/mL, these patients should receive a booster dose of hepatitis B vaccine and continue to be retested for anti-HBs annually. Retesting immediately after the booster dose is not necessary.

For staff members who initially respond to the vaccine, neither booster doses of vaccine nor periodic serologic testing to monitor antibody concentrations are necessary.

The facility and the responsible physicians should consult the CDC recommendations on dosing and revaccination.

FED - V0128 - IC-HBV-ISOLATION (EXISTING FACILITY)

Title IC-HBV-ISOLATION (EXISTING FACILITY)

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Isolation of HBV+ Patients

To isolate HBsAg positive patients, designate a separate room for their treatment.

For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity.

Interpretive Guideline

Beginning February 9, 2009, all new facilities must have a separate isolation room unless the facility has obtained a waiver from CMS for this requirement. See V129 for the details of this requirement.

According to the CDC, HBV+ patients must dialyze in a separate isolation room during dialysis to prevent contact and transmission by contact with blood spills, splattering, or spurting of blood and other body fluids.

A separate room with a door is required both to contain any spurting of blood, body fluids, and other contaminates and to prevent cross-transmission that can occur as a result of environmental contamination. HBV is stable in the environment and can survive on surfaces (and remain infectious) for at least 1 week. Since Hepatitis B is not airborne,

the walls of the room do not need to reach the ceiling, but would need to go to the floor in order to contain blood spills and the door must be closed during times when blood spurting or spattering is possible, e.g., at initiation and termination of treatment. The walls need to allow visual monitoring of the patients in the room (unless a staff member is continually present in the room) and to contain any potential blood or fluid spills or spurts.

A separate room is the safer and preferred method of isolation; however, "existing" facilities, meaning those facilities that were treating HBV+ patients as of the effective date of the regulations, i.e. October 14, 2008, and that were using a separate area rather than a separate room, may continue to use the separate "isolation" area, unless they are expanding the physical location, in which case they must add an isolation room or obtain a waiver of the requirement. If an existing facility uses a designated isolation area rather than a room, the area used for HBV+ patients must be separated from other stations by a space at least equivalent to the width of one hemodialysis station. The "isolation" station could be an "end of row" station to facilitate the separation of the area from the mainstream of the dialysis facility's activities and to decrease the number of adjacent dialysis stations.

If there are current HBV+ patients on census, the isolation area/room and equipment cannot be used for HBV- patients on other shifts or days due to the risk of cross-contamination. When any HBV+ patients are no longer on census, the "isolation" area/room may be terminally cleaned, disinfected and used for HBV- patients.

Existing units, currently without HBV+ patients, that accept HBV+ patients after the effective date of these regulations may establish a separate area (as described above) for the care of these patients. Any facility which expands its physical capacity after February 9, 2009 must include an isolation room or secure a waiver. See V129.

Every facility must have the capacity to separate potentially HBV+ patients during treatment. Existing units which do not currently accept or treat HBV+ patients may have a transfer agreement with a local chronic facility which has capacity for isolation stations. If there is no local facility available to accept such transfers, the existing facility must establish an isolation room or area for use with HBV+ patients.

If an HBV+ patient chooses home dialysis, precautions must be exercised during the training of that patient to prevent potential cross-contamination of the training environment and other home patients. These could include conducting the training in the patient's home, rather than at the dialysis facility, or limiting the use of the training space to the HBV+ patient until training is completed. Different precautions would be necessary depending on the modality: home HD vs. PD. Relatives or other individuals who assist with dialysis for an HBV+ patient should be instructed to ask their physician regarding vaccination against hepatitis B infection.

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FED - V0129 - IC-HBV-ISOLATION (NEW FACILITY)

Title IC-HBV-ISOLATION (NEW FACILITY)

Type Standard

CFR 494.30(a)(1)(ii)

Regulation Definition

When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

Interpretive Guideline

As of February 9, 2009, all new facilities must have an isolation room or have been granted a waiver of this requirement from CMS by showing there is sufficient capacity in their geographic area for isolation rooms. New facilities that have not obtained approval for all required building permits or have not completed the required plan reviews in a jurisdiction that does not require building permits prior to the effective date of these regulations (October 14, 2008), must either provide a separate isolation room by February 9, 2009, or obtain a waiver of the requirement for an isolation room. Waiver requests, including information on geographical accessibility of isolation rooms, should be referred to the applicable CMS Regional Office.

FED - V0130 - IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES

Title IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Isolation of HBV+ Patients

To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients.

Interpretive Guideline

Separate dedicated supplies and equipment, including blood glucose monitors, must be used to provide care to the HBV+ patient. All supplies used in the isolation room/area, such as clamps, blood-pressure cuffs, testing reagents, etc., should be labeled "isolation" and not routinely removed from the isolation room/area.

Refillable concentrate containers must be surface disinfected at the completion of each treatment. Refillable concentrate containers may be kept in the isolation area and refilled at the door or removed for cleaning and disinfection. In the disinfection area, the "isolation" container(s) and pick-up tube(s) must be segregated in a dedicated, designated area away from all other containers and pick-up tubes. If the container/pick-up tube is to be rotated out of the isolation area, it must be bleached before subsequent use.

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Separate gowns should be used in the isolation area and removed before leaving the isolation area/room. Any one entering the isolation area/room during the patient ' s treatment must wear a protective gown.

HBV+ patients must undergo dialysis on dedicated machines. Because of the risk of cross-contamination, facilities should avoid switching equipment used for HBV+ patients for use with HBV- patients. Equipment used for HBV+ patients should be reserved for the HBV+ patients unless repair or maintenance is needed, or until all HBV+ patients have been discharged.

Dialyzers for HBV+ patients must not be reused. Refer to V301 under Reuse.

When the machine is no longer dedicated to an HBV+ patient, internal pathways of the machine can be disinfected using conventional protocols, external surfaces cleaned and disinfected and the machine returned to general use.

FED - V0131 - IC-HBV-ISOLATION-STAFFING

Title IC-HBV-ISOLATION-STAFFING

Type Standard

CFR 494.30(a)(1)(i)

Regulation Definition

Isolation of HBV+ Patients

Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.

Interpretive Guideline

One staff person may care for one or more HBV+ patients and one or more immune patients at the same time, but may not simultaneously care for Hepatitis B susceptible patients. Hepatitis B status should be considered when patients are assigned to stations nearest the isolation area. If a staff member assigned to care for an HVB+ patient must concurrently care for someone other than another HBV+ patient, the additional patient(s) must be HBV immune. Patients who require a booster dose of the HBV vaccine should not be assigned to a staff member concurrently caring for HBV+ positive patients. When possible, only HBV immune staff should be assigned to care for HBV+ patients.

FED - V0132 - IC-TRAINING & EDUCATION

Title IC-TRAINING & EDUCATION

Type Standard

CFR 494.30(a)(1)(i)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

Infection Control Training and Education

Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.

Interpretive Guideline

Training and education in infection control rationales and practices appropriate to the responsibilities and task assignments of the staff member at risk for occupational exposure to blood must be provided initially on employment and periodically, as determined by facility policy, but at least annually. OSHA mandates dialysis staff receive bloodborne pathogen training annually and CDC recommends infection control training initially on employment and annually.

Topics must include (but are not limited to):
o Proper hand hygiene technique
o Proper use of personal protective equipment (PPE)
o Infection control practices recommended for hemodialysis units and differences from Standard Precautions
o Special precautions for HBsAg-positive patients
o Proper infection control techniques for initiation, care, and maintenance of access sites
o Modes of transmission for bloodborne viruses, pathogenic bacteria, and other microorganisms as appropriate
o Proper handling, preparation, and administration of parenteral medications maintaining aseptic technique; and
o Proper methods to clean and disinfect equipment and environmental surfaces to minimize transmission of microorganisms.

Staff must demonstrate knowledge of infection control policies/procedures and practices. Personnel records must reflect staff having received appropriate infection control training.

FED - V0142 - IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P

Title IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P

Type Standard

CFR 494.30(b)(1)

Regulation Definition

The facility must-
(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

Interpretive Guideline

The facility should have written policies and procedures covering the infection control program and practices including, but not limited to, isolation and any additional precautions for patients with communicable diseases with different modes of transmission such as tuberculosis (TB), influenza, and multidrug resistant organisms. The facility must review practices and update policies and procedures as needed to ensure infection control practices are rigorously followed.

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FED - V0143 - IC-ASEPTIC TECHNIQUES FOR IV MEDS

Title IC-ASEPTIC TECHNIQUES FOR IV MEDS

Type Standard

CFR 494.30(b)(2)

Regulation Definition

[The facility must-]
(2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

Interpretive Guideline

The facility must have a mechanism in place to ensure expired medications are not available for use. Opened multiple-dose vials should be handled aseptically and used and discarded in accordance with the manufacturer's set time frames and/or other accepted standards for use (e.g., US Pharmacopeia). Staff preparing medications should clean the septum of any multi-use vial with alcohol before inserting the needle and the injection port before using the port to administer a medication.

FED - V0144 - IC-STAFF REPORT IC ISSUES

Title IC-STAFF REPORT IC ISSUES

Type Standard

CFR 494.30(b)(3)

Regulation Definition

[The facility must-]
(3) Require all clinical staff to report infection control issues to the dialysis facility ' s medical director (see § 494.150 of this part) and the quality improvement committee.

Interpretive Guideline

There should be a documented reporting mechanism for infection control issues. The nurse manager, administrator and medical director should each be able to describe the infection control program and reporting mechanisms.

Infection control and patient safety issues should be continuously reported and discussed in QAPI meetings, and the response taken to address these issues should be documented. Records of tracking infections should be a part of the facility's QAPI program. Refer to V637.

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FED - V0145 - IC-REPORT COMMUNICABLE DISEASES

Title IC-REPORT COMMUNICABLE DISEASES

Type Standard

CFR 494.30(c)

Regulation Definition

The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

Interpretive Guideline

The reporting of incidences of communicable diseases should be documented and become a part of the QAPI record. Clusters of adverse events should be promptly reported to the appropriate State or local public health authority. The QAPI process does not preclude the need to report serious adverse events to public health authorities in a timely manner.

FED - V0146 - IC-CATHETERS:GENERAL

Title IC-CATHETERS:GENERAL

Type Standard

CFR 494.30(c)(2)

Regulation Definition

(2) The "Guidelines for the Prevention of Intravascular Catheter-Related Infections" entitled "Recommendations for Placement of Intravascular Catheters in Adults and Children" parts I - IV; and "Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients," Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA).

Interpretive Guideline

It is the intention of the Conditions for Coverage to incorporate relevant guidance from the CDC "Guidelines for the Prevention of Intravascular Catheter-Related Infections," MMWR August 9, 2002/Vol. 51/No. RR-10 into the requirements for facility infection control practices. Much of the material in this referenced guideline is general or relates to catheter selection, insertion, and use in acute or relatively short-term situations. The elements of this guidance which are most on point for hemodialysis facilities address the risks posed by intravascular catheters and the need for appropriate staff education, surveillance, vascular access care, and rigorous hand hygiene in order to reduce these risks.

For purposes of these Conditions for Coverage the portions of this document which are incorporated by reference are mandatory and must be adhered to and demonstrated within the dialysis facility. Language incorporated from these documents has been edited for clarity, brevity and to eliminate redundant requirements when utilized in the "Interpretive Guidance." However, the language incorporated into the "Regulation" column represents excerpted exact language. The entire CDC document "Guidelines for the Prevention of Intravascular Catheter-Related

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Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html

Infections" includes background information and rationale for the CDC recommended practices and can be used as an informational resource.

FED - V0147 - IC-STAFF EDUCATION-CATHETERS/CATHETER CARE

Title IC-STAFF EDUCATION-CATHETERS/CATHETER CARE

Type Standard

CFR 494.30(a)(2)

Regulation Definition

Recommendations for Placement of Intravascular Catheters in Adults and Children

I. Health care worker education and training
A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.
B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters.

II. Surveillance
A. Monitor the catheter sites visually of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

Interpretive Guideline

According to the CDC, intravascular catheters solve the problem of attaining vascular access quickly when there is insufficient time for development of a longer-term internal access: ideally a fistula, or secondarily a graft. Catheters also provide a solution of last resort when internal access site opportunities have been exhausted. However, despite their expedience, these catheters pose a threat of infection with the potential for immediate and long-term morbidity and mortality consequences for the patient.

The use of catheters for hemodialysis is the most common factor contributing to bacteremia in dialysis patients and the relative risk for bacteremia in patients with dialysis catheters is seven times the risk for patients with primary arteriovenous fistulas. Staff must maintain aseptic technique for the care of all vascular accesses, including intravascular catheters.

The CDC lists the two most common routes of catheter infection as (1) migration of skin organisms through the insertion site and into the cutaneous catheter tract resulting in colonization of the catheter tip; and (2) contamination of the hub, resulting in intraluminal colonization of the catheter. The initiation and termination of the dialysis process and manipulation and tension on the catheter provide frequent opportunity for such contamination. Minimizing the use of intravascular catheters and protection of the insertion site and the catheter hub from contamination through education and training about rigorous care is important in reducing catheter-related infections.

Catheter insertion sites should be routinely assessed by staff at each treatment. Most catheter sites are covered with either transparent dressings or gauze. Patients with catheters should be instructed to replace the dressing if a catheter site has sufficient bleeding or drainage to dampen or soil the dressing between treatments.

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VI. Catheter and catheter-site care
B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections].

The CDC advises that prophylactic antibiotic lock solutions be reserved for use only in special circumstances, e.g. in units where the rate of catheter-related bloodstream infection (CRBSI) has not decreased despite optimal maximal adherence to aseptic technique.

Facility staff should follow guidance from the NKF KDOQI Vascular Access Guideline (2006), which states "Airborne contaminants from both patients and staff are prevented best by the use of surgical masks when the catheter lumens or exit site are exposed. Wearing clean gloves and avoiding touching exposed surfaces further decreases the risk for infection. Aseptic technique includes minimizing the time that the catheter lumens or exit site are exposed."

Manufacturers' directions should be adhered to for the types of antiseptics recommended for safe cleaning of the skin and catheter.

The facility should have an initial and ongoing training program for infection control practices, which includes information on the prevention of intravascular catheter-related infections.

Facility policies should address the training and qualifications of staff who may access catheters, in accordance with any State licensure requirements, as well as the frequency for periodic practice audits to verify staff knowledge and adherence to infection control guidelines for intravascular catheters.

FED - V0148 - IC-MONITOR CATH-RELATED BSI RATES/SURV

Title IC-MONITOR CATH-RELATED BSI RATES/SURV

Type Standard

CFR 494.30(a)(2)

Regulation Definition

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

I. Surveillance
A. Conduct surveillance ...to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection-control practices.

Interpretive Guideline

Non-compliance with this requirement should be considered if there is lack of evidence of surveillance for catheter-related infections. A log or another tracking mechanism, such as the Dialysis Module of the National Healthcare Safety Network (NHSN), should be used. Both the surveillance log/database and the patient's individual medical records should contain detailed information on catheter infections and other adverse events, such as, but not limited to prolonged bleeding, stenosis/clotting, allergic reactions, pyrogenic reactions, cardiac arrests, hospitalizations, and deaths.

Refer to V637 under the Condition: Quality assessment and performance improvement (QAPI).

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C. Investigate events leading to unexpected life-threatening or fatal outcomes. This includes any process variation for which a recurrence would likely present an adverse outcome.

FED - V0175 - CFC-WATER & DIALYSATE QUALITY

Title CFC-WATER & DIALYSATE QUALITY

Type Condition

CFR 494.40

Regulation Definition

Interpretive Guideline

This Condition incorporates by reference the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," 2004 (RD52:2004) 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. When "should" or "recommend" are included in the AAMI language adopted as regulation (i.e., the language in the "Regulation" column), the referenced item or practice must be in use or in place.

Survey of this Condition requires inspection of the water treatment and dialysate preparation equipment and their distribution systems; interview of personnel responsible for day-to-day operation of those systems; and review of the records of operation and testing for those systems. Supervisory personnel may be interviewed to clarify issues or questions. Critical to ensuring patient safety is the expectation that every survey visit include direct observation of water testing for chlorine/chloramine.

Noncompliance at the Condition level should be considered if identified deficient practices are pervasive throughout the Standards included in this Condition, serious in nature, or a potential risk to patient health and safety. Examples of potential Condition level non-compliance may include, but are not be limited, to:
o Demonstrated lack of knowledge or training of staff assigned responsibility for the operation or monitoring of the water treatment or dialysate preparation systems;
o Failure to perform and document the test(s) for chlorine and chloramine accurately, including use of testing strips or reagents that are expired or not sensitive to the required levels;
o Unsafe practices in the preparation, labeling or delivery of dialysate;
o Failure to address out of range results for tests of water or dialysate (bacteria, endotoxin or chemical analysis).

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FED - V0176 - H20 PURITY-ANSI/AAMI RD52:2004

Title H20 PURITY-ANSI/AAMI RD52:2004

Type Standard

CFR 494.40(a)

Regulation Definition

The facility must be able to demonstrate the following:

Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis," ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 75000 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html.
Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

Interpretive Guideline

The practice guideline of the Association for the Advancement of Medical Instrumentation (AAMI) for "Dialysate for hemodialysis" (ANSI/AAMI RD52:2004) is incorporated by reference at 42 CFR 494.40 and is reflected in the tags and the interpretative guidelines at V176 to V278. AAMI is a professional organization in which committees composed of representatives of the industry, providers, and regulatory agencies develop voluntary guidelines for medical products and procedures.

Some explanatory language from ANSI/AAMI RD52:2004 and from the Annex to that document has been included below as guidance to surveyors. While the language in the "Regulation" column is taken exactly from the document, the AAMI language in the Surveyor Guidance area has been edited for clarity, brevity and to decrease redundancy. The order of the AAMI document has in some cases been altered, to organize requirements to more closely follow the survey process.

AAMI standards, to be fully understood, should be read in their entirety and anyone attempting to apply AAMI standards and recommended practices is encouraged to obtain the complete standard. The Association for the Advancement of Medical Instrumentation (AAMI) disclaims responsibility for any characterization or explanation of its standards and recommended practices that was not developed and communicated in accordance with AAMI procedures for the official interpretation of technical documents. This CMS document does not meet the AAMI criteria for official interpretations, therefore, all characterizations and representations regarding the content of AAMI standards contained within this document are solely the responsibility of CMS.

FED - V0177 - MAX LEVEL OF CHEM CONTAM H20/CHEM ANALYSIS

Title MAX LEVEL OF CHEM CONTAM H20/CHEM ANALYSIS

Type Standard

CFR 494.40(a)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

4 Fluid quality
4.1 Water
4.1.1 Maximum level of chemical contaminants in water: chem analysis
Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall not contain chemical contaminants at concentrations in excess of those listed in ANSI/AAMI RD62, which is reproduced in Table 1 below:

Table 1-Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple uses (Reproduced from ANSI/AAMI RD62:2001)

Contaminant	Maximum concentration (mg/L)
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20

Interpretive Guideline

ANSI/AAMI RD62:2001 sets forth maximum levels of chemical contaminants in three categories: chemicals known to have particular toxicity for hemodialysis patients, chemicals included in the U.S. Environmental Protection Agency's Safe Drinking Water Act and physiological substances that can adversely affect the patient if present in the dialysate in excessive amounts.

Several chemicals have been clearly shown to be toxic to dialysis patients at concentrations that are not necessarily toxic to the general population. Those chemicals include aluminum, copper, chloramines, fluoride, nitrate, sulfate, and zinc.

Uptake of aluminum from the dialysate is associated with bone disease, anemia, and the dialysis encephalopathy syndrome, which is usually fatal. The suggested maximum aluminum level has been specified to prevent accumulation of this toxic metal in the patient. Aluminum is particularly likely to increase suddenly to high levels as a result of changing the method of water treatment to include aluminum-containing compounds.

Chloramines damage red blood cells by oxidizing hemoglobin to methemoglobin and by inhibiting antioxidant pathways. Their toxicity in hemodialysis patients is undisputed. Although the role of free chlorine in oxidative blood damage is unclear, its high oxidation potential and its ability to form chloramines suggest that the use of highly chlorinated water in preparation of dialysate should be avoided.

High levels (>20 ppm) of fluoride in the water used to prepare dialysate are clearly toxic to hemodialysis patients, and have resulted in patient deaths. Such high levels of fluoride have resulted from accidental over fluoridation of a municipal water supply, as well as from deionizer exhaustion. Toxicity of fluoride in dialysis patients is questionable at the levels usually associated with fluoridated water (1 ppm). However, in the absence of a consensus on its role in uremic bone disease, the AAMI Renal Disease and Detoxification (RDD) Committee thought it prudent to restrict the fluoride level of dialysate.

Nitrates are a marker for bacterial contamination and fertilizer runoff and have caused methemoglobinemia. Nitrates should be permitted only at very low levels. Sulfate at levels above 200 mg/L has been related to nausea, vomiting, and metabolic acidosis. The symptoms disappear when the level remains below 100 mg/L. Both copper and zinc toxicity have been demonstrated when those substances are present in dialysate at levels below those permitted by the EPA standard. Hence, a lower level has been chosen.

The second group of chemical contaminants included in ANSI/AAMI RD62:2001 is based on the U.S. Environmental Protection Agency's Safe Drinking Water Act (see 2.6). The standard specifies maximum allowable limits for most contaminants in this group at 1/10 of the EPA maximum allowable limit. The lower levels were chosen because the

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Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

NOTE-American National Standards are revised every three to five years. Users should consult the most recent edition of ANSI/AAMI RD62 to ensure that the levels listed in this table are still valid.

The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause at the time of installation given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality.

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this standard.

volume of water used for dialysis far exceeds that used for drinking water, because protein binding of these solutes may occur in the blood, and because there is reduced renal excretion of these substances. Selenium and chromium levels were set at the "no-transfer" level. The no-transfer level was chosen even though it is above the EPA limit for selenium and 28 % of the EPA limit for chromium, because there is no need for a restriction below the level at which there is no passage from the dialysate to the blood.

The third group of substances included in ANSI/AAMI RD62:2001 consists of physiological substances that can adversely affect the patient if they are present in the dialysate in excessive amounts. Calcium, potassium, and sodium are examples of those substances.

The chemical contaminants regulated by ANSI/AAMI RD62:2001 and reproduced in Table 1 should not be taken as a definitive list of harmful substances; they are only a partial listing of the contaminants that might reasonably be expected to be present and have clinical implications. Iron is not included because it does not enter the patient's blood in sufficient quantities to cause toxicity. However, iron may cause fouling of water purification devices or dialysate proportioning systems. Furthermore, municipal water supplies are dynamic systems, which may change with the seasons or in response to new regulations from the EPA.

Additional Guidance:
Table 1 reflects the Standard adopted by CMS as regulation on April 15, 2008. Individual or groups of facilities may adopt newer requirements by policy.

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.

The medical director must be knowledgeable of the water treatment system installed and assure that the system as installed will produce AAMI quality water. Ways to assure this result would include use of an analysis of the source water and consultation with experts in water treatment, as well as confirmation that the planned installation would be sufficient to produce AAMI quality water by the manufacturer or vendor of the water treatment equipment. For initial surveys, the facility should provide a copy of a chemical analysis with results within AAMI standards accomplished prior to starting any patient treatment in the new facility. For resurveys, there must be evidence of on-going monitoring of the chemical quality of the water, and actions taken when levels were outside the AAMI standards.

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. 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 contaminates known to be toxic to dialysis patients). 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. Refer to V182.

If the water supply utility has notified the city that the source water is highly chlorinated due to a water main break, flooding, or bacterial contamination of the municipal system, the dialysis facility will need to do more frequent monitoring of chlorine/chloramines (i.e., every 30-60 minutes).

For frequency of monitoring water for chemical contaminants, refer to V201 for Reverse Osmosis (RO) systems and to V206 for Deionization (DI) systems.

FED - V0178 - BACT OF H20-MAXIMUM & ACTION LEVELS

Title BACT OF H20-MAXIMUM & ACTION LEVELS

Type Standard

CFR 494.40(a)

Regulation Definition

4.1.2 Bacteriology of water: max & action levels
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

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. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels.

Interpretive Guideline

AAMI Rationale for the Development and Provision of This Recommended Practice

A.4.1.2 Bacteriology of water
When ANSI/AAMI RD5:1981 was initially developed, it was generally considered that the water used to prepare dialysate need not be sterile. Studies have demonstrated that the incidence of pyrogenic reactions is related directly to the number of bacteria in dialysate. It is also known that a dialysate delivery system can amplify the level of bacteria in the water used to supply the system. Those studies provided the rationale for setting a recommended maximum concentration of 200 bacteria per mL in the water used to prepare dialysate.

Several groups of investigators have shown convincingly that pyrogenic reactions are caused by lipopolysaccharides or endotoxins associated with gram-negative bacteria. Gram-negative water bacteria are able to multiply rapidly in the chemically pure water used to supply hemodialysis systems. It has also been demonstrated clearly that endotoxins and endotoxin fragments can cross both low-flux and high-flux hemodialysis membranes.

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Because 48 hours can elapse between sampling water to determine microbial contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts and endotoxin concentrations are included in these regulations. Those action levels allow the user to initiate corrective action before levels exceed the recommended maximum levels. Unlike cultures, endotoxin testing does not require extended incubation times. Endotoxin testing, if performed in the dialysis facility, can give results in about 1 hour, eliminating the long delay between sampling and obtaining a result.

During the development of this recommended practice, the AAMI RDD Committee was asked to recommend levels of bacteria and endotoxin above which the water should not be used for dialysis applications. In making the recommendations set forth in ANSI/AAMI RD52:2004 Section 4.1.2, the AAMI RDD Committee understood that dialysis would be continued at contaminant levels above the action level but below the recommended maximum level. Establishing a recommended maximum level of contamination at which dialysis should be stopped immediately is difficult, because the risk of adverse events, such as pyrogenic reactions, must be balanced against the risks of uremia if a patient is not dialyzed. The balance between those two risks will depend on the level of contamination and time of exposure on the one hand, and the medical condition of the patient on the other hand. 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. The final decision of whether to discontinue dialysis rests with the medical director of a facility. Whatever decision is made, the AAMI RDD Committee recommends that the water treatment and distribution system be disinfected promptly any time the levels of bacteria or endotoxins exceed the action levels recommended in AAMI 4.1.2. In addition, it may be prudent to discontinue dialyzer reuse if the levels of bacteria or endotoxins exceed the recommended maximum levels set forth in AAMI 4.1.2, since the water is introduced directly into the blood compartment of the dialyzer.

Additional Guidance:
If the facility reaches the "action" level, remedial action is required. Action could be to repeat a culture, particularly if only one in a set of cultures was above the action limit. Action could also be to disinfect the system and repeat cultures at several sites.

Some states require this testing to be done in a laboratory approved for analysis of potable water.

FED - V0179 - BACT OF H20-MEDICAL DIRECTOR RESPONSIBLE

Title BACT OF H20-MEDICAL DIRECTOR RESPONSIBLE

Type Standard

CFR 494.40(a)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

4.1.2 Bacteriology of water: med dir resp
The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.

Interpretive Guideline

Additional Guidance:
Existing facilities must monitor the AAMI water chemical analysis and microbial testing and take action if results are outside of the AAMI standards. In the event of culture results above the action levels, the facility may need to repeat cultures, or disinfect the system and repeat cultures (depending on the number of positive cultures, etc.) and continue treatment while awaiting results.

If the water supply for the facility is from a private well, annual analysis of the quality of the product water may not be sufficient to ensure the feed water requirements of the water treatment system in use are continuously met. The quality of water from the well may change over time, and private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. Such monitoring might not need to be the full AAMI analysis if only certain contaminants are known to be of concern.

Frequency and methods for monitoring water bacteriology are addressed at V252 & V255.

FED - V0180 - BACT CONVENT DIALYSATE-MAX & ACTION LEVELS

Title BACT CONVENT DIALYSATE-MAX & ACTION LEVELS

Type Standard

CFR 494.40(a)

Regulation Definition

4.3.2.1 Bacteriology of conventional dialysate: max & action limits
Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.

The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action 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

Interpretive Guideline

ANSI/AAMI RD52:2004

5.4.4.3 Bicarbonate concentrate mixing systems:
The concentrate shall be shown to routinely produce dialysate meeting these regulations related to allowable bacterial and endotoxin levels.

AAMI Rationale for the Development and Provision of This Recommended Practice

A.4.3.2.1 Bacteriology of conventional dialysate:
It is now clear that endotoxins, endotoxin fragments, or other bacterial products cross at least some dialysis membranes under some operating conditions.

retesting, should promptly be taken to reduce the levels.

In addition to the risk of acute pyrogenic reactions, indirect evidence increasingly shows that chronic exposure to low amounts of endotoxin may play a role in some of the long-term complications of hemodialysis therapy. Patients treated with ultrafiltered dialysate have demonstrated a decrease in serum ß2-microglobulin concentrations, a decrease in markers of inflammation, and an increased responsiveness to erythropoietin. In longer-term studies, use of microbiologically ultrapure dialysate has been associated with a decreased incidence of ß2-microglobulin-associated amyloidosis, better preservation of residual renal function, and improved nutritional status. For those reasons, the AAMI RDD Committee reduced the recommended maximum microbial count in the dialysate to 200 CFU/mL and added a recommendation that the endotoxin concentration not exceed 2 EU/mL. The values are the same as those for water used to prepare the dialysate (ANSI/AAMI RD62:2001), implying that the dialysate proportioning system should not add significantly to the microbiological burden in the water. Although the AAMI RDD Committee did not review supporting data, it considered contemporary dialysate delivery systems to be fully capable of performing at this level provided that the user followed the manufacturer's instructions on cleaning and disinfecting the system, including disinfection of the line between the water distribution system and the concentrate mixing chambers of the dialysate proportioning system.

Additional Guidance:
"Conventional dialysate" is a term referring to the dialysate generally used for hemodialysis in the U.S., as opposed to "ultrapure dialysate." Recognize that the purity of dialysate is important, in that "reverse" ultrafiltration can occur, allowing dialysate to cross the dialyzer membrane and enter the patient's blood stream. This can occur with most dialyzers, especially high flux dialyzers at the distal end of the dialyzer and especially if the patient does not have much fluid weight to remove (allowing less ultrafiltration pressure to be used). A minimum ultrafiltration rate (UFR), as per the dialysis machine manufacturer ' s DFU should be maintained to prevent reverse ultrafiltration.

It is not expected that concentrates would be cultured or tested for endotoxin levels. Machine cultures (of dialysate) are the evidence used to determine if this requirement is met.

"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. Action would also include notifying the medical director of the results.

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FED - V0181 - BACT OF ULTRAPURE DIALYSATE

Title BACT OF ULTRAPURE DIALYSATE

Type Standard

CFR 494.40(a)

Regulation Definition

4.3.2.2 Bacteriology of ultrapure dialysate: ultrapure
Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/mL and an endotoxin concentration lower than 0.03 EU/mL. If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.

Interpretive Guideline

AAMI Rationale for the Development and Provision of This Recommended Practice

A.4.3.2.2 Bacteriology of ultrapure dialysate
Ultrapure dialysate is defined as one having a bacterial content of less than 0.1 CFU/mL and an endotoxin content of less than 0.03 EU/mL using sensitive assays. This definition is now widely accepted, particularly in Europe, and use of ultrapure dialysate is considered a requirement for on-line convective therapies (see AAMI A.4.3.2.3). Ultrapure dialysate is prepared by sequential ultrafiltration of dialysate prepared from purified water meeting the requirements of AAMI 4.1 and concentrates. Dry powder cartridges are frequently used for on-line preparation of the bicarbonate concentrate to minimize the potential for the bicarbonate concentrate to contribute high levels of bacteria and endotoxin to the dialysate.

Additional Guidance:
At the time of publication of these regulations, most dialysis facilities in the U.S. were using conventional dialysate, rather than ultrapure. There is no requirement to use ultrapure dialysate.

FED - V0182 - EQUIPMENT-GENERAL/BACK UP PLAN

Title EQUIPMENT-GENERAL/BACK UP PLAN

Type Standard

CFR 494.40(a)

Regulation Definition

5 Equipment
5.1 General: back up plan
A dialysis facility should develop contingency plans to cover

Interpretive Guideline

ANSI/AAMI RD52:2004

5 Equipment

the failure of its water purification and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component of the water purification and distribution system.

5.1 General
This section on equipment provides a brief description of the different components that may be included in a water purification and distribution system used for hemodialysis applications. Since feed water quality and product water requirements may vary from facility to facility, not all of the components described will be necessary in every purification and distribution system.

Routine dialysis requires a well-functioning water purification and distribution system, since dialysis cannot be performed without an adequate supply of water. In addition, certain components of the water purification and distribution system are critical to its operation. An example of such a critical component is the circulating pump in an indirect feed system.

Additional Guidance:
An emergency or contingency "plan" that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence the water intended for use 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 contaminates known to be toxic to dialysis patients). Refer to also to the requirements for emergency policies and procedures found under the Condition for Physical Environment at V408.

FED - V0184 - ENVIRONMENT-SECURE & RESTRICTED

Title ENVIRONMENT-SECURE & RESTRICTED

Type Standard

CFR 494.40(a)

Regulation Definition

8 Environment: secure & restricted
The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

Interpretive Guideline

Additional Guidance:
Older systems (installed prior to the effective date of these regulations) may have been installed in a small space, with components added over the years to crowd the available space. To ensure access is restricted, the delivery doors/loading dock must not be left unlocked, open and unattended. Many water systems are in the same room as stored treatment supplies; staff members who are not responsible for the water system may come into that area to retrieve supplies.

Hospital based chronic outpatient units may share the water room with an acute unit; staff from each unit would be expected to have access to the equipment.

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

FED - V0185 - ENVIRONMENT-ACCESS TO PORTS/METERS

Title ENVIRONMENT-ACCESS TO PORTS/METERS

Type Standard

CFR 494.40(a)

Regulation Definition

8 Environment: access to ports/meters
The layout of the water purification system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance.

Interpretive Guideline

ANSI/AAMI RD52:2004

8 Environment
An area for processing samples and performing on-site tests is also recommended.

Additional Guidance:
Older systems (installed prior to the effective date of these regulations) may not be as easy to access: provision must be made to allow staff to access all equipment, ports, etc. to operate and monitor the system. In all cases, the operator should be able to describe and identify the various components and the distribution system.

FED - V0186 - ENVIRONMENT- ALARMS IN TREATMENT AREA

Title ENVIRONMENT- ALARMS IN TREATMENT AREA

Type Standard

CFR 494.40(a)

Regulation Definition

8 Environment: alarms in treatment area
Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to sound in the patient treatment area, as well as in the water treatment room.

Interpretive Guideline

Additional Guidance:
Responsible staff members must be able to test the alarms to validate they can be heard in the treatment area. If alarms normally sound during certain events during the treatment day, documenting that these are heard in the treatment area will suffice for testing. The alarms in the patient treatment area and water treatment rooms must be loud enough to be heard while patients are on dialysis, and cannot be muted for more than 3 minutes (reference AAMI RD62:2001).

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FED - V0187 - ENVIRONMENT-SCHEMATIC DIAGRAMS/LABELS

Title ENVIRONMENT-SCHEMATIC DIAGRAMS/LABELS

Type Standard

CFR 494.40(a)

Regulation Definition

8 Environment: schematic diagrams/labels
Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.

Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.

If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

Interpretive Guideline

8 Environment
The use of text labels, such as "RO Water," and color-coded "arrow tape" provide a convenient means of identifying pipe content and flow direction.

WATER SOFTENER: System protections RO membrane by removing calcium and magnesium "hardness ions," adding sodium ions in their place. - Using sample port #4 [varies from system to system], test water hardness at end of each treatment day. Result must be 1 grain/gallon or less - Check brine tank daily to be sure the tank is at least half filled with salt, adding salt pellets if necessary. Water may become "hard" if salt pellet level is low. - Check timer daily to verify that it shows the correct time of day. Incorrect timer settings may cause the softener to regenerate during dialysis and can result in automatic shutdown of the RO. - Notify charge nurse and facility technician if hardness test is greater than 1 grain/gallon or if timer does not show correct time of day.
Figure 2 - An example of labeling for a regenerable softener.

Additional Guidance:
There must be a schematic diagram which allows the staff to follow the flow of the water through the components and each component and the piping must be labeled as described.

FED - V0188 - SEDIMENT FILTERS-CONFIG & MONITORING

Title SEDIMENT FILTERS-CONFIG & MONITORING

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.2 Sediment filters: config and monitoring

Interpretive Guideline

5.2.2 Sediment filters

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

[Refer to RD62:2001, 4.3.8 Sediment filters:]
Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.

5.2.2 Sediment filters:
Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.

6.2.2 Sediment filters:
Sediment filters should be monitored on a periodic basis ... [for a] pressure drop (delta pressure) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations. Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.

Permanent, backwashable sediment filters, also known as "bed filters," are frequently located at or near the beginning of hemodialysis water treatment systems and are intended to remove relatively coarse particulate materials from incoming water. Although a single filtration medium may be used, bed filters known as multimedia filters are more commonly selected. These units contain multiple layers, each layer retaining progressively smaller particles. In this way, the bed is used to its fullest extent; the largest particles are removed in the first layer contacted by the water and the smallest in the final layer.

As the bed accumulates particulate material, open passages begin to clog and resistance to the water flowing through the filter increases. Ultimately, the increased resistance to flow will lead to a reduction in water supply to downstream components. To prevent this situation from occurring, bed filters are cleaned by periodic backwashing, which is accomplished either manually or by using a timer-activated control valve.

(Bed filter gauges) are used to determine the dynamic pressure drop across the filter (delta pressure), which serves as an index of resistance to flow and provides a basis for setting the frequency of backwashing of the filter.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For sediment filters: monitor for pressure drop across the filter daily, looking for a pressure drop less than a number determined by facility policy. For sediment filter backwashing cycle: monitor the backwash cycle timer setting daily, at the beginning of the day, looking for backwash clock set to time determined by facility policy.

Additional Guidance:
This is the first of many references to language from ANSI/AAMI RD62, the AAMI "American National Standard for Water Treatment Equipment for Hemodialysis Applications" (RD62:2001) which is referenced in RD52:2004 for the specifications for various water treatment components. The referenced portions of RD62:2001 provided here are also incorporated by reference, and have the authority of regulation.

Sediment filters are not required in every facility: the source water should determine the water treatment components needed. If sediment filters are in use, the facility must follow these requirements.

If a water treatment system includes multiple components that backwash, the "time" set on each timer may need to be staggered to allow sufficient water to be available for the backwashing. This may result in some timers being set an hour or two different from the correct time. If so, there should be a posted notice to that effect. Pressure readings must be taken while the equipment is running. To determine the pressure drop (or delta P), observe the pressure readings on the gauges before and after the filter. If the gauge before the filter reads 70 mmHg and the gauge after the filter reads 50 mmHg, the pressure drop or "Delta P (DP)" is 20. The DP must be within the facility set limits; a result higher than the limits indicates that the filter needs to be backwashed or replaced.

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

FED - V0189 - CARTRIDGE FILTERS-CONFIG & MONITORING

Title CARTRIDGE FILTERS-CONFIG & MONITORING

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.3 Cartridge filters: config and monitoring
The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams.

When the maximum [pressure drop] ?P recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer ' s instructions.

6.2.3 Cartridge filters
Cartridge filters should be monitored on a periodic .... basis for a [pressure drop] ?P across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A marked decrease in ?P without a corresponding decrease in flow rate may indicate a loss of filter integrity. Follow the manufacturer ' s recommendations concerning when to replace cartridge filters. Replacement of the cartridge will usually be indicated by an increase in ?P to some specified value. A log sheet should be developed to record the pressure drop measurements.

Interpretive Guideline

5.2.3 Cartridge filters
Cartridge filters consist of a cylindrical cartridge of the filter medium with a central drainage core. Although cartridge filters may be installed at the inlet to a water system, their usual application is as a final filtration step prior to reverse osmosis.

As the cartridge accumulates particulate material, resistance to flow through the filter increases, as indicated by an increase in ?P.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4: include: For cartridge filters: monitor for pressure drop across the filter daily, looking for a pressure drop less than a number determined by facility policy.

Additional Guidance:
Cartridge filters are not required in every facility: the source water should determine the water treatment components needed. If cartridge filters are in use, the facility must follow these requirements.

A marked decrease in the DP could mean there is no filter in the container.

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FED - V0190 - SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL

Title SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.4 Softeners: auto regen/timers/salt/salt level
Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution.

5.2.4 Softeners
Refer to RD62:2001, 4.3.10
Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

The face of the timers used to control the regeneration cycle should be visible to the user.

6.2.4 Softeners
Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.

The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities

Interpretive Guideline

5.2.4 Softeners
Water that contains calcium or magnesium can form relatively hard deposits and is called "hard water." Water that has had these elements replaced by sodium ion exchange is called "soft water," hence, the term "softener." Softeners also remove other polyvalent cations, most notably iron and manganese, although they are somewhat limited in this regard. The primary use of softeners in hemodialysis water systems is to prevent hard water deposits from damaging sensitive reverse osmosis membranes.

A softener is a cylinder or vessel that contains insoluble spheres or beads, called "resin," to which sodium ions are attached. During operation, exchangeable sodium ions in the resin are progressively replaced by calcium and magnesium ions. When all the sodium ions have been used, the resin bed has reached a condition referred to as "exhaustion."

Softeners that automatically regenerate also include a brine tank, from which saturated sodium chloride solution is drawn during regeneration, and a control valve that regulates regeneration and service cycles.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For water softener regeneration cycle: monitor the regeneration cycle timer setting daily at the beginning of the day to determine the softener timer is set to correct time or a time set by the facility to allow multiple tanks to backwash in sequence, rather than at once.

Additional Guidance:
Softeners are not required in every facility: the source water should determine the water treatment components needed. If softeners are in use, the facility must follow these requirements.

The requirement to prevent water with a high concentration of sodium from entering the product water line is especially important when a facility offers nocturnal dialysis, as regeneration cycles for most components are set for nighttime.

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that may damage O-rings and pistons and clog orifices in the softener control head.

The timer box cover must have a clear window allowing the timers to be seen, or the cover must be removed when timers need to be viewed. Facility policy should define the expected level of salt in the brine tank, with a minimum requirement that salt pellets fill at least half of the tank.

Rarely, dual bed softeners are used. These allow one bed to function while the other bed regenerates. If used, expect installation to ensure the effluent of the regenerating bed goes to drain, rather than downstream to other water treatment components, or that the regeneration occurs when the RO is not in use.

FED - V0191 - SOFTENERS: TESTING HARDNESS/LOG

Title SOFTENERS: TESTING HARDNESS/LOG

Type Standard

CFR 494.40(a)

Regulation Definition

6.2.4 Softeners: Testing hardness/log
Users should ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reverse osmosis machine manufacturer. Total hardness of the water exiting the water softener should be measured at the end of each treatment day.

Water hardness test results should be recorded in a water softener log.

Interpretive Guideline

6.2.4 Softeners
Softener monitoring, which should be done each treatment day, consists of testing effluent water for total hardness to ensure that limits established by the reverse osmosis machine manufacturer are not exceeded. In the case of automatically regenerating softeners, monitoring also includes verification that the brine tank contains a sufficient supply of undissolved sodium chloride and that the control valve timer, when present, indicates the correct time of day.

Testing for hardness should be performed using an ethylenediaminetetracetic acid (EDTA) titration test, with "dip and read" test strips, or a similar method.

The hardness test at the end of the day will indicate the overall effectiveness of the water softener under worst case conditions and will ensure that the softener is sized properly-that is, that it has sufficient capacity expressed in grains of calcium carbonate.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For softeners: monitor product water softness daily at the end of the treatment day for hardness as calcium carbonate, <l grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment.

Additional Guidance:
The water softener log may be incorporated as a part of another log kept for the water treatment system. For hardness

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tests requiring color differentiation, the person performing the analysis should be able to distinguish between the colors of blue, purple, and red. If the person cannot differentiate these colors, an automated meter should be used.

FED - V0192 - CARBON ADSORPTION-TWO TANKS/SAMPLE PORTS

Title CARBON ADSORPTION-TWO TANKS/SAMPLE PORTS

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.5 Carbon adsorption: two tanks/sample ports
Refer to RD62:2001, 4.3.9 Carbon adsorption media: Carbon adsorption systems shall be adapted specifically to the maximum anticipated water flow rate of the system. Two carbon adsorption beds shall be installed in a series configuration.

5.2.5 Carbon adsorption
Two carbon beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed.

Interpretive Guideline

5.2.5 Carbon adsorption
Carbon adsorption systems, often referred to as carbon filters, are the principal means of removing both free chlorine and chloramine. Removal of free chlorine to a maximum level of 0.5 mg/L and chloramine to a maximum level of <0.1< mg/L is necessary to protect hemodialysis patients from red cell hemolysis. In addition, free chlorine may also degrade some reverse osmosis membranes, depending on the membrane material.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.2.5 Carbon adsorption
Although treatment of water by carbon adsorption is the method usually used to meet these requirements for chloramines, the AAMI RDD Committee recognized that in certain situations carbon adsorption might not adequately remove chloramines. Inadequate removal of chloramines may occur when the chloramines are in the form of naturally occurring N-chloramines or when practices such as the use of high pH or the inclusion of orthophosphate or polyphosphates are used (by the supplier's water treatment plant) to comply with the EPA's lead and copper rule. In such circumstances, other strategies for chloramine removal may be needed to supplement carbon adsorption. The AAMI RDD Committee is aware that adding sodium metabisulfite prior to the reverse osmosis system has been successful in eliminating chloramine in hemodialysis applications. Other means of removing chloramines, such as redox alloy media and ultraviolet irradiation at 185 nm, are used in the pharmaceutical and electronics industries. These processes are currently being evaluated for hemodialysis applications. The final choice of a system for chloramine removal in hemodialysis settings will depend on local conditions and may need to include more than one of the processes outlined above.

Additional Guidance:
If a facility has employed supplemental strategies for chlorine removal these must be in addition to the use of at least two carbon tanks. The medical director and the chief technician should to be able to discuss the rationale for use of supplemental strategies. Facility records must document the systems in place protect patients from exposure to

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chlorine and chloramine and are monitored according to the manufacturer ' s direction.

FED - V0193 - CARBON ADSORPTION-BANKS OF TANKS

Title CARBON ADSORPTION-BANKS OF TANKS

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.5 Carbon adsorption: banks of tanks:
Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed. When series connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure that an equal volume of water flows through all beds.

Interpretive Guideline

Additional Guidance:
Carbon beds may be plumbed in 2 ways: with the tanks/beds connected consecutively, so that all of the water flows through both tanks/beds; or in "parallel" so that approximately half of the water flows through each set of tanks/beds. In the case of the latter, each tank/bed can be of smaller size, as several smaller tanks would be in use to provide the required empty bed contact time (EBCT). For parallel-connected tanks/beds, there must be sample ports, as addressed at V192, for each set of tanks/banks, as testing of one set of tanks/beds is irrelevant to the function of the other set of tanks/beds.

FED - V0194 - CARBON ADSORPTION-IODINE #900/REPLACEMENT

Title CARBON ADSORPTION-IODINE #900/REPLACEMENT

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.5 Carbon adsorption: Iodine #900/replacement
Refer to RD62:2001, 4.3.9 Carbon adsorption media:
Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring.

Interpretive Guideline

ANSI/AAMI RD62:2001
4.3.9 Carbon adsorption media
For example, when testing between the beds shows that the first bed is exhausted, the second bed should be moved into the first position, the second bed replaced with a new bed, and the exhausted bed discarded.

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5.2.5 Carbon adsorption
When granular activated carbon is used as the media, it shall have a minimum iodine number of 900. Other forms of carbon should not be used unless there is performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines.

Regenerated carbon shall not be used for hemodialysis applications.

When other forms of carbon are used, the manufacturer shall provide performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than <0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines.

ANSI/AAMI RD52
5.2.5 Carbon adsorption
Some granular activated carbon contains aluminum, which can elute from the carbon and add to the burden of aluminum to be removed by reverse osmosis or ion exchange. The use of acid-washed carbon minimizes this source of aluminum in the water.

Additional Guidance:
Facilities using an exchange tank system should determine a schedule of replacement of the exhausted carbon absorption media based on their experience of use of these tanks to prevent interruption of patient services. The date of exchange of tanks should be documented on the tank and in the appropriate log. Facilities using back-washable carbon systems should determine a schedule for the back-washing of the tanks, and documentation of the function of that system. Back-washing does NOT regenerate the carbon; it rearranges the carbon in the tank, exposing sites that have not yet been used to adsorb chlorine or chloramine. Back-washable systems do exhaust; the responsible staff member should be able to describe how they will replace the carbon when indicated. A "schedule" could refer to "every X months" rather than a specific date or month, and should be based on past experience at the facility. Carbon in the tanks can be removed and replaced ("rebedding") on site when the tanks are off line.

Granulated activated carbon (GAC) with a minimum iodine number of 900 must be specified when replacement carbon is ordered. Acid-washed carbon is recommended, as it will protect the RO from exposure to excess aluminum, but is not required as the RO would still protect the patient.

FED - V0195 - CARBON ADSORPTION-10 MINUTES EBCT

Title CARBON ADSORPTION-10 MINUTES EBCT

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.5 Carbon adsorption: 10 min EBCT
Refer to RD62:2001, 4.3.9 Carbon adsorption media: When

Interpretive Guideline

Additional Guidance:
The empty bed contact time (EBCT) of the granulated activated carbon (GAC) system should be periodically

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granulated activated carbon is used as the adsorption medium ... each adsorption bed shall have an [empty bed contact time] EBCT of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes).

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. 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.

FED - V0196 - CARBON ADSORP-MONITOR, TEST FREQUENCY

Title CARBON ADSORP-MONITOR, TEST FREQUENCY

Type Standard

CFR 494.40(a)

Regulation Definition

6.2.5 Carbon adsorption: monitoring, testing freq
Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.

Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.

Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].
Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

Interpretive Guideline

5.2.5 Carbon adsorption
In addition to removing free chlorine and chloramine, carbon also adsorbs a wide variety of other substances, including both naturally occurring and synthetic organic compounds. The capacity of carbon to remove free chlorine and chloramine may be reduced when other substances "mask" reactive sites on the carbon media. In addition, the efficiency of free chlorine and chloramine removal is reduced as pH increases or as temperature decreases. The net effect of those variables is that the finite capacity of carbon beds to remove free chlorine and chloramine cannot be predicted with any certainty. Therefore, their performance needs to be monitored frequently.

6.2.5 Carbon adsorption
Carbon adsorption performance is monitored by measuring free chlorine and/or chloramine concentrations in the water exiting the first carbon bed of a series-connected pair. It should be noted that sampling for total chlorine (the sum of free chlorine and chloramine), allowing a maximum level of <0.1 mg/L of total chlorine, is often simpler than analyzing for free chlorine and chloramine separately.

More frequent monitoring may be appropriate during temporary operation with a single carbon bed, which can occur following breakthrough of the first bed. In such instances, testing is performed on water exiting the second carbon bed in a series-connected pair. The decision to increase the frequency of monitoring should be based on the past performance of the system and on whether changes in feed water quality have occurred.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.6 Monitoring
A.6.2.5 Carbon adsorption

Intensive monitoring of carbon adsorption beds is recommended because of the long history of adverse events related to chloramine contamination of dialysate. Chloramine concentrations in municipal water may change from day to day and the capacity of carbon adsorption beds to remove chloramine can vary with the pH and temperature of the water, the nature of the chloramine compounds present, and the presence of other substances in the water. The dependence of chloramine removal on multiple factors makes the performance of carbon adsorption beds unpredictable. Patient safety can only be ensured by intensively monitoring the performance of the carbon adsorption bed. Configuring carbon adsorption beds in series and sampling from a port located between the two beds provides one margin of protection against chloramine breakthrough. When chloramine is first detected in the effluent from the first adsorption bed, essentially the full capacity of the second bed remains available for chloramine removal. This reserve capacity allows the user to conveniently replace the exhausted bed without risk to patients. The exhausted bed is discarded, the second bed is moved into the first position, and a new bed is placed in the second position. A new bed of virgin carbon shall be used for replacement. Carbon cannot be regenerated in a dialysis facility, and the use of regenerated carbon is prohibited by ANSI/AAMI RD62:2001 (see 2.3 in that AAMI document). Backwashing of carbon beds does not regenerate the carbon, although it may allow more efficient use of the bed's capacity by removing channels that can form in the bed during routine operation.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.6.2.5 Carbon adsorption
The recommendation that the water purification system should operate for at least 15 minutes before samples are drawn is to guard against inadvertently sampling water that has been in the bed for an extended period.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For carbon adsorption beds, monitor the product water levels of free chlorine and/or total chlorine between the beds prior to beginning each patient shift. Expected result is <0.1 mg/L of total chlorine.

Additional Guidance:
For parallel connected tanks/beds, testing must be done for each set of tanks/beds each time testing is performed.

Test strips with color comparison charts that indicate a low level reading of zero and a first "number" of 0.5 are not sufficiently sensitive to detect levels as low as 0.1 and must not be used for testing of product water for safe levels of chlorine/chloramine. An indication of "0" on the comparison charts does not suffice to demonstrate the strips are sensitive to "0." Consult the manufacturer's guidance or contact the manufacturer if there is any question regarding the sensitivity of specific test strips. In choosing whether to use "quantitative" or "qualitative" test methodology, it is important to recognize that the determination of low levels of chlorine (i.e., <0.1 ppm) requires the use of the quantitative method.

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If an on-line chlorine/chloramines monitor is in use which incorporates an automated alarm, particular testing times are not required. Facility policy and practice must follow manufacturer's guidance regarding any required comparison testing and calibration of the monitor.

The ability to discern colors is an essential job function for persons responsible for reading colormetric tests. Depending on the test method used, staff assigned this responsibility must be capable of distinguishing between different shades of pink and other colors or a digital meter must be used.

For deficient practices with exceeding the acceptable level of chlorine or chloramine refer to V 270-273 of this section.

FED - V0197 - CARBON ADSORP-ACTION IF FIRST TEST +

Title CARBON ADSORP-ACTION IF FIRST TEST +

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.5 Carbon adsorption: action if first test positive
When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced.

Interpretive Guideline

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.2.5 Carbon adsorption
The AAMI RDD Committee recognized that it might not be practical to rotate the bed positions in installations that use large, backwashable carbon beds. However, there was concern that the capacity of the second bed might decrease unpredictably and no longer provide adequate backup if there was breakthrough of the first bed. For this reason, the AAMI RDD Committee recommended replacing both beds if bed rotation was not possible.

Additional Guidance:
When facilities operate with one exhausted carbon bed for up to 72 hours, the log of testing should include the actual times testing was done rather than indicating "1st, 2nd, or 3rd" shift.

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FED - V0198 - CHEMICAL INJECTION SYSTEMS

Title CHEMICAL INJECTION SYSTEMS

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.6 Chemical injection systems
Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line.
Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use.

When acid is added to adjust pH, a mineral acid should be used.

6.2.6 Chemical injection systems
Systems for chemical injection should be monitored according to the manufacturer's instructions. If a facility designs its own system, procedures should be developed to ensure proper preparation of the chemical, adequate mixing of the injected

Interpretive Guideline

5.2.5 Carbon adsorption:
In some circumstances, carbon adsorption may not adequately remove chloramines from water. High pH of feed water, the occurrence of N-chloramines, and the use of orthophosphate or polyphosphate for corrosion control have been associated with a decrease in the removal of chloramines by carbon adsorption. In those situations, carbon adsorption may need to be supplemented with other methods of chloramine removal.

5.2.6 Chemical injection systems
Chemical injection systems may be used in the pretreatment section of a water purification system to supplement the physical purification processes described in the previous clauses. Applications of chemical injection include the addition of sodium metabisulfite to remove chloramines and the addition of acid to adjust pH.

Organic acids may act as a nutrient and allow bacteria to proliferate.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.2.6 Chemical injection systems
The AAMI RDD Committee expressed reservations about the addition of chemicals to the water. However, it recognized that the addition of chemicals may be necessary in some circumstances if a facility is to meet the maximum contaminant levels set forth in AAMI 4.1.1. For example, if the municipal water contains high levels of N-chloramines or chloramine in the presence of orthophosphate or polyphosphate, injection of sodium metabisulfite may be one of the few options available for chloramine removal.

If chemical injection is used in the pretreatment cascade, users should ensure that the addition of the chemical does not interfere with the operation of subsequent purification processes, including the primary purification process. For example, the performance of thin-film composite reverse osmosis membranes may be affected by the pH of the feed water. At pH levels below 7, the rejection of fluoride may be substantially reduced, compared to its rejection at a pH of 8.

chemical with the water flowing through the pretreatment cascade, and reduction to a safe level of the concentration of any chemical residuals before the point of water use. The facility should also verify that the injected chemical does not degrade the performance of downstream devices, including the primary purification process. The adequacy of these procedures must be verified using an independent laboratory. Verification can be accomplished by testing samples from the chemical reservoir and the water line after the point of injection for at least three batches of chemical.

When the chemical to be injected is prepared at a facility from powder or by dilution of a liquid concentrate, the chemical injection reservoir must be labeled with the name of the chemical and its concentration, the date the solution was prepared, and the name of the person who mixed the solution.

Each batch of chemical should be tested for correct formulation before use. A batch of chemical must not be used or transferred to the injection system reservoir until all tests are completed. The test results-and verification that they meet all applicable criteria-should be recorded and signed by the individual performing the tests.

Protective clothing and an appropriate environment, including ventilation adequate to meet applicable OSHA environmental exposure limits, should be provided when chemicals for injection are prepared in a dialysis facility.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For chemical injection systems, monitor the level of chemical in the reservoir, injector function, and value of the controlling parameter (pH) daily. Results should show that chemical level in the reservoir greater than or equal to the facility set value, and the controlling parameter in range of the facility set values.

Additional Guidance:
There are other chemicals that may be injected to address problems with excessive chlorination or pH levels. If chemical injection is in use, facility policy must address this, and reflect the manufacturer's direction in the use of any system. If the acid is being used to lower pH, a monitor including an audible alarm in the treatment area is needed. If a flocculant is being injected to address excessive organic matter, an alarm will not be needed.

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. 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.

Labels must be updated at least every time solution for use in the system is prepared.

The requirement for "testing of each batch" could be met by the use of a test specified by the manufacturer of the chemical or the injection device, such as pH or conductivity. "Verification that the test results meet all applicable criteria" means the person doing the test compares the test result with the expected result to ensure the test result is within the expected range(s). If the test result does not match the expected range, that batch of chemical must not be used. Policy should direct the next steps: mixing another batch and retesting and notifying supervisory staff for direction would be options.

Staff must follow manufacturer's guidance (found in Material Safety Data Sheets [MSDS]) for protective gear and ventilation necessary for preparation of chemicals for injection.

Chemical injection systems are not required in every facility: the source water should determine the water treatment components needed. If chemical injection is in use, the facility must follow these requirements.

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FED - V0199 - RO-MEETS AAMI/MONITORED, RECORDED ON LOG

Title RO-MEETS AAMI/MONITORED, RECORDED ON LOG

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.7 Reverse osmosis: meets AAMI/monitored/recorded on log
Refer to RD62:2001, 4.3.7 Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2.

5.2.7 Reverse osmosis
Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.

6.2.7 Reverse osmosis
All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review.

Interpretive Guideline

5.2.7 Reverse osmosis
Reverse osmosis (RO) systems have become widely used in hemodialysis water purification systems, largely because these devices remove dissolved inorganic solutes as well as bacteria and bacterial endotoxins.

The RO membrane separation process components are a semipermeable membrane, typically in a spiral-wound configuration, a pump, and various flow and pressure controls to direct the flow of water through the system. In operation, feed water is pressurized by the RO pump and is then directed along the surface of the semipermeable membrane. A portion of the water is forced through the membrane, a process that removes inorganic salts, bacteria, and bacterial endotoxins. The remainder of the water continues along the membrane surface and is directed to drain. Water passing through the membrane is referred to as "product water" or "permeate." The water that flows along the membrane surface and to the drain is known as "reject water" or "concentrate." This flow configuration, known as "cross-flow filtration," prevents a progressive build-up of materials on the membrane surface that would eventually lead to fouling and membrane failure. In some reverse osmosis systems, a portion of the reject water stream is recycled to the feed water stream. This recycling allows higher velocities across the membrane surface, which may help reduce membrane fouling, as well as allowing higher overall use of water. RO systems usually operate in a single-stage configuration. However, if a higher level of purification is required, a two-stage RO can be used. In a two-stage RO, the product water from the first stage acts as the feed water for the second stage.

Depending on membrane configuration and materials of construction, RO systems are sensitive to various feed water conditions that may lead to diminished performance or premature failure.

Additional Guidance:
DFU = directions for use.
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. The medical director, nurse manager and chief technician must be able to describe how trends in the RO function are monitored to detect problems.

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FED - V0200 - RO-MONITOR/ALARM/PREVENT UNSAFE H20 USE

Title RO-MONITOR/ALARM/PREVENT UNSAFE H20 USE

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.7 Reverse osmosis: alarm/prevent use of unsafe water
Refer to RD62:2001, 4.3.7 Reverse osmosis: Reverse osmosis devices shall be equipped with on-line monitors that allow determination of rejection rates and product water conductivity. The product water conductivity monitor should activate audible and visual alarms when the product water conductivity exceeds the preset alarm limit. The audible alarm must be audible in the patient care area when reverse osmosis is the last chemical purification process in the water treatment system. Monitors that measure resistivity or TDS may be used in place of conductivity monitors.

6.2.7 Reverse osmosis:
Reverse osmosis systems should be monitored daily using continuous-reading monitors that measure product water conductivity (or total dissolved solids (TDS)).

5.2.7 Reverse osmosis:
Refer to RD62:2001, 4.3.7 Reverse osmosis: When a reverse osmosis system is the last chemical purification process in the water treatment system, it [should] include a means to prevent patient exposure to unsafe product water, such as diversion of the product water to drain, in the event of a product water conductivity or rejection alarm.

Interpretive Guideline

5.2.7 Reverse osmosis
RO systems should be fitted with a variety of sensors to monitor the system's performance. Conductivity or total dissolved solids (TDS) sensors in the feed water and product water streams are used to monitor the membrane's ability to remove dissolved inorganic solutes. Flow meters, usually in the product water and reject water streams, are used to monitor the output of the RO system. RO systems are also fitted with gauges to monitor the pressure at various points in the system. Although not indicative of treated water quality, monitoring flow rates and pressures can help ensure that the system is operating within the manufacturer's specifications and thus will help ensure RO reliability.

6.2.7 Reverse osmosis
Other parameters that must be measured daily include product and reject stream flow rates and various internal pressures to the extent permitted by RO instrumentation. Although these parameters are not directly indicative of treated water quality, monitoring them can help ensure that the system is operating within the manufacturer's specifications and thus will aid in maintaining the performance of the RO membranes.

The measurements can be used to calculate rejection of solutes by the RO membrane and provide a measure of equipment performance. Percent rejection is calculated using the following formula:

Rejection (%) = (Feed water conductivity-permeate conductivity/ Feed water conductivity) x 100

Newer RO systems may have a direct reading for percent rejection.

Flow rates can be used to calculate the percent recovery of the RO using the following formula:

Recovery (%) = (Permeate water flow rate/(Permeate water flow rate + Reject water flow rate)) x 100

NOTE-The percent recovery is also known as the "water conversion factor." The terms are equivalent if none of the

reject water stream is recycled to the feed water stream (see AAMI 5.2.7). If some of the reject water stream is recycled, the equation given above provides a measure of overall water utilization by the reverse osmosis system, rather than the recovery of water during a single pass through the membrane module.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For reverse osmosis, 1) Monitor the product water conductivity, total dissolved solids (TDS), or resistivity and calculated rejection rate according to the manufacturer's recommendations (continuous monitors) with a result showing a rejection rate greater than or equal to the facility set parameter percentage; 2) Monitor the product and reject flow rates, and calculated recovery daily (continuous monitors), with a result showing product water flow rate greater than a facility set number of gpm; and recovery rate in the facility set % range.

Additional Guidance:
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. 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 contaminates. Different criteria would apply if the RO is followed by DI polishing.

The conductivity or TDS of the product water is an important monitoring parameter. There may be a lower percent rejection in areas where the feed water is fairly pure (e.g., has a low TDS).

The determination of rejection rates may require staff to calculate this from data displayed. If the RO does not display rejection rates, expect any staff member assigned responsibility for monitoring the water treatment system to be able to calculate the percent rejection. Normal ranges should be known to the operator.

In the absence of an automatic divert to drain valve for the RO, facility staff must demonstrate knowledge of the requirement to manually stop water flow to the dialysis machines and other dialysis related equipment (e.g., concentrate mixing stations, reprocessing equipment) should the water quality alarm sound.

FED - V0201 - RO-CHEMICAL ANALYSIS-FREQUENCY

Title RO-CHEMICAL ANALYSIS-FREQUENCY

Type Standard

CFR 494.40(a)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition	Interpretive Guideline
6.2.7 Reverse osmosis: Chemical analysis: frequency Chemical analysis for the contaminants listed in 4.1.1 (Table 1) should be done when the RO system is installed, when membranes are replaced, and at not less than annual intervals thereafter to ensure that the limits specified in 4.1.1 are met (see Table 1). Chemical analyses should be done when seasonal variations in source water suggest worsening quality or when rejection rates fall below 90 %.	Additional Guidance: If your state has more stringent requirements, those must be followed for this requirement to be met.

FED - V0202 - DI-CONTIN MONITOR/LOGGED 2X/DAY

Title DI-CONTIN MONITOR/LOGGED 2X/DAY

Type Standard

CFR 494.40(a)

Regulation Definition	Interpretive Guideline
5.2.8 Deionization: continuous monitor resistivity/logged 2 X day Refer to RD62:2001, 4.3.6 Deionization: Deionization systems, when used to prepare water for hemodialysis applications, shall be monitored continuously to produce water of one megohm/cm or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25°C. 6.2.8 Deionization Deionizers shall be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Resistivity monitors shall have a minimum sensitivity of 1.0 megohm-cm. Patients shall not be dialyzed on deionized water with resistivity less than 1.0 megohm-cm measured at the output of the deionizer Resistivity monitor readings should be recorded on a log sheet	5.2.8 Deionization Deionization (DI) is an ion exchange process that removes both anions (negatively charged ions) and cations (positively charged ions) from water. During the exchange process, hydroxyl ions replace other feed water anions, and hydrogen ions replace other feed water cations; the hydroxyl and hydrogen ions then combine to form pure water. Water treated by DI may be very high quality with regard to the absence of ionized contaminants, but the process does not remove nonionized substances, including bacteria and bacterial endotoxins. DI systems may contain anion and cation resin in separate vessels, known as "dual-bed systems," or may have both resin types mixed together in a single vessel, known as "mixed-bed" or "unibed systems." Rationale for the Development and Provision of this Recommended Practice A.5.2.8 Deionization Deionizers are an effective means of removing ionic contaminants from water. However, they do not remove nonionic species (such as bacteria), and they may contribute bacterial contaminants to the water rather than remove them. The inability of deionizers to remove nonionic contaminants may limit aluminum removal by deionization. Deionizers have a finite capacity for contaminant removal. Once the deionizer is depleted of hydrogen and hydroxyl ions, the next least avidly bound ions will be displaced by more avidly bound ions. For example, once the hydroxyl ions are

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twice each treatment day.

depleted, anionic contaminants in the water will displace fluoride ions from the anion exchange resin. This phenomenon has led to high levels of fluoride in the product water, with subsequent patient injury and death. For the above reasons, use of deionization as the primary means of purification is strongly discouraged. Deionization may be used to polish product water from a reverse osmosis system or may be used as a standby if the reverse osmosis system fails.

Deionizers offer a large surface area for bacterial proliferation and deionizers generally contribute to the bioburden in the water. The tendency for deionizers to contribute bacterial contaminants to the water is greater when deionizers are kept as a backup for a reverse osmosis system, particularly if there is no flow through the deionizers. Some facilities counter this tendency by connecting the deionizers in parallel to the main water line and by maintaining a low flow through them. An alternative approach is to contract with a local vendor to provide backup deionizers on demand.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For deionizers, product water resistivity must be continuously monitored, with a result of resistivity >1 megohm-cm.

Additional Guidance:
If DI tanks are available for back-up use, the facility must take action to counter the tendency of DI to contribute bacterial contaminants to the water. This may be accomplished by either storing the tanks dry, placing the tanks on line post-RO so that there is a low flow of water through them, or flushing the DI tanks daily. DI tanks should not be stored "wet," i.e., filled with stagnant water.

Exhausted DI tanks (<1.0 megohm-cm) present a serious risk to patients, and use of exhausted DI tanks have resulted in deaths. If the water system uses DI as primary purification or as a polish, the system must be closely monitored by knowledgeable staff. Pure water has a resistivity of 18.3 megohms. Documentation of a reading greater than 18.3 megohms would indicate some error. Exhausted DI tanks must be returned to the vendor for recharging. The date of exchange should be posted on the tank(s) and recorded in a log.

Deionization is not required in every facility: the source water should determine the water treatment components needed. If deionization is in use, the facility must follow these requirements.

FED - V0203 - DI-ALARMS/DIVERT TO DRAIN

Title DI-ALARMS/DIVERT TO DRAIN

Type Standard

CFR 494.40(a)

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Regulation Definition

5.2.8 Deionization: alarms/divert to drain
Refer to RD62:2001, 4.3.6 Deionization:
An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use, for example by being diverted to drain. The alarm must be audible in the patient care area.

The resistivity monitor following the final deionizer bed shall be connected to an audible and visible alarm in the dialysis treatment area, and the DI system shall divert product water to drain or otherwise prevent product water from entering the distribution system should an alarm condition occur. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

Interpretive Guideline

5.2.8 Deionization
DI has a finite capacity that, when exceeded, will cause dangerously high levels of contaminants in the product water. Fortunately, the quality of product water from DI is easily monitored by resistivity monitors that, when used as specified (e.g., minimum resistivity 1 megohm-cm or greater), can prevent inadvertent operation of an exhausted deionization system.

Additional Guidance:
Except for home patients, there must be an automatic divert-to-drain system for any DI system in use. While an RO system may use an alarm to cause a staff member to stop flow before the RO product water reaches patients, the increased risk to patient health and safety of the use of water from an exhausted DI tank mandates the use of an automated protection system, such as a divert-to-drain valve.

FED - V0204 - DI-REQUIRE CARBON PRE/UF POST

Title DI-REQUIRE CARBON PRE/UF POST

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.8 Deionization: require carbon pre & UF post
Systems that include deionizers as a component shall also contain carbon adsorption upstream of the deionizer to avoid formation of carcinogenic nitrosamines.

In all instances, deionizers shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device to remove microbiological contaminants that may originate in the deionizer resin bed.

Interpretive Guideline

5.2.8 Deionization
Refer to RD62:2001, 4.3.6 Deionization: Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

Refer to RD62:2001, 4.3.6 Deionization: If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device.

5.2.9 Ultrafiltration
Endotoxin-retentive ultrafilters should be placed in dialysis water systems in locations downstream of deionization, if deionization is the last process in a water treatment system.

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Additional guidance: Endotoxin-reducing devices and endotoxin-reducing ultrafilters may be used interchangeably in these applications. The typical range of micron filter size is .001 to .05 microns.

FED - V0205 - DI-POLISH OR BACK UP

Title DI-POLISH OR BACK UP

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.8 Deionization: polish or backup
The usual application for a deionizer is as a polisher following reverse osmosis or as a standby process if the reverse osmosis system fails. Use of deionization as the primary means of purification in an outpatient facility is not recommended because of the inability of deionization and ultrafiltration to remove certain low-molecular-weight toxic bacterial products, such as microcystins.

Interpretive Guideline

5.2.8 Deionization
The most common configuration for DI is to have two mixed beds in series, with resistivity monitors being placed downstream of each bed. Upon exhaustion of the first bed, reliance for water of sufficiently high resistivity shifts to the second bed, and dialysis operations may be continued for a short time (up to 72 hours) until a replacement bed is installed. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

Additional Guidance:
The routine use of DI as the primary means of water treatment in an out-patient facility is rare.

FED - V0206 - DI-CHEMICAL ANALYSIS-FREQUENCY

Title DI-CHEMICAL ANALYSIS-FREQUENCY

Type Standard

CFR 494.40(a)

Regulation Definition

6.2.8 Deionization: chemical analysis: frequency
When deionization is employed as the primary method for removing inorganic contaminants (reverse osmosis is not employed), or when deionization is necessary to polish RO-treated water, chemical analyses to ensure that the

Interpretive Guideline

Additional Guidance:
Samples for chemical analysis should be drawn after the last treatment component; if the water treatment system includes DI as primary or polish, the routine chemical analysis samples should be taken after the DI. Taking the sample from the last patient treatment station would also meet this requirement.

requirements of AAMI 4.1.1 (Table 1) are met should be performed when the system is installed and at annual intervals thereafter.

Note: requirements for preconfigured systems which may include DI are given at V276.

FED - V0207 - UF-EFFECTIVE/OPAQUE HOUSING/MONITOR

Title UF-EFFECTIVE/OPAQUE HOUSING/MONITOR

Type Standard

CFR 494.40(a)

Regulation Definition

5.2.9 Ultrafiltration: effective/opaque housing/monitoring
Refer to RD62:2001, 4.3.12 Ultrafilters: When used in a water purification system for hemodialysis applications, an ultrafilter shall be shown to reduce the concentrations of bacteria and endotoxin in the feed water to the ultrafilter by factors at least as great as those specified in the manufacturer's labeling.

5.2.9 Ultrafiltration
Refer to RD62:2001, 4.3.12 Ultrafilters: Ultrafilters [should] have an opaque housing or that other means be used to inhibit proliferation of algae.

5.2.9 Ultrafiltration
Ultrafilters should be included in routine disinfection procedures to prevent uncontrolled proliferation of bacteria in the feed water compartment of the filter.

6.2.9 Ultrafiltration
The pressure drop across the ultrafilter (?P) should be measured using simple inlet and outlet pressure gauges. Ultrafilters operated in the cross-flow mode should also be monitored in terms of the flow rate of water being directed to drain (concentrate).

Interpretive Guideline

5.2.9 Ultrafiltration
Ultrafilters are membrane-based separation devices that may be used to remove particles as small as 1,000 daltons and are thus well suited to remove both bacteria and endotoxins.

If bacterial proliferation is not controlled, bacteria may "grow through" the membrane and contaminate the product water compartment of the filter.

6.2.9 Ultrafiltration
Such monitoring will indicate when membrane fouling has progressed to the point that membrane replacement or cleaning is needed. Monitoring is also necessary to ensure that the device is being operated in accordance with the manufacturer's instructions.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For ultrafilters, monitor pressure drops across the filter daily for pressure drop less than a value set by the facility.

Additional Guidance:
Test results drawn pre and post ultrafilter should be used to determine if the concentrations of bacteria and endotoxin are reduced as stated by the manufacturer's label. These samples can be drawn at usual testing points: e.g., the post RO sample would function as the pre-UF sample, and the sample from the first water distribution outlet would serve as the post-UF sample. Such testing should be performed whenever an UF is originally installed, and whenever the specific type of UF is changed. Low levels of bacteria and endotoxin in the feed water to the ultrafilter may prevent the user from being able to show the manufacturer's specified level of reduction; an acceptable test result should be defined by facility policy, and in all cases must be within the AAMI standards for microbial contamination.

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Results of pressure measurements and bacteria and endotoxin levels should be recorded in a log.

Disposable ultrafilters do not require disinfection when used within the manufacturer's parameters and pressure monitored to detect fouling.

Every filter has an initial pressure drop when installed new. Users should monitor the change in pressure and validate the acceptable pressure change each time the filter is replaced.

Ultrafilters are not required in every facility: the source water should determine the water treatment components needed. As referenced in V204, an ultrafilter is required if DI is the last water treatment component in the system. If ultrafilters are in use, the facility must follow these requirements. The typical range of micron filter size is .001 to .05 microns.

FED - V0208 - H20 STORAGE & DISTRIBUTION-DESIGN

Title H20 STORAGE & DISTRIBUTION-DESIGN

Type Standard

CFR 494.40(a)

Regulation Definition

5.3 Water storage and distribution
5.3.1 General: Design
A water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.

Interpretive Guideline

5.3 Water storage and distribution
5.3.1 General
The function of the water storage and distribution system is to distribute product water from the purification cascade to its points of use, including individual hemodialysis machines, hemodialyzer reprocessing equipment, and concentrate preparation systems. A water storage and distribution system typically contains a large volume of water exposed to a large surface area of piping and storage tank walls. Because chlorine and chloramines are removed in the purification process, the water does not contain a bacteriostatic agent. This combination of circumstances predisposes wetted surfaces to bacterial proliferation and biofilm formation.

5.3.3 Water distribution systems
Two types of water distribution systems are used: direct feed systems and indirect feed systems. In a direct feed system, water flows directly from the last stage of the purification cascade to the points of use. In an indirect feed system, water flows from the end of the purification cascade to a storage tank. From there, it is distributed to the points of use. In general, direct feed systems offer the least favorable environment for bacterial proliferation. However, with a direct feed system the purification cascade must be sized to provide sufficient water to meet the peak demand, and the system must have sufficient pressure at the end of the purification cascade to distribute the water to the points of use. Those two requirements often preclude the use of a direct feed system.

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AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.3 Water storage and distribution
Direct feed water distribution systems typically return unused water to the feed side of the reverse osmosis unit. If the pressure at the end of the distribution loop decreases to a value below the water pressure at the inlet to the reverse osmosis pressurizing pump, retrograde flow of nonpurified water into the distribution loop can occur. To minimize this risk, the AAMI RDD Committee recommends that dual check valves be used to prevent retrograde flow and that the pressure at the end of the distribution loop be monitored.

FED - V0209 - H20 TANK-SHAPE/VENT/DISINFECT/FILTER P

Title H20 TANK-SHAPE/VENT/DISINFECT/FILTER P

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.2 Water storage tank: shape/vent/disinfected/filter post
When used, storage tanks should have a conical or bowl-shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2 µm air filter. The filter should be changed on a regular schedule according to the manufacturer's instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

7.1 General strategies for bacterial control [in storage tanks]:
An ultrafilter, distal to the storage tank, or some other form of bacterial control device is recommended.

Storage tanks are therefore not recommended for use in dialysis systems unless they are frequently drained and adequately disinfected.

Interpretive Guideline

5.3.2 Water storage
Internal spray mechanisms can facilitate effective disinfection and rinsing of a storage tank.

7 Strategies for bacterial control
7.1 General
A storage tank in the distribution system greatly increases the volume of fluid and surface area available and can serve as a niche for water bacteria. It may be necessary for the user to scrub the sides of the tank to remove bacterial biofilm if the tank design and maintenance are not adequate to prevent bacterial proliferation.

Additional Guidance:
If existing facilities with older storage tanks can demonstrate a history of water and dialysate cultures being below action levels, replacement of the existing tanks is not required.

Bacterial control device(s) in use following the storage tank may include an ultrafilter or individual filters in the water supply line in each patient's dialysis machine.

The facility must follow the manufacturer ' s guidance for the disinfection of the water storage tank. Tanks which fill from the top and drain from the bottom may, in fact, drain several times a day. The goal is to not have stagnant water. A properly designed and functional storage tank replaces its total volume throughout the day as part of the normal

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operation and does not require manual or frequent draining of the tank.

FED - V0210 - H20 STORAGE-MONITORING

Title H20 STORAGE-MONITORING

Type Standard

CFR 494.40(a)

Regulation Definition	Interpretive Guideline
6.3 Water storage and distribution 6.3.2 Water storage: monitoring Routine monitoring of water storage tanks for bacteria and endotoxin levels is generally accomplished indirectly by monitoring the water at the first outlet to the distribution loop (see 6.3.3). If direct monitoring of a water storage tank is performed as part of a troubleshooting process, bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3). All bacteria and endotoxin results should be recorded on a log sheet.	Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: To monitor the water storage tank, measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated. Action levels for bacterial growth are 50 CFU/mL; for endotoxin 1 EU/mL. While Table 4 includes a "<" sign before these numbers, section 4.1.2 does not include that "<" designation, and the designation is removed here. Expect action to be taken for levels above 50 CFU/mL and above 1 EU/mL. Additional Guidance: A "pattern of consistent compliance" could be demonstrated by showing results within these limits on weekly cultures for at least four weeks in a row. Laboratory generated reports are an acceptable alternative to recording results on a log if the laboratory provides an aggregate report allowing multiple monthly reports to be easily compared for trends.

FED - V0211 - H2O DIST SYS-CONSTANT FLOW/NO DEAD ENDS

Title H2O DIST SYS-CONSTANT FLOW/NO DEAD ENDS

Type Standard

CFR 494.40(a)

Regulation Definition	Interpretive Guideline
5.3.3 Water distribution systems: continuous flow rates/no dead ends Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water	5.3.3 Water distribution systems A multistage centrifugal pump is preferred for this purpose. 7 Strategies for bacterial control 7.1 General Other measures can also help protect pipes from contamination.

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and aid in effective disinfection.

7 Strategies for bacterial control
7.1 General
To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/s in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand.

Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.

Additional Guidance:
It is not the intent of this regulation to dictate the type of pump used for this purpose, other than that the pump be made of inert material.

It is not intended that surveyors would measure flow rates; responsible staff (i.e., the chief technician) should be able to describe how the system is monitored to assure at least minimum flow during operation.

The facility must identify and remove any potential dead-end pipes. For example, if the facility has discontinued reprocessing dialyzers, any unused piping should be removed to prevent stagnant water or trapping of disinfectant.

FED - V0212 - H20 DIST SYSTEMS-NO ADDED BURDEN

Title H20 DIST SYSTEMS-NO ADDED BURDEN

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.3 Water distribution systems: no added burden
Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water.

Interpretive Guideline

5.3.3 Water distribution systems
The choice of materials used for a water distribution system will also depend on the proposed method of disinfection. Whatever material is used, care should be taken to select a product with properties that provide the least favorable environment for bacterial proliferation, such as smooth internal surface.

Table 2-Compatibility of common disinfectants with piping materials used in water distribution systems

Material	Bleach	Peracetic Acid	Formaldehyde	Hot water	Ozone
PVC	X	X	X		
CPVC	X	X	X		X

PVDF	X	X	X	X	X
PEX	X	X	X	X	
SS		X	X	X	X
PP	X	X	X	X	
PE	X	X	X		
ABS		X			
PTFE	X	X	X	X	X
Glass	X	X	X	X	X

PVC = polyvinylchloride, CPVC = chlorinated polyvinylchloride, PVDF = polyvinylidene fluoride, PEX = cross-linked polyethylene, SS = stainless steel, PP = polypropylene, PE = polyethylene, ABS = acrylonitrile butadiene styrene, PTFE = polytetrafluoroethylene.

NOTE-Table 2 is not intended as an exhaustive compilation of all possible compatible combinations of piping material and disinfectant. Users should verify compatibility between a given germicide and the materials of a piping system with the supplier of that piping system before using the germicide. Considerations of compatibility should include any joint materials and pipe fittings, as well as the actual piping material. The concentration of germicide and the duration and frequency of exposure also should be taken into account.

Additional Guidance:
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 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.

FED - V0213 - DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG

Title DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG

Type Standard

CFR 494.40(a)

Regulation Definition

6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log
Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall

Interpretive Guideline

7.2 Microbial monitoring methods
7.2.1 General
Additional testing, such as at the end of the water purification cascade and at the outlet of the storage tank, if one is used, may be necessary during initial qualification of a system or when troubleshooting the cause of contamination

not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL]

Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits.

Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).

All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.

within the distribution loop.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: To monitor the water distribution piping system, measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated, then monthly. Action levels for bacterial growth are >50 CFU/mL; for endotoxin >1 EU/mL.

Additional Guidance:
An example of a change to the existing system would be changes to the RO membranes or installation of a new storage tank. Changes to the pre-treatment components (e.g., sediment filters, cartridge filters, softener, or carbon tanks) do not require a period of more frequent testing.

The sites listed must be cultured routinely, with additional sites considered if the results of routine test sites indicate a problem.

The log could be graphic reports or documents generated by the laboratory, or created by staff from laboratory data, in order to include results from multiple months to allow identification of trends.

V252 should be used when routine cultures/endotoxin testing is not done at least monthly. Use this tag if more frequent testing is not done when indicated (e.g., for new facilities, when a major change has been made to an existing water system, or when monthly cultures taken from several sites are repeatedly positive).

Note: refer to V276 for requirements for preconfigured systems.

FED - V0214 - BACT CONTROL DEVICE-UV LIGHT

Title BACT CONTROL DEVICE-UV LIGHT

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.4 Bacterial control devices:
5.3.4.1 Ultraviolet irradiators: UV dose
Refer to RD62:2001, 4.3.13 Ultraviolet irradiators: When

Interpretive Guideline

5.3.4 Bacterial control devices
5.3.4.1 Ultraviolet irradiators
The recommendations provided in this clause concern UV irradiators used specifically for bacterial control.

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used to control bacterial proliferation in water storage and distribution systems, UV irradiation devices shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2, [except in the case described below]. The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions.

5.3.4.1 Ultraviolet irradiators
If the irradiator includes a meter as described above, the minimum dose of radiant energy should be at least 16 milliwatt-sec/cm2.

To prevent the use of sublethal doses of radiation that may lead to the development of resistant strains of bacteria, UV irradiators shall be equipped with a calibrated ultraviolet intensity meter ...or with an on-line monitor of radiant energy output that activates a visible alarm, which indicates that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output.

6.3.4 Bacterial control devices
6.3.4.1 Ultraviolet irradiators
Ultraviolet irradiators intended for use as a direct means of bacterial control shall be monitored for radiant energy output. UV irradiators should be monitored at the frequency recommended by the manufacturer. A log sheet should be used to indicate that monitoring has been performed.

Ultraviolet irradiators (also known as UV lights) may be used to control bacterial proliferation in purified water storage and distribution systems. UV irradiators contain a low-pressure mercury lamp that emits ultraviolet light at a wavelength of 254 nm. The lamp is housed in a transparent quartz sleeve that isolates it from direct contact with the water. If the irradiator is not fitted with a calibrated ultraviolet intensity meter that is filtered to restrict its sensitivity to the disinfection spectrum and that is installed in the wall of the disinfection chamber at the point of greatest water depth from the lamp, the dose of radiant energy provided by the lamp shall be at least 30 milliwatt-sec/cm2.

6.3.4 Bacterial control devices
6.3.4.1 Ultraviolet irradiators
UV irradiators are available equipped with radiant energy intensity sensors. A visual alarm or an output meter is acceptable for determining if the UV lamp is emitting sufficient radiant energy. Because the radiant energy decreases with time, annual lamp replacement is typically required. Periodic cleaning of the quartz sleeve may also be required, depending on the water quality.

Additional Guidance:
Monitoring may be accomplished by either of the following options: use of a meter to monitor intensity of the lamp, use of an on-line monitor that activates an alarm; or replacement on a predetermined schedule.

The use of a UV irradiator in a bicarbonate distribution system may have a totally different role. If ozone is used to disinfect that system, the UV irradiator may be used to break down the ozone. If the UV irradiator is part of the bicarbonate distribution system, responsible staff must be able to describe the intended purpose of the UV in that application. Monitoring of the irradiator is still required, but there is no need to follow an irradiator used in the bicarbonate distribution system with an ultrafilter or other endotoxin-retentive device.

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FED - V0215 - UV LIGHTS-FILTERS POST

Title UV LIGHTS-FILTERS POST

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.4.1 Ultraviolet irradiators: filters post
UV irradiators [shall] be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water distribution system or reverse osmosis in the pretreatment cascade.

Interpretive Guideline

5.3.4.1 Ultraviolet irradiators
Ultraviolet irradiation also can be used to control bacteria in the pretreatment section of a water purification system, such as following carbon adsorption beds to reduce the bacterial burden presented to a reverse osmosis unit. Using UV irradiation to kill bacteria increases the level of endotoxins in the water.

Additional Guidance:
An ultrafilter or other endotoxin-retentive device may be used. If an RO follows the UV, the RO functions as an ultrafilter. This requirement is not intended to apply to UV irradiators placed in some bicarbonate distribution systems.

FED - V0216 - 0ZONE-SYS REQUIREMENTS/MONITORING

Title 0ZONE-SYS REQUIREMENTS/MONITORING

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.4.2 Ozone generators: system requirements/monitoring
Ozone can be used for bacterial control only in systems constructed from ozone-resistant materials (see AAMI 5.3.3 for suitable piping materials).

5.3.4.2 Ozone generators
Refer to RD62:2001, 4.3.15 Ozone disinfection systems:
When used to control bacterial proliferation in water storage

Interpretive Guideline

5.3.4.2 Ozone generators
Ozone may be used to control bacterial proliferation in water storage and distribution systems. Ozone may also degrade endotoxins. Ozone generators convert oxygen in air to ozone using a corona discharge or ultraviolet irradiation. The ozonated air is then injected into the water stream. An ozone concentration of 0.2 mg/L to 0.5 mg/L, combined with a contact time of 10 minutes, is capable of killing bacteria, bacterial spores, and viruses in water. Destruction of established biofilm may require longer exposure times and/or higher concentrations of ozone.

Ozone may degrade many plastic materials, including PVC and elastomeric O-rings and seals.

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and distribution systems, an ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer.

6.3.4 Bacterial control devices
6.3.4.2 Ozone generators
Ozone generators should be monitored for ozone output at a level specified by the manufacturer. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration ...each time disinfection is performed. An ozone-in-ambient-air test should be conducted on a periodic basis, as recommended by the manufacturer, to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. A log sheet should be used to indicate that monitoring has been performed.

Additional Guidance:
Ozone is not recommended for disinfection of many of the water distribution loop materials. Refer to Table 2 at V212.

Refer to the manufacturer's guidance for required concentrations and contact time.

Staff must monitor the system being disinfected with ozone for the expected concentration of ozone during the disinfection and for the absence of ozone when the disinfection is completed. Facility policy must define the frequency for "periodic basis" for testing the ozone-in-ambient-air levels; this policy should reflect the manufacturer's guidance and OSHA requirements for exposure limits.

FED - V0217 - HOT H2O DISINF SYS-TEMP/TIME/FOLLOW DFU/PIPE

Title HOT H2O DISINF SYS-TEMP/TIME/FOLLOW DFU/PIPE

Type Standard

CFR 494.40(a)

Regulation Definition

5.3.4.3 Hot water disinfection systems: temp/time/follow DFU/piping
Refer to RD62:2001, 4.3.14 Hot water disinfection systems: When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of delivering hot water at the temperature and for the exposure time specified by the manufacturer.

5.3.4.3 Hot water disinfection systems

Interpretive Guideline

5.3.4.3 Hot water disinfection systems
Hot water (=80 °C) may be used to control bacterial proliferation in water storage and distribution systems. Bacterial kill studies are not required

Additional Guidance:
See Table 2 at V212 for acceptable heat-resistant materials.

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Hot water disinfection systems can be used only in systems constructed from heat-resistant materials, such as crosslinked polyethylene, polypropylene, and stainless steel (see [AAMI] 5.3.3).

The manufacturer's instructions for using hot water disinfection systems should be followed. If no manufacturer's instructions are available, the effectiveness of the system can be demonstrated by verifying that the system maintains a specified temperature for a specified time and by performing ongoing surveillance with bacterial cultures and endotoxin testing.

FED - V0218 - HOT H20 DISINF SYS-MONITORING

Title HOT H20 DISINF SYS-MONITORING

Type Standard

CFR 494.40(a)

Regulation Definition

6.3.4 Bacterial control devices
6.3.4.3 Hot water disinfection systems: monitoring
Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Also, hot water disinfection should be performed at least as often as recommended by the manufacturer. The temperature of the water should be recorded at a point farthest from the water heater-that is, where the lowest water temperature is likely to occur ...and measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.

Interpretive Guideline

Additional Guidance:
Records of use of hot water disinfection systems must include logs or recorded evidence to verify that the specified water temperature was maintained for the specified period of time in order to accomplish the intended disinfection.

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FED - V0219 - BACT CONTROL-DISINFECT 1X/MO/DWELL

Title BACT CONTROL-DISINFECT 1X/MO/DWELL

Type Standard

CFR 494.40(a)

Regulation Definition

7 Strategies for bacterial control
7.1 General: disinfect monthly/disinfection dwell
Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly.

A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.

Interpretive Guideline

7 Strategies for bacterial control
7.1 General
The strategy for controlling the proliferation of microorganisms in hemodialysis systems primarily involves proper system design and operation, and regular disinfection of water treatment system and hemodialysis machines. A key concept in ensuring compliance with water bacteriology standards is that disinfection schedules should be designed to prevent bacterial proliferation, rather than being designed to eliminate bacteria once they have proliferated to an unacceptable level (i.e., above the action level). With this strategy, monitoring levels of bacteria and endotoxin serves to demonstrate that the disinfection program is effective, not to indicate when disinfection should be performed. Gram-negative water bacteria, their associated lipopolysaccharides (bacterial endotoxins), and nontuberculous mycobacteria (NTM) most frequently come from the community water supply, and levels of those bacteria can be amplified depending on the water treatment system, dialysate distribution system, type of dialysis machine, and method of disinfection.

Two components of hemodialysis water distribution systems-pipes and storage tanks-can serve as reservoirs of microbial contamination. Hemodialysis systems frequently use pipes that are of larger diameter and longer than are needed to handle the required flow. Oversized piping slows the fluid velocity and increases both the total fluid volume and the wetted surface area of the system. Gram-negative bacteria in fluids remaining in pipes overnight multiply rapidly and colonize the wet surfaces, thus producing bacterial populations and endotoxin quantities in proportion to the volume and surface area. Such colonization results in the formation of protective biofilm that is difficult to remove once formed and that provides a barrier between the bacteria and germicide during disinfection.

Biofilms are communities of microorganisms attached to surfaces. They form just about anywhere a nonsterile fluid flows over a surface. Biofilm increases the ability of microorganisms to compete for nutrients and other resources. The complexity of biofilm depends on the degree of water or fluid movement and the availability of nutrients. Thicker biofilm, and usually a greater diversity of microorganisms, will form in slower moving waters; in faster moving waters, it is harder for microorganisms to become (and remain) attached to the surface, so biofilm formation takes longer. Organisms living within biofilm are shielded by an extracellular polymer or glycocalyx. This glycocalyx

provides the bacteria with some protection from the action of disinfectants. Biofilm may exist throughout a hemodialysis distribution system. Once established in a distribution system or dialysis machine, biofilm can be difficult to eradicate. Bleach and ozone are generally the most effective agents for biofilm removal, and their use may be more efficacious if the pipes are treated first with a descaling agent. However, in some cases, complete or partial replacement of the distribution system may be the only way to eliminate biofilm.

Additional Guidance:
In order to prevent or limit the development of biofilm, every dialysis facility must disinfect their water distribution system at least monthly. All surfaces in the water distribution system must have sufficient contact time with the disinfectant prior to its being rinsed from the system.

FED - V0220 - BACT CONTROL-SUPPLY LINE DISINFECTED

Title BACT CONTROL-SUPPLY LINE DISINFECTED

Type Standard

CFR 494.40(a)

Regulation Definition

7 Strategies for bacterial control
7.1 General: machine supply line disinfected
Users should establish a procedure for regular disinfection of [the line between the outlet from the water distribution system and the back of the dialysis machine].

Interpretive Guideline

7 Strategies for bacterial control
7.1 General
For most dialysis machines, routine disinfection with hot water or with a chemical germicide connected to a disinfection port on the machine does not disinfect the line between the outlet from the water distribution system and the back of the dialysis machine. One approach is to rinse the dialysis machines with water containing germicide or hot water when the water distribution loop is disinfected. If this procedure is used with a chemical germicide, each dialysis machine should be rinsed and tested for the absence of residual germicide following disinfection.

Additional Guidance: The machine supply line is the hose that connects the dialysis machine to the treated water outlet. This hose should be disinfected at the same frequency as the water distribution loop is disinfected, i.e., monthly.

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FED - V0222 - ACID BULK STORAGE TANKS-SAFETY CONTROLS

Title ACID BULK STORAGE TANKS-SAFETY CONTROLS

Type Standard

CFR 494.40(a)

Regulation Definition

5.4 Concentrate preparation
5.4.3 Bulk storage tanks (acid concentrate): safety controls
Procedures should be in place to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.

Interpretive Guideline

5.4 Concentrate preparation
5.4.1 General
Acid concentrates supplied in 55 gallon drums or gallon containers by the manufacturer are the responsibility of that manufacturer (see AAMI 2.4). In some cases, the manufacturer will pump the acid concentrate from the 55 gallon drums into a holding tank at the dialysis facility. In those cases, the user is responsible for maintaining the concentrate in its original state and to ensure that the correct formula is used according to the patient ' s prescription.

Additional Guidance:
Acid concentrates supplied in 55 gallon drums or gallon containers are the responsibility of the manufacturer until delivered; proper handling after delivery is the responsibility of the dialysis facility. If an inlet opening to the acid concentrate storage system is located on the outside of the building, there must be safety controls in place to prevent inadvertent mix-ups, tampering, or contamination of acid concentrates.

FED - V0223 - CONC PREP-MATERIALS COMPATIBILITY

Title CONC PREP-MATERIALS COMPATIBILITY

Type Standard

CFR 494.40(a)

Regulation Definition

5.4 Concentrate preparation
5.4.2 Materials compatibility
All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or

Interpretive Guideline

appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides or germicidal procedure used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

FED - V0224 - MIXING SYSTEMS-H20/DRAIN/ELECTRIC

Title MIXING SYSTEMS-H20/DRAIN/ELECTRIC

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.1 Mixing systems: water/drain/electric
Concentrate mixing systems require a purified water source, a suitable drain, and a ground fault protected electrical outlet.

Interpretive Guideline

FED - V0225 - MIXING SYSTEMS-SAFE ENVIRONMENT/PPE

Title MIXING SYSTEMS-SAFE ENVIRONMENT/PPE

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.1 Mixing systems: safe environment/PPE
Protective measures should be used to ensure a safe work environment.

Operators should at all times use appropriate personal protective equipment, such as face shields, masks, gloves, gowns, and shoe protectors, as recommended by the manufacturer.

Interpretive Guideline

5.4.4.1 Mixing systems
For example, ventilation and personal protective equipment should be used to handle any residual dust that is introduced into the atmosphere as powdered concentrates are added to the system and to handle any additional heat produced by the device.

Additional Guidance:
Shoe protectors are rarely, if ever, required by the manufacturers. Process controls, such as limiting the number of bags emptied at one time, may decrease the requirements for PPE.

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FED - V0226 - MIX SYS-DFU/MONITOR/PM/LOG/SANITIZE

Title MIX SYS-DFU/MONITOR/PM/LOG/SANITIZE

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.1 Mixing systems: follow DFU/monitor/PM/log/sanitization
If a concentrate mixing system is used, the preparer should follow the manufacturer's instructions for mixing the powder with the correct amount of water.

If a concentrate mixing system is used, the number of bags or the weight of powder added should be determined and recorded.

Manufacturer's recommendations should be followed regarding any preventive maintenance and sanitization procedures. Records should be maintained indicating the date, time, person performing the procedure, and results (if applicable).

6.4.1 Mixing systems:
Systems for preparing either bicarbonate or acid concentrate from powder should be monitored according to the manufacturer's instructions.

Interpretive Guideline

Additional Guidance:
There must be a log or other method of recording the preparation of concentrates, to include the number of bags or weight of the powder and the amount of water used. See also the requirements for records of mixing detailed at V229.

The facility must have records of the manufacturer's instructions for the sanitizing, maintenance and monitoring of the mixing system.

Individuals assigned responsibility for mixing concentrates or for preventative maintenance of these systems must demonstrate competency in following the manufacturer's DFU.

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FED - V0227 - MIXING SYSTEMS-SELF DESIGNED

Title MIXING SYSTEMS-SELF DESIGNED

Type Standard

CFR 494.40(a)

Regulation Definition

6.4.1 Mixing systems: self designed
If a facility designs its own system, procedures should be developed and demonstrated to ensure proper mixing of the concentrate, including establishment of acceptable limits for tests of proper concentration. The adequacy of those procedures must be verified using an independent laboratory that is capable of meeting the requirements of ANSI/AAMI RD61:2000 (see 2.4). Verification can be accomplished by testing a sample from each batch prepared over a 3-day period

Interpretive Guideline

Additional Guidance:
If a facility designs its own mixing systems, there must be documentation of the verification testing available for review.

FED - V0228 - MIXING SYSTEMS-LABELING

Title MIXING SYSTEMS-LABELING

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.1 Mixing systems: labeling
Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.

Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation

Interpretive Guideline

5.4.4.1 Mixing systems
Requirements for such positive identification will vary among facilities, depending on the differences between concentrate formulations used and on whether single or multiple dialysate proportioning ratios are used. The use of multiple dialysate proportioning ratios (e.g., 35X and 45X) in a single facility is strongly discouraged.

Using a photocopy of the concentrate manufacturer's package label provides a convenient and comprehensive means of identifying the chemical composition or formulation of the concentrate; however, the lot number and expiration date should be marked out because they apply only to the dry powder.

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and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.

Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.

Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.

As with mixing tanks, bulk storage/dispensing tank labeling can be conveniently accomplished by affixing a copy of the concentrate manufacturer's package label.

Concentrate jugs are typically nondisposable vessels provided by hemodialysis machine manufacturers and having a capacity sufficient for one or two hemodialysis sessions. The extent of labeling for these containers depends on the variety of concentrate formulations used and on whether the facility uses dialysis machines with different proportioning ratios (a practice that is strongly discouraged).

Additional Guidance:
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. 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.

FED - V0229 - MIXING SYSTEMS-PERM RECORD/VERIF TEST

Title MIXING SYSTEMS-PERM RECORD/VERIF TEST

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.1 Mixing systems: perm record/verification testing
In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable).

6.4.1 Mixing systems

Interpretive Guideline

6.4.1 Mixing systems
Although not required, some manufacturers may provide allowable ranges for either the conductivity or the specific gravity of concentrates prepared from their powder. The use of pH as an indicator of proper dissolution is inappropriate for both acid and bicarbonate concentrates, because large variations in concentration do not produce significant changes in pH.

Additional Guidance:
The mixing logs must demonstrate complete documentation of this required information. Test results may include conductivity or specific gravity. Facility policy must stipulate the expected ranges for the test(s) used to verify correct mixing. Standards used to calibrate the instrument used to measure conductivity should encompass the expected results; for example, it would be unacceptable to use a "14" standard for an expected result of "70." "Verifying

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Acid and bicarbonate concentrates may be tested by using conductivity or by using a hydrometer. Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests.

mixing and test results" means the staff member performing this task checks the results against the expected ranges for the test and does not release mixtures for use that test outside those ranges.

FED - V0230 - MIXING SYSTEMS-CLEANING

Title MIXING SYSTEMS-CLEANING

Type Standard

CFR 494.40(a)

Regulation Definition

6.4.1 Mixing systems: cleaning Concentrate mixing equipment should be either: (1) completely emptied, cleaned, and disinfected according to the manufacturer's instructions; or (2) cleaned and disinfected using a procedure demonstrated by the facility to be effective in routinely producing concentrate meeting [these regulations related to allowable bacterial and endotoxin levels].

The disinfection data should be recorded for each ...disinfection cycle using a dedicated log.

Interpretive Guideline

Additional Guidance:
The log may be kept electronically or on paper and may be for only this purpose or inclusive of other operations.

FED - V0231 - ACID CONC MIX SYS-EMPTY ALL/PREV CORROSION

Title ACID CONC MIX SYS-EMPTY ALL/PREV CORROSION

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.2 Acid concentrate mixing systems: empty

Interpretive Guideline

5.4.4.2 Acid concentrate mixing systems

completely/prevent corrosion
Acid concentrate mixing tanks should be designed to allow the inside of the tank to be completely emptied and rinsed according to the manufacturer's instructions when concentrate formulas are changed.

Acid concentrate mixing tanks should be emptied completely before mixing another batch of concentrate.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Use of a tank with a sloping bottom that drains from the lowest point is one means of facilitating this process.

Additional Guidance:
Facility policy and practice must ensure the tank is completely emptied between mixing batches of concentrate.

Facilities generally have little control over the design of these systems, but should maintain the system clean and free of spills of concentrate to reduce the potential of corrosion.

FED - V0232 - BICARB MIX SYS-EMPTY/DISINFECT/PREV CORROSION

Title BICARB MIX SYS-EMPTY/DISINFECT/PREV CORROSION

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.3 Bicarbonate concentrate mixing systems: empty/ disinfect/prevent corrosion
Bicarbonate concentrate mixing tanks should be designed to drain completely.

Mixing tanks should have a tight-fitting lid and should be designed to allow all internal surfaces to be disinfected and rinsed.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Interpretive Guideline

5.4.4.3 Bicarbonate concentrate mixing systems
For example, they should have a sloping bottom and a drain at the lowest point. High- and low-level alarms can prevent overfilling and air damage to the pump.

A translucent tank allows users to see the liquid level; the use of sight tubes is not recommended because of the potential for microbial growth, such as bacteria, algae, and fungi.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.4.4.3 Bicarbonate concentrate mixing systems
Bicarbonate concentrates have been shown to support bacterial growth and to provide another source of initial bioburden capable of rapidly increasing after dilution. Therefore, additional precautions should be taken when preparing and handling bicarbonate concentrate to avoid excess growth of haloduric organisms. Also, prompt use of bicarbonate concentrates prepared in dialysis facilities from powder and purified water is strongly recommended.

Additional Guidance:

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High and low level alarms are not required. Facilities generally have little control over the design of these systems, but should maintain the system clean and free of spills of concentrate to reduce the potential of corrosion. Expect that systems will have little to no build-up of precipitate.

FED - V0233 - BICARB MIX SYS-STOR/USE TIME/MIN COMBINE

Title BICARB MIX SYS-STOR/USE TIME/MIN COMBINE

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.3 Bicarbonate concentrate mixing systems: storage/use time limits/min combine
Once mixed, bicarbonate concentrate should be used within the time specified by the manufacturer of the concentrate.

7 Strategies for bacterial control
7.1 General
Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch. The manufacturer's instructions should be followed if they are available.

Interpretive Guideline

Additional Guidance:
Bicarbonate concentrates must be used or discarded within the manufacturer ' s timelines, if these are available. If facility staff members combine bicarbonate concentrate from partially used jugs, there must be some system to ensure the concentrate is not kept past the maximum storage time of the oldest portion. For example, if the facility policy is to discard all unused concentrate at the end of each treatment day, combining jugs during the day would not exceed the limit if the allowable storage time was at least one day or 24 hours. If the facility policy allows carryover of unused concentrate to the following day, there could be potential for that time limit to be exceeded should the contents of jugs (which may have been mixed at various times) be combined.

Central delivery systems should be cleared of bicarbonate solution at some point during the treatment day and rinsed clear. Generally this is done at the end of the treatment day.

FED - V0234 - BICARB MIXING SYS-NOT OVERMIXED

Title BICARB MIXING SYS-NOT OVERMIXED

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.4.3 Bicarbonate concentrate mixing systems: not overmixed

Interpretive Guideline

5.4.4.3 Bicarbonate concentrate mixing systems
Systems designed for mixing dry acid concentrates may use methods that are too vigorous for dissolving dry

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Overagitating or overmixing of bicarbonate concentrate should be avoided, as this can cause CO2 loss and can increase pH.

bicarbonate.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.4.4.3 Bicarbonate concentrate mixing systems
Overagitation or mixing of bicarbonate concentrate may result in loss of CO2 from the solution. Loss of CO2 results in an increase in pH and favors the formation of carbonate that can lead to precipitation of calcium and magnesium carbonate in the fluid pathways of the dialysis machine following dialysate proportioning.

Additional Guidance:
There must be a system to prevent overmixing of bicarbonate. This could include a timer integrated into the mixing system for automatic cut-off, or a policy to require staff to monitor the mixer and cut it off immediately when the time period for mixing is completed. Use of overmixed bicarbonate concentrate can result in a low calcium level in the dialysate and a concomitant drop in patients ' serum calcium levels.

FED - V0235 - ADDITIVES-MIXING SPIKES

Title ADDITIVES-MIXING SPIKES

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.5 Additives: mixing spikes
Concentrate additives should be mixed with liquid acid concentrates according to the manufacturer's instructions, taking care to ensure that the additive is formulated for use in concentrates of the appropriate dilution ratio. When liquid additives are used, the volume contributed by the additive should be considered when calculating the effect of dilution on the concentration of the other components in the resulting concentrate. When powder additives are used, care should be taken to ensure that the additive is completely dissolved and mixed before the concentrate is used.

Interpretive Guideline

5.4.5 Additives
Manufacturers provide acid concentrates with a wide range of electrolyte compositions for different proportioning ratios. Most typical dialysate prescriptions can be obtained by using one or more of these commercially available concentrates. If particular formulations are not available, manufacturers provide additives that can be used to adjust the level of potassium or calcium in the dialysate. These additives are commonly referred to as "spikes."

6.4.2 Additives:
When additives are used to increase concentrations of specific electrolytes in the acid concentrate, mixing procedures shall be followed as specified by the additive manufacturer.

Additional Guidance:
The State nurse practice act must be considered in determining the appropriateness of the staff allowed to use a "spike" to change the concentration of electrolytes in the acid concentrate. Since the concentrate is a prescription medication, many states require a licensed nurse to perform this task. When facility policy allows use of "spikes,"

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appropriate additives must be accurately mixed according to manufacturer's directions, labeled as required by these rules, and documented in the patient record to accurately reflect the composition of the dialysate used for treatment.

FED - V0236 - ADDITIVES-LABEL SPIKED JUGS/LABEL SPECIFIC PT

Title ADDITIVES-LABEL SPIKED JUGS/LABEL SPECIFIC PT

Type Standard

CFR 494.40(a)

Regulation Definition

5.4.5 Additives: labeling spiked jugs/labeling if for specific pt (5.4.4.1 Concentrate jugs): If a chemical spike is added to an individual container to increase the concentration of an electrolyte, the label should show the added electrolyte, the date and time added, and the name of the person making the addition.

Containers should be labeled to indicate the final concentration of the added electrolyte ...This information should also be recorded in a permanent record. Labels should be affixed to the containers when the mixing process begins.

6.4.2 Additives
When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate should be labeled with the name of the patient, the final concentration of the added electrolyte, the date on which the prescribed concentrate was made, and the name of the person who mixed the additive.

Interpretive Guideline

Additional Guidance:
Spiked jugs must be clearly labeled with this required information. If the jug is prepared for a specific patient, the label must include the name of the patient as well as the other required information.

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FED - V0237 - CONC DISTRIBUTE-MATERIALS COMPATIBLE

Title CONC DISTRIBUTE-MATERIALS COMPATIBLE

Type Standard

CFR 494.40(a)

Regulation Definition

5.5 Concentrate distribution:
5.5.1 Materials compatibility
All components used in concentrate distribution systems (including concentrate jugs, storage tanks, and piping) that contact the fluid shall be fabricated from nonreactive materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

Interpretive Guideline

FED - V0238 - SYSTEM CONFIGURATIONS-ELEVATED TANKS

Title SYSTEM CONFIGURATIONS-ELEVATED TANKS

Type Standard

CFR 494.40(a)

Regulation Definition

5.5.2 System configurations: elevated tanks
Elevated tanks for bicarbonate concentrate distribution should be equipped with conical or bowl-shaped bottoms, tight-fitting lids, a spray mechanism, and high- and low-level alarms. Any air vents should have 0.2 µm hydrophobic vent filters.

Interpretive Guideline

5.5.2 System configurations
Concentrate may be distributed from a central preparation point using reusable concentrate jugs that contain sufficient concentrate for one to two treatments, or it may be distributed through a piping system that provides concentrate connections at each treatment station. A combination of these two systems may also be used, with some concentrates distributed by concentrate jug and others through a piping system. Two common configurations used for distributing concentrate through a piping system are gravity feed and pressurized. Gravity feed systems require an elevated tank; pressurized systems deliver the concentrate using a pump and motor and do not require an elevated tank. The

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maximum allowable concentrate delivery pressure is specified by the manufacturer of the dialysate delivery machine and should not be exceeded.

Elevated tanks are usually smaller than those used for preparing concentrates.

FED - V0239 - BICARB CONC DISTRIB-WKLY DISINFECT/DWELL/CONC

Title BICARB CONC DISTRIB-WKLY DISINFECT/DWELL/CONC

Type Standard

CFR 494.40(a)

Regulation Definition

5.5.4 Bicarbonate concentrate distribution systems: weekly disinfection/dwell times/conc
Bicarbonate concentrate delivery systems should be disinfected on a regular basis to ensure that the dialysate routinely achieves the level of bacteriological purity [required by these regulations].

For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a "dead leg" in the system.

Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems.

6.5 Concentrate distribution:
The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the

Interpretive Guideline

5.5.4 Bicarbonate concentrate distribution systems
Bicarbonate concentrates provide excellent media for bacterial proliferation. The manufacturer's instructions can provide an initial disinfection schedule. This schedule may need to be adjusted on the basis of the user ' s bacteriological monitoring.

All chemical disinfectants (e.g., bleach and peracetic acid products) that are compatible with dialysis machines can be used to disinfect bicarbonate concentrate delivery systems. However, some disinfectants attack biofilm better than others.

In the event that precipitation or salt build-up impedes flow through a piping system, cleaning with a 1:34 solution of 5 % acetic acid (e.g., distilled white vinegar) is recommended. Some manufacturers supply bicarbonate concentrate systems with UV irradiation or ozone systems for bacterial control.

Additional Guidance:
Alternatively, a 5% citric acid solution may be used instead of acetic acid if the manufacturer allows. It is not expected that concentrates would be cultured or tested for endotoxin levels. Bicarbonate concentrates are monitored via dialysate cultures.

user must develop and validate a disinfection protocol.

FED - V0240 - BICARB DISTRIBUTION SYS-USE OF UV

Title BICARB DISTRIBUTION SYS-USE OF UV

Type Standard

CFR 494.40(a)

Regulation Definition	Interpretive Guideline
5.5.4 Bicarbonate concentrate distribution systems: use of UV UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm2. The device should be sized for the maximum anticipated flow rate according to the manufacturer's instructions and be equipped with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced. Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely.	Additional Guidance: This requirement applies to UV irradiators used in the bicarbonate delivery system, rather than to an UV irradiator used in the water treatment/distribution system. A facility may have an UV irradiator in one system, and not in the other. The UV irradiator in the bicarbonate delivery system may also be used to help breakdown the ozone used to disinfect the bicarbonate delivery system.

FED - V0241 - BICARB DISTRIBUTE SYS-OZONE DISINFECT

Title BICARB DISTRIBUTE SYS-OZONE DISINFECT

Type Standard

CFR 494.40(a)

Regulation Definition	Interpretive Guideline
5.5.4 Bicarbonate concentrate distribution systems: ozone	

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disinfection
When used to disinfect the pipes of a bicarbonate concentrate delivery system, an ozone generator should be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer. When ozone disinfection systems are used, ambient air should be monitored for ozone as required by the U.S. Occupational Safety and Health Administration (OSHA).

FED - V0242 - CONC DISTRIBUTE-BICARB MONITOR INITIALLY

Title CONC DISTRIBUTE-BICARB MONITOR INITIALLY

Type Standard

CFR 494.40(a)

Regulation Definition

6.5 Concentrate distribution: bicarb monitoring initially
Once a bicarbonate distribution system has been activated, dialysate should be monitored weekly until sufficient data has been obtained to demonstrate consistent compliance with acceptable levels of contamination. The frequency of monitoring may then be reduced, but monitoring should be performed at least monthly. If elevated bacteria or endotoxin levels are found in the dialysate, all systems involved in dialysate preparation, including the bicarbonate concentrate distribution system should be evaluated and appropriate action, such as disinfection, should be taken. The frequency of monitoring should then be increased until it can be demonstrated that the problem has been resolved.

Interpretive Guideline

6.5 Concentrate distribution
Because acid concentrate distribution systems have been shown not to be subject to bacterial proliferation, it is not necessary to perform bacteria and endotoxin testing on those systems.

Additional Guidance:
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. The medical director must be involved in these decisions.

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FED - V0243 - BICARB JUGS RINSED DAILY/STORED DRY

Title BICARB JUGS RINSED DAILY/STORED DRY

Type Standard

CFR 494.40(a)

Regulation Definition

6.5 Concentrate distribution: bicarb jugs rinsed daily/stored dry
Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day.

Interpretive Guideline

Additional Guidance:
Pick-up tubes are the tubes which go into the concentrate jugs to take up the concentrate. These look like large straws, and are usually attached to the lids of the jugs.

FED - V0244 - BICARB JUG MAINTENANCE/DISINFECTION

Title BICARB JUG MAINTENANCE/DISINFECTION

Type Standard

CFR 494.40(a)

Regulation Definition

5.5.4 Bicarbonate concentrate distribution systems: jug disinfection
When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be rinsed free of residual concentrate before disinfection.

6.5 Concentrate distribution
When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be disinfected at least weekly.

Interpretive Guideline

7 Strategies for bacterial control
7.1 General
Facilities that reuse concentrate jugs for bicarbonate concentrate should disinfect the jugs at least weekly. Bicarbonate concentrate can support prolific growth of microorganisms. Jugs can be disinfected with household bleach solutions (300 mg to 600 mg free chlorine, or 30 mL to 60 mL of 6.15 % household bleach per gallon of water) with a contact time of about 30 minutes or another EPA-registered disinfectant according to the manufacturer ' s instructions.

Additional Guidance:
A 1:100 solution of household bleach: treated water may be used, which yields about 500-615 ppm available chloride. If the facility uses less contact time than 30 minutes, there must be evidence of the use of dialysate culture results to determine the needed disinfectant contact time. In all cases, the bicarbonate container disinfection process must result

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7 Strategies for bacterial control
7.1 General
Following disinfection, jugs should be drained, rinsed, and inverted to dry.

in compliance with the allowable dialysate microbiological levels of <200 cfu and <2 EU.

FED - V0245 - ACID CONC DIST-CONC LABELED & COLOR-CODED RED

Title ACID CONC DIST-CONC LABELED & COLOR-CODED RED

Type Standard

CFR 494.40(a)

Regulation Definition

5.5.3 Acid concentrate distribution systems: labeled & color-coded red
Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection).

All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary.

More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains.

Interpretive Guideline

5.5.3 Acid concentrate distribution systems
Acid concentrate is not susceptible to bacteria contamination, but every effort should be made to keep the system closed to prevent nonbacterial contamination and evaporation.

Additional Guidance:
If more than one acid is centrally delivered to treatment stations, outlets must be clearly labeled with the acid type.

FED - V0246 - BICARB CONC DIST-COLOR CODED BLUE & SEALED

Title BICARB CONC DIST-COLOR CODED BLUE & SEALED

Type Standard

CFR 494.40(a)

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Regulation Definition

5.5.4 Bicarbonate concentrate distribution systems: color coded blue & sealed
Bicarbonate concentrate delivery piping should be color-coded blue at the point of use (at the jug filling station or dialysis machine connection). All joints should be sealed to prevent leakage of concentrate.

Interpretive Guideline

FED - V0247 - CONC OUTLETS-SEPARATE/LABELED/CONNECT SAFETY

Title CONC OUTLETS-SEPARATE/LABELED/CONNECT SAFETY

Type Standard

CFR 494.40(a)

Regulation Definition

5.5.5 Concentrate outlets: separate/labeled/connection safety
To prevent mix-ups with delivery of two or more types of acid concentrate, each concentrate should have its own outlet. Concentrate outlets should be compatible with the dialysis machine and have a means of minimizing the risk that the wrong concentrate will be connected to an outlet. The dispensing outlets should be labeled with the appropriate symbol (see AAMI Table 3) indicating the proportioning ratio for the dialysis machine and should be color-coded blue for bicarbonate, red for acid.

6.5 Concentrate distribution
A daily check to ensure that the appropriate acid and bicarbonate concentrate is connected to the corresponding concentrate delivery line is recommended if the storage tank is not permanently connected to its distribution piping.

Interpretive Guideline

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FED - V0248 - DIALYS PROPORT-MATCH RATIO-ALL CONC/MACHINE

Title DIALYS PROPORT-MATCH RATIO-ALL CONC/MACHINE

Type Standard

CFR 494.40(a)

Regulation Definition

5.6 Dialysate proportioning: match ratio all conc/machine
The acid and bicarbonate concentrates [must] be matched with respect to the proportioning ratio and with the model and setup configuration of the dialysis machine. Several types of three-stream concentrates are available, with different ratios of acid concentrate to bicarbonate concentrate to water (see Table 3). The different proportioning types are not compatible with one another.

Interpretive Guideline

5.6 Dialysate proportioning
Essentially, all dialysate is produced with three fluid streams: water, acid concentrate, and bicarbonate concentrate. This three-stream combination produces a highly buffered dialysate with a pH between 6.9 and 7.6. Dialysate can also be prepared from a single concentrate that contains acetate to provide a dialysate in which buffer is provided to the patient in the form of acetate, which is subsequently metabolized to yield bicarbonate. However, acetate containing dialysate is now rarely used in clinical practice.

Different manufacturers of dialysis machines use different methods of controlling the proportions of the concentrates. These can be generally grouped into two categories: "fixed proportioning" and "servo control." With both methods, the operator can select a desired sodium and bicarbonate level, and the machine will make the necessary adjustments to achieve the selected levels. Both types use a redundant system of controls and monitoring. With fixed proportioning systems, the pumps are set to established volumes, and the final conductivity is verified. With servo control machines, the individual concentrates are added until the conductivity achieves the expected value. A final redundant conductivity monitor verifies the mixture. Some machines may also monitor the pH of the dialysate as an additional safeguard against gross errors in dialysate formulation.

Generally, bicarbonate is available in one or two forms for each proportioning type (in liquid, cartridge, or dry powder, and in various sizes). Each proportioning type has numerous acid concentrate formulations ("codes") with different amounts of potassium, calcium, and magnesium ions, plus dextrose. To help differentiate between concentrates of different proportioning types, AAMI recommends that the manufacturer include a geometric symbol on the labels along with acid/base color coding.

Table 3-Symbols and color coding for different concentrate proportioning ratios

Concentrate type	Acid proportioning ratio (Red color coding)	Geometric symbol	Bicarbonate concentrate (Blue color coding)	Comments

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35X	1:34	Square	Dry, liquid, or cartridge	
36.8X	1:35.83	Circle	Dry or liquid	Bicarbonate concentrate contains some NaCl.
45X	1:44	Triangle	Dry, liquid, or cartridge	
36.1X	1:35.1	Hexagon	Cartridge	Powder cartridges may be used for other proportioning ratios, except for 36.83X, in which the bicarbonate concentrate also contains NaCl.

NOTE 1-The acid proportionin ratio refers to acid concentrate water + bicarbonate concentrate.
NOTE 2-Acetate-containing concentrate is color-coded white.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.6 Dialysate proportioning
Dialysate is usually prepared by a proportioning system that sequentially adds acid concentrate and bicarbonate concentrate to purified water. These systems produce a buffered physiologic dialysate with a pH between 6.9 and 7.6. More recently, systems have been developed that use three concentrates (bicarbonate, sodium chloride, and an acid concentrate containing the remaining electrolytes) to allow more sophisticated variation of the dialysate composition during dialysis.

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FED - V0249 - DIALYS PROPORT-MATCH MACH CONFIG W/RATIO USED

Title DIALYS PROPORT-MATCH MACH CONFIG W/RATIO USED

Type Standard

CFR 494.40(a)

Regulation Definition

5.6 Dialysate proportioning: match machine config w/ratio in use
Changing from one proportioning ratio to another requires recalibration for some models of dialysis machines. For those machines, the type of concentrate should be labeled on the machine or clearly indicated by the machine display. It is strongly recommended that facilities configure every machine to use only one type of concentrate.

6.6 Dialysate proportioning
Dialysate proportioning should be monitored following the procedures specified by the equipment manufacturer. The user should maintain a record of critical parameters such as conductivity and approximate pH. When the user has specific requirements for monitoring dialysate proportioning, such as when dialysis machine settings are changed to allow the use of concentrates with a different proportioning ratio, the user should develop procedures for routine monitoring of dialysate electrolyte values.

Interpretive Guideline

5.6 Dialysate proportioning
Some models of dialysis machines can use concentrates of only one type of proportioning ratio, but others may be set up or calibrated for use with concentrates of more than one proportioning type.

Additional Guidance:
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.

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 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. 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.

If machines are changed from one ratio to another, responsible staff members must be able to describe how they verified the machine functioned correctly after the change was made and how they monitored the dialysate electrolyte values.

FED - V0250 - DIALYS PROPORT-MONITOR PH/CONDUCTIVITY

Title DIALYS PROPORT-MONITOR PH/CONDUCTIVITY

Type Standard

CFR 494.40(a)

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Regulation Definition

5.6 Dialysate proportioning: monitor pH/conductivity
It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.

Interpretive Guideline

5.6 Dialysate proportioning
Injuries related to improper dialysate are rare, but they can and do happen when all procedures are not followed. Frequently, when the error occurs, several patients have been exposed before the facility recognizes the mistake. For example, because one of the concentrates is quite acidic and the other is basic, connecting the wrong concentrates to the machine could result in dialysate that could harm the patient.

Even though a single concentrate is used to prepare acetate dialysate, conductivity and pH should be checked, because certain mix-ups involving acid concentrate and other chemicals can result in an acceptable conductivity and very low pH.

Additional Guidance:
Each machine must be tested for pH using a hand held meter or other appropriate testing device (i.e., adequately-sensitive testing strips) before every dialysis treatment and whenever a different composition of acid concentrate is used. If the dialysis machine manufacturer requires testing of conductivity, this must also be tested using an independent testing device prior to each treatment and before using a different composition of acid concentrate during the same treatment. The facility must have set limits for the allowable variability of the hand held values from the machine readings. As new technology evolves, the manufacturer's guidance related to this requirement should be followed.

FED - V0252 - MICROB MONITOR-MO H20 SAMPLES/METHOD

Title MICROB MONITOR-MO H20 SAMPLES/METHOD

Type Standard

CFR 494.40(a)

Regulation Definition

7.2 Microbial monitoring methods: monthly water samples/method
7.2.1 General
Culture water ...weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Interpretive Guideline

7.2.2 Sample collection
All new sterile plastic ware is endotoxin-free because of the high temperatures involved in the manufacturing process.

Additional Guidance:
Bacterial colony counts may be done by an outside lab (thus the reference to direct plate counts) or by the use of dip samplers, as described at V256. If a pattern of results greater than the accepted limits is identified, the frequency of cultures (and subsequent disinfection) should be increased to reach a frequency that ensures the system is being

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Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin.

7.2.2 Sample collection
Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected. Sample taps should not be disinfected.

maintained below the allowed contamination level between scheduled sampling. Refer to V255.

FED - V0253 - MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ

Title MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ

Type Standard

CFR 494.40(a)

Regulation Definition

7.2 Microbial monitoring methods:
7.2.1 General: Dialysate: monthly dialysate sample/collection/freq
Culture ...dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. 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

Interpretive Guideline

7.2.2 Sample collection
In some newer dialysis machines, dialysate flow stops when the effluent line is disconnected from the port. In these instances, the machines are equipped with dialysate sampling ports that can be accessed using a syringe. These sample ports may be disinfected with alcohol and allowed to air dry. A 30 mL sterile syringe should then be used to aspirate dialysate out of and into the port before filling the syringe. The filled syringe should be discarded, and a fresh sample of dialysate collected using a new sterile syringe.

Additional Guidance:
Facilities may take samples of dialysate using a "clean catch" technique of the effluent from the Hansen connectors into sterile endotoxin-free collection containers, use a needleless system to access the port on the dialysate line, or use a syringe and needle to aspirate a sample from the port on the dialysate line.

A flow chart which gives suggestions for actions can be found in the original AAMI RD52:2004 document.

compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1.

7.2.2 Sample collection
Dialysate samples should be collected from a dialysate port of the dialyzer ... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.

FED - V0254 - MICROB MONITOR-SAMPLE BEFORE DISINFECT

Title MICROB MONITOR-SAMPLE BEFORE DISINFECT

Type Standard

CFR 494.40(a)

Regulation Definition

7.2 Microbial monitoring methods
7.2.1 General: samples before disinfect
Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines.

Interpretive Guideline

Additional Guidance:
Samples must be collected in the "worst case" scenario: before sanitation and disinfection, with consideration of logistics: i.e., samples sent to labs must arrive during the lab's hours of operation. If disinfection is scheduled for Sunday, for example, samples may need to be collected on Wednesday or Thursday to allow transit time and arrival before the lab closes on Friday.

FED - V0255 - MICROB MONITOR-REPEAT CULTURES

Title MICROB MONITOR-REPEAT CULTURES

Type Standard

CFR 494.40(a)

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Regulation Definition

7.2 Microbial monitoring methods
7.2.1 General: repeat cultures
Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia, and following a specific request by the clinician or the infection control practitioner.

If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer detected before collecting samples.

Interpretive Guideline

Additional Guidance:
Responsible staff members must be able to describe what is done when counts exceed action levels.

FED - V0256 - CULTURES-DIP SAMPLERS REQUIRE QC

Title CULTURES-DIP SAMPLERS REQUIRE QC

Type Standard

CFR 494.40(a)

Regulation Definition

7.2.3 Heterotrophic plate count: dip samplers require QC
Dip samplers may be used for bacterial surveillance ... in conjunction with a quality assurance program designed to ensure their appropriate use. Elements of the quality assurance program should include staff training in areas such as the correct methods of inoculation, incubation, and interpretation, and verification involving duplicate samples sent to a certified laboratory on at least an annual basis. Plates shall be incubated

Interpretive Guideline

7.2.3 Heterotrophic plate count
This method is an indicator of water quality only and is not to be confused with total heterotrophic plate counts, which require much longer incubation times at 28° C.

If a more accurate count from plates containing fewer than 30 or more than 300 colonies is desired, larger or smaller volumes may be cultured. Smaller volumes can be obtained by making 1:10 serial dilutions in sterile phosphate buffer. If larger volumes are required, the membrane filtration method should generally be used.

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at 35 °C for 48 hours.

Colonies should be counted using a magnifying device.

Erratic colony counts may indicate the presence of biofilm since sloughing of biofilm may occur with release of bacteria into the water. When contamination persists in spite of frequent and aggressive disinfection, if may be necessary to determine if biofilm is present in the system.

Additional Guidance:
Facilities that use dip samplers must send duplicate samples to a laboratory at least annually to evaluate the accuracy of the testing done with the dip samplers.

FED - V0257 - CULTURES-REFRIG OVER 2 HRS/NO CALIB LOOP

Title CULTURES-REFRIG OVER 2 HRS/NO CALIB LOOP

Type Standard

CFR 494.40(a)

Regulation Definition

7.2.3 Heterotrophic plate count: refrig if delay >2 hours/no calib loop
Samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours.

Use of a calibrated loop to apply the sample to the agar plate is not permitted.

Interpretive Guideline

7.2.3 Heterotrophic plate count
The reference method for culturing is the membrane filtration technique. With this method, a known volume of sample or diluted sample is filtered through a 0.45 µm membrane filter and the membrane filter is aseptically transferred to the surface of an agar plate. Trypticase soy agar (TSA, a soybean casein digest agar) is the medium of choice for culturing water and dialysate; other acceptable media include standard methods agar and plate count agar (also known as TGYE). Blood and chocolate agars are not appropriate for this test. The spread plate technique may also be used. With this method, an inoculum of at least 0.5 mL of sample is spread equally over the surface of the agar plate.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.7 Strategies for bacterial control
A.7.2.3 Heterotrophic plate count
Sensitive culturing methods must be used to measure the low total viable microbial counts permitted for water used for hemodialysis applications under the provisions of ANSI/AAMI RD62:2001 and recommended for dialysate in this recommended practice. The membrane filter technique is particularly suited for this application because it permits large volumes of water to be assayed. Because the membrane filter technique may not be readily available in clinical laboratories, the spread plate assay can be used as an alternative. However, if the spread plate assay is used, a calibrated loop shall not be used to apply sample to the plate. The sensitivity of an assay performed with a calibrated loop is low. A standard calibrated loop transfers 0.001 mL of sample to the culture medium, so that the minimum sensitivity of the assay is 1,000 CFU/mL. This sensitivity is unacceptable when the maximum allowable limit for

microorganisms is 200 CFU/mL. Therefore, when the spread plate method is used, a pipette should be used to place 0.1 mL to 0.5 mL of water on the culture medium.

Additional Guidance:
Responsible staff must be knowledgeable of the culture methods in use and must inform any outside labs that the samples are water and dialysate and that use of a calibrated loop to inoculate the culture plate is not acceptable.

FED - V0258 - ENDOTOXIN TESTING IN HOUSE-HOW TO

Title ENDOTOXIN TESTING IN HOUSE-HOW TO

Type Standard

CFR 494.40(a)

Regulation Definition

7.2.4 Bacterial endotoxin test: LAL testing in house: how to
At a minimum, two tubes should be run each time the assay is performed. The first tube contains LAL reagent and the sample to be tested. The second tube contains LAL reagent, a known amount of endotoxin, and the sample to be tested. The second tube acts as a positive control to confirm the absence of any interference that might lead to a false negative result.

Interpretive Guideline

7.2.4 Bacterial endotoxin test
Bacterial endotoxin testing is done using the Limulus amoebocyte lysate (LAL) assay. Two basic types of assay can be performed. The first is a kinetic assay, which is available in a colorimetric or turbidimetric format, and the second is a gel-clot assay.

The kinetic LAL assay uses control standard endotoxin to generate a standard curve to which unknowns are compared and concentrations are determined using linear regression. The kinetic assays employed in laboratories generally use a computer-driven spectrophotometer that automatically calculates the amount of endotoxin on the basis of color development or onset times for gel formation.

The gel-clot LAL assay is not as sensitive as the kinetic assay and provides only a positive or negative result; that is, it shows if endotoxin is present-or not-at a particular concentration. Single tube gel-clot tubes are available from several commercial sources, and kits with the following sensitivities are available: 0.015 EU, 0.03 EU, 0.06 EU, 0.125 EU, 0.25 EU, and 0.5 EU.

Positive control tubes are available from the suppliers of commercial LAL assays. More sophisticated testing protocols involving reagent controls may also be used (see 2.7), but their use is optional in this application.

Additional Guidance:
Technology for endotoxin testing is evolving and these regulations are not meant to prevent the use of a newer testing methodology, once such methodology is approved by FDA.

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FED - V0259 - PERSONNEL-P&P

Title PERSONNEL-P&P

Type Standard

CFR 494.40(a)

Regulation Definition

9 Personnel: P & P
Policies and procedures that are understandable and accessible are mandatory.

Interpretive Guideline

FED - V0260 - PERSONNEL-TRAINING PROGRAM/PERIODIC AUDITS

Title PERSONNEL-TRAINING PROGRAM/PERIODIC AUDITS

Type Standard

CFR 494.40(a)

Regulation Definition

9 Personnel: training program/periodic audits
A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.

Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.

The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).

Periodic audits of the operators' compliance with procedures should be performed.

Interpretive Guideline

The operators of the water/dialysate system equipment must be trained by the manufacturer of the equipment, or the training must be done from materials provided by the manufacturer. Water treatment service vendors may do the training using materials from the manufacturer.

The facility must define the frequency of audits to evaluate the operators' compliance: these should include actual observation of the work: e.g., collecting samples, performing water testing. Audits should be done at least annually and more frequently if problems are identified.

This tag addresses the content of the training for personnel responsible for the water and dialysate systems, and audits for compliance with procedures. Whether the personnel responsible for the water treatment system have been trained is addressed in the Condition for Personnel qualifications, at V696.

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The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

FED - V0270 - CH/CHL BREAKTHROUGH-CORRECTIVE ACTION

Title CH/CHL BREAKTHROUGH-CORRECTIVE ACTION

Type Standard

CFR 494.40(b)(2)(ii)

Regulation Definition

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-
(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

Interpretive Guideline

"Corrective action" here could include backwashing carbon tanks, rebedding or replacement of the tanks or addition of an adjunct system such as chemical injection to address an extremely high chlorine or chloramine load from the municipal supplier. In any case, testing must confirm acceptable levels of chlorine/chloramine before dialysis treatments can resume. It could be necessary for the patient treatments to be rescheduled, or patients to be transferred to another facility for one or more treatments.

FED - V0271 - CH/CHL BREAKTHROUGH-HOLDING TANK USE

Title CH/CHL BREAKTHROUGH-HOLDING TANK USE

Type Standard

CFR 494.40(b)(2)(ii)

Regulation Definition

(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-

Interpretive Guideline

If the system includes a holding tank and the water in that tank tests safe for chlorine and chloramine, that water may be used for patient treatment. Responsible staff must know how to prevent the water treatment system from continuing to make product water, thus adding water containing unsafe levels of chlorine to the storage or holding tank. Water produced by exhausted carbon tanks must not be used for treatment.

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(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section;

FED - V0272 - CH/CHL BREAKTHROUGH-NOTIFY MED DIRECTOR

Title CH/CHL BREAKTHROUGH-NOTIFY MED DIRECTOR

Type Standard

CFR 494.40(b)(2)(ii)

Regulation Definition	Interpretive Guideline
(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-	Policy and practice must demonstrate this requirement is met. Responsible staff should list notifying the medical director as an action they would take immediately in the event of a chlorine or chloramine breakthrough.

(C) Immediately notify the medical director

FED - V0273 - CH/CHL BREAKTHROUGH-ACTION=CORRECTION

Title CH/CHL BREAKTHROUGH-ACTION=CORRECTION

Type Standard

CFR 494.40(b)(2)(ii)

Regulation Definition	Interpretive Guideline
(ii) If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must-	"Corrective action" in this context would include a root cause analysis to determine the cause of the chlorine and chloramine breakthrough, and development and implementation of a corrective action plan to address the identified cause.

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in

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paragraph (b)(2)(i) of this section.

FED - V0274 - H20 TEST-DEVIATIONS REQUIRE RESPONSE

Title H20 TEST-DEVIATIONS REQUIRE RESPONSE

Type Standard

CFR 494.40(c)

Regulation Definition

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.

Interpretive Guideline

Facility policy must include requirements to develop and implement a corrective action plan that ensures patient safety if water testing results are outside accepted limits or action levels.

A corrective action plan to ensure patient safety must be developed and implemented if any of the results of water chemical analysis or microbial and endotoxin testing for water and dialysate meet the AAMI action levels or are outside the AAMI standards. 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.

FED - V0275 - ADVERSE EVENTS-ACTIONS EXPECTED

Title ADVERSE EVENTS-ACTIONS EXPECTED

Type Standard

CFR 494.40(d)

Regulation Definition

A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must-
(1) Obtain blood and dialysate cultures and endotoxin levels;
(2) Evaluate the water purification system; and
(3) Take corrective action.

Interpretive Guideline

Responsible staff (nurses and patient care technicians) must be familiar with symptoms which might indicate a patient could be having a reaction related to water or dialysate and must be able to describe appropriate actions to take in the event a patient or group of patients experienced such symptoms.

Facility or patient medical records (as appropriate) must demonstrate that any adverse incidents (fever, chills, or an infection) were identified by staff and these required actions were taken.

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.

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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.

FED - V0276 - IC USE PRECONFIG HD SYS-FOLLOW FDA LABEL

Title IC USE PRECONFIG HD SYS-FOLLOW FDA LABEL

Type Standard

CFR 494.40(e)

Regulation Definition

When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system's FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality.

Interpretive Guideline

At the time of publishing these regulations, several different preconfigured hemodialysis systems were available. These included conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which incorporated water treatment and dialysate preparation and delivery into one system; and sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer. Although primarily used for home therapies, a preconfigured hemodialysis system may be used in-center. Such use might be for training a home patient, for back-up treatment of home patients, or for routine in-center treatment. In all cases, the system's FDA-approved labeling must be followed for machine use and monitoring of the water and dialysate quality.

If the preconfigured hemodialysis system incorporates a water treatment system, a chemical analysis of the product water must be done at least annually near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other than the replacement of disposable components). When any repairs are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if indicated.

Chlorine/chloramine levels must be tested prior to the start of each treatment (or before use of each new batch of dialysate) in accordance with AAMI guidance and manufacturer's recommendations/instructions for that test method. An appropriate volume of water for the testing method in use should be tested for the presence of chlorine/chloramine. For batch systems (integrated systems which prepare enough dialysate for multiple treatments), the chlorine/chloramine testing must be performed at the worst case scenario, i.e., after the preparation of each batch of dialysate, but before use of that batch. If the test shows results above AAMI's maximum allowable level, then the user must discard that batch, change any applicable components, prepare another batch of dialysate, and test again.

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Systems that use sorbent technology do not produce water; the product of the sorbent cartridge is dialysate, thus the requirements for the chemical, bacteriological and endotoxin testing of water do not apply. With sorbent technology, due to the low volume of exposure of patients to water (i.e., 6 liters per treatment) and the capacity of the single use sorbent cartridge to remove chlorine and chloramine, testing for chlorines and chloramine is not required. Sorbent system users are expected to perform bacteriological and endotoxin testing on dialysate.

Monitoring of the system must be in accordance with the FDA-approved labeling, which includes the manufacturers' directions for use (DFU). The facility should have the manufacturers' DFUs on file, and facility procedures should reflect those.

FED - V0277 - IN-CENTER PRECONFIG HD-MEETS AAMI RD52

Title IN-CENTER PRECONFIG HD-MEETS AAMI RD52

Type Standard

CFR 494.40(e)

Regulation Definition	Interpretive Guideline
The facility must meet all AAMI RD52:2004 requirements for water and dialysate.	If the facility is using a preconfigured FDA-approved hemodialysis system for in-center treatments, the facility must meet the requirements of ANSI/AAMI RD52:2004 in the use of that system.

FED - V0278 - IN-CENTER PRECONFIG HD-CULTURES & LAL 4X/YR

Title IN-CENTER PRECONFIG HD-CULTURES & LAL 4X/YR

Type Standard

CFR 494.40(e)

Regulation Definition	Interpretive Guideline
Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.	Preconfigured systems used for in-center treatments must be tested at least quarterly for bacteria and endotoxins.

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FED - V0300 - CFC-REUSE OF HEMODIALYZERS & BLOODLINES

Title CFC-REUSE OF HEMODIALYZERS & BLOODLINES

Type Condition

CFR 494.50

Regulation Definition

Interpretive Guideline

This Condition 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).

The observation of actual practice of reprocessing and reuse is critical to the survey of this Condition, as are interviews with the staff responsible for reprocessing and reuse. Additionally, records of the reprocessing process and medical records of patients included in the reuse program must be reviewed. Surveys of facilities that participate in centralized reprocessing programs require onsite visits at the reprocessing site, on a rotating basis, as part of the survey process. Deficiencies identified at the centralized reprocessing site apply to all user facilities.

Condition-level citation should be considered if there are major deficient practices that have affected, or could potentially affect patient health and safety. Examples would include, but are not limited to:
o Staff members assigned responsibility do not demonstrate competency;
o Less than sufficient concentration of germicide is in use;
o Direct care staff do not test for residual levels of germicide prior to reusing a dialyzer or the testing methods in use are not sufficiently sensitive;
o Reprocessing a dialyzer of a HBV+ patient.

FED - V0301 - GENERAL REQUIREMENTS-NO REUSE FOR HBV+ PTS

Title GENERAL REQUIREMENTS-NO REUSE FOR HBV+ PTS

Type Standard

CFR 494.50(a)(1)

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Regulation Definition

Certain hemodialyzers and bloodlines-
(1) May be reused for certain patients with the exception of Hepatitis B positive patients(1) May be reused for certain patients with the exception of Hepatitis B positive patients

Interpretive Guideline

Note that, in the Interpretive Guidance, the term "reprocessing" refers to the processes of cleaning and the installation of germicide into a dialyzer, and the term " reuse " refers to the clinical use of a reprocessed dialyzer for hemodialysis.

Hepatitis B positive (HBV+) patients must be excluded from any reprocessing/reuse program. Facilities must provide single-use dialyzers and bloodlines for patients who are HBV+.

If the facility reuses dialyzers and/or bloodlines for Hepatitis B positive patients, this requirement is not met. This practice may impact the health and safety of the other patients whose dialyzers are reprocessed and should be considered as Condition level non-compliance.

FED - V0303 - DIALYZER LABELED FOR MULTIPLE REUSE

Title DIALYZER LABELED FOR MULTIPLE REUSE

Type Standard

CFR 494.50(a)(3)

Regulation Definition

Certain hemodialyzers and bloodlines-
(3) Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

Interpretive Guideline

Any dialyzer included in the reprocessing/reuse program must be labeled by the manufacturer for multiple use and must have a manufacturer's label indicating the dialyzer may be used multiple times.

FED - V0304 - REPROCESSING-MEETS AAMI RD47 2001/2002

Title REPROCESSING-MEETS AAMI RD47 2001/2002

Type Standard

CFR 494.50(b)

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Regulation Definition

A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:
(1) Meet the requirements of AAMI published in "Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:
http://code_of_regulations/ibr_locations.html
Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

Interpretive Guideline

The AAMI "Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference. The recommendations are provided in the "Regulation" column and carry the full weight of regulation. Language from the AAMI recommendations that is explanatory and portions of the AAMI rationale for the development and provisions of the recommended practice are provided in the "Interpretive Guidance" column as an aid to understanding the regulation. In some cases, the AAMI identification numbers may appear out of order, as they have been rearranged for better flow with the survey process. While exact language from the AAMI document has been incorporated as regulation, the language in the "Interpretive Guidance" column has been edited for clarity, brevity and to minimize redundancy.

When "should" or "recommend" are included in the AAMI language adopted as regulation (i.e., the language in the "Regulation" area), the referenced item or practice must be in use or in place.

AAMI RD47:2002/A1:2003
11 Reprocessing
The multiple use of a dialyzer begins with the labeling of the new dialyzer (see AAMI section 10) and then continues with the reprocessing procedures described in this section. Preparation of the reprocessed dialyzer for the next dialysis is described in AAMI section 12. The cycle is repeated after the next use of the dialyzer until the dialyzer does not meet the criteria for continued use. The results of the tests and the signature or other unique means of identifying the person performing each step should be maintained in a permanent record (see AAMI 4.2). Completion of all reprocessing steps, tests, and inspections should be documented in the reprocessing record, accompanied by the signature or other unique means of identification of the person completing them. When appropriate for the reprocessing procedure in use, all dialyzer manufacturer's instructions regarding reuse should be carefully followed.

FED - V0305 - RECORDS-MEET REQ FOR MED RECORDS

Title RECORDS-MEET REQ FOR MED RECORDS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

4 Records: meet req for medical records
All records described in this recommended practice shall meet the requirements for medical records, including completeness,

Interpretive Guideline

Additional Guidance:
Reprocessing records must be complete, legible and protected from unauthorized access. The record of use of a dialyzer may be included in the patient record, in computer listings, and in separate records of reprocessing. The

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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). Maintaining these records is the responsibility of the medical director.

history of each dialyzer from first use to discard must be able to be followed. Staff may use computer entries to "sign" as completing various steps of the process.

FED - V0306 - DIALYZER REPROCESSING MANUAL

Title DIALYZER REPROCESSING MANUAL

Type Standard

CFR 494.50(b)(1)

Regulation Definition

4.1 Dialyzer reprocessing manual: dialyzer reprocessing manual
The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.4 Records
Documentation is essential to a safe, effective hemodialyzer reprocessing program. The overall dialyzer reuse procedure documentation includes reference materials, procedures, and policies, some of which may be distributed in the facility for operating purposes. The other records serve to document aspects of the reuse procedure for each dialyzer, along with QC and QA measures, so that a complete history of the reprocessing of each dialyzer and QC/QA procedures exists.

Allowance is made for keeping the reprocessing record data in the reprocessing log, the patient ' s chart, or a combination of the two, because both of them are traceable, permanent records, and it may be inconvenient to record all of the information in one location.

Additional Guidance:
The reprocessing manual must be complete for the reprocessing method, germicide, and system in use. The manual must address test procedures, maintenance and calibration of the reprocessing equipment and training and competency testing of personnel. The manual may be separate or combined with the general policy and procedure manual. The manufacturer's "labeling" of a dialyzer includes the package insert, usually found in the shipping container for multiple dialyzers of the same type, and contains the dialyzer manufacturer's directions for use. If a specific dialyzer in use requires special consideration, the reprocessing manual should reflect the manufacturer's

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guidance.

FED - V0307 - PERSONNEL QUALIFICATIONS

Title PERSONNEL QUALIFICATIONS

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
5 Personnel qualifications and training 5.1 Qualifications Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple-use program. Education shall be geared to meet the needs of this wide range of personnel.	5 Personnel qualifications and training New personnel range in knowledge from those with no medical background who are fully trained by the facility, to licensed practitioners with extensive medical background. Additional Guidance: The reuse education provided must be sufficient to ensure patient safety and an effective and safe reprocessing/reuse program.

FED - V0308 - TRAINING-CURRICULUM

Title TRAINING-CURRICULUM

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
5.2 Training 5.2.1 Curriculum The dialysis facility's physician or director shall establish a training course for the persons performing hemodialyzer reprocessing. A written document should give details about the curriculum and, in particular, address the potential risks to patients and staff members of not following correct procedures. The curriculum should include at least the following information:	Additional Guidance: Available training materials must include all required topics and be congruent with the processes observed.

a) the facility's specific reprocessing procedure, including a rationale for each step;
b) basic documentation requirements of the program;
c) the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;
d) microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;
e) the risks and hazards of multiple use of hemodialyzers;
f) the consequences of not performing tasks properly;
g) the risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances;
h) the use and location of protective eyewear, respirators, masks, and special clothing;
i) emergency procedures as required by the facility; and
j) the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.

FED - V0309 - TRAINING DOCU INCLUDES MED DIR CERT

Title TRAINING DOCU INCLUDES MED DIR CERT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

5.2.2 Documentation: includes med dir certification
Each person performing procedures for the multiple use of dialyzers shall have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training shall be certified

Interpretive Guideline

Additional Guidance:
Facilities may cross-train staff from other positions, such as hemodialysis technicians or clerical staff, to perform reprocessing. Each person who is assigned dialyzer reprocessing must complete all the components of the training and demonstrate competency.

Personnel files should include:

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by the medical director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee having received the instruction. Retraining is necessary when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found.

o Evidence the medical director/designee has certified each of the reprocessing personnel who have successfully completed the required training;
o Annual competence review and applicable retraining;
o Retraining for any major change in the reuse program (e.g., a change in equipment or germicide).

FED - V0310 - PERSONNEL HEALTH MONITORING RECORDS

Title PERSONNEL HEALTH MONITORING RECORDS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

4 Records
4.4 Personnel health monitoring records
A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies.

Interpretive Guideline

Additional Guidance:
Health screening of personnel is dependent on the germicide in use. Specific requirements may be found on the OSHA material safety data sheets (MSDS) on file in each facility for applicable germicides. Personnel files of reprocessing personnel should reflect any required testing. Specific requirements for testing may be obtained from www.osha.gov (http://www.osha.gov) and www.cdc.gov/niosh/ (http://www.cdc.gov/niosh/).

FED - V0311 - PT CONSIDERATIONS-MEDICAL ISSUES

Title PT CONSIDERATIONS-MEDICAL ISSUES

Type Standard

CFR 494.50(b)(1)

Regulation Definition

6 Patient considerations
6.1 Medical issues
An order to reprocess hemodialyzers shall be made by a physician knowledgeable about reprocessing and its medical and economic implications. Because the current human immunodeficiency virus (HIV), hepatitis B, or hepatitis C

Interpretive Guideline

6 Patient considerations
6.1 Medical issues
Dialyzers should not be reprocessed from patients who have tested positive with hepatitis B surface antigens.

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status of a patient cannot be known with certainty, all staff potentially exposed to the patient's blood shall observe Standard Precautions. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures should stipulate whether and how reprocessing will be done for patients who have shown sensitivity to materials used in the reprocessing of hemodialyzers.

A.6 Patient considerations
A.6.1 Medical issues
The AAMI Renal Disease and Detoxification (RDD) Committee's primary objective was not to recommend medical indications for reprocessing or evaluate the medical or economic implications of reprocessing but to provide recommendations for safe reuse practice.

At the time of this writing, the Centers for Disease Control and Prevention (CDC) does not object to reprocessing and reusing dialyzers from patients with hepatitis C or patients with known HIV infection because of the low viral burden and transmission efficiencies. The AAMI RDD Committee recommends, however, that standard precautions be used in the reprocessing of all dialyzers. These precautions include the use of gowns, masks, and gloves. Each facility should be aware of the hazards of infection and set policies accordingly.

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. Orders for treatment (which may be provided by the physician, advanced practice registered nurse or physician assistant) must include whether or not the patient will participate in the reuse program. If a patient has shown sensitivity to the materials used in reprocessing, this problem must be addressed in the patient assessment and plan of care.

Standard precautions must be followed in all reprocessing/reuse activities; PPE appropriate to the task must be worn; all blood spills must be immediately cleaned. While it is not expected that reprocessing staff would change gloves between handling separate dialyzers during routine tasks, gloves that are visibly soiled with blood, as would occur during header cleaning, must be changed between dialyzers, as well as when reprocessing staff goes from "dirty" tasks to a "clean" task, with appropriate hand hygiene performed prior to donning fresh gloves.

FED - V0312 - PTS INFORM RE DIALYZER REUSE PROCESS

Title PTS INFORM RE DIALYZER REUSE PROCESS

Type Standard

CFR 494.50(b)(1)

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Regulation Definition

6.2 Informed consent: regarding dialyzer reuse process
All patients in a dialysis facility will be fully informed regarding reuse of dialyzers. Printed material such as brochures describing the facility's services should contain a statement about dialyzer reprocessing if reuse is performed.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.6.2 Informed consent
Establishing QA practices such as those recommended here and sharing information with patients, may aid in solutions to these problems.

The National Kidney Foundation and the American Association of Kidney Patients recommend that patient consent for dialyzer reuse be obtained.

Additional Guidance:
CMS does not require specific written patient consent, but does require that patients be informed that the facility does reprocess dialyzers and about that process. Refer to V460 under the Condition for Patients ' rights.

FED - V0313 - EQUIPMENT-DESIGN/CONSTRUCTION/FUNCTION

Title EQUIPMENT-DESIGN/CONSTRUCTION/FUNCTION

Type Standard

CFR 494.50(b)(1)

Regulation Definition

7 Equipment: design/construction/function
Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. Satisfactory operation of manual and automated systems shall be ensured by appropriate functional tests. Strict QC and QA shall be maintained for any type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operating procedures, potential system failures, and dialyzer-reuse criteria shall be included in the dialyzer reprocessing manual, known to the operator, and available for review.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.7 Equipment
Types of reprocessing systems vary from sophisticated microprocessor-controlled systems to hand-operated valving systems.

It is particularly important that all water that comes into contact with the fluid pathways for blood or dialysate be of AAMI quality because the blood side of the dialyzer might take up endotoxin that could be released into the circulation system during the subsequent dialysis.

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FED - V0314 - H20 SYS MEET AAMI BACTI/CHEM QUALITY

Title H20 SYS MEET AAMI BACTI/CHEM QUALITY

Type Standard

CFR 494.50(b)(1)

Regulation Definition

7.1 Water systems: meet AAMI bacti/chem quality monitoring
The system providing water for reprocessing shall meet all of the requirements for pressure and flow rate for operating the reprocessing equipment under minimal and peak load conditions. Product water used for rinsing, cleaning, filling, and diluting the germicide shall be shown to comply with the chemical and microbiological quality requirements [specified in these regulations]. Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.

11.4 Germicide
11.4.1.5 Water quality monitoring
The water used to rinse and clean dialyzers and dilute the germicide should be tested for bacterial contamination and pyrogens according to the requirements [of these regulations] before a reprocessing program is undertaken. Once dialysis with the reprocessed hemodialyzers has begun, testing for bacterial contamination should be frequent (e.g., weekly). Less frequent testing, but not less than monthly, may be appropriate if there is a documented history of at least 3 months of results consistently below the required levels.

Interpretive Guideline

Additional Guidance:
The product water chemical and microbiological requirements outlined in this section are the same as those in ANSI/AAMI RD52:2004 incorporated by reference in these regulations under the Condition for Water and dialysate quality.

Water samples for microbial and endotoxin testing must be routinely taken each month from the water supplying each reprocessing system, as close as possible to the point where the dialyzer would be connected to the system. If more than one automated reprocessing system is in use, the water supply to each system must be monitored monthly.

New facilities or facilities which add dialyzer reprocessing must validate the safety of the water supply to the reprocessing system by testing for bacteria (microbial content) and pyrogens (endotoxins) weekly for at least 3 months, and at least monthly thereafter. The sites to be tested include the water supply to the sinks used for rinsing dialyzers, to outlets used for mixing germicide, and to each reprocessing system.

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FED - V0315 - REPROCESSING SYSTEMS-UTILITY REQUIREMENTS

Title REPROCESSING SYSTEMS-UTILITY REQUIREMENTS

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
7.2 Reprocessing systems 7.2.1 Utility requirements The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer or designer's recommendations for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.	Additional Guidance: In the reprocessing area, there must be sufficient drains to accommodate the reprocessing systems, air ventilation equipment to minimize exposure to germicide vapors (as listed in AAMI 8.1 "Reprocessing area and ventilation"), and an adequate number of electrical outlets for the equipment in use. The pressure of the water used for reprocessing should be monitored. There should be a pressure gauge in the water line of any sink used for dialyzer rinsing, with defined parameters for the accepted pressures to use during that procedure. Dialyzer manufacturers specify maximum pressures for rinsing; exceeding those pressures can result in rupture of the dialyzer membranes and a potential for blood leaks. Use this tag if there is no pressure gauge in the water line at the rinse sink; use V332 if the manufacturer's specified pressures are exceeded.

FED - V0316 - MAINTENANCE PER DFU OR 2X/YR;RECORD

Title MAINTENANCE PER DFU OR 2X/YR;RECORD

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
7.2.3 Maintenance: per DFU or semiannual/maintenance record Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, the recommendations of the vendor should be followed unless	Additional Guidance: There should be a written plan which incorporates the manufacturer's guidance detailing expected preventative maintenance of the reprocessing systems in use. The records of maintenance should be congruent with the plan. If manufacturer's guidance is not available, preventative maintenance of reprocessing systems must be done on a semiannual basis, at a minimum.

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documented experience supports alternative approaches. If the manufacturer's recommendations are not available, reuse equipment and safety equipment should be inspected on a semiannual basis.

4 Records
4.3 Equipment maintenance record
Records shall be maintained of the dates of preventive maintenance procedures and the results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.

4 Records
A place should be provided for the signature or other unique mark of identification of the person ...performing preventative maintenance procedures.

FED - V0317 - REPAIRS=QUAL PERSONNEL;TEST B4 RET TO USE

Title REPAIRS=QUAL PERSONNEL;TEST B4 RET TO USE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

7.2.4 Repairs: by qualified personnel: fxn test before return to use
If the reprocessing system fails to function as expected, qualified personnel should investigate and repair the problem. The reprocessing system function testing should be repeated after repairs of automated equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.

Interpretive Guideline

Additional Guidance:
There should be documentation to verify that testing of repaired equipment for expected functioning was completed successfully prior to returning the equipment to service.

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FED - V0318 - REPROCESSING AREA & VENTILATION

Title REPROCESSING AREA & VENTILATION

Type Standard

CFR 494.50(b)(1)

Regulation Definition

ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1
8 Physical plant and environmental safety considerations
8.1 Reprocessing area and ventilation
The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see [AAMI] 8.5).

Table 1-OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated

Substance/material	Limits (PEL)a
Acetic acid	10 ppm TWAb
Chlorine dioxide (syn: chlorine oxide)	0.1 ppm TWA
Citric acid	None developed
Formaldehyde	0.75 ppm TWA 2 ppm STELc(15 min) 0.5 ppm action level
Glutaraldehyde	0.2 ppm ceiling

Interpretive Guideline

Additional Guidance:
Although the equipment for air testing may not be kept on-site, it should be available for use if staff or patients complain about germicide vapors.

There should be a schedule for routine air-level testing for germicides vapors, along with references describing the safe exposure levels, and if there are any circumstances which would require an unscheduled test.

The reprocessing area must be kept clean and free of clutter. Blood splashes should be immediately cleaned and the affected surfaces disinfected.

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	NIOSH/OSHA
Hydrogen peroxide	1 ppm TWA
Peracetic acid	None developed
Phenol	5 ppm TWA

ppm = parts per million
a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs.
b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period.
c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.

FED - V0319 - ENVIRONMENTAL SAFETY REGARDING CHEMICALS

Title ENVIRONMENTAL SAFETY REGARDING CHEMICALS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

8.5 Environmental safety: regarding chemicals
The dialysis facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute for Occupational Safety and Health [NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets [MSDS]).

Interpretive Guideline

Additional Guidance:
MSDS must be available in the facility for the germicide in use. Policy must address and personnel must be knowledgeable of procedures for minor and major germicide spills.

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FED - V0320 - PERSONNEL PROTECTIVE GEAR

Title PERSONNEL PROTECTIVE GEAR

Type Standard

CFR 494.50(b)(1)

Regulation Definition

8.4 Personnel protection: gear
Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard Precautions shall be observed. Personnel shall wear eye protection when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. When personnel are handling concentrated toxic substances, they shall wear aprons impervious to these substances.

Interpretive Guideline

Additional Guidance:
Reprocessing personnel and patient care staff must wear PPE appropriate to the risk of potential exposure to germicide, blood and other potentially infectious substances for the tasks performed.

Various germicides require different precautions as to PPE, eyewash, respirators, and spill control materials. The germicide manufacturer's guidance or the MSDS provide this specific information.

The supplies for managing a minor germicide spill (containment materials, additional protective equipment, etc.) must be easily accessible from the reuse room.

FED - V0321 - STORAGE AREA/SEGREGATE DIALYZERS

Title STORAGE AREA/SEGREGATE DIALYZERS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

8.2 Storage area: segregation of dialyzers in process
Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. New, used, and reprocessed dialyzers should be segregated to make

Interpretive Guideline

Additional Guidance:
"Clean" and "dirty" dialyzers must be stored separately; the status (in the reprocessing cycle) of any dialyzer must be clearly apparent at all times. Stock must be organized to allow rotation and prevent use of out-of-date materials. Reprocessed dialyzers in storage should be protected from unauthorized access to prevent tampering and to protect the confidentiality of the patients involved in the reuse program.

clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored, if the personnel determine those actions to be necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.

FED - V0322 - REPROCESS SUPPLIES-SPECS & TESTING

Title REPROCESS SUPPLIES-SPECS & TESTING

Type Standard

CFR 494.50(b)(1)

Regulation Definition

9 Reprocessing supplies
9.1 Specifications and testing
Each reprocessing material should meet a written specification. The fulfillment of that requirement may be determined by certification by the product's supplier that the product meets necessary specifications, labeling for its intended purpose, or by testing procedures by trained personnel, as appropriate. The requirement may also be complied with by purchasing a specific grade as specified by the process, such as USP citric acid. When the user performs testing, he or she should maintain a log of the date of test, the identifying number (lot number) of the batch, the person performing any testing, and the test results.
When bleach is purchased from a commercial outlet, the labeled concentration should be between 5.25% and 6.15%, and the formula should not contain fragrances or scents.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.9 Reprocessing supplies
A.9.1 Specifications and testing
Testing of all incoming materials had been proposed. In recognition of the fact that most medical supplies are certified by the vendor and not tested by the user, the AAMI RDD Committee decided to recommend that supplies need not be tested by the facility doing hemodialyzer reprocessing if they are marketed for hemodialyzer reprocessing.

Additional Guidance:
Most materials used in reprocessing will not require testing by the user. If the facility is using a material not commonly used in reprocessing, there must be documentation of testing done to verify that the product meets the necessary specifications.

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FED - V0323 - INVENTORY CONTROL

Title INVENTORY CONTROL

Type Standard

CFR 494.50(b)(1)

Regulation Definition

9.2 Inventory control
Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.9.2 Inventory control
The AAMI RDD Committee suggested that supplies should be used on a first-in, first-out basis to avoid deterioration over time in storage.

Additional Guidance:
Expired supplies must be discarded or quarantined for return to the vendor. Note that testing strips (which may be found in multiple locations in the reuse room and treatment floor) may require dating when opening and discard based on the number of days since opening. Note that some reprocessing supplies, such as blood port caps, do not have expiration dates.

FED - V0324 - PROCESS CONTROL TEST-METHODS ESTABLISHED

Title PROCESS CONTROL TEST-METHODS ESTABLISHED

Type Standard

CFR 494.50(b)(1)

Regulation Definition

7.2.2 Process control testing: methods established
7.2.2.1 Dialyzer test methods ([AAMI] 11.3) shall be established before clinical use of the reprocessed dialyzers. Verification of tests should be repeated after each significant change in the reprocessing system. For automated systems, adherence to the manufacturer's instructions can verify the tests. For manual systems, confirmation of the accuracy of

Interpretive Guideline

Additional Guidance:
Process control allows the user to ensure the equipment is functioning correctly. This can be done by testing for the expected parameters (e.g., checking the accuracy of the measurement of the TCV) or by adherence to the manufacturer ' s guidance for automated equipment.

A "significant change" would include a change from a manual to an automated system, a change from one automated system to another, a change in the germicide, or a major repair of the reprocessing equipment.

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total cell volume (TCV) measurement and the membrane integrity test can verify the tests.

FED - V0325 - PROCESS CONTROL TEST-CONC OF GERMICIDE

Title PROCESS CONTROL TEST-CONC OF GERMICIDE

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
7.2.2 Process control testing: concentration of germicide 7.2.2.2 The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers ([AAMI] 11.4.1.6 and 12.3.2). For systems using heat disinfection, verifiable evidence shall be available before the next use that dialyzers have been exposed to the appropriate temperature for the time required. If chemicals are used to enhance heat disinfection, both a presence test and a verification of time and temperature shall be performed.	Additional Guidance: The reuse manual should document how the concentration of germicide will be tested. If heat disinfection is the reprocessing method, records of each batch of dialyzers processed must include an indicator, such as an automated time/temperature recording log, that the dialyzers were exposed to the appropriate temperature for the time required. If a chemical, such as citric acid, is used to enhance heat disinfection, a presence test for citric acid is also required before clinical use of the dialyzers. If an incubator or oven is used to raise the dialyzer storage temperatures, a recording thermometer should be in use to assure sufficient temperature is consistently maintained. Records should document that these devices functioned as expected.

FED - V0326 - REPROCESS RECORD COMPLETE/AVAILABLE TO PT

Title REPROCESS RECORD COMPLETE/AVAILABLE TO PT

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
4 Records 4.2 Reprocessing record: complete/available to patient Records shall be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the	Additional Guidance: A permanent record (paper or electronic) must be maintained to enable tracking each dialyzer's history and performance testing; information recorded on the dialyzer label must also be recorded either in a log or in the patient record, as the labels are discarded with the dialyzers.

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procedure, his or her signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a reprocessing log or the patient's chart, whichever is more convenient. Patients must be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers.

The record of reprocessing of the dialyzer is considered part of the patient's medical record, and must be kept separate from the dialyzer reprocessing records of other patients and not be combined into one document.

The systems in place must allow patients access to the record of use/reprocessing of their dialyzer while ensuring the privacy of the other patients' records.

FED - V0327 - HEMODIALYZER LABELING-UNIQUE TO PT

Title HEMODIALYZER LABELING-UNIQUE TO PT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

10 Hemodialyzer labeling: unique to patient
Each reprocessed hemodialyzer shall be used for only one patient. The labeling shall uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.

Interpretive Guideline

Additional Guidance:
There must be precautions in place to assure each dialyzer is used only for one patient. Each reprocessed dialyzer must have a permanently affixed label uniquely identifying the patient using that dialyzer. Each patient must always receive treatment on his/her own dialyzer and dialyzers must not be mis-matched to patients.

FED - V0328 - TIME LABELED-B4 OR 1ST USE, UPDATE EACH USE

Title TIME LABELED-B4 OR 1ST USE, UPDATE EACH USE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

10.1 Time of labeling: before or at first use, updated p each use
Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see AAMI 10.3).

Interpretive Guideline

Additional Guidance:
When a patient is provided a new dialyzer that is intended to be reprocessed, that dialyzer must be labeled with the patient's name before or at the first use. Dialyzers that are used without being labeled with the applicable patient's name must be discarded.

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FED - V0329 - LABEL COMPOSITION & PLACEMENT

Title LABEL COMPOSITION & PLACEMENT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

10.2 Label composition and placement
Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood or dialysate flow or other pertinent information unless provision is made for recording this information on the label. The label on hemodialyzers with transparent casings should permit the blood path to be readily inspected.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.10.2 Label composition
The AAMI RDD Committee initially recommended using indelible ink to label the dialyzer, but changed the recommendation to any method resistant to normal reprocessing and use procedures; other satisfactory materials exist, and requiring indelible ink might preclude some techniques, such as bar coding.

Additional Guidance:
Facility-applied labels must not obscure the pertinent information on the manufacturer's label and must leave at least a portion of the blood path uncovered to allow visualization of a section of the fibers from header to header.

FED - V0330 - INFORMATION REC ON LABEL/SIMILAR NAME WARN

Title INFORMATION REC ON LABEL/SIMILAR NAME WARN

Type Standard

CFR 494.50(b)(1)

Regulation Definition

10.3 Information recorded on label/similar name warning
The dialyzer shall be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with similar last names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.10.3 Information recorded
A proposal that the label contain all of the recommended information was rejected because space is limited on the label, and such extensive labeling is unnecessary. Displaying the number of previous uses on the label is recommended so that this information is readily available. Displaying the date of the last reprocessing facilitates verification that sufficient time has elapsed since the introduction of the germicide to achieve sterilization or disinfection.

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unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. If this information appears on the label, a permanent record should also be kept (see [AAMI] 4.2) Electronic records are acceptable. If records are electronic, the test results should be available to the user.

Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing.

Additional Guidance:
At a minimum, each dialyzer must be labeled with the patient's name, the number of previous uses, and the date and time of the last reprocessing.

For patients with similar names, a warning is necessary to alert staff and prevent dialyzer mix ups. Direct care staff must be knowledgeable of the method used to alert them about dialyzers of patients with same/similar names. Dialyzers in use must demonstrate use of warning labels if there are two or more patients with similar names on census.

Since the labels are discarded with the dialyzer, the information on the label must also be kept in a permanent record, which may be electronic. The record of reprocessing of the dialyzer is considered part of the patient's medical record.

FED - V0331 - REPROCESSING-TRANSPORTATION & HANDLING

Title REPROCESSING-TRANSPORTATION & HANDLING

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11 Reprocessing
11.1 Transportation and handling
Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.1 Transportation and handling
During the 2002 revision of this recommended practice, the AAMI RDD Committee recognized that the refrigeration temperature of the dialyzers stored for extended periods of time was not specified. It was decided to recommend that dialyzers not reprocessed within 2 hours should be refrigerated and not allowed to freeze. The AAMI RDD Committee believed that this was sufficient to retard bacterial growth.

Additional Guidance:
Personnel should wear appropriate PPE to handle used dialyzers until reprocessing is complete. The infection control recommendations from the Centers for Disease Control and Prevention for transporting dialyzers include the following: "For dialyzers and blood tubing that will be reprocessed, cap dialyzer ports and clamp tubing. Place all used dialyzers and tubing in leakproof containers for transport from station to reprocessing or disposal area." This requirement would be considered met if the tubing is disposed of at the patient's chairside directly into a waste receptacle and all the ports on the dialyzer are immediately capped.

All dialyzer ports should be capped when the dialyzer is not in use or not being currently reprocessed, to prevent

spills of blood or blood products, leakage of germicide, and entrance of air into the dialyzer. If used dialyzers are transported in a common carrier (e.g., a basket) the potential for cross-contamination must be eliminated (i.e. exteriors must be free of visible blood and all ports capped or each dialyzer contained in a sealed bag).

If used dialyzers are refrigerated prior to reprocessing, facility policy must define and personnel must be aware of maximum refrigeration times, temperature ranges, and quality controls in place to assure the practice is safe.

Practices such as allowing dialyzers to remain at room temperature for prolonged periods during the reprocessing process (e.g., after rinsing and prior to filling the dialyzer with germicide) must be validated to ensure patient safety is not impacted.

If dialyzers are sent to an off-site location for reprocessing, the survey process must include a visit to that site to determine compliance with this and all other reprocessing requirements.

FED - V0332 - RINSE/CLEAN-PRECLEAN EQUIP/PRESSURES

Title RINSE/CLEAN-PRECLEAN EQUIP/PRESSURES

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.2 Rinsing/cleaning: precleaning equipment/pressures
11.2.1 When precleaning is done, it is part of the reprocessing procedures. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for precleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to.

Interpretive Guideline

ANSI/AAMI RD47:2002/A1:2003
11.2.1 Rinsing/cleaning
Many facilities preclean dialyzers. This process is typically accomplished with an apparatus developed by users and is intended to remove gross deposits of blood and products before rinsing and cleaning with a reprocessing machine or device.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.2.1 Rinsing/cleaning
Aqueous liquids rather than gases such as air are the preferred fluid for rinsing and cleaning.

Additional Guidance:
Maximum pressures allowed during reprocessing will be defined in the dialyzer manufacturer ' s directions for use (DFU). Use of higher pressures may cause breaks in the dialyzer fibers and potential blood leaks. A pressure gauge must be in place to monitor the pressure of the treated water source used for rinsing the used dialyzers, and the

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maximum limits of the pressure to be used must be defined and known to the operator.

Use V315 if there is no pressure gauge in the water line at the rinse sink; use this tag if the manufacturer ' s specified pressures are exceeded.

FED - V0333 - RINSING/CLEANING-USE AAMI QUALITY H20

Title RINSING/CLEANING-USE AAMI QUALITY H20

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
11.2 Rinsing/cleaning: use AAMI quality water 11.2.3 Precleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the requirements of these regulations related to allowable bacterial and endotoxin levels.	Additional Guidance: All water that is used in rinsing and reprocessing the interior of the dialyzer must meet the requirements of AAMI RD52:2004 related to the allowable bacterial and endotoxin levels. Refer to V178. The interior of the dialyzer should never be exposed to tap water. The facility must monitor the water supply to the reprocessing station(s) for bacteria and endotoxins.

FED - V0334 - DIALYZER HEADER CLEANING & DISINFECTION

Title DIALYZER HEADER CLEANING & DISINFECTION

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
11.4.1.2 Dialyzer header cleaning and disinfection The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and O-rings shall be kept with their respective dialyzers. If the header cap is removed to clean the header space,	ANSI/AAMI RD47:2002 11.4.1.2 Dialyzer header cleaning and disinfection Over tightening the header caps may cause damage to the cap, and under tightening the cap may cause blood leaks. AAMI Rationale for the Development and Provisions of this Recommended Practice A.11.4.1.2 Dialyzer header cleaning and disinfection The practice of header removal to remove clotted material has increased over the years. Removing the header allows the user to remove the clotted material from the end of the fiber bundle and the O-ring header assembly. The method

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cleaning shall be done with water meeting the requirements of these regulations related to allowable bacterial and endotoxin levels.

Once the O-ring and the header cap are cleaned and before they are reassembled at the end of the dialyzer, they should be disinfected. The disinfectant shall not be rinsed and shall be allowed to remain on the dialyzer components as they are reassembled. If any cracking of the header occurs, the process should be evaluated.

If the header space is cleaned with the header cap in place, it is necessary to ensure that the end of the fiber bundle is not damaged. If water is used, it shall meet the requirements of these regulations.

If automated equipment is used, the manufacturer's instruction for use shall be followed.

of removal of the clotted material has been of concern. Some facilities use running water (AAMI quality) to remove the clotted material, whereas others use 4x4s or instruments to scrape away the clotted material. The main concerns of using 4x4s or instruments to scrape away the clotted material are (1) infection, (2) plugging of fibers, and (3) damage to the end of the fiber bundle.

In the past, removing the headers was associated with reported incidents of bacterial and pyrogenic reactions in patients. The patient reactions no longer occurred when the headers were disinfected by dipping the O-ring, header, and end of the dialyzer into the appropriate disinfectant. The research on this problem pointed to a double-fault failure system: 1) the bacteria seemed to be coming from a contaminated water source, and 2) the bacteria were not killed by the normal disinfection process. Dipping the dialyzer corrected that situation.

Several concerns are raised when the headers are not removed and the user attempts to clear the header space of clots. These concerns include infection and damage to the end of the fiber bundle. A multitude of items are used to clean the header space, including water sprays, paper clips, tie wraps, and the like. With water sprays, the possibility of contaminated water always exists. Other items that are inserted can damage the end of the fiber bundle. If the item inserted into the dialyzer is not disinfected between uses, it can cause bacterial transmission; however, the dialyzer is usually disinfected after the header space is cleaned. Automated header cleaning devices are commercially available.

Additional Guidance:
According to the Centers for Disease Control and Prevention (CDC), if the ends of the dialyzer (header caps) are removed for cleaning, only a stream of AAMI quality water may be used to clean blood clots, etc. from the exposed ends and the header caps of dialyzers.

If the header caps are removed during reprocessing, facility staff must ensure that the caps, O-rings, and the ends of the dialyzer are immersed or saturated with germicide prior to reassembly, and that the components are reassembled wet with germicide. Cleaning of header caps and dialyzer ends must be closely audited for any breaks in technique which could put the patient at risk.

FED - V0335 - RINSE/CLEAN-CHEM USED/RINSE AFTER EACH

Title RINSE/CLEAN-CHEM USED/RINSE AFTER EACH

Type Standard

CFR 494.50(b)(1)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

11.2 Rinsing/cleaning: chemicals used/rinse after each
11.2.4 Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, or other chemicals may be used as cleaning agents for the blood compartment, provided that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and has no significant adverse effects on the structural integrity and performance of the dialyzer.

Each chemical shall be rinsed from the dialyzer before the next chemical is added, unless mixing is known to be safe and effective for reprocessing.

Interpretive Guideline

11.2 Rinsing/cleaning
11.2.4 A cleaning agent, such as sodium hypochlorite, shall be rinsed from the dialyzer before adding formaldehyde in order to avoid noxious fumes and degradation of disinfectant. Combining sodium hypochlorite and peracetic acid may produce hydrochloric acid vapors, which are harmful if inhaled.

Additional Guidance:
While one chemical may be used as a cleaning agent and a second chemical used as a germicide, the first chemical must be rinsed from the dialyzer before the next chemical is added, unless it has been demonstrated that mixing of the two chemicals is safe and effective. Allowing chemicals to mix may risk unexpected reactions that could lead to staff injury or damage to the structural integrity and performance of the dialyzer. If bleach is used as a cleaning agent, a procedure must be in effect to limit the time the dialyzer may be exposed to bleach, as prolonged exposure may damage the dialyzer membrane.

FED - V0336 - TCV MEASURED Q USE/ORIG VOL KNOWN

Title TCV MEASURED Q USE/ORIG VOL KNOWN

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.3 Performance measurements
11.3.1 Performance test after each use: TCV measured after q use/original volume known
Total cell volume (TCV) may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80% of the original TCV. The dialyzer prescription should take into account the 10% loss in clearance (20% loss in TCV) that may occur with dialyzer reuse.

Interpretive Guideline

ANSI/AAMI RD47:2002/A1:2003
11.3 Performance measurements
The performance characteristics of dialyzers may change following reprocessing. The ultrafiltration coefficient may increase or decrease. Clearances of small or large molecular weight solutes may also increase or decrease depending on the chemicals, methods, and dialyzer membrane used. The dialyzer labeling and medical literature should be consulted for information related to changes in in vitro and in vivo performance.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.3 Performance measurements
The essential function of the hemodialyzer is mass transfer adequate to provide the prescribed care to the patient. Change in TCV has been documented in the medical literature as an indirect measurement having a close relationship to the retained mass transfer of small molecules by the hemodialyzer, and may be used for the routine test of residual dialyzer performance.

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A.11.3.1 Performance test after each use
Clearance, a measure of the solute transport of the hemodialyzer, should be maintained within acceptable limits to ensure that dialysis is adequate to prevent uremic complications. Although direct clearance measurements could be used to demonstrate compliance with the ± 10% change in urea clearance, determining the urea clearance for each dialyzer reprocessed is impractical. There are also indirect tests that reflect the mass transfer characteristics of a dialyzer, which may be used in lieu of clearance measurements. A change in the residual TCV of hollow-fiber hemodialyzers is the most widely used indirect test for changes in small molecule clearance. This method has been shown to be a good index to monitor the solute transport capacity of the reprocessed hollow-fiber hemodialyzer. The volume of a hollow-fiber hemodialyzer (TCV) is readily measured in the clinical setting. When methods of reprocessing are used that do not cause a significant change in the permeability or geometry of the membrane, a loss of TCV of 20% corresponds to a loss of urea clearance of less than 10%. Volume change is recommended as a QC test only for hollow-fiber hemodialyzers because other hemodialyzer geometries do not have the relatively noncompliant blood compartment necessary for the validity of this measurement in predicting solute transport.

The AAMI RDD Committee recognized that other factors can influence the effective clearance of toxins during the dialysis session or can influence interpretation of the results. These factors include the following:
a) Fistula recirculation;
b) Accurate blood and dialysate flow rates;
c) Accurate time of dialysis;
d) Compliance with dietary limitations;
e) Selection of appropriate hemodialyzer type and blood and dialysate flow rates;
f) Membrane surface coating that may affect higher molecular weight toxins;
g) Variations in the original clearance of the hemodialyzer;
h) Variations in the clearance of the hemodialyzer caused by reuse.

Users should be aware that the HEMO Study in 1999 identified reductions as well as increases in the clearance of ß2 microglobulin with the use of certain combinations of dialyzers, cleaning agents, and reuse germicides.

Of particular concern to the AAMI RDD Committee were any variations in hemodialyzer functions related to reuse procedures. Although cases have been documented, they are rare, especially when compared to the frequency of other factors listed above. For this reason, the AAMI RDD Committee strongly felt that the monitoring requirements of AAMI section 13 are of great importance to use in conjunction with the individual hemodialyzer measurements recommended in AAMI 11.3.

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Additional Guidance:
Every dialyzer expected to be reprocessed must have its original total cell volume (TCV) measured prior to the first use. "Dry pack" dialyzers, i.e., dialyzers used without preprocessing, must be discarded and not reprocessed. Refer to the Measures Assessment Tool (MAT) for this current community-accepted standard.

All staff who reprocess or reuse dialyzers must demonstrate understanding that a drop in TCV to less than 80% of the dialyzer ' s original volume requires discard of that dialyzer, to prevent that patient from receiving a less than adequate treatment. Staff must also be aware of other criteria dialyzers must meet for continued reuse (e.g., limit on number of times a dialyzer may be reused, reasons for discard).

If a manual reprocessing system is in use, the graduated cylinder used for measuring TCV must be emptied completely between uses and placed on a level surface to be read. The reading should be made at eye level, and the operator should have charts available to use in determining whether the remaining volume is sufficient (at least 80% of original volume) to continue using that dialyzer.

For automated systems, a system must be in use to validate that the volume measurements are accurate.

FED - V0337 - BLOOD PATH INTEGRITY TEST AFTER Q USE

Title BLOOD PATH INTEGRITY TEST AFTER Q USE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.3.3 Blood path integrity test after q use
A membrane integrity test such as an air pressure leak test shall be done between uses.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.3.3 Blood path integrity test
The 1986 edition of the AAMI recommended practice did not include a blood path integrity test. Because of recommendations by the Centers for Disease Control and Prevention (CDC), the AAMI RDD Committee agreed to add such a test to the second edition of the recommended practice. This test is based on the observation that only a small amount of air leaks through wetted membranes, resulting in a pressure drop of less than 10% of the test pressure. A maximum allowable pressure drop is not given because of variations among test systems and dialyzers.

Additional Guidance:
Recognize that manual reprocessing systems may require each dialyzer be tested separately. Automated systems must include the pressure leak test in the program selected.

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FED - V0338 - GERMICIDE-SUFFICIENT FOR POINT OF USE

Title GERMICIDE-SUFFICIENT FOR POINT OF USE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.4 Germicide: sufficient for point of use
The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device. The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.

Interpretive Guideline

11.4 Germicide: sufficient for point of use
The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device. The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.

FED - V0339 - GERM PROCESS=HIGH-LEVEL DISINFECT

Title GERM PROCESS=HIGH-LEVEL DISINFECT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.4.1 Interior (blood/dialysate compartment)
11.4.1.1 Germicidal process: high-level disinfection achieved
Chemical germicides or other procedures used for disinfecting of hemodialyzers shall have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms.

Interpretive Guideline

11.4.1 Interior (blood/dialysate compartment)
11.4.1.1 Germicidal process
If formaldehyde is used as the sole germicidal agent, the CDC recommends that a concentration of 4% (W/V) be used in both the blood and dialysate compartments with a minimum contact time of 24 hours at a temperature of at least 20° C; lower concentrations or shorter contact times are appropriate if equivalent results can be demonstrated under other conditions. Formaldehyde used for reprocessing dialyzers shall not be cloudy. Concentrated formaldehyde

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If the germicide has an expiration date from the manufacturer, staff members should be sure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If this is the case, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins.

The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see AAMI 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde.

stored under adverse conditions can polymerize to formparaformaldehyde, a white precipitate. Formaldehyde should be of United States Pharmacopoeia (USP) standards or better quality. When other germicides are used, the manufacturer's instructions should be followed. If maximum storage temperature limitations exist, records should be maintained to document this criterion.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.4.1.1 Germicidal process
Unfortunately, no realistic procedure exists whereby a dialysis center can monitor the effectiveness of the disinfection procedure. Such sophisticated microbiologic tests cannot be performed in dialysis centers, because the tests require the use of specialized equipment and highly-trained microbiologists. Instead, a center should adhere rigidly to established protocols for QC and QA. Tests for total bacteria and endotoxin in the water used to make up the germicide should be conducted at least monthly. If there are problems in maintaining water quality at the level established by ANSI/AAMI RD62:2001, Water treatment equipment for hemodialysis applications, (referenced in RD52:2004) the testing may need to be performed more frequently. Testing the germicide's final-use concentration should be a part of the center's QC program as well as verifying that each dialyzer was filled with germicide.

Potency testing of each batch of germicide is specifically recommended for batches of manually-prepared germicides regardless of whether they are used with a manual or an automated system. Germicide solutions that are diluted on-line by automated machines are to be checked for concentration at least monthly. Other requirements for verification of germicide presence are contained in section 12.

CMS requires (at 42 CFR §494.50) that dialyzers not be subjected to multiple germicide solutions because of possible combined actions of the germicides on the hemodialyzer membrane. This requirement does not apply to the original sterilization process or chemical cleaning agents that the hemodialyzer might be exposed to for short periods during the cleaning process for reuse.

Additional Guidance:
The reuse staff must be knowledgeable about the germicide used and the risks this germicide presents to him/her and to the patients. Containers of germicide should be dated to indicate dilution and discard dates.

FED - V0340 - DIALYZER GERM=90% CONC/CAPS DISINFECT

Title DIALYZER GERM=90% CONC/CAPS DISINFECT

Type Standard

CFR 494.50(b)(1)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

11.4.1.4 Chemical germicidal procedure: = 90% conc/port caps disinfected
If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration.

The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer.

Interpretive Guideline

Additional Guidance:
If a manual reprocessing system is in use, the blood and dialysate compartments must be filled with a volume of germicide equal to three times the total volume of the blood and dialysate compartments of the dialyzer (to equal three compartment volumes) in order to reach at least 90% of the prescribed germicide concentration. Reuse logs must include documentation of verification of the desired (prescribed) concentration of germicide.

Used and new port caps must be disinfected prior to use. The reuse technician should be knowledgeable about the minimum germicide contact time required for port cap disinfection.

FED - V0341 - CHEMICAL GERM CONC-VERIFICATION TESTING

Title CHEMICAL GERM CONC-VERIFICATION TESTING

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.4.1.6 Chemical germicide concentration: verification testing
Reprocessing systems in which each batch of germicide is manually prepared, each batch of germicide shall be tested before use to verify the proper concentration of the germicide. This requirement does not apply in cases in which each dialyzer is tested for concentration before setup.

When the germicide is diluted on-line, its concentration in the hemodialyzer immediately after reprocessing should be checked at least monthly for each reprocessing system.

When the germicide is partially or fully diluted by the user, ...

Interpretive Guideline

Additional Guidance:
The system in use must include verification of germicide concentration in the dialyzers after reprocessing.

If the germicide is diluted by the user (batch), the germicide manufacturer's instructions for dilution must be followed, and the solution thoroughly mixed before use. If each dialyzer is tested for germicide concentration prior to rinsing, it is not necessary to test the germicide concentration before use of the batch.

If the germicide is diluted on-line, the concentration in a dialyzer from each reprocessing system must be checked immediately after reprocessing at least monthly.

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the solution [should] be thoroughly mixed.

FED - V0342 - DIALYZER EXTERIOR-LOW-LEVEL DISINFECTION

Title DIALYZER EXTERIOR-LOW-LEVEL DISINFECTION

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.4.2 Exterior: low-level disinfection
The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material. For chemically disinfected dialyzers, a low-level germicide that is compatible with the dialyzer's materials of construction should be used for this purpose.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.4.2 Exterior
Sodium hypochlorite at a concentration of 0.05% is usually suitable for external cleaning. Certain commercial low-level disinfectants may cause some plastics used for dialyzers to crack after repeated or prolonged exposure.

Low-level germicides satisfactorily clean the exterior of the device to a degree comparable with what a new dialyzer receives. For example, 1:100 dilution of household bleach will achieve the concentration of sodium hypochlorite specified here.

Additional Guidance:
The exterior of each dialyzer must be cleaned after reprocessing steps are complete. Spraying the dialyzer with germicide is generally unsatisfactory, unless all the surfaces of the dialyzer are covered with the spray. Dialyzers may be dipped or allowed to soak in a germicide solution, or wiped with a disposable cloth saturated with a germicide solution.

FED - V0343 - DIALYZER INSPECT P REPROCESS-ALL ASPECTS

Title DIALYZER INSPECT P REPROCESS-ALL ASPECTS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.5 Inspection: after reprocessing: all aspects/aesthetics
The hemodialyzer shall be examined after reprocessing to

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.5 Inspection

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ensure that the external surface is clean, the dialyzer is not damaged, and the rinsing of blood has been satisfactorily completed. The dialyzer should also be aesthetically acceptable in appearance to patients and staff.

11.5.1
The dialyzer jacket should be free of visible blood or other foreign material.
11.5.2
There shall be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports.
11.5.3
No more than a few dark, clotted fibers should be evident on inspection of the exterior of the hollow fibers.
11.5.4
The headers of hollow-fiber dialyzers should be free of all but small peripheral clots or other deposits.
11.5.5
Blood and dialysate ports shall be capped without evidence of leakage.
11.5.6
The label shall be properly filled out and legible.

The AAMI RDD Committee considered a recommendation not to accept hemodialyzers with visible clots because venous filters are not used for all hemodialyzer circuits, leading to the risk of embolization to the patient if a clot were to break loose. The AAMI RDD Committee decided to reject this proposal because the allowable clots are required to be small and in stagnant areas that are present during the first use of the hemodialyzer and because there is no evidence of embolization from reprocessed hemodialyzers that meet this criterion.

A proposal that the number of dark, clotted fibers evident upon external inspection be limited to five was not accepted because a considerably larger number may be clotted without significant adverse effect on performance and because some authorities do not agree that this criterion is essential to an aesthetically pleasing appearance. A recommendation that hemodialyzers with a pink or brownish tint not be acceptable was also deleted because this condition is difficult to define and because glutaraldehyde disinfection results in a slight tan color of the membranes that has not been shown to impair the safety or performance of the hemodialyzer.

FED - V0344 - DISPOSITION OF REJECTED DIALYZERS

Title DISPOSITION OF REJECTED DIALYZERS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11.6 Disposition of rejected dialyzers
Reprocessed dialyzers that have been rejected for failure to meet performance, inspection, or other release criteria should either be immediately discarded or further reprocessed and subjected to the performance requirements of [AAMI] 11.3,

Interpretive Guideline

Additional Guidance:
The status of all dialyzers being reprocessed must be clear. If facility policy allows dialyzers which initially fail criteria to be repeatedly reprocessed, or if dialyzers which have failed are not immediately discarded, the status of those "failed" dialyzers must be clearly indicated.

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11.4, and 11.5. If the dialyzer is to be further reprocessed, rather than discarded, it shall be labeled as rejected and stored in a quarantine area to preclude use until requirements are met.

FED - V0345 - REPROCESSED DIALYZER STORAGE

Title REPROCESSED DIALYZER STORAGE

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
11.7 Storage: reprocessed dialyzer Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of [AAMI] 8.2. Prolonged storage (greater than 1 month) should be documented to be safe and effective. Dialyzers that have exceeded the facility's maximum storage time shall be reprocessed or discarded. The dialyzer and disinfectant labeling should be consulted regarding proper storage conditions.	AAMI Rationale for the Development and Provisions of this Recommended Practice A.11.7 Storage The AAMI RDD Committee acknowledged that the selection of 1 month as the maximum storage period permitted without validation was arbitrary. They were, however, unaware of any adverse effects of storage for up to 1 month and, therefore, felt that this period of time was reasonable. Additional Guidance: There might be occasions when reprocessed dialyzers are stored for extended periods of time, such as when patients are absent (e.g. hospitalized, vacation). There must be a system for ensuring dialyzers are not stored longer (without reprocessing) than the maximum time limit specified by the germicide manufacturer and facility policy.

FED - V0346 - PREP 4 DIALYSIS-WRITTEN P&PS FOR GERM TEST

Title PREP 4 DIALYSIS-WRITTEN P&PS FOR GERM TEST

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues A written procedure that has been shown to be effective shall	AAMI Rationale for the Development and Provisions of this Recommended Practice A.12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues When the AAMI RDD Committee revised RD:47 in 2002, it decided that there was sufficient information available to

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be followed.

12.5 Written procedure for tests for germicide or other residues
There shall be a written procedure for all tests employed in preparing the dialyzer for use, including mention of each test's sensitivity. The germicide manufacturer's instructions for use should be consulted in determining the maximum residual level. The physician in charge of the reuse program shall approve any alterations in the procedures.

indicate that the residual level of formaldehyde should be reduced to less than 3 ppm. The testing technology for residual formaldehyde had also improved, and it was feasible to easily test to less than 3 ppm.

The AAMI RDD Committee considered establishing maximum residual levels for germicides other than formaldehyde. Because these newer germicides are all cleared by the FDA and could have different allowable levels of residuals even for the same generic type of germicide, they determined that it is best to recommend that the manufacturer ' s instructions for use be followed. The AAMI RDD Committee noted that toxicology studies are favorable for some of these agents, and the FDA reviews labeling information for them, which includes the maximum residual level.

When checking for the presence or concentration of the germicide in the hemodialyzer, do not place anything into the blood or dialysate ports of the device (e.g., test strip or syringe) to withdraw the sample. Doing so may damage the fibers of the dialyzer and lead to blood leaks during dialysis. If a germicide test strip or kit is being used, the instructions provided by the manufacturer should be followed.

Additional Guidance:
The reagents used for the germicide tests must be sensitive to the levels specified by the germicide manufacturer (i.e. high level for presence test, low level for residual test).

FED - V0347 - PREP 4 DIALYSIS-VISUAL INSPECT-ALL ASPECTS

Title PREP 4 DIALYSIS-VISUAL INSPECT-ALL ASPECTS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.1 Visual inspection: prep for dialysis; all aspects
The dialyzer should be inspected before it is prepared for use. Completion of this inspection should be recorded in the reprocessing record (see [AAMI] 4.2), along with the signature or other unique means of identifying the person completing the inspection. The inspection should include the following:
a) The reprocessed dialyzer shall be legibly labeled with the information recommended in [AAMI] 10.3.

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.5 Inspection
The AAMI RDD Committee recognized that the patient should be included in the aesthetic evaluation of the hemodialyzer.

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b) There should be no indication of structural damage or tampering with the dialyzer.
c) The ports of the dialyzer should be properly capped.
d) The presence of germicide in the dialysate and blood compartments, including headers, should be confirmed, and there should be no evidence of leakage from the ports or other portions of the dialyzer.
e) The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; and
f) The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient.

FED - V0348 - VERIFY PT ID-2 PEOPLE

Title VERIFY PT ID-2 PEOPLE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.2 Verification of patient identification: 2 people
Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be recorded, along with the signature or other unique means of identifying the person verifying patient identification.

NOTE-This step may be done later in the procedure but shall precede initiation of dialysis.

Interpretive Guideline

Additional Guidance:
Standard of practice requires the final check be done when the patient is present for that treatment. If possible, patients should be encouraged to check their dialyzers for their names. Patients who sign the treatment record for this item should understand what their signature means. If patients are unable to identify their dialyzers, two staff should do so and record the verification prior to initiating the dialysis. Note that some facility policies require two staff to verify patient/dialyzer identification for all reused dialyzers.

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FED - V0349 - VERIFY OF GERMICIDAL CONTACT

Title VERIFY OF GERMICIDAL CONTACT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.3 Verification of germicidal contact
The contact time of the germicide or disinfection procedure shall comply with the facility's protocol and the manufacturer's recommendations.
The presence of chemical germicide in each hemodialyzer shall be ensured through either direct testing or an on-line process and procedural control.
If other disinfection (e.g., heat) procedures are used, there shall be methods to ensure that each hemodialyzer has been properly subjected to the disinfection process.
A record shall be kept indicating that the dialyzer has undergone the appropriate storage time, and the record shall be appropriately verified.

Interpretive Guideline

Additional Guidance:
Staff must be able to determine the date and time of each dialyzer's last reprocessing. Responsible staff (e.g., reuse technician, direct care staff) must ensure the dialyzers have been exposed to the germicide for the required contact time before set up and use.

For systems using heat disinfection, staff must verify the dialyzer was exposed to the appropriate temperature for the required time period to assure disinfection.

FED - V0350 - GERMICIDE PRESENCE TEST OF EACH DIALYZER

Title GERMICIDE PRESENCE TEST OF EACH DIALYZER

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.3.1 Presence test of each hemodialyzer
Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.

Interpretive Guideline

Additional Guidance:
Manufacturers of peracetic acid and glutaraldehyde require every dialyzer be tested for presence of a sufficient concentration of germicide after storage and before use.

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The test for germicide presence (at the potency recommended by the germicide manufacturer) should be done before rinsing and priming.

FED - V0351 - GERMICIDE PRESENCE-PROCESS CONTROL/SAMPLE

Title GERMICIDE PRESENCE-PROCESS CONTROL/SAMPLE

Type Standard

CFR 494.50(B)(1)

Regulation Definition

12.3.2 Process control and sampling: germicide presence
[If a germicide manufacturer does not require testing each hemodialyzer for the presence of germicide], the presence of germicide may be ensured by [either] a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide.

12.3.2.1 Process control
a) Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or
b) Use an indicator substance (e.g., FD&C Blue #1), which has been added to the germicide, and that reliably indicates the presence of germicide. If blue dye is used, it should be added to the germicide concentrate before dilution, not to the fully diluted solution.

Interpretive Guideline

ANSI/AAMI RD47:2002/A1:2003
12.3.2.1 Process control
Note that use of dye may be inappropriate with certain germicides such as peracetic acid.

12.3.2.2 Sampling for process validation
NOTE-The requirements of this section are fulfilled if every dialyzer is subjected to post-storage/pre-priming direct presence testing.

Additional Guidance:
This tag refer to procedures which may be used to validate that dialyzers, reprocessed with germicides that don't require presence testing of each dialyzer, are adequately disinfected and safe for use. If each dialyzer is not tested for germicide presence, procedures for both process control and testing a sample of dialyzers for germicide concentration are required.

For certain germicides, the facility may use a blue dye (as process control) to indicate the presence of germicide in the dialyzers. The absence of blue coloring must not be used as an indicator of the absence of germicide. Any process control procedure must be used in conjunction with a procedure for testing a sampling of dialyzers as described at this tag.

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FED - V0352 - DIALYZER PRIMING/RINSING THE GERMICIDE

Title DIALYZER PRIMING/RINSING THE GERMICIDE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.4 Priming the dialyzer and rinsing the germicide
If the manufacturer's instructions so require, a germicide presence test shall be performed before the germicide is rinsed from the dialyzer.

The dialyzer shall be rinsed and primed according to a written procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and result in a physiological solution in the blood and dialysate compartments. The dialyzer manufacturer ' s instructions should be considered in developing these procedures.

Interpretive Guideline

Additional Guidance:
The dialyzer rinsing/priming and preparation for use procedures followed must be in accordance with the dialyzer manufacturer's requirements for the germicide in use

FED - V0353 - TEST FOR RESID GERM/MAX TIME RINSE TO USE

Title TEST FOR RESID GERM/MAX TIME RINSE TO USE

Type Standard

CFR 494.50(b)(1)

Regulation Definition

12.4.1 Testing for residual germicide: max time rinsed to use
Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure to ensure that the germicide level is below the maximum recommended residual concentration. Completion of this step shall be documented, along with the signature or other unique means of identifying

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.12.4.1 Testing for residual germicide
Germicides have been demonstrated to disperse into the solid components of the hemodialyzer.

A number of procedural steps have been identified that, if not followed, may cause residual germicide to remain in the hemodialyzer following rinsing. The following list of instructions, though not all inclusive, have been developed by

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the person performing the test.

A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. The priming, removal, and residual testing process should be reinstituted after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis.

A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it.

If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline.

AAMI to help facilities develop facility ' s rinsing procedure.
a) Air bubbles in the fibers can cause individual fibers to become blocked. Be sure that the arterial line is fully primed before it is connected to the hemodialyzer. If using peracetic acid-type germicide, the blood side should be flushed before beginning dialysate flow.
b) Air trapped in the dialysate side of the hemodialyzer may cause germicide to also remain trapped in portions of the hemodialyzer. The dialyzer should be rotated during the rinsing process. This action normally will release the trapped air and allow the germicide to be fully rinsed.
c) Germicide may back up into the heparin or monitor lines. The heparin line must be clamped so that fluid is not forced into the monitor lines.
d) Germicide may back up into the saline bag during the rinsing procedure. Procedures for initiation of treatment must account for all situations that may force fluid from the dialysis circuit back into the saline bag.
e) Sampling too quickly after a quantity of saline has been infused may result in a false negative residual disinfection test.
f) The prime solution should be discarded when beginning blood flow to the hemodialyzer.

Additional Guidance:
If the extracorporeal circuit is prepared ahead of time, staff must repeat the residual germicide test just prior to treatment initiation to allow detection of any "rebound" of germicide. This is particularly a concern if fluid circulation through the circuit and dialyzer is stopped, as may happen when a patient is late coming to treatment.

If facility practice is to discard the priming solution by "bleeding patients on," policy and practice must reflect a requirement that a staff member constantly attend that patient while the venous line is open as blood fills the extracorporeal circuit, to prevent accidental blood loss.

Generally, manufacturers of dialyzers labeled for reuse address the need to discard the prime solution by advising users to replace the saline bag used for priming and refresh all fluid in the extracorporeal circuit with saline from the new bag prior to beginning patient treatment.

FED - V0354 - MONITOR-DIALYSIS/PT'S CLINICAL COURSE

Title MONITOR-DIALYSIS/PT'S CLINICAL COURSE

Type Standard

CFR 494.50(b)(1)

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Regulation Definition

13 Monitoring
13.1 Dialysis: patient's clinical course
The clinical course of the patient should be observed and recorded during each dialysis to identify possible complications caused by new or reprocessed dialyzers. Dialyzer failures should be recorded and systematically evaluated. Applicable home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.

Interpretive Guideline

Additional Guidance:
Adequacy, fluid removal, anemia management and patterns of infection may be related to poor reprocessing practices. If reuse is being done for home patients, which is rare, those patients or their dialysis helpers must be instructed in and fully cognizant of their responsibilities for reuse.

FED - V0355 - MONITORING-FEVER/CHILLS/OTHER SYMPTOMS

Title MONITORING-FEVER/CHILLS/OTHER SYMPTOMS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

13.2 Symptoms
13.2.1 Fever and chills: other symptoms
Patients' temperatures should be measured and recorded at least before and after dialysis with new and reprocessed dialyzers. A temperature of over 37.8° C or 100° F, taken orally, or chills should be reported to the physician, [advanced practice registered nurse or physician assistant]. Any patient with an unexplained fever and/or chills should be evaluated for the possibility of a pre-existing infection (e.g., [at an] access site). The dialysis procedure should also be evaluated to rule out the use of contaminated water, errors in treatment delivery, or incorrect dialyzer reprocessing.

13.2.2 Other symptoms
Other unexplained symptoms such as pain in the blood-access arm at the onset of dialysis should be evaluated by the

Interpretive Guideline

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.13.2 Symptoms
Evaluation by a physician is required to determine whether symptoms might constitute an adverse reaction to the reprocessed dialyzer because symptoms during dialysis are commonly the result of other factors, such as infections not attributable to dialysis, and to hypovolemia. First-use syndrome is a symptom complex characterized by nervousness, chest pain, back pain, palpitations, pruritus, and other usually mild symptoms, occurring minutes following the initiation of dialysis with a new dialyzer. The syndrome is defined by some authorities to include the anaphylactoid reaction occurring usually immediately after the initiation of dialysis in some patients using dialyzers sterilized with ethylene oxide. In addition to first-use syndrome, serious reactions have been reported in patients taking ACE inhibitors and dialyzed on certain synthetic membranes. This reaction is now known to involve increased bradykinin release accompanied by suppression of bradykinin degradation.

Additional Guidance:
Physicians or non-physician practitioners (i.e., advanced practice registered nurses or physician assistants) functioning in lieu of physicians are responsible to evaluate the symptoms discussed in this regulation. Patient temperatures must be checked pre and post treatment, and signs of infection must be evaluated for any potential

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physician, [advanced practice registered nurse or physician assistant] and consideration given to the possibility that the symptom may be attributed to residual disinfectant in the new or reprocessed dialyzer or contamination of the water treatment equipment. Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and a test for residual germicide (see [AAMI] 12.4.1).

relationship to reprocessing/reuse.

One of the symptoms of germicide infusion is severe pain and burning in the patient's vascular access. Patients may interpret pain in the vascular access at the onset of dialysis as pertaining to needle insertion pain.

FED - V0356 - RECORD ADV EVENTS/DIALYZER C/O LOG

Title RECORD ADV EVENTS/DIALYZER C/O LOG

Type Standard

CFR 494.50(b)(1)

Regulation Definition

13.2.3 Recording: adverse events dialyzer complaint log
Any significant events such as the occurrence of symptoms listed in [AAMI] 13.2.1 and 13.2.2 should be recorded on an incident report form which would include the results of any evaluations conducted by the physician and others, and the event should be considered for reporting to the manufacturer(s) in accordance with the FDA's Medical Device User Reporting procedures. The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated. This form should be kept in the complaint investigation record file (see [AAMI] 4.5).

4 Records
4.5 Complaint investigation record
Records shall be kept of all complaints by patients and staff members about failures of preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken. The records shall be reviewed periodically for trends of

Interpretive Guideline

Additional Guidance:
In dialyzer reprocessing, the term "complaint" refers to deviations from expected outcomes (e.g. dialyzer failures, patient reactions, blood leaks), as well as to patient complaints related to reused dialyzers.

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.

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adverse reactions. Compliance with the FDA's Medical Device User Reporting procedures shall be demonstrated.

FED - V0357 - DIALYZER FAILURES/BLOOD LEAKS RECORDED

Title DIALYZER FAILURES/BLOOD LEAKS RECORDED

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
13.3 Dialyzer failures: blood leaks recorded Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file (see [AAMI] 4.5). If there is excessive deviation from the expected performance, testing should be repeated (see [AAMI] 11.3.1) and appropriate adjustments made in the reprocessing procedure.	Additional Guidance: The complaint investigation records should include reports of any blood leaks.

FED - V0358 - MONITORING-PT CLINICAL RESULTS/KT/V

Title MONITORING-PT CLINICAL RESULTS/KT/V

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
13.4 Clinical results: monitoring Kt/V Monitoring of relevant patient results is recommended to ensure that all parameters relating to hemodialyzer clearance are being met. Specifically, examination of urea reduction ratio (URR) or Kt/V over time is necessary. The failure of these results to meet the expectations of the dialysis prescription should be investigated. Deterioration of a patient's clinical condition or variability of routine dialysis procedures (heparinization, ultrafiltration, erythropoietin requirement)	AAMI Rationale for the Development and Provisions of this Recommended Practice A.13.4 Clinical results Critical assessment of chemistries and the delivered dose of dialysis (Kt/V or urea reduction ratio), as is done monthly, provides a clear trend line to assess treatment. This scrutiny of the patient ' s treatment and course is the primary confirmation that hemodialyzer performance anticipated from TCV or other indirect estimation is accurate and adequate. The overall effectiveness of the entire treatment, not only the clearance of the dialyzers, is measured. No other measure of the effectiveness of new or reused dialyzers is as clear or relevant. Trend lines developed from this data characterize the quality of therapy. If the practitioner has concerns for "middle molecules" or other clinical parameters, these factors should also be part of the assessment of the delivered therapy.

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requires investigation of all practices, including reuse. Reports of investigations should be filed in the complaint log.

There are many reasons for an apparent reduction in the mass transfer of urea, other than decreased hemodialyzer clearance as a result of inadequate reprocessing (such as recirculation, decreased dialysis time or blood flow rate, or an inappropriate dialysis prescription). To document adequate mass transfer parallel measurements of pre- and post-creatinine levels are helpful. When problems develop with any patient or group of patients, monitoring intensity should be increased, and other methods should be used to analyze the problem and define corrective action.

FED - V0359 - ULTRAFILTRATION-MONITORING PT-S WEIGHT

Title ULTRAFILTRATION-MONITORING PT-S WEIGHT

Type Standard

CFR 494.50(b)(1)

Regulation Definition

11 Reprocessing
11.3.2 Ultrafiltration: monitoring patient's weight
If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.

Interpretive Guideline

ANSI/AAMI RD47:2002/A1:2003
11.3.2 Ultrafiltration
In vitro ultrafiltration coefficients should not be used to predict in vivo results.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.3.2 Ultrafiltration
Ultrafiltration rate (UFR) is the flow rate of fluid that passes through the membrane under a given pressure gradient at a given temperature. It is the product of the ultrafiltration coefficient of the hemodialyzer (KUF) and the transmembrane pressure. The KUF, and thus the UFR at a given transmembrane pressure, may be affected by changes in the intrinsic permeability of the membrane, the surface area of the membrane, and the presence of hydraulically resistive deposits on the membrane. Cleaning agents, such as sodium hypochlorite, may affect the intrinsic water permeability of many types of dialysis membranes.

In vitro KUF is not recommended to predict in vivo ultrafiltration performance because the former overestimates the latter in hollow-fiber hemodialyzers. This difference occurs in part because of the additional hydraulic resistance of the formed elements and proteins in blood.

Additional Guidance:
Assessment for compliance with this requirement should find patients are weighed before and after each treatment. Missed weights should be rare and include an explanation for the weight not being obtained. Repeated entries of "unable to stand" should result in a change in the plan of care to allow determination of pre- and post-treatment

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weights.

FED - V0360 - QA-GENERAL/RECORDS/TREND ANALYSIS

Title QA-GENERAL/RECORDS/TREND ANALYSIS

Type Standard

CFR 494.50(b)(1)

Regulation Definition

14 Quality assurance: general/records/trend analysis
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. See Table 2 for a summary of the audit schedule.

14.1 Records
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.

Interpretive Guideline

ANSI/AAMI RD47:2002/A1:2003
It is the responsibility of all staff members to critically scrutinize all materials, practices, operations, and outcomes. Criteria that serve as the scale for evaluation may be drawn from local experience and practice relative to the specific activity under review, consensus documents such as AAMI guidelines or standards, aggregated regional or national data, or other accepted norms.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.14 Quality assurance
The FDA's 1987 compliance policy guide (7124.16) advises reuse practitioners to establish the following: (a) adequate device cleaning and sterilization; (b) the lack of adverse effects on device quality or physical characteristics; and (c) certainty that the device remains safe, reliable, and effective for its intended use. The AAMI RDD Committee believes that compliance with those recommendations necessitates use of regularly examined reprocessing procedures that are based on methods of demonstrated effectiveness and are carried out under conditions safe to the patient and the personnel.

Table 2-Quality assurance audit schedule

	Monthly	Quarterly	Semi-Annually	Annually
Patient information policy (14.3)				x
Equipment manuals and procedures (14.4)				x
Equipment maintenance and repair policies (14.4)				x
Environmental safety (8.1)				x

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Environmental safety (8.2)		x	
Environmental safety (8.4)		x	
Reprocessing supplies (9)			x
Water treatment* (11.4.1.5)	x		
Hemodialyzer labeling (10)		x	
Reprocessing procedures** (14.8)	x		x
Procedures for preparation for dialysis (14.9)		x	

* More frequent monitoring may be required initially as described in 11.4.1.5.
** These functions may allow for the less frequent review period indicated according to the circumstances specified in their respective sections.
Numbers in parenthesis refer to AAMI sections.

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 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).

If the facility participates in a centralized reprocessing program, the QA audits done in the reprocessing facility must be provided to the patient treatment facility and reviewed as part of the QAPI of that facility. Any complaints related to the reprocessing of dialyzers would need to be reported to the patient treatment facility sending the applicable dialyzers.

FED - V0361 - SCH OF QA ACTS-MED DIR RESPONSIBLE

Title SCH OF QA ACTS-MED DIR RESPONSIBLE

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
14.2 Schedule of quality assurance activities: medical director responsible Problems in a particular aspect of operations should be	ANSI/AAMI RD47:2002/A1:2003 14.2 Schedule of quality assurance activities High-volume tasks that are recognized as hazardous should have frequent (weekly or daily) oversight. Practices with

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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.

little potential for harm may need critical scrutiny on only a quarterly or annual basis.

Additional Guidance:
Reuse procedures/tasks/logs must be audited according to Table 2 (above at 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.

FED - V0362 - QA AUDITS-PT CONSIDERATIONS ANNUALLY

Title QA AUDITS-PT CONSIDERATIONS ANNUALLY

Type Standard

CFR 494.50(b)(1)

Regulation Definition

ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)
14.3 Patient considerations: audit annually
Personnel should audit at least annually compliance with the facility's policy to inform patients of the facility's reuse practices

Interpretive Guideline

FED - V0363 - QA AUDITS-MANUALS/P&P ANNUAL & PRN

Title QA AUDITS-MANUALS/P&P ANNUAL & PRN

Type Standard

CFR 494.50(b)(1)

Regulation Definition

14.4 Equipment Manuals and Procedures: audit annually & prn
Designated staff members should audit written procedures and manuals for relevance at least annually and whenever adverse findings could be attributed to equipment failure. Designated

Interpretive Guideline

Additional Guidance:
Centralized reprocessing requires that relevant procedures and manuals be audited at both the reprocessing site and the user facility.

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staff should also audit maintenance and repair policies at least annually.

FED - V0364 - QA AUDITS-PHYS PLANT/ENVIRON SAFE 1X/YR

Title QA AUDITS-PHYS PLANT/ENVIRON SAFE 1X/YR

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
14.5 Physical plant and environmental safety considerations: audit annually Designated staff members should audit the provisions of [AAMI] 8.1, [Reprocessing area and ventilation], at least annually. The provisions of [AAMI] 8.2, [Storage area], and [AAMI] 8.4, [Personnel protection] should be audited quarterly.	Additional Guidance: There must be documentation to support that designated staff conducted an annual review of the implementation of germicide air testing procedures, and the physical condition of the reprocessing area. Quarterly evaluations of the area where dialyzers and supplies are stored are required, as well as evaluation of the implementation of policies for use of PPE and Standard Precautions when direct care and reprocessing staff are working with reprocessed dialyzers. Centralized reprocessing requires that this audit be done at the reprocessing site as well as at the user facility.

FED - V0365 - QA AUDITS-REPROCESSING SUPPLIES 2X/YR

Title QA AUDITS-REPROCESSING SUPPLIES 2X/YR

Type Standard

CFR 494.50(b)(1)

Regulation Definition	Interpretive Guideline
14.6 Reprocessing supplies: audit semiannually Designated staff members should audit the provisions of [AAMI] section 9[: Reprocessing supplies: Specifications and testing, and inventory control] at least semiannually.	

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FED - V0366 - QA AUDITS-HEMODIALYZER LABELING QUARTERLY

Title QA AUDITS-HEMODIALYZER LABELING QUARTERLY

Type Standard

CFR 494.50(b)(1)

Regulation Definition

14.7 Hemodialyzer labeling: audit quarterly
Designated staff members should audit the provisions of [AAMI] section 10.

Interpretive Guideline

Additional Guidance:
AAMI Section 10 includes the following: Hemodialyzer labeling, Time of labeling, Label composition, and Information recorded. These audits should be recorded quarterly.

Centralized reprocessing requires that this audit be done at the reprocessing site as well as at the user facility.

FED - V0367 - QA AUDITS-REPROCESS PROCED MONTHLY;2X/YR

Title QA AUDITS-REPROCESS PROCED MONTHLY;2X/YR

Type Standard

CFR 494.50(b)(1)

Regulation Definition

14.8 Reprocessing: audit monthly; semiannually
Initially, designated staff members should audit the written procedures for the various steps in this process and verify implementation at least monthly. Subsequently, semiannual audits may be sufficient if there is a documented history of favorable results. Trend analysis should be performed.

Interpretive Guideline

Additional Guidance:
For a new reuse program, monthly audits of reprocessing steps must be done at a minimum. For an established program, audits of the practice of reprocessing must be done semiannually, unless problems are identified, which would require more frequent audits until a pattern of compliance is established.

Centralized reprocessing requires that the reprocessing site perform these audits and report the results to all user facilities.

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FED - V0368 - QA AUDITS-PREPARATION FOR DIALYSIS;4X/YR

Title QA AUDITS-PREPARATION FOR DIALYSIS;4X/YR

Type Standard

CFR 494.50(b)(1)

Regulation Definition

14.9 Preparation for dialysis: audit quarterly
At least quarterly, designated personnel should audit the written procedures and verify their implementation. At least quarterly, designated staff members should verify the tests for the presence of germicide and the test for residual germicide by using positive and negative control solutions, on those products that are not specifically intended for use in dialyzer reuse germicide indicator tests and which have not been cleared by the FDA.

Interpretive Guideline

Additional Guidance:
This regulation requires at least quarterly audits (observations) of the set-up for dialysis, including testing for presence of germicide, testing for residual germicide, and verification of the patient identity with the reprocessed dialyzer.

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.

Facilities that participate in centralized reprocessing are responsible for performing the audits of the steps in the reuse process which occur during preparation for dialysis when reprocessed dialyzers are being prepared for reuse.

FED - V0378 - REPROCESS DIALYZERS & BLOODLINES BY DFU

Title REPROCESS DIALYZERS & BLOODLINES BY DFU

Type Standard

CFR 494.50(b)(2)

Regulation Definition

A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(2) Reprocess hemodialyzers and bloodlines-follow DFU
(i) By following manufacturer's recommendations; or
(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

Interpretive Guideline

Each manufacturer of dialyzers for multiple use is required by FDA to provide at least one acceptable reprocessing method with at least one germicide. The facility may use that method/germicide or choose an alternate method. If the facility has chosen an alternate method, there must be documentation that the chosen method has been validated as safe and effective.

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FED - V0379 - DIALYZERS EXPOSED TO ONLY ONE GERMICIDE

Title DIALYZERS EXPOSED TO ONLY ONE GERMICIDE

Type Standard

CFR 494.50(b)(3)

Regulation Definition

A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

Dialyzers not exposed to more than one germicide
(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

Interpretive Guideline

FED - V0381 - BLOOD/DIALYSATE CULTURES FOR ADV PT REACT

Title BLOOD/DIALYSATE CULTURES FOR ADV PT REACT

Type Standard

CFR 494.50(c)(2)

Regulation Definition

(2) When clinically indicated (for example, after adverse patient reactions), the facility must-
(i) Obtain blood and dialysate cultures and endotoxin levels;

Interpretive Guideline

The facility must have a standardized procedure to ensure blood and dialysate cultures and dialysate endotoxin testing are obtained in the event of a patient reaction possibly related to dialyzer reprocessing and/or reuse.

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FED - V0382 - CLUSTER OF ADV PT REACTIONS=SUSPEND REUSE

Title CLUSTER OF ADV PT REACTIONS=SUSPEND REUSE

Type Standard

CFR 494.50(c)(2)

Regulation Definition	Interpretive Guideline
(2) When clinically indicated (for example, after adverse patient reactions), the facility must-	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.
(ii) Undertake evaluation of its dialyzer reprocessing and water purification system. When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.	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. If a cluster of adverse patient reactions associated with reprocessing/reuse was identified, dialyzer reprocessing/reuse should have been suspended, pending investigation.

FED - V0383 - FDA REPORTING OF ADVERSE OUTCOMES

Title FDA REPORTING OF ADVERSE OUTCOMES

Type Standard

CFR 494.50(c)(2)

Regulation Definition	Interpretive Guideline
(2) When clinically indicated (for example, after adverse patient reactions), the facility must-	The dialyzer manufacturer is not responsible for adverse outcomes related to reprocessing/reuse. The facility would be responsible for reporting any adverse outcomes potentially related to reprocessing/reuse, as required by law. Facility policy should address adverse occurrence reporting.
(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.	

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FED - V0400 - CFC-PHYSICAL ENVIRONMENT

Title CFC-PHYSICAL ENVIRONMENT

Type Condition

CFR 494.60

Regulation Definition

Interpretive Guideline

This Condition 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.

The primary survey task used in assessing compliance with this Condition is observation: of the environment, equipment maintenance, and readiness of emergency equipment. Survey of the requirements found at V400-V416 of this Condition will be done by the health and safety surveyors who conduct the usual ESRD surveys. Survey of the requirements related to Life Safety Code (LSC), found at V417-V418, will be done by specific surveyors trained as fire specialists and may be conducted at a separate time.

Noncompliance at the Condition level should be considered if identified deficient practices are pervasive, serious in nature, or a potential risk to health and safety. Examples of potential Condition level non-compliance would include, but not be limited, to:
o Serious deficient practices in the construction or maintenance of the physical environment and/or equipment which have or are likely to have an impact the health and safety of patients, staff or the public;
o Serious deficient practices in the development and/or implementation of an effective program for dealing with patient medical emergencies and/or potential disaster situations.

FED - V0401 - PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT

Title PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT

Type Standard

CFR 494.60

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Regulation Definition

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

Interpretive Guideline

"Safe environment" means that there are no obstacles which would present risks for trips and falls, such as loose floor tiles; no areas that would pose infection control risks, such as broken work surfaces; and no outside doors that remain propped open allowing entry of unauthorized individuals, insects, or animals or creating a hazard in the event of fire.

"Functional environment" means that all systems in the building, such as lighting, heating and air conditioning, are operational.

"Comfortable environment" means providing sufficient space for patient privacy and access for needed equipment; and maintaining a reasonable noise level, e.g., requiring the use of earphones when televisions or other entertainment devices are in use which may disturb others. Monitoring a comfortable temperature is addressed at V405.

FED - V0402 - PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY

Title PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY

Type Standard

CFR 494.60(a)

Regulation Definition

The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.

Interpretive Guideline

The dialysis facility building must be constructed in accordance with applicable State and local building codes. The plumbing, electrical and heating, ventilation and air conditioning (HVAC) systems must be appropriately constructed and effectively maintained.

All buildings and building systems must be maintained free from defects and/or hazards to ensure safety and functionality. Integrity of all surfaces, (e.g., countertops, floors, walls) must be intact, clean and free from damage. Intact surface integrity allows for effective cleaning and limits the potential for microbial growth on a porous surface.

Systems to assure patient safety must be in place, such as a method for patients to call for help from the restrooms and exam rooms. Access to patient treatment areas, reprocessing areas, water treatment systems, supply storage and dialysis equipment must be restricted to authorized personnel only. Access limitation does not preclude visits or tours by individual(s) authorized and supervised by facility personnel.

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FED - V0403 - PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU

Title PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU

Type Standard

CFR 494.60(b)

Regulation Definition

The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

Interpretive Guideline

All equipment used at the dialysis facility and dialysis equipment used by home dialysis patients must be maintained in safe and functional working condition. The facility's program for preventive maintenance and repair of all equipment must be in accordance with the equipment manufacturer's instructions.

Staff must operate and maintain the equipment in accordance with manufacturer's instructions. Malfunctioning machines awaiting repair must be removed from service and labeled or tagged to prevent use. The facility should have a plan for the operation and routine maintenance of at least the following equipment and equipment systems:

Hemodialysis delivery system:
o High flux dialyzers may only be used with machines specified by the manufacturer as capable of accurately monitoring and controlling fluid removal
o If heparin pumps are incorporated into the delivery system, the pumps must be maintained as clean and functional.
o As required by manufacturers, testing of safety features, e.g., alarms, pressure holding tests, and independent verification of dialysate pH and conductivity should be conducted prior to each dialysis treatment.

"Dummy" drip chambers:
o "Dummy" drip chambers are fluid-filled chambers that are used to bypass the dialysis machine's air detectors.
o The practice of using a "dummy" drip chamber to prepare a dialysis machine for patient use is hazardous to patient safety and risks the undetected infusion of air into a patient if the "dummy" drip chamber is not removed at the initiation of dialysis.
o The presence and availability of "dummy" drip chambers in the hemodialysis patient treatment area is considered an immediate and serious threat to patient health and safety.
o The use of "dummy" drip chambers is acceptable only for machine maintenance purposes and only for use outside of the patient treatment area.

Water treatment system:
Requirements for monitoring and maintenance of the water treatment system are incorporated into the Condition for

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Water and dialysate quality at §494.40 and should be cited there.

Dialyzer reprocessing system:
Requirements for monitoring and maintenance of dialyzer reprocessing systems are incorporated into the Condition for Reuse of hemodialyzers and bloodlines at §494.50 and should be cited there.

Ancillary equipment:
o Ancillary equipment may include, but is not limited to: functional and clean patient scales, centrifuge, refrigerators, incubators for in-house performance of water/dialysate cultures, emergency generators, blood pressure monitoring equipment, infusion pumps, patient thermometers, eye wash stations, conductivity and pH meters, Hoyer lifts, and equipment required to provide in-house laboratory testing (e.g. blood glucose meters, heat blocks, equipment for activated clotting times [ACT], supplies for testing for occult blood and hematocrit levels).
o Maintenance of refrigerators should include the monitoring of temperatures to assure these are appropriate for the items stored.
o If a generator is present, documentation should be available regarding testing and maintenance per manufacturer's instructions.
o Records should be available regarding the daily cleaning and testing and periodic calibration of pH and conductivity meters as recommended by the manufacturer.
o Documentation of periodic calibration of patient scales, blood pressure devices, blood volume monitors, and laboratory equipment, as applicable, should be available.

Emergency equipment:
o Emergency equipment as referenced at V413 of this section should be clean, functional, and accessible. Use V413 for the lack of required emergency equipment; use this tag for failure to maintain the emergency equipment.

Furniture:
o Patient treatment chairs, facility wheelchairs, and waiting area · chairs must be maintained to allow effective cleaning/disinfection
o Torn upholstery must be repaired or replaced; broken mechanisms (e.g. footrests, reclining levers) must be repaired or the equipment removed from use.

The facility equipment maintenance program should include documentation regarding all equipment or devices used for home patients, whether maintained by the facility or by durable medical equipment suppliers (DME). Refer to the Condition for Care at home at V597 if problems with the maintenance and/or exchange of home dialysis equipment are identified.

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FED - V0404 - PE-PT CARE ENVIRONMENT-SUFFICIENT SPACE

Title PE-PT CARE ENVIRONMENT-SUFFICIENT SPACE

Type Standard

CFR 494.60(c)(1)

Regulation Definition

The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

Interpretive Guideline

There are no specific square-footage requirements for dialysis treatment areas unless specified by state or local regulations.

"Sufficient space" to provide needed care would allow space for:
o All dialysis equipment, supplies and items for each patient;
o Caregivers to provide emergency care including cardiopulmonary resuscitation (CPR), the use of emergency equipment including access to needed supplies, stretcher and emergency personnel; and
o The provision of personal privacy when needed, i.e., sufficient space to allow for use of some type of privacy screens. Note that privacy requirements are addressed in V406 of this section, and under the Condition for Patients' rights at V454.

"Sufficient space" to prevent cross-contamination would allow space to:
o Prevent blood or body fluid spatters from one patient or station to another;
o Prevent contact between machines, chairs and other equipment;
o Reasonably accommodate patient belongings;
o Provide privacy and aseptic care of catheters including dressing changes;
o Safely dispose of bodily wastes/fluids and hazardous waste; and
o Readily access hazardous waste receptacles.

The space around the hemodialysis stations should be sufficient for all of the above. The space allowance should take into consideration the space taken up by patients ' dialysis chairs when reclined with foot rests up.

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FED - V0405 - PE-COMFORTABLE TEMPERATURE

Title PE-COMFORTABLE TEMPERATURE

Type Standard

CFR 494.60(c)(2)

Regulation Definition

The dialysis facility must:
(i) Maintain a comfortable temperature within the facility; and
(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

Interpretive Guideline

The facility must make reasonable efforts to provide a comfortable environment for patients and staff, in spite of conflicting perceptions of "comfortable." Staff's use of personal protective equipment paired with the restricted activity levels of patients and the nature of dialysis treatments affect the perceptions of what constitutes a "comfortable" temperature. Generally, staff members are hot and patients are cold. The facility must develop an acceptable plan to determine the temperature in the patient treatment area. An "acceptable plan" could be to set the thermostat for a reasonable temperature, inform patients and staff of the set temperature, and suggest patients may want to bring a light blanket. It is not acceptable to allow the temperature to be randomly raised or lowered, dependent on one person's comfort level. If some areas of the treatment room are served by a different thermostat, the facility may be able to set the thermostats at different levels based on patients' desires.

"Reasonable accommodations" would include moving patients who are not comfortable with the set temperature to an area of the room which is determined to be more comfortable in temperature due to the location of vents, windows, etc. When cold, some patients find it helpful to use a glove for the hand on their access arm, others find wearing a cap helpful.

If patients choose to use a blanket or other covering, their vascular access site, bloodline connections, and face must be visible throughout the treatment. A head covering on a patient is acceptable, as are gloves. If you note a problem in this area, refer to V407.

FED - V0406 - PE-ACCOMMODATE PT PRIVACY

Title PE-ACCOMMODATE PT PRIVACY

Type Standard

CFR 494.60(c)(3)

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Regulation Definition	Interpretive Guideline
The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.	Privacy must be provided for the use of a bedpan or commode during dialysis, initiating and discontinuing treatment when the vascular access is placed in an intimate area, for physical exams, and for sensitive communications. There should be sufficient numbers of privacy screens or other methods of visual separation available and used to afford patients full visual privacy when indicated. Exam rooms should have a door or other method to ensure privacy can be provided. Arrangements for private conversations may need to be outside of the patient treatment area in a private location.

FED - V0407 - PE-HD PTS IN VIEW DURING TREATMENTS

Title PE-HD PTS IN VIEW DURING TREATMENTS

Type Standard

CFR 494.60(c)(4)

Regulation Definition	Interpretive Guideline
Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).	Each patient, including his/her face, vascular access site, and bloodline connections, must be able to be seen by a staff member throughout the dialysis treatment. Allowing patients to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes.

FED - V0417 - PE-FIRE SAFETY-LIFE SAFETY CODE

Title PE-FIRE SAFETY-LIFE SAFETY CODE

Type Standard

CFR 494.60(d)(1)

Regulation Definition	Interpretive Guideline
(1) Except as provided in paragraph (d)(2) of this section, dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must comply with provisions of the Life Safety Code (NFPA	Guidance is pending and will be updated in a future release.

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101 and its Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4) applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

FED - V0418 - PE-LSC-SPRINKLERS

Title PE-LSC-SPRINKLERS

Type Standard

CFR 494.60(d)(2)

Regulation Definition	Interpretive Guideline
(2) Notwithstanding paragraph (d)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the Life Safety Code, section 21.1.6.1, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.	Guidance is pending and will be updated in future release.

FED - V0419 - PE-LSC-WAIVER IF STATE REQ MEET FED REQ

Title PE-LSC-WAIVER IF STATE REQ MEET FED REQ

Type Standard

CFR 494.60(d)(3)

Regulation Definition	Interpretive Guideline
If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.	A State may apply to CMS for review to determine if a State's fire and LSC requirements adequately protect a dialysis facility's patients from fire hazards. The CMS review process will determine if a State is allowed to substitute the state rules in this area for the requirements of the LSC, NFPA 101. If CMS approves the State Code, the LSC, NFPA 101 shall not apply.

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FED - V0420 - PE-LSC-WAIVER

Title PE-LSC-WAIVER

Type Standard

CFR 494.60(d)(4)

Regulation Definition

(4) In consideration of a recommendation by the State survey agency or at the discretion of the Secretary, the Secretary may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ESRD facility, but only if the waiver will not adversely affect the health and safety of the patients.

Interpretive Guideline

CMS may waive specific provisions of the Life Safety Code (LSC). This waiver may be granted if the facility is unable to comply with a specific requirement of the LSC, and if complying with that requirement would cause an unreasonable hardship for the dialysis facility. The waiver will only be granted if it is determined that the health and safety of the dialysis facility's patients are not adversely affected by the waiver. In some cases, the waiver may be limited to a specific time period.

Guidance on the LSC waiver process is found in Appendix I of the State Operations Manual (SOM).

FED - V0421 - PE- INDUSTRIAL HIGH HAZARD AREA

Title PE- INDUSTRIAL HIGH HAZARD AREA

Type Standard

CFR 494.60(d)(5)

Regulation Definition

(5) No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the Health Care Facilities Code (NFPA 99 and its Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6).

Interpretive Guideline

Guidance is pending and will be updated in a future release.

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FED - V0422 - PE- BUILDING SAFETY

Title PE- BUILDING SAFETY

Type Standard

CFR 494.60(e)(1)

Regulation Definition	Interpretive Guideline
(e) Standard: Building safety. (1) Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the Health Care Facilities Code, regardless of the number of patients served.	Guidance is pending and will be updated in a future release.

FED - V0423 - PE- HCFC WAIVER

Title PE- HCFC WAIVER

Type Standard

CFR 494.60(e)(3)

Regulation Definition	Interpretive Guideline
(3) If application of the Health Care Facilities Code would result in unreasonable hardship for the dialysis facility, CMS may waive specific provisions of the Health Care Facilities Code for such facility, but only if the waiver does not adversely affect the health and safety of patients.	Guidance is pending and will be updated in a future release.

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FED - V0424 - PE-INCORPORATION BY REFERENCE

Title PE-INCORPORATION BY REFERENCE

Type Standard

CFR 494.60(f)

Regulation Definition

(f) Incorporation by reference. The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal__register/cfr/ibr-locations.html. If any changes in the editions of the Codes are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1-617-770-3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

Interpretive Guideline

Guidance pending and will be updated in a future release.

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(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

FED - V0450 - CFC-PATIENTS- RIGHTS

Title CFC-PATIENTS- RIGHTS

Type Condition

CFR 494.70

Regulation Definition

Interpretive Guideline

This Condition 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.

The survey of this Condition is primarily accomplished by interviews of patients and observations of care delivery and the interactions of staff with patients. Review of medical records and applicable policies for these requirements are indicated if any issues are identified by the observations or interviews.

Condition level non-compliance should be considered if there are serious and/or pervasive deficient practices identified that seriously threaten one or more of these rights. Examples of Condition level non-compliance include, but are not limited, to a pattern of:
o Failure to treat patients with respect and dignity, to provide an opportunity for private communication, or to prevent

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exposure of · private body areas during dialysis causing patients emotional discomfort;
o Cognizant patients/designees not being aware of their options for treatment modalities or grievance mechanisms.

FED - V0451 - PR-PTS INFORMED OF RIGHTS WHEN BEGIN TX

Title PR-PTS INFORMED OF RIGHTS WHEN BEGIN TX

Type Standard

CFR 494.70

Regulation Definition

The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

Interpretive Guideline

"Inform" could include providing verbal explanations, audiovisual presentations, and/or written materials. Documentation should confirm that this information is provided.

"When they begin their treatment" means within the first six (6) treatments after admission to the facility. While basic information about all the "rights" listed in this Condition must be provided within those first 6 treatments, it is expected that more in-depth discussions regarding these "rights" may extend over a longer period of time.

A "patient representative" (also referred to as a "designee") means a legally-appointed representative or someone who the patient has authorized to participate with or in the patient's place. If patient-appointed, the patient has the right to determine the extent to which the designee serves as a health care decision-maker or proxy. The parent of a child under age 18 is automatically determined to be a "designee" for that child. However, older youths with decision-making capacity may be included in decision-making with the parent ' s consent.

FED - V0452 - PR-RESPECT & DIGNITY

Title PR-RESPECT & DIGNITY

Type Standard

CFR 494.70(a)(1)

Regulation Definition

The patient has the right to-
(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological

Interpretive Guideline

Survey Procedures and Probes:
The patient's daily records should be adequately maintained and up to date. There should be documentation in the records showing that all required support services are being furnished to the self-dialysis patient.

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needs and ability to cope with ESRD

FED - V0453 - PR-RECEIVE UNDERSTANDABLE INFORMATION

Title PR-RECEIVE UNDERSTANDABLE INFORMATION

Type Standard

CFR 494.70(a)(2)

Regulation Definition

The patient has the right to-

(2) Receive all information in a way that he or she can understand;

Interpretive Guideline

Patients and/or designees need to receive information in a way that he/she can understand. Staff should consider patients' literacy levels, whether they have communication disorders (low vision/blindness, hearing loss, or speech impairment), and whether a language other than English is their primary language. Methods to validate that provided information was understood should be employed; examples would include "teach back," asking the patient to reflect back to the staff member what they understood, or return demonstration of a skill.

The interdisciplinary team comprehensive assessment and plan of care must assess patient needs for information and barriers to receipt of that information, and develop ways to address those barriers. Communication options for those with vision loss include verbal communications, large print, and Braille. Communication options for those with hearing loss include lip reading, sign language, pictograms, telecommunication devices for the deaf, and written communications. Options to communicate with those who cannot speak include providing written documents, audio formats, and using sign language.

There should be a reasonable facility plan for communicating information in various languages if there is a need. Since there may be a variety of languages spoken at any facility, it would be unreasonable to expect that all written patient materials will be translated into every language that is spoken at the facility. However, the facility must comply with legal requirements for communicating with those with limited English proficiency under Title VI of the Civil Rights Act of 1964 and Executive Order 13166 that require recipients of federal funds to have policies and procedures for communicating with patients who speak languages other than English, especially vital documents such as consents for treatment, forms that require a legal signature and patients' rights policies. Staff should document in the patient's medical record how forms requiring a signature were explained to patients/designees who have vision, speech, or hearing barriers and those who do not speak or read English. Facilities may use web-based language translation services, such as Babel Fish to translate words or phrases, or audio interpreter services, such as Language Line, for communicating more than a short phrase.

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FED - V0454 - PR-PRIVACY & CONFIDENTIALITY-TREATMENT

Title PR-PRIVACY & CONFIDENTIALITY-TREATMENT

Type Standard

CFR 494.70(a)(3)

Regulation Definition	Interpretive Guideline
The patient has the right to-	Patients have the right to privacy and confidentiality in both the verbal and physical aspects of their treatment.
(3) Privacy and confidentiality in all aspects of treatment;	Patients have the right to privately discuss their condition and treatment. Staff should allow the patient to direct where discussions of sensitive topics should occur, and ask the patient if he/she wants to schedule a time to discuss a sensitive issue away from the treatment area. Any staff-patient interactions that require privacy should be conducted in private. To allow for private conversations between patients and staff members, there should be ready access to a room in the facility where patient and/or family meetings can be held in private. Plan of care conferences may be conducted chairside rather than in a private location if a patient grants permission. Patients have the right to privacy during activities that expose private body parts while in the dialysis facility. This includes activities related to use of vascular access sites located in the groin or chest and physical examinations. Options for ways to comply with this requirement include the use of privacy screens, curtains, or blankets. Staff must be able to observe the patient's vascular access, bloodline connections, and face at all times. Refer to V407 under the Condition for Physical environment.

FED - V0455 - PR-PRIVACY & CONFIDENTIALITY-RECORDS

Title PR-PRIVACY & CONFIDENTIALITY-RECORDS

Type Standard

CFR 494.70(a)(4)

Regulation Definition	Interpretive Guideline
The patient has the right to-	Patients should be able to expect the facility to maintain confidentiality of their medical record information. Patients' health records must be protected from casual access. Hard copy medical records should be stored in a secure location when not in use. Computer screens containing patient information should not be left open and unattended with patient
(4) Privacy and confidentiality in personal medical records;	

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specific information on display and computerized systems should require passwords and permissions to access medical records.

The facility must inform patients of their privacy rights under the Health Insurance Portability and Accountability Act (HIPAA).

A signed release is not required by HIPAA to share protected health information for continuity of care, such as but not limited to providing emergency care or contacting other dialysis facilities as a part of the protocol for involuntary discharge or termination of treatment or when asking the police to help locate a patient so he/she can receive dialysis.

Patients have the right to read their own medical record, have corrections made to that record, and to have a copy of their record for which a nominal fee may be charged. The facility must actively seek to honor patients' requests to have a copy of their medical record as quickly as its recordkeeping system permits. Under HIPAA, reasons why a patient or his/her designee would not have the right to review his/her record include:
o The patient is an inmate of a correctional facility and access could jeopardize the health, safety, security, custody or rehabilitation of the patient, other inmates, or the safety of any officer, employee or other correctional system employee, including the transporter;
o The patient is participating in a research project;
o Access to the medical record would reveal a confidential source;
o Access to the medical record could endanger the life or physical safety of another;
o Access to the medical record by the patient's authorized representative is likely to cause substantial harm to patient or another.

Confidential treatment and release of patient medical record information is also addressed in the Condition for Medical records at V727 and V728.

FED - V0456 - PR-PARTICIPATE IN CARE;DISC/REFUSE TX

Title PR-PARTICIPATE IN CARE;DISC/REFUSE TX

Type Standard

CFR 494.70(a)(5)

Regulation Definition	Interpretive Guideline
The patient has the right to-	Patients have the right to know about and participate in their care and treatment to the extent they desire. Self-cannulation may be performed by the patient in any facility upon receiving appropriate training and

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(5) Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

demonstrating competence, should they so choose. The facility must encourage patient participation in care planning. Examples of ways to promote this participation include, but are not limited to, offering the patient the option to participate in interdisciplinary team care planning or to attend a planning meeting in-person or by teleconference from home. "Chair-side" review of the plan of care is also acceptable, if sufficient privacy can be provided. Patients also have the right to accept or decline to participate in their care.

Patients must be notified of changes to their dialysis prescription and the reason for those changes. Patients should be encouraged to disclose any concerns they have with the proposed changes. Patients have the right to refuse the change without fear of discharge.

Patients have the right to refuse any aspect of treatment, to refuse to participate in experimental research, and to discontinue their dialysis treatments completely.

FED - V0457 - PR-CAN HAVE ADVANCE DIR,TOLD FAC AD P&P

Title PR-CAN HAVE ADVANCE DIR,TOLD FAC AD P&P

Type Standard

CFR 494.70(a)(6)

Regulation Definition

The patient has the right to-

(6) Be informed about his or her right to execute advance directives, and the facility ' s policy regarding advance directives;

Interpretive Guideline

This standard requires the facility to inform patients about advance directives, including the right to formulate advance directives. The standard does not require that all patients have an advance directive.

Advance directives establish in writing an individual ' s preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. Advance directives include written documents such as living wills and durable powers of attorney for health care decisions (also called a health care proxy or medical power of attorney) as recognized by State law.

Many states have enacted laws requiring patients ' advance directives and " do not resuscitate " (DNR) preferences to be honored. Facilities are required to know and comply with such state laws. If state law does not address this facet of health care, and the facility ' s policy does not allow the honoring of a patient ' s advance directive, there must be a protocol in place for facilitating the patient ' s transfer to a facility that will honor the advance directive, if the patient so chooses.

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The inclusion of patients ' advanced directives in their medical records is addressed at V730.

FED - V0458 - PR-INFORMED-ALL MODALITIES/SETTINGS

Title PR-INFORMED-ALL MODALITIES/SETTINGS

Type Standard

CFR 494.70(a)(7)

Regulation Definition

The patient has the right to-

(7) Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

Interpretive Guideline

Documentation in patient records must demonstrate that facility staff provide unbiased education to patients/designees about transplantation and all dialysis treatment options (modalities and settings) offered for kidney failure, whether or not those options are offered at the current dialysis facility. This includes alternate scheduling options for in-center hemodialysis patients who attend school or are working. Patients who work or attend school should be encouraged to continue doing so and facilities should recommend the most appropriate modality and setting for their dialysis. Examples of how facilities may meet this requirement include developing a resource information packet for patients or providing patients an existing resource list of facilities that offer alternate schedules or home dialysis treatment options can be found at Medicare's Dialysis Facility Compare, and Home Dialysis Central.

The requirements for assessment of patients for home dialysis and transplantation are addressed at V512 and V513 and at V553 and V554 respectively under the Condition for Patient plan of care.

FED - V0459 - PR-INFORMED OF PT CARE POLICIES

Title PR-INFORMED OF PT CARE POLICIES

Type Standard

CFR 494.70(a)(8)

Regulation Definition

The patient has the right to-

(8) Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

Interpretive Guideline

Facility staff must inform patients regarding facility policies related to patient care, including the isolation of patients with infectious diseases. For example, patients should be informed if changes in their treatment location and/or schedule can be expected if they are diagnosed with an infectious disease requiring isolation (i.e., hepatitis B). Refer to V128 under the Condition for Infection Control for requirements regarding isolation of patients.

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FED - V0460 - PR-INFORMED OF REUSE & OPTIONS

Title PR-INFORMED OF REUSE & OPTIONS

Type Standard

CFR 494.70(a)(9)

Regulation Definition	Interpretive Guideline
The patient has the right to- (9) Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;	This requirement only applies to facilities that practice reprocessing and reuse of dialyzers or dialysis supplies. The patient must be informed if the facility practices reuse of dialyzers and/or dialysis supplies and of options available if they opt not to participate in the reuse program. Some State laws require facilities to allow patients to opt not to reuse their dialyzers and/or require the patient's written consent for dialyzer reuse. The requirements for informed consent for dialyzer reuse are addressed at V312 under the Condition for Reuse.

FED - V0461 - PR-INFORMED OF OWN MEDICAL STATUS

Title PR-INFORMED OF OWN MEDICAL STATUS

Type Standard

CFR 494.70(a)(10)

Regulation Definition	Interpretive Guideline
The patient has the right to- (10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;	Medical records should show that a patient's medical status was discussed with a patient/designee by a physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant). There should be few, if any, cases when a patient/designee cannot be informed about the patient's medical status.

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FED - V0462 - PR-INFORMED OF SERVICES & CHARGES

Title PR-INFORMED OF SERVICES & CHARGES

Type Standard

CFR 494.70(a)(11)

Regulation Definition	Interpretive Guideline
The patient has the right to- (11) Be informed of services available in the facility and charges for services not covered under Medicare;	Patients must be made aware of charges for any services that may not be covered under Medicare. If a facility plans to bill a patient for items and/or services which are usually covered by Medicare, but may not be considered reasonable and necessary in a particular situation (according to §1862 of the Social Security Act), the patient must be informed and be offered an Advanced Beneficiary Notice (ABN) to sign pursuant to §1879 of the Social Security Act.

FED - V0463 - PR-RECEIVE SERVICES OUTLINED IN POC

Title PR-RECEIVE SERVICES OUTLINED IN POC

Type Standard

CFR 494.70(a)(12)

Regulation Definition	Interpretive Guideline
The patient has the right to- (12) Receive the necessary services outlined in the patient plan of care described in §494.90;	Patients have the right to receive individualized care as determined by the facility interdisciplinary team and to be included on that team. The care specified in the plan of care should be delivered to the patient or the plan of care should be revisited.

FED - V0464 - PR-INFORMED OF RULES/EXPECTS-CONDUCT

Title PR-INFORMED OF RULES/EXPECTS-CONDUCT

Type Standard

CFR 494.70(a)(13)

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Regulation Definition	Interpretive Guideline
The patient has the right to- (13) Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;	Facility staff should inform patients about what is expected of them (the patient), while receiving services at the facility. Some examples of facility expectations for patient conduct and responsibilities include, but are not limited to, treating others (staff, patients, visitors) with mutual respect; following the plan of care (e.g., taking ordered medications, following fluid and diet restrictions); keeping appointments and/or notifying the facility if he/she will be late or miss a scheduled appointment: notifying the facility of changes in residence and contact information; and providing information on payers and changes in insurance.

FED - V0465 - PR-INFORMED OF INTERNAL GRIEVANCE PROCESS

Title PR-INFORMED OF INTERNAL GRIEVANCE PROCESS

Type Standard

CFR 494.70(a)(14)

Regulation Definition	Interpretive Guideline
The patient has the right to- (14) Be informed of the facility's internal grievance process;	Each facility should develop and implement an internal grievance process, as is stated in the Condition for Governance at V765. Facility staff must inform patients about the internal grievance process and the steps to follow for filing an internal grievance. Refer to V765 for the components of the internal grievance process. Use those tags for failure to implement the process. Use this tag for failure to inform patients about the process.

FED - V0466 - PR-INFORMED OF EXTERNAL GRIEVANCE PROCESSES

Title PR-INFORMED OF EXTERNAL GRIEVANCE PROCESSES

Type Standard

CFR 494.70(a)(15)

Regulation Definition	Interpretive Guideline
The patient has the right to- (15) Be informed of external grievance mechanisms and	The facility must establish a procedure for informing patients about seeking external help to resolve grievances that cannot be resolved internally or if patients are not comfortable using the internal process. The facility staff must inform each patient/designee how to contact the appropriate external entity to file a grievance, including the ESRD

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processes, including how to contact the ESRD Network and the State survey agency;

Network and the State survey agency.

Refer to V470 for the requirement of posting contact information for the Network and State survey agency.

FED - V0467 - PR-INFORMED-MAY FILE INT/EXT GRIEVANCE ANON

Title PR-INFORMED-MAY FILE INT/EXT GRIEVANCE ANON

Type Standard

CFR 494.70(a)(16), (17)

Regulation Definition

The patient has the right to-

(16) Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and
(17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

Interpretive Guideline

Every patient must be free to file a complaint or grievance within the facility or externally with the ESRD Network or State survey agency. Facility staff should inform patients that they can file a grievance anonymously or through a representative without being afraid that they will be treated differently or denied services.

"Reprisal" would include retaliation or revenge and could include perceived punishment, isolation, the intentional infliction of physical pain or emotional distress or involuntary discharge from the facility.

FED - V0468 - PR-INFORMED-D/C & TRANS P&P INC IVD

Title PR-INFORMED-D/C & TRANS P&P INC IVD

Type Standard

CFR 494.70(b)(1)

Regulation Definition

The patient has the right to-

(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients;

Interpretive Guideline

Patients must be given information about the facility policies for routine and involuntary discharges.

Refer to the Condition for Governance at V766-V767 for involuntary discharge or transfer regulations and guidance, including acceptable reasons for involuntary discharge. Use those tags for failure to follow the involuntary discharge procedures. Use this tag for failure to inform patients about the transfer and discharge policies.

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FED - V0469 - PR-RECEIVE WRITTEN NOTICE 30 DAYS PRE IVD

Title PR-RECEIVE WRITTEN NOTICE 30 DAYS PRE IVD

Type Standard

CFR 494.70(b)(2)

Regulation Definition

The patient has the right to-

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in §494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

Interpretive Guideline

The involuntary discharge procedures described at V767 identify the steps that a facility must follow prior to the involuntary discharge of a disruptive and abusive patient. After following the required procedures, a facility must give at least 30-days prior notice to any patient whom they opt to discharge involuntarily, except in the case of a patient who makes severe and immediate threats to the health and safety of others.

An "immediate threat to the health and safety of others" 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 can be considered an "immediate threat." Verbal abuse is not considered to be an immediate threat. In instances of an immediate 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, advance notice is not possible or required and there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer, as outlined at V767.

FED - V0470 - PR-RIGHTS POSTED,STATE/NW ONTACT INFO

Title PR-RIGHTS POSTED,STATE/NW ONTACT INFO

Type Standard

CFR 494.70(c)

Regulation Definition

The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

Interpretive Guideline

The facility must post all of the rights listed in V452-V469 in a common area of the facility which is routinely available to in-center and home dialysis patients. This posting is meant to augment, not substitute for communicating these rights to each individual patient in a way the patient can understand.

Information that must be posted includes the list of patient rights and the mailing addresses and contact information

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for the applicable ESRD Network and State survey agency, as well as the complaint telephone numbers for each.

FED - V0500 - CFC-PATIENT ASSESSMENT

Title CFC-PATIENT ASSESSMENT

Type Condition

CFR 494.80

Regulation Definition

Interpretive Guideline

The requirements in this Condition address the requirements for an interdisciplinary team assessment of patient needs; the requirements related to meeting those needs are contained in the Condition for Patient plan of care at 494.90.

Compliance with this Condition is determined by observation of practices; interviews of patients, personnel and medical staff; and review of medical records.

Condition level noncompliance should be considered if there are serious and/or pervasive deficient practices identified in the provision of individualized interdisciplinary comprehensive assessments of patients and their care needs. Examples of Condition level noncompliance include, but are not limited to:
o Assessments not being completed for multiple patients within the timelines required;
o One or more professional members of the interdisciplinary team (IDT) not participating in the patient assessment;
A pattern of general standardized assessment "findings" without evidence that individual patient needs are assessed.

FED - V0501 - PA-IDT MEMBERS/RESPONSIBILITIES

Title PA-IDT MEMBERS/RESPONSIBILITIES

Type Standard

CFR 494.80

Regulation Definition

Interpretive Guideline

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is

While multidisciplinary team members work sequentially and use the medical record as the chief means of communication, interdisciplinary teams work collaboratively with regular meetings to discuss patient status and the evolving plan of care. Working as a team allows for working toward common goals, pooling of expertise, and a forum for problem solving.

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responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

The interdisciplinary team (IDT) is composed of the members designated in the regulations, including the patient or a patient designee if the patient so chooses. Patients must be given the option and encouraged to participate in their assessment and care planning process. The professional members of the IDT participating in the patient comprehensive assessment must meet the qualifications outlined in the Condition for Personnel qualifications at §494.140.

"Individualized" means each assessment is unique to a particular patient and addresses that patient's needs. "Comprehensive" means the assessment covers and addresses all issues that are actionable by the dialysis facility; this could include referrals to specialists for assessments that are beyond the capacity of a dialysis facility.

The comprehensive patient assessment must demonstrate a congruent integration of the evaluations completed by each team member, identifying the patient's individual needs and allowing for planning for necessary care and services. Team members may choose to conduct one-on-one interviews with the patient or may opt to set up team meetings which would include the patient in order to collect the appropriate assessment information.

This assessment may be incorporated into one document or composed of sections developed by each team member, but must address the specific criteria as outlined in V502-V515. Electronic or paper formats may be used.

Required frequencies of patient assessments are addressed at V516-V520.

FED - V0502 - PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS

Title PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS

Type Standard

CFR 494.80(a)(1)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(1) Evaluation of current health status and medical condition, including co-morbid conditions.

Interpretive Guideline

ESRD patients may have many co-morbid conditions which impact their individual care needs. The IDT evaluation of the patient's current medical and co-morbid conditions includes information from medical history, physical exams, and nursing histories.

Non-physician practitioners, i.e., advanced practice registered nurses or physician assistants, functioning in lieu of physicians may conduct medical portions of this evaluation, in accordance with State law and facility policy.

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The nursing assessment must be conducted by a registered nurse and include evidence of assessment of the clinical needs of the patient.

Documentation of the etiology of the patient's kidney disease and a listing of any co-morbid conditions should be in the medical record. While copies of histories and physicals (H&P) from hospital admissions may be included, the assessment should address the patient's current presentation and health status, including the patient's medical condition related to his/her kidney disease.

FED - V0503 - PA-APPROPRIATENESS OF DIALYSIS RX

Title PA-APPROPRIATENESS OF DIALYSIS RX

Type Standard

CFR 494.80(a)(2)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(2) Evaluation of the appropriateness of the dialysis prescription,

Interpretive Guideline

A hemodialysis (HD) prescription includes the number of treatments per week, length of treatment time, the dialyzer, specific parameters of the dialysis delivery system (e.g., electrolyte composition of the dialysate, blood flow rate, dialysate flow rate), anticoagulation, and the patient's target weight. An appropriate HD prescription is individualized to meet the dialysis needs of the patient. For example, if the patient experiences intradialytic muscular cramping or a fall in blood pressure, a reevaluation of the related components of the dialysis prescription (e.g., target weight, ultrafiltration rate (UFR), dialysate sodium level) would be indicated; if a patient's laboratory values show an elevated or low potassium, a change in the dialysate potassium may be indicated.

A peritoneal dialysis (PD) prescription must take into consideration the peritoneal transport rate (determined by peritoneal equilibration testing [PET]), residual renal function, total body surface area, certain medical conditions, and personal preference. The PD prescription includes the number of exchanges or cycles to be done each day, the volume of fluid to be used with each exchange, whether fluid is always present in the peritoneal cavity (except for brief periods between draining and reinfusion of dialysate), and the concentration of glucose or other osmotic agent to be used for fluid removal (which may vary according to a prescribed sliding scale). Use of an automated, a manual, or a combination of automated/manual techniques should also be addressed. An appropriate PD prescription meets the dialysis needs of the patient. As examples: if the patient has difficulty accomplishing 5 exchanges during the day, the IDT should consider other options, such as overnight treatments using a cycler.

The patient record should show evidence that the patient's individual dialysis needs have been assessed and the current dialysis prescription evaluated as to whether it is meeting those needs. Refer to V715 for the requirement for

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the initial dialysis prescription to be provided prior to the patient ' s first treatment in the facility.

FED - V0504 - PA-ASSESS B/P, FLUID MANAGEMENT NEEDS

Title PA-ASSESS B/P, FLUID MANAGEMENT NEEDS

Type Standard

CFR 494.80(a)(2)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs.	Because of the adverse effects of ESRD, many patients experience lability of blood pressure and fluid management, the management of which may require reassessment of medication needs, adjustments in target weight, and changes to the POC. The comprehensive assessment should include evaluation of the patient's pre/intra/post and interdialytic blood pressures, interdialytic weight gains, target weight, and related intradialytic symptoms (e.g., hypertension, hypotension, muscular cramping) along with an analysis for potential root causes. For pediatric patients weighing less than 35 kg., blood volume monitoring during hemodialysis should be available in order to evaluate body weight changes for gains in muscle weight vs. fluid overload.

FED - V0505 - PA-ASSESS LAB PROFILE

Title PA-ASSESS LAB PROFILE

Type Standard

CFR 494.80(a)(3)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following: (3) Laboratory profile,	Laboratory work-up should include, but not be limited to, comprehensive metabolic testing, dialysis adequacy, complete blood count, iron studies and screening for HBV. The IDT evaluation should reflect recognition of values/results that would need to be addressed in the patient plan of care.

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As laboratory results may fluctuate, the IDT must evaluate the values as they become available and take indicated actions.

FED - V0506 - PA-IMMUNIZATION/MEDICATION HISTORY

Title PA-IMMUNIZATION/MEDICATION HISTORY

Type Standard

CFR 494.80(a)(3)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following: Immunization history, and medication history.	"Immunization history" should include whether the patient has received standard immunizations (pneumococcal, hepatitis, and influenza), and has been screened for tuberculosis. The immunization record is expected to include at least the patient's immunization history as of the effective date of this regulation. The Centers for Disease Control and Prevention (CDC) recommends that all dialysis patients: o Be tested at least once for baseline tuberculin skin test results (TST) and re-screened if TB exposure is detected. Chest x-rays may be used for individuals for whom the TST is not an option. o Be offered influenza and pneumococcal vaccine and have immunization histories for these vaccines be tracked. Both are universally recommended for this population and relate directly to infection control issues. o The CDC expectations for hepatitis vaccinations are detailed at V126 and V127. "Medication history" should include a review of the patient's allergies and of all medications including over-the-counter medications and supplements that the patient is taking. The assessment should demonstrate that all current medications were reviewed for possible adverse effects/interactions and continued need.

FED - V0507 - PA-ASSESS ANEMIA

Title PA-ASSESS ANEMIA

Type Standard

CFR 494.80(a)(4)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is	Each patient's hematologic status must be evaluated for determination of their individual anemia management needs.

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not limited to, the following:

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

Evaluation should address the patient's anemia, including an assessment of the need for erythropoiesis-stimulating agents (ESA) and/or iron therapy. Evaluation should also address the patient's volume status, potential for bleeding, infection and other causes of hypo-response.

Requirements for the plan of care for anemia management are at V547.

FED - V0508 - PA-ASSESS RENAL BONE DISEASE

Title PA-ASSESS RENAL BONE DISEASE

Type Standard

CFR 494.80(a)(5)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(5) Evaluation of factors associated with renal bone disease.

Interpretive Guideline

Disturbances in mineral and bone metabolism are common in patients with ESRD, often resulting in hyperparathyroidism and Chronic Kidney Disease (CKD) mineral and bone disorder if not managed effectively.

Evaluation should include the patient's laboratory values for calcium, phosphorous, and parathyroid hormone (PTH) along with a review of the patient's current CKD mineral and bone disorder medications (e.g. phosphate binders, vitamin D analogs, calcimimetic agents), over-the-counter medications, dietary factors, and medical conditions that impact this issue.

Pediatric patients present significant special needs in the areas of growth and development and CKD mineral and bone disorder. A facility treating pediatric patients should follow current professionally-accepted clinical practice standards for evaluating and monitoring the pediatric patient population in this area.

Requirements for the plan of care for CKD mineral and bone disorder management are at V546.

FED - V0509 - PA-RD-NUTRITIONAL STATUS

Title PA-RD-NUTRITIONAL STATUS

Type Standard

CFR 494.80(a)(6)

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Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following: (6) Evaluation of nutritional status by a dietitian	The evaluation of each patient's nutritional status must be conducted by a qualified dietitian as defined in these regulations at V689 and V690. Examples of nutritional parameters to be addressed include, but are not limited to: o Nutritional status; o Hydration status; o Metabolic parameters such as glycemic control (if diabetic) and cardiovascular health; o Anthropometric data such as height, weight, weight history, weight changes, volume status, amputations; o Appetite and intake; o Ability to chew and swallow; o Gastrointestinal issues; o Use of prescribed and over-the-counter nutritional, dietary, or herbal supplements; o Previous diets and/or nutrition education; o Route of nutrition; o Self-management skills; o Attitude to nutrition, health, and well-being; and o Motivation to make changes to meet nutrition and other health goals. The assessment may include information from the person that cooks and provides meals for the patient, whether this is the patient, family, caregiver or nursing home. Before interviewing family members or caregivers, the dietitian should seek the patient's permission to interview the relevant individual(s). If the patient is a resident of a long-term care (LTC) facility, the dietitian should contact the staff of the LTC facility as part of the assessment and to provide continuity of care. Other members of the IDT may contribute to portions of the comprehensive assessment which correlate with the nutritional evaluation (e.g., medical history/co-morbid conditions at V502, fluid management at V504, laboratory profile at V505, medication history at V506, CKD mineral and bone disorder at V508, psychosocial factors at V510, and adequacy of the patient's dialysis prescription at V518). Recognize this area is critically important in pediatric patients. A facility treating pediatric patients should follow current professionally-accepted clinical practice standards for evaluating and monitoring the pediatric patient population. The dietitian must consider the special nutritional needs of these patients. Requirements for the plan of care for nutritional status are at V545.

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FED - V0510 - PA-MSW-PSYCHOSOCIAL NEEDS

Title PA-MSW-PSYCHOSOCIAL NEEDS

Type Standard

CFR 494.80(a)(7)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(7) Evaluation of psychosocial needs by a social worker.

Interpretive Guideline

The evaluation of psychosocial needs must be conducted by a qualified social worker as defined by these regulations at V691.

Examples of psychosocial parameters to be addressed by the qualified social worker include, but are not limited to:
o Cognitive status and capacity to understand;
o Ability to meet basic needs;
o Ability to follow the treatment prescription;
o Mental health history, capacities, and needs for counseling;
o Substance abuse history, if any;
o Current ability to cope with and adjust to dialysis;
o Expectations for the future and living with kidney failure and treatment;
o Educational and employment status, concerns, and goals;
o Home environment including current living situation;
o Legal issues (e.g., court appointed guardian, advance directive status, and health care proxy)
o Need for advocacy with traditional (nursing home) and non-traditional housing (e.g., homeless shelters, group homes);
o Financial capabilities and resources;
o Access to available community resources; and
o Eligibility for Federal, State, or local resources.

Other members of the IDT may contribute to portions of the comprehensive assessment which correlate with the psychosocial evaluation (e.g., patient preferences for modality and self-care at V512, evaluation for transplant referral at V513, family/support systems at V514, and evaluation for referral to rehabilitation services at V515).

Requirements for the plan of care for psychosocial status are at V552.

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FED - V0511 - PA-DIALYSIS ACCESS TYPE & MAINTENANCE

Title PA-DIALYSIS ACCESS TYPE & MAINTENANCE

Type Standard

CFR 494.80(a)(8)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following: (8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters).	The efficacy of the HD patient's vascular access and the PD patient's peritoneal catheter correlates to the quality (adequacy) of their dialysis treatments and is of vital importance to their overall health status. Each HD patient should have an evaluation for the most appropriate type and location of vascular access and of the capacity of the vascular access to facilitate adequate dialysis treatments. Completion of this evaluation may include referrals to other entities, such as a radiologist or interventionist for vessel mapping or a vascular surgeon for access placement. Such referrals might take place as part of an assessment or as part of a plan of care, if the referral is to address an inadequate vascular access. Evaluation of a PD patient's peritoneal catheter would include assessment of the exit site and tunnel for condition and absence of infection, and of the catheter for patency and function. The requirements for vascular access plan of care are at V550 and V551.

FED - V0512 - PA-EVAL FOR SELF CARE/MODALITY/SETTING

Title PA-EVAL FOR SELF CARE/MODALITY/SETTING

Type Standard

CFR 494.80(a)(9)

Regulation Definition	Interpretive Guideline
The patient's comprehensive assessment must include, but is not limited to, the following:	Evaluation of abilities, interests, preferences and goals would be demonstrated by at least one member of the team documenting an assessment of the patient's current interests in life and ability to pursue those interests, preferences for treatment, and goals, including what he/she expects from dialysis treatment. Patients must be encouraged to

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(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.

participate in their care, within the limits of their capacity and desire.

If patients express a desire for enhanced participation in their own care (e.g., weighing themselves, monitoring blood pressure, holding needle sites, self-cannulation), the facility staff should evaluate and plan for applicable self-care training.

Refer to the Condition for Care at home at V585.

Evaluation of the preferred modality means that all options of modalities (hemodialysis, peritoneal dialysis) and settings (in-center, home) were presented to each patient, and that their goals, preferences, and expectations were given priority in decision-making.

If a patient is determined not suitable for or declines home dialysis therapy, the reason must be documented in their plan of care, as required at V553.

FED - V0513 - PA-TRANSPLANTATION REFERRAL

Title PA-TRANSPLANTATION REFERRAL

Type Standard

CFR 494.80(a)(10)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

Interpretive Guideline

The IDT comprehensive assessment must demonstrate that each patient is evaluated for suitability for transplantation referral, using selection/exclusion criteria provided by the transplant center.

The regulations for transplant programs require written selection criteria to be developed and provided upon request to patients and dialysis facilities. Selection criteria vary among transplant centers; if the dialysis facility refers patients to multiple transplant centers, the dialysis facility should have the selection criteria for each center on file and available to patients; patient are also free to select a transplant center other than the ones normally utilized by the dialysis facility for referrals.

If the assessment finds a patient is not suitable for transplantation, the reason for the non-referral should be documented as part of the comprehensive assessment.

The requirements for plan of care for transplant status are at V554.

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FED - V0514 - PA-EVAL FAMILY/SUPPORT SYSTEMS

Title PA-EVAL FAMILY/SUPPORT SYSTEMS

Type Standard

CFR 494.80(a)(11)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

(11) Evaluation of family and other support systems.

Interpretive Guideline

This evaluation should start with an interview of the patient. If one or more members of the IDT need to seek additional protected health information about the patient from family or other supporting individuals, they must obtain the patient's permission to discuss these topics with those individuals. It is not a breach of HIPAA privacy requirements for staff to ask family or other caregivers for information they may know about a patient to help the IDT provide care for the patient. HIPAA does not prohibit a staff member from educating a family member or other support person about how to help the patient with diet, medications, and cope with kidney failure. Ideally, it is best to seek approval from the patient. Educating the patient with family or other caregiver(s) (when possible) assures that everyone receives the same information.

Areas which would be included in this evaluation include family composition and history, the patient's willingness to ask for help; spiritual or religious support systems; etc. Some or all portions of this evaluation may overlap with the requirements for the psychosocial assessment described at V510.

Pediatric patients present special situations. Facilities that treat pediatric patients must have policies that address the need to evaluate the family and other support systems of the pediatric patients.

FED - V0515 - PA-EVAL CURRENT PHYS ACT LVL/VOC/PHYS REHAB

Title PA-EVAL CURRENT PHYS ACT LVL/VOC/PHYS REHAB

Type Standard

CFR 494.80(a)(12), (13)

Regulation Definition

The patient's comprehensive assessment must include, but is not limited to, the following:

Interpretive Guideline

These requirements are not intended to indicate that the facility is responsible for fully assessing each patient's activity level/physical capabilities. It is expected that the IDT would be able to evaluate each patient's activity level to

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(12) Evaluation of current patient physical activity level.

(13) Evaluation for referral to vocational and physical rehabilitation services.

the extent necessary to determine whether the patient is a candidate for referral to the appropriate professional(s) for further evaluation and possible rehabilitation services.

A member of the IDT should interview the patient/designee about the patient's current level of "physical activity," ability to perform activities of daily living, and/or barriers to independence. The assessment should include observation of the patient's ability to ambulate, transfer, and other physical activities pertinent to the dialysis environment (e.g. holding needle sites, etc).

Pediatric patients may also warrant rehabilitation services. Pediatric patients should be encouraged to attend school full-time if possible. If school attendance is not possible, other options should be offered for school-age children to obtain education.

Vocational rehabilitation referrals may be appropriate for older youth and adult patients who desire to return to work and/or improve independent living skills.

Patients who may warrant physical rehabilitation referrals include those with physical limitations and/or difficulty in performing activities of daily living independently.

The requirements for the plan of care for rehabilitation status (including making referrals) are at V555.

FED - V0516 - PA-FREQUENCY-INITIAL-30 DAYS/13 TX

Title PA-FREQUENCY-INITIAL-30 DAYS/13 TX

Type Standard

CFR 494.80(b)(1)

Regulation Definition

An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.

Interpretive Guideline

Each patient new to dialysis must have a comprehensive assessment completed within 30 days or 13 treatments of admission. This requirement applies to all new dialysis patients, without regard to the modality of treatment. Patients returning to dialysis from a failed transplant or changing modalities are also considered "new" patients.

If the comprehensive patient assessment and plan of care for an experienced dialysis patient transferring from one dialysis facility to another is received with the patient in transfer, the receiving facility's IDT must conduct a reassessment within three months of the patient's admission to the new facility. This same provision (i.e., completion of a reassessment within 3 months of admission) would also apply to transient patients received with an assessment

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and plan of care. Refer to V408 for disaster situations and requirements.

Prior to the first dialysis treatment, an "initial assessment" must be completed. This initial assessment is addressed in the Condition for Medical director at V715 and is different from the "initial comprehensive interdisciplinary" assessment.

Recognize that the transfer in of a large number of patients at once (e.g., with the opening of a new facility, or in the event of an adverse occurrence or disaster impacting the functionality of the transferring facility) may affect the staff's ability to complete this requirement within the mandated timeline. If this is the case, the facility should develop a plan to ensure completion of the assessments of the transferred patients promptly and a method to triage patients' needs for assessment.

FED - V0517 - PA-F/U REASSESSMENT-WITHIN 3 MO OF INITIAL

Title PA-F/U REASSESSMENT-WITHIN 3 MO OF INITIAL

Type Standard

CFR 494.80(b)(2)

Regulation Definition

A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.

Interpretive Guideline

Patients new to dialysis and/or a new dialysis setting frequently need time to adjust and adapt to the treatment. The 3 month comprehensive reassessment enables the IDT to re-evaluate how well patients follow their treatment plan, their educational, psychosocial, rehabilitation, and nutritional needs, their current adjustment to the dialysis regimen and coping, and the accuracy and appropriateness of patients ' plans of care.

Determine what system is in place to ensure completion of the 3 month comprehensive patient reassessments.

FED - V0518 - PA-ASSESS HD ADEQ Q MO;PD ADEQ Q 4 MO

Title PA-ASSESS HD ADEQ Q MO;PD ADEQ Q 4 MO

Type Standard

CFR 494.80(c)

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Regulation Definition

The adequacy of the patient's dialysis prescription, as described in §494.90(a)(1), must be assessed on an ongoing basis as follows:
(1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure.
(2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

Interpretive Guideline

Monthly assessment of dialysis adequacy for all HD patients, and at least every 4 months for PD patients must be demonstrated.

The facility must have a method or procedure in place for obtaining the blood samples used for the Kt/V or an equivalent measure. The facility must ensure the method/procedure used would result in an accurate result. At the time of the publication of these regulations, the recommended method stipulated for drawing blood samples to measure Kt/V included the following:
o Pre- and post- samples are drawn at the same treatment;
o Pre sample is drawn just prior to the start of treatment;
o Slow flow or stop pump technique is used for the post sample; staff should slow the blood pump speed to 50-100 mL/min for 15 seconds before drawing blood; in the event the equipment in use does not allow for "slow flow," then "stop flow" may be substituted;
o After 15 seconds, staff should draw the post dialysis BUN sample from the arterial port closest to the patients.

All facility staff members must follow the same prescribed procedure for obtaining blood samples used for assessing the adequacy of the patient's prescription.

Home hemodialysis patients should be instructed to draw their samples in this same way.

Recognize that obtaining the sample to measure adequacy for PD patients depends on their cooperation with bringing samples of dialysate effluent and urine. If a scheduled sample is not obtained, staff should document the missed test, reschedule the test (including obtaining a blood sample on the same date as the fluid samples are collected), and consider reminders and re-education of the patient.

FED - V0519 - PA-FREQUENCY REASSESSMENT-STABLE 1X/YR

Title PA-FREQUENCY REASSESSMENT-STABLE 1X/YR

Type Standard

CFR 494.80(d)(1)

Regulation Definition

In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive

Interpretive Guideline

There must be a complete, comprehensive reassessment of all stable patients annually. The first annual reassessment would be due 12 months after the 3 month reassessment, or 15 months after the patient's admission to the facility.

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reassessment of each patient and a revision of the plan of care must be conducted-
(1) At least annually for stable patients;

Annual reassessments for stable patients are the required minimum; more frequent reassessments of stable patients may be done if required by facility policy or by clinical concerns.

If patients who have been identified by staff as "stable" demonstrate one of the issues listed as criteria for being considered "unstable," this finding would be cited at V520.

FED - V0520 - PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO

Title PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO

Type Standard

CFR 494.80(d)(2)

Regulation Definition

In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-

At least monthly for unstable patients including, but not limited to, patients with the following:
(i) Extended or frequent hospitalizations;
(ii) Marked deterioration in health status;
(iii) Significant change in psychosocial needs; or
(iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.

Interpretive Guideline

The criteria listed here are the minimum criteria for classifying patients as "unstable." The IDT members have the flexibility to use their professional judgment to develop more stringent policies regarding the definition of "unstable," based on their unique patient population and patient characteristics and to add other assessment criteria.

"Extended hospitalizations" would include hospitalizations longer than 15 days, which was longer than the average length of stay nationally at the time these regulations were published.

"Frequent hospitalizations" would include more than three hospitalizations in a month, which was more than the average number of hospitalizations annually at the time these regulations were published. The reason for hospitalization may also result in a patient being classified as "unstable, for example, if the hospitalization results in amputation of a limb.

"Marked deterioration in health status" would be specifically identified and documented by the IDT. The following conditions have been suggested by representatives of the renal community:
o Change in ambulation severe enough to interfere with the patient's ability to follow aspects of the treatment plan;
o Hypotension, restlessness, pruritus or other symptoms severe enough to prevent completion of the majority of dialysis treatments;
o Sudden onset of recurrent cardiac arrhythmias;
o Recurrent infections (not recurring hospitalization);
o Chronic congestive heart failure with chronic hypotension;
o Advanced or metastatic cancer or other organ system disease which interferes with the patient's ability to follow

aspects of the treatment plan;
o Chronic or recurrent peritonitis

"Significant change in psychosocial needs" would include any event that interferes with the patient's ability to follow aspects of the treatment plan. Such events may include instability in one's own or immediate family member's employment, physical or emotional abuse, deterioration in mental or functional status, amputation, housing instability, death or major illness in the family, consideration of terminating treatment, and loss of emotional support. In addition, any patient considered at risk for involuntary discharge or transfer must be considered "unstable." Note that V767 requires that patients at risk for involuntary discharge be reassessed.

"Poor nutritional status" would include failure to thrive symptoms, with loss of body weight and low serum albumin.

"Unmanaged anemia" would include continued lab findings of hemoglobin/hematocrit values which are out of range as defined by community-accepted standards or Centers for Medicare and Medicaid Services (CMS) Clinical Performance Measures (CPMs). Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical standards and current CMS CPMs.

"Inadequate dialysis" would include a trend of results for Kt/V or URR which do not meet minimum expectations as defined by community-accepted standards or CMS CPMs for a three month period of time. Refer to the MAT. Inadequate dialysis would also include symptoms related to fluid management such as volume overload or depletion; intradialytic symptoms such as syncope or congestive heart failure; hypertension; or the need for extra treatment(s) for fluid removal.

Facilities must have a method for classifying patients as "unstable." Documentation should be available of a monthly re-assessment and plan of care revision that addresses the issues related to the classification of the patient as "unstable" until the issues have been resolved or the IDT (including the patient if possible) determine that the condition is chronic and the active care plan adequately addresses the issues.

Some "changes" leading to the patient classification of "unstable" are clearly within the purview of a specific member of the IDT. For example, while housing instability falls within the realm of the social worker, expect to see documentation of communication regarding a change in housing between the social worker and other members of the IDT who can determine the specific impact of that change on their specialty. The participation of some team members around some changes that do not impact their specialty may be limited.

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FED - V0540 - CFC-PATIENT PLAN OF CARE

Title CFC-PATIENT PLAN OF CARE

Type Condition

CFR 494.90

Regulation Definition

Interpretive Guideline

The Condition is directly related to the Condition for 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.

The Condition for Patient plan of care reviews individual patient outcome data and addresses the goals and plans set for individual patients, while the Condition for Quality assessment and performance improvement (QAPI) reviews aggregate data for trends and commonalities and addresses facility-wide goals and improvement plans.

Survey tasks of observation, patient and staff interviews and medical record review are used to evaluate compliance with this Condition. Identification of issues such as lack of blood pressure monitoring at the frequencies required by facility policy or as indicated by the patient's condition, or the failure to respond to hypertension or hypotension may indicate a failure to develop or implement a portion of the plan of care. Use the Measures Assessment Tool (MAT) during review of records for a ready reference of the current professionally-accepted clinical practice standards which facilities should be using to establish targets for individual patient's clinical outcomes. Recognize that the standards included in the MAT are targets. Each patient should be treated individually. When a specified target is not met, the plan of care should either be adjusted to achieve the target or to provide an explanation by the IDT in areas where the targets are not able to be achieved.

Examples of Condition level non-compliance would include, but not be limited to:
o Serious and/or pervasive deficient practices identified in the development or implementation of individualized plans of care;
o A pattern of failure to revise the applicable portion of the plans of care when the current plan did not result in achieving or sustaining the intended outcome; or
o A pattern of failure in updating the plans of care when indicated by the patient's condition.

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FED - V0541 - POC-GOALS=COMMUNITY-BASED STANDARDS

Title POC-GOALS=COMMUNITY-BASED STANDARDS

Type Standard

CFR 494.90

Regulation Definition

The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.

Interpretive Guideline

The interdisciplinary team (IDT) consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician who is treating the patient for ESRD, a social worker, and a dietitian. Each team member must meet the qualifications outlined in the Condition for Personnel qualifications at §494.140.

The facility must recognize the patient or his/her designee as a member of the IDT and encourage the patient's participation in developing and updating the plan of care. The patient's needs, wishes, and goals must be considered in making decisions about the plan of care. If a patient chooses to use a designee, there must be written authorization from the patient for sharing of protected health information with the designee.

A registered nurse with knowledge of the patient must serve as a member of the team. The registered nurse participating in the plan of care for home dialysis patients should work in the home dialysis program and have knowledge of the home dialysis patient.

The written patient plan of care must be individualized for the patient, built on the comprehensive assessment as outlined at V502-515 under the Condition for Patient assessment, and include at minimum:
problem(s) identified at assessment/reassessment, measurable goals/outcomes, planned interventions for achieving the goals, timetables and reassessment date(s). Review of the plan of care, treatment records, progress notes, laboratory reports, etc. should demonstrate implementation of the plan of care.

The patient plan of care includes all of the care, services, and treatment interventions the IDT determines to implement to meet the specific needs of the patient. The written patient plan of care may be one document or composed of separate sections, but must be congruent and reflect the integration of the comprehensive assessments contributed by all the members of the IDT. Electronic or paper formats may be used.

Timelines for meeting the specified targets should be based on setting reasonable targets for the individual patient, and appropriate to the severity of the problem and the extent of the planned interventions (e.g., acute issues should have shorter timelines).

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Professionally-accepted clinical practice standards, guidelines and CMS Clinical Performance Measures (CPM) must be used to derive the measurable and expected outcomes. Where applicable, refer to the "Measures Assessment Tool" (MAT) provided which lists the current professionally-accepted clinical standards and current CMS CPMs. Goals for some patients may need to be initially different from these targets, then incrementally changed to the standard target value as the patient outcome improves.

FED - V0542 - POC-IDT DEVELOPS PLAN OF CARE

Title POC-IDT DEVELOPS PLAN OF CARE

Type Standard

CFR 494.90(a)

Regulation Definition	Interpretive Guideline
The interdisciplinary team must develop a plan of care for each patient.	There must be an interdisciplinary plan of care developed for each patient. Facilities must have a system for developing patients' plans of care. The IDT members are expected to interact and share information from the comprehensive assessment to facilitate the development of the plan of care. To ensure the development of a congruent, integrated patient plan of care, the facility may conduct IDT conferences or use another mechanism that ensures the development of an integrated plan. A substitute mechanism for a team conference needs to facilitate discussion among team members about the information gathered from the comprehensive patient assessment and provide the opportunity for team coordination and development of an effective, individualized plan of care for the patient to ensure the desired outcomes are achieved. To facilitate full team participation in conferences, any member, including the patient, may participate through telecommunication.

FED - V0543 - POC-MANAGE VOLUME STATUS

Title POC-MANAGE VOLUME STATUS

Type Standard

CFR 494.90(a)(1)

Regulation Definition	Interpretive Guideline
The plan of care must address, but not be limited to, the	Volume status is measured in terms of the dialysis patient's "target weight," or estimated dry weight (EDW): what the

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following:
(1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status;

patient would weigh if he/she were "dry." A patient at their EDW should be asymptomatic and normotensive on minimum blood pressure medications, while preserving organ perfusion and maintaining existing residual renal function. A patient at their EDW attains normotension for most of the interdialytic period, while avoiding orthostatic hypotension or postural symptoms either during or after dialysis. Excess fluid accumulation may have adverse effects (e.g., hypertension, left ventricular hypertrophy, cardiovascular complications, hospitalizations). Removal of too much fluid or removing it too fast in one dialysis treatment or going below the patient's target weight may cause hypotension, muscle cramping, and clotting of the vascular access. Each patient should be weighed before and after each treatment. The ultrafiltration component of the hemodialysis prescription should be optimized with a goal to render the patient euvolemic and normotensive. With successful fluid management, the number of medications a patient needs for blood pressure control may be able to be reduced. There should be a target weight identified for each patient, and evidence that failure to achieve the target weight through the dialysis treatment is addressed.

Evidence of implementation of the plan of care for this aspect would include treatment records reflecting attaining the target weight at the end of each treatment or documentation acknowledging the target weight was not attained with an assessment of the reason for not attaining it, and a plan to correct this issue. The plan should include frequent assessment of the target weight with changes as indicated; scheduling an extra treatment; educating staff regarding machine settings and monitoring; counseling the patient regarding fluid intake; etc., as indicated for the specific patient and circumstance.

Patients' blood pressures must be monitored pre, during, and post treatment and abnormally high or low values must be addressed. Excessively high or low blood pressure measurements during treatment without evidence of assessment and action to address those values would indicate the plan of care for this parameter was either not developed or not implemented.

FED - V0544 - POC-ACHIEVE ADEQUATE CLEARANCE

Title POC-ACHIEVE ADEQUATE CLEARANCE

Type Standard

CFR 494.90(a)(1)

Regulation Definition

Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for

Interpretive Guideline

The patient plan of care should use dialysis adequacy goals in accordance with current professionally-accepted clinical practice standards/CMS CPMs. Refer to the Measures Assessment Tool (MAT) which lists those for dialysis adequacy.

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adequacy of dialysis.

The patients' dialysis prescriptions (dialyzer, blood flow rate, dialysate flow rate, length of treatment time) and the efficacy of the vascular access affect the dose of dialysis delivered. If alarms stop the dialysis ultrafiltration "clock", the "remaining treatment time" or planned treatment time may need to be extended to fulfill the patient's dialysis prescription.

In meeting this requirement, the IDT should review the Kt/V results to determine if the patient's adequacy values attain the goal; if not, the IDT should compare treatment orders and dialysis treatment records to determine if the prescribed dose of dialysis is being delivered. If the patient is not receiving an adequate treatment, the IDT should develop a plan to address the problem. For example, if a conventional 3 times a week HD patient's Kt/V is below 1.2 for several testing consecutive periods, a causal analysis should be done and the plan of care revised to address the identified problems.

Patients should have an understanding of dialysis adequacy and the consequences of skipping dialysis treatments or cutting treatments short. If the patient shortens treatments, misses treatments, or gains excessive fluid between treatments, the prescribed dose of dialysis may not be able to be delivered. If a patient routinely shortens or skips treatments, the plan of care for adequate treatment should investigate the root cause(s) (e.g., fear of intradialytic morbidity, prolonged recovery time, schedule conflicts with life responsibilities, transportation issues) and work with the patient to reduce or correct the cause(s). Ultimately, the patient can choose to continue behaviors that result in lessened treatment results. With documentation of educational efforts, the patient ' s choice can be an explanation on a plan of care for not achieving standard treatment results.

The requirements for patient assessment of dose of dialysis are at V518.

FED - V0545 - POC-EFFECTIVE NUTRITIONAL STATUS

Title POC-EFFECTIVE NUTRITIONAL STATUS

Type Standard

CFR 494.90(a)(2)

Regulation Definition

The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be

Interpretive Guideline

The facility must have established target goals for patients' albumin levels, and monitor each patient's body weight trends. Other nutritional markers including, but not limited to, sodium, calcium, phosphorus, and potassium, should also be routinely monitored. Facilities may use additional nutritional markers and assessments as determined by the IDT. The nutritional marker targets, including albumin, should reflect professionally-accepted clinical practice standards. Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical

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monitored, as appropriate.

standards for nutritional status markers. At the time of publishing these regulations, there were two methods of measuring albumin in use, with different ranges.

If the patient record shows a trend of problems in the patient's nutritional status, the IDT must develop an outcome-oriented plan of care for nutritional status and implement the plan. For example, if the patient's albumin levels were consistently below target levels, there should be an individualized plan of care to address the possible causes (e.g., inadequate dialysis, poor understanding of diet, limited availability of nutritious food, fluid volume overload). To meet the requirement to "achieve and sustain an effective nutritional status," the medical records of patients with outcomes lower than the expected standard should demonstrate continuing efforts tailored, implemented, assessed for success, and revised to address the individual patient challenges in this area. In the event the patient has a wasting disease, cachexia, or chronic inflammation contributing to a poor nutritional state, the plan of care should acknowledge these as limiting factors in achieving and sustaining the goal for nutritional status.

While it is not expected or required for facilities to provide nutritional supplements, the dietitian is expected to assist patients in achieving their nutritional goals by providing education, counseling and encouragement.

The requirements for patient assessment of nutritional status are at V509.

FED - V0546 - POC-MANAGE MINERAL METABOLISM

Title POC-MANAGE MINERAL METABOLISM

Type Standard

CFR 494.90(a)(3)

Regulation Definition

Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

Interpretive Guideline

Disturbances in mineral and bone metabolism are common in patients with ESRD, often resulting in hyperparathyroidism and Chronic Kidney Disease (CKD) mineral and bone disorder, if not managed effectively. The lab markers of calcium, phosphorous and parathyroid hormone (PTH) are generally used to monitor mineral metabolism.

Expect the facility to have established target goals for patients' calcium, phosphorus and PTH levels which reflect professionally-accepted clinical practice standards and CMS CPMs. Refer to the Measures Assessment Tool (MAT) which lists the targets for CKD mineral and bone disorder.

Interventions for prevention and management of CKD mineral and bone disorder may include nutritional counseling,

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and the administration of medications (e.g., phosphate binders, vitamin D analogs, calcimimetic agents). If the facility is using a medication algorithm/protocol for managing CKD mineral and bone disorder, the care for each patient must be individualized. The physician or non physician practitioner (i.e., advanced practice registered nurse or physician assistant) is responsible for ordering medications and laboratory tests and may or may not prescribe standing orders or the use of a standard algorithm.

Pediatric patients present special growth and development needs for management in this area. Facilities treating pediatric patients should have specialized methods for monitoring and management of CKD mineral and bone disorder.

The methods used for management of CKD mineral and bone disorder should be evident in review of records for laboratory reports, orders for CKD mineral and bone disorder management medications (e.g. vitamin D analogs) and medication administration records. Each patient's laboratory values must be monitored, values outside the target levels addressed, doses adjusted, and medications administered as ordered. If the patient ' s mineral metabolism goals are not being attained to "manage and prevent or treat" CKD mineral and bone disorder, the team should identify potential causes and address the barriers that may be preventing the patient from reaching the target values (e.g., failure to take medications or follow prescribed diet, lack of understanding or resources to obtain medications). Patients must be educated to understand their role in managing the prescribed diet, medications, and managing bone health. Enlistment of patients to be involved in their care is critical to success and attainment of these goals.

The requirements for patient assessment of CKD mineral and bone disorder are at V508.

FED - V0547 - POC-MANAGE ANEMIA/H/H MEASURED Q MO

Title POC-MANAGE ANEMIA/H/H MEASURED Q MO

Type Standard

CFR 494.90(a)(4)

Regulation Definition

The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level.

The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of

Interpretive Guideline

The facility must establish targets in anemia management that reflect professionally-accepted clinical practice standards/CMS CPMs. Refer to the MAT which lists these for anemia management.

The IDT should have a plan for managing patients' anemia. The laboratory reports, orders for erythropoiesis-stimulating agents (ESAs) and medication administration records should be considered as a part of the anemia management program. Facilities that use medication algorithms or protocols for managing anemia must

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the patient's anemia management needs.

ensure that the care for each patient is individualized. The physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant) is responsible for ordering medications and laboratory tests and may or may not use standing orders or a standard algorithm.

Each patient's laboratory values must be monitored, and values outside the target levels must be addressed, doses adjusted, and ESAs administered as ordered. Hemoglobin/hematocrit values must be measured at least monthly; many facilities measure these more frequently, especially if the values are outside the recommended target range or the patient has co-morbid conditions (such as cardiovascular disease) which may warrant more frequent monitoring. The IDT team must assess each patient to identify his or her unique needs for anemia management.

If there is a trend of problems in managing an individual patient's anemia, the IDT must develop an outcome-oriented plan based on their assessment of the problem and identification of possible barriers to attaining the goals. Due to various co-morbid conditions (e.g., sickle cell disease, persistent iron deficiency, frequent hospitalizations, chronic blood loss, cancer, infection, fluid volume overload), some patients may not respond to ESA therapy as expected. In the event of hyporesponse, there must be evidence that the patient was evaluated as to the possible underlying cause(s) for the resistance to anemia management therapy and the plan of care revised accordingly. ESA therapies have been found to be detrimental to some patients when administered at high doses or when the hemoglobin level is driven above 13. The IDT must take all information regarding ESA therapies into account as they manage the anemia of individual patients.

The requirements for patient assessment of anemia are at V507.

FED - V0548 - POC-HOME PT-EVAL SAFE ESA ADMIN

Title POC-HOME PT-EVAL SAFE ESA ADMIN

Type Standard

CFR 494.90(a)(4)

Regulation Definition

For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary.

Interpretive Guideline

The home dialysis patient and/or caregiver must be trained and determined competent by a home dialysis nurse in the safe administration and storage of ESAs. Use this tag if issues specifically related to safe use and storage of ESAs are identified. Refer to the Condition for Care at home at V585.

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FED - V0549 - POC-MONITOR ESA RESPONSE

Title POC-MONITOR ESA RESPONSE

Type Standard

CFR 494.90(a)(4)

Regulation Definition

The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

Interpretive Guideline

The facility must monitor patients' blood pressures and act upon significant abnormalities for that patient. Hypertension may have many causes; failure to develop and implement a plan to control high blood pressure should be cited at V543.

Measurements of patients' iron stores include serum ferritin and transferrin saturation. The facility must establish targets for iron management that reflect professionally-accepted clinical practice standards/CMS CPMs. Refer to the Measures Assessment Tool (MAT) which lists these for anemia/iron management.

If the IDT chooses to use medication algorithms or protocols for anemia/iron management, the care for each patient must be individualized. The physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant) is responsible for ordering medications and laboratory tests and may or may not use standing orders or an algorithm.

The IDT must develop a program for anemia and iron management, and monitor laboratory results, orders for intravenous iron preparations and medication administration records to address values outside the target levels. Laboratory values outside the target levels must be addressed, doses adjusted, and medications administered as ordered.

If there is a trend of problems in iron management for an individual patient, the IDT must develop an outcome-oriented plan based on their assessment of the problem and identification of possible barriers to attaining the goals.

The requirements for patient assessment of anemia/iron are at V507 and for blood pressure/fluid management at V504.

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FED - V0550 - POC-VASCULAR ACCESS-MONITOR/REFERRALS

Title POC-VASCULAR ACCESS-MONITOR/REFERRALS

Type Standard

CFR 494.90(a)(5)

Regulation Definition

The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.

Interpretive Guideline

Based on the comprehensive assessment, the facility IDT must develop and implement a plan of care to facilitate each hemodialysis patient receiving and maintaining the most appropriate and optimal vascular access identified for that patient.

A well functioning vascular access enables the hemodialysis patient to receive efficient/adequate dialysis treatments, enhancing their quality of life. The determination of which type of vascular access is the most appropriate for the individual patient requires the integration and coordination between the facility IDT, including the patient/designee, and may include referrals for vessel mapping, surgical consult, Doppler studies, etc., enlisting the participation of other entities, such as primary care physicians, surgeons, interventional radiology, and surgical or vascular access centers for access placement and maintenance.

To meet this requirement to "achieve and sustain" vascular access, the patient's medical record must include evidence of the evaluation and the basis for the decision for placement of the current vascular access. If the records from the surgeon are not available, the patient's physician, advanced practice registered nurse or physician assistant is expected to provide this information from communication with the surgeon. If the patient's vascular access is not an arteriovenous fistula, the record should indicate why the patient was determined to not be a candidate for a fistula. If a patient has been dialyzed with a central venous catheter in excess of 90 days, there should be an active plan in process for the placement of a more permanent vascular access or information in the record to demonstrate that a catheter is the most appropriate vascular access for that patient. Some patients may not be candidates for a fistula or graft; each patient has a right to make an informed choice. Patients must be informed and educated about the benefits, risks and hazards of each type of vascular access. Repeated education may be needed. The IDT must involve the patient/designee in the plan for vascular access. The facility social worker should be involved and determine whether psychosocial considerations, such as body image, needle fear or anxiety need to be addressed.

Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical standards and CMS CPMs for vascular access. The MAT incorporates measures/standards from the Department of Health and Human Services ' Fistula First Breakthrough Initiative. This initiative has joint goals of increasing fistula use in

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dialysis patients, while also decreasing the inappropriate use of catheters in these patients.

Vascular access monitoring is addressed in V551. Requirements for vascular access assessment are at V511.

FED - V0551 - POC-VA MONITOR/PREVENT FAILURE/STENOSIS

Title POC-VA MONITOR/PREVENT FAILURE/STENOSIS

Type Standard

CFR 494.90(a)(5)

Regulation Definition

The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

Interpretive Guideline

The facility must have an on-going program for vascular access monitoring and surveillance for early detection of failure and to allow timely referral of patients for intervention when indications of significant stenosis are present. Patient education should address self-monitoring of the vascular access.

"Monitoring" strategies may include physical examination of the vascular access; observance of changes in adequacy or in pressures measured during dialysis; difficulties in cannulation; or in achieving hemostasis. Precipitating events should also be noted, such as hypotension or hypovolemia. Surveillance strategies include device-based methods such as access flow measurements, direct or derived static venous pressure ratios, duplex ultrasound, etc.

For patients with grafts and fistulas, the medical record should show evidence of periodic monitoring and surveillance of the vascular access for stenosis and signs of impending failure. The documentation of this may be on the dialysis treatment record, progress notes, or on a separate log. A member of the facility staff must review the vascular access monitoring/surveillance documentation to identify adverse trends and take action if indicated.

Refer to the Condition for Infection Control at V147 and V148 and the Condition for QAPI at V633 which also cover monitoring and surveillance of vascular accesses.

FED - V0552 - POC-P/S COUNSELING/REFERRALS/HRQOL TOOL

Title POC-P/S COUNSELING/REFERRALS/HRQOL TOOL

Type Standard

CFR 494.90(a)(6)

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Regulation Definition

The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

Interpretive Guideline

To address the patient's psychosocial needs and "achieve and sustain" an appropriate psychosocial status, each patient's plan of care must reflect the information obtained from the applicable components of the IDT comprehensive assessment under the Condition for Patient assessment at V502-V515, including the psychosocial assessment at V510. The plan of care must include interventions individualized to meet that patient's psychosocial needs and aimed at optimizing the patient's adjustment to kidney failure and its treatment. The social worker is expected to assist patients in achieving their psychosocial goals. Counseling services to patients and their families should be directed at helping the patient and family cope with kidney failure and dialysis, follow the treatment plan, and achieve the patient's goals for rehabilitation.

While this regulation allows the social worker to choose a "standardized mental and physical assessment tool," the tool selected by the National Quality Forum and the CMS CPMs for adult patients is the KDQOL-36 assessment survey. In the future, the percentage of patients taking this assessment survey annually will need to be reported electronically to CMS. Facilities may choose to use the KDQOL-36 from the implementation date of these regulations in order to have more comparable data once the KDQOL-36 is mandated. Pediatric patients should be assessed using an age appropriate assessment tool.

"At regular intervals" means that the assessment survey is administered by the time of the first reassessment (i.e., within 4 months of initiating treatment), and repeated at least annually. Examples of an "as needed basis" would include repeat use of the survey with the patient who has a significant life changing event (e.g., loss of spouse, loss of job, recent move to a nursing home) or a change in health status.

The social worker must have a system for routine use of the assessment survey, evaluation of the results, and incorporation of the survey results into the development and updating of the psychosocial portion of the plan of care.

Referrals for social services may include those to providers of community mental health services, transportation providers, in-home support services, food banks or other available community resources. Patients will vary in their needs for interaction with the social worker and referral for other social services. Enhanced and more frequent social services interventions are expected for patients who present with or develop greater psychological, social, and/or financial issues.

Refer to the MAT which lists the current professionally-accepted clinical standards and current CMS CPMs for psychosocial status.

The requirements for assessment of patients' psychosocial needs are at V510.

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FED - V0553 - POC-HOME DIALYSIS PLAN OR WHY NOT

Title POC-HOME DIALYSIS PLAN OR WHY NOT

Type Standard

CFR 494.90(a)(7)(i)

Regulation Definition

The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

Interpretive Guideline

The patient plan of care must reflect the information from the IDT evaluation of the patient's suitability for and level of interest in home dialysis modalities required under the Condition for Patient assessment at V512.

Patient records must demonstrate that each patient was informed about all available dialysis modalities and locations for home dialysis training if that service is not available at this facility. If the patient expressed interest in home dialysis and was determined to be a suitable candidate, the plan of care should list use of this modality as a goal and identify ways to achieve it (e.g., timeline for training in home dialysis at current facility, referral to a facility certified for home training and support). If the patient declined or was determined not suitable for home dialysis, the IDT must document their rationale for this decision.

FED - V0554 - POC-TRANSPLANT STATUS PLAN OR WHY NOT

Title POC-TRANSPLANT STATUS PLAN OR WHY NOT

Type Standard

CFR 494.90(a)(7)(ii)

Regulation Definition

When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the-
(A) Plan for transplantation, if the patient accepts the transplantation referral;
(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or

Interpretive Guideline

The patient's plan of care must reflect the information from the interdisciplinary team's evaluation of the patient's suitability for transplantation referral, required under the Condition for Patient assessment at V513.

The patient record must show evidence that the patient was informed about transplantation as an option, living and deceased kidney donation, area transplant center(s) and each transplant facility's selection criteria. Each patient's record must reflect the IDT's determination about the patient's suitability and whether the patient accepted or declined referral for transplantation and reason for nonreferral.

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(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with §494.80(a)(10).

If a patient was determined as suitable for transplantation referral, the IDT must document making the referral and providing applicable information to the transplant center as appropriate or when requested.

Documentation in patient records should agree with the patient's understanding of their status as a transplant candidate. Patients may independently contact a transplant center for an appointment for more information and evaluation. If this is the case, the IDT should be aware of the self-referral. A patient's insurance coverage and a transplant center's selection criteria may dictate which transplant center(s) the patient can access.

FED - V0555 - POC-REHAB STATUS ADDRESSED

Title POC-REHAB STATUS ADDRESSED

Type Standard

CFR 494.90(a)(8)

Regulation Definition

The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

Interpretive Guideline

The patient plan of care must reflect the information from the interdisciplinary patient evaluation/assessment for rehabilitation status required at V515. The goals for the plan of care in this area must be individualized for the patient (e.g., return to a former occupation, attain an educational certificate or diploma, return to normal activities within a household, etc.) and reflect the patient's preferences.

Pediatric patient services should address normal growth and development needs, education needs, and age-appropriate activities, especially if dialysis treatments take place during hours when the child would normally be in school.

The social worker should be aware of the availability of community referral options for physical and vocational rehabilitation services for all patients, and educational resources for pediatric patients, if applicable for this facility. The IDT should have a plan and procedure for making referrals for rehabilitation.

The IDT must provide and document assistance (e.g., education, encouragement) and referrals, if indicated, which were aimed at enabling patients to maintain or return to their desired level of functioning at work, school, home and in their community.

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FED - V0556 - POC-COMPLETED/SIGNED BY IDT & PT

Title POC-COMPLETED/SIGNED BY IDT & PT

Type Standard

CFR 494.90(b)(1)

Regulation Definition

The patient's plan of care must-
(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and
(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

Interpretive Guideline

The IDT consists of, at a minimum, the patient/designee, a registered nurse, the qualified social worker, the qualified dietitian, and the patient's physician. Refer to the Condition for Patient assessment at V501. The patient ' s level of participation should be controlled by the patient's (not the staff's) motivation; however, staff encouragement can improve patient motivation. Each patient's plan of care must show evidence of the participation/contribution from all of the professional members of the IDT.

Each team member is expected to sign the plan of care, including the patient. The patient's signature is to acknowledge the information in the plan. If the patient chooses not to sign their plan of care, the reason for refusal must be documented.

FED - V0557 - POC-INITIAL IMPLEMENTED-30 DAYS/13 TX

Title POC-INITIAL IMPLEMENTED-30 DAYS/13 TX

Type Standard

CFR 494.90(b)(2)

Regulation Definition

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.

Interpretive Guideline

The timeline for both the completion of the initial comprehensive assessment and the beginning of implementation of the initial patient plan of care is the latter of 30 days from the date of admission or 13 hemodialysis treatments at the facility. Refer to V516. For patients who have more than 3 treatments a week, e.g., those on peritoneal dialysis or daily/nocturnal hemodialysis, the plan of care is expected to be completed within 30 days from the date of admission, excluding any days the patient is hospitalized during that period.

The plan of care should be dated to indicate when the plan was initiated. Although the plan of care must be initiated within the required timeline, the schedule for full implementation of the plan will vary depending upon the complexity

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of the plan.

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. See V715 under the Condition for Medical director for this requirement.

FED - V0558 - POC-IMPLEMENT UPDATE-15 DAYS P PT ASSESS

Title POC-IMPLEMENT UPDATE-15 DAYS P PT ASSESS

Type Standard

CFR 494.90(b)(2)

Regulation Definition

Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in §494.80(d).

Interpretive Guideline

As specified in the Condition for Patient assessment at V519 and V520, when there is an interdisciplinary comprehensive reassessment of the patient, the plan of care must be updated accordingly and implementation initiated within this timeline.

Monthly updates of the plan of care are required for unstable patients, while annual updates are acceptable for stable patients. Refer to V520 for the minimum criteria for stable vs. unstable status.

The implementation of updates to the patient plan of care must be completed within 15 days of the reassessment.

FED - V0559 - POC-OUTCOME NOT ACHIEVED-ADJUST POC

Title POC-OUTCOME NOT ACHIEVED-ADJUST POC

Type Standard

CFR 494.90(b)(3)

Regulation Definition

If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-

Interpretive Guideline

If the current plan of care has not been successful in achieving the goals identified by and for the patient within the identified timetables, there must be evidence that barriers to achievement of the goals were identified and that the plan was reviewed and revised, as indicated. For example, if the patient's Kt/V is below the expected goal for more than one month, the physician or the non-physician practitioner might adjust the dialysis prescription by extending the

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(i) Adjust the plan of care to reflect the patient's current condition;
(ii) Document in the record the reasons why the patient was unable to achieve the goals; and
(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

treatment time or changing the dialyzer. If the patient's Kt/V remained below target the following month, the team should collaboratively identify the potential reasons the patient is not reaching the minimum goal for hemodialysis adequacy and implement changes in the plan of care to address and resolve the identified barriers. This example would not require a reassessment and completely new plan of care; if this is the only area where the goal was not met, the patient could be considered "stable," and only the plan of care for adequacy would require adjustment.

This requirement is not met if the patient's plan of care is not adjusted and there is no evidence the IDT is working to address ongoing problems (e.g., uncontrolled hypertension, hyperkalemia, missed treatments, inaccurate or unattainable target weight) which may result in adverse outcomes for the patient. This requirement is not satisfied if the only reason documented for failure to achieve goal(s) is "patient non-compliance" or "non-adherence." If the team believes the cause of the failure to reach the goal is non-adherence, the IDT efforts should focus on identifying potential causes of the non-adherence and addressing those causes. The IDT must recognize each patient has the right to choose less than optimal care when the patient determines optimal care would negatively impact his/her quality of life.

These regulations require the IDT to demonstrate its members are actively attempting to meet each patient ' s plan of care goals. This Condition does not "require" a patient to meet every goal. Any member of the IDT, including the patient, may document why goals are not met or cannot be met.

FED - V0560 - POC-PTS SEEN BY MED STAFF 1X/MO

Title POC-PTS SEEN BY MED STAFF 1X/MO

Type Standard

CFR 494.90(b)(4)

Regulation Definition

The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

Interpretive Guideline

This requirement is to ensure that patients see a medical practitioner (i.e., physician, advanced practice registered nurse or physician assistant) at least monthly. The patient may see the practitioner in the dialysis facility (before, during or after treatment), or in the physician's office if the record of care for that visit is incorporated into the dialysis facility medical record.

"Periodically while the hemodialysis patient is receiving in-facility dialysis" is meant to refer to in-center patients and should generally result in at least quarterly practitioner visits at the dialysis center during dialysis treatment. By periodically visiting the patient in the dialysis facility, the physician has an opportunity to assess the patient's response to treatment and to observe the team care.

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At a minimum, monthly medical progress notes should document that a physician or that a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) who functions in lieu of the physician, has seen each patient and addressed the status and plan for that patient's renal and active comorbid problems

This requirement applies equally to home patients, who are expected to receive equivalent care to in-center patients. A monthly visit is required for each home patient by either a physician, an advanced practice registered nurse, or a physician assistant. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient ' s home.

Any patient may choose not to be seen by a physician every month. However, if there is a pattern of a patient consistently missing physician visits, the IDT should determine whether or not the patient is unstable according to these regulations, and should address the lack of medical oversight with the patient in the plan of care.

FED - V0561 - POC-TRACK TP REFER/STATUS;CONTACT TP CTR YRLY

Title POC-TRACK TP REFER/STATUS;CONTACT TP CTR YRLY

Type Standard

CFR 494.90(c)

Regulation Definition

The interdisciplinary team must-
(1) Track the results of each kidney transplant center referral;
(2) Monitor the status of any facility patients who are on the transplant wait list; and
(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

Interpretive Guideline

Requiring the facility to track patients' transplant referrals and their status on the transplant wait list is intended to enhance the communication and coordination between the transplant center and the dialysis facility so that patients do not get "lost" along the way in the transplant referral, work up and waiting period.

Tracking completion of the tests and evaluations required for a transplant work up and waiting list active status is primarily the responsibility of the patient in partnership with the transplant center. However, by communicating and coordinating activities with the transplant center, the dialysis facility IDT may be able to adjust their plan of care to facilitate the patient's transplantation goal. This communication should be systematic and documented.

A "change in status" refers to a medical or psychosocial event that could either temporarily or permanently change a transplant patient's status. The "change" could either enhance or limit a dialysis patient's opportunities to receive a transplant. Examples of "change" events are cardiac events, weight loss, cessation of smoking, or identification of a new potential living organ donor. The transplant center should be notified at the time of any change in status.

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The facility's patient transplant referral/waiting list status tracking may be centralized, but must also be documented in each referred patient's medical record.

FED - V0562 - POC-PT/FAMILY EDUCATION & TRAINING

Title POC-PT/FAMILY EDUCATION & TRAINING

Type Standard

CFR 494.90(d)

Regulation Definition

The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

Interpretive Guideline

The dialysis facility must provide patients and their family members/caregivers with education and training in these listed areas, at a minimum.

The IDT must have the skills and expertise needed to educate dialysis patients in these subjects, and to provide this education in a manner understood by the patient and family/caregiver.

Patients/designees must receive education regarding the types, risks, benefits and care of their vascular access, personal hygiene related to dialysis access, infection prevention, dietary and fluid management, etc. The patient's medical record must demonstrate the provision of patient education and training in all of the listed subject areas. There may be a single form or section of the medical record for information on patient education or it may be located in various parts of the record, such as the progress notes of the members of the IDT.

FED - V0580 - CFC-CARE AT HOME

Title CFC-CARE AT HOME

Type Condition

CFR 494.100

Regulation Definition

Interpretive Guideline

This Condition 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.

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Patient and staff interviews are critical to the survey of this Condition. Other important aspects of the survey process for this Condition include observation of training (if the opportunity is available) and review of patient medical records and administrative records. Home patients may be available for in-person interviews during training or a clinic visit, or if there are no home dialysis patients on-site at the facility during the survey, interviews with these patients or their helpers may be conducted by phone.

Condition-level noncompliance should be considered in, but not limited to, the following circumstances:
o Serious or pervasive problems with the oversight of care or provision of services for home dialysis patients which has or could impact the health and safety of those patients;
o Patients and/or helpers inadequately trained yet verified as competent in performing home dialysis procedures, resulting in poor clinical outcomes or adverse events;
o A pattern of failure to review clinical or technical lab reports and records; and
o Insufficient monitoring of the water treatment system for home hemodialysis.

FED - V0581 - H-IDT RESP FOR SERVICES=IN-CENTER PTS

Title H-IDT RESP FOR SERVICES=IN-CENTER PTS

Type Standard

CFR 494.100

Regulation Definition

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

Interpretive Guideline

Home dialysis patients are considered part of the census of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected patient outcomes as the in-center dialysis patients of the facility. All of the requirements of these regulations including those listed at the Conditions for Patients' rights, Patient assessment, Patient plan of care, and QAPI apply equally to home dialysis patients as well as to in-center dialysis patients.

Home dialysis patients include those receiving peritoneal dialysis (PD) and hemodialysis (HD) therapies in their homes. At the time of publishing these regulations, there were:
o Two methods of PD routinely available to home patients: continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) also known as automated PD (APD); and
o Three methods of HD routinely available to home patients: conventional home HD (treatments generally 3 to 4 hours, 3 days a week); short daily home HD (2-3 hours, 5-6 days/week); and nocturnal home HD (6-8 hours, 3 to 6 nights/week).

At the time of publishing these regulations, several different technologies for home hemodialysis were available.

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These included conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which used manufacturer packaged, bagged dialysate or which incorporated water treatment and dialysate preparation and delivery into one system; and sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer. All of these, and any future home hemodialysis technologies developed, present the home dialysis facility with both common and unique challenges for monitoring to ensure the continued efficacy and safety of the home hemodialysis patients' treatments.

For all home dialysis patients of the certified ESRD facility whose treatments incorporate the use of a dialysis machine, CMS reimbursement rules require that there be one machine used exclusively for each individual patient's home dialysis treatments. The same dialysis machine must not be used for treatment of multiple home patients.

The "interdisciplinary" team (IDT) consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian who meet the requirements as specified under the Condition for Personnel qualifications. Most home dialysis patients are active participants in their care and actively engaged with the interdisciplinary team in their plan of care.

The medical records of home dialysis patients should contain evidence of the care and management aspects of patient assessment, plan of care development and implementation of that plan of care by the facility interdisciplinary team as outlined in these regulations.

FED - V0582 - H-IDT OVERSEES HOME TRAINING

Title H-IDT OVERSEES HOME TRAINING

Type Standard

CFR 494.100(a)

Regulation Definition

The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in §494.10) and when the home dialysis caregiver or home dialysis modality changes.

Interpretive Guideline

As defined at §494.10 Definitions, "Home dialysis" means dialysis performed at home by an ESRD patient or "caregiver" (also called a "helper") who has completed an appropriate course of training as described in §494.100(a) of this part; "Self-dialysis" means dialysis performed with little or no professional assistance by an ESRD patient or helper who has completed an appropriate course of training as specified in §494.100(a) of this part.

A certified dialysis facility approved for outpatient maintenance dialysis services needs no additional certification or approval to provide in-center self-dialysis or to teach an in-center patient to perform all or part of their dialysis treatment (e.g., self-cannulate, monitor blood pressure). If a patient expresses the desire to perform self-dialysis

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in-center, the facility interdisciplinary team's response should incorporate assessment of that patient for self-care training and planning for the goal of self-care as appropriate. Refer to V512 under Patient assessment. Any patient who performs aspects of self-dialysis care must be trained and verified as competent prior to independently performing any part of his/her care.

Home dialysis training must be provided, and the patient and/or helper verified as competent to perform home dialysis before they are allowed to function independently. Although it is expected that most training for home dialysis would take place at the facility, home training may be provided in the patient's home to meet the individual needs of the patient and/or helper. Retraining must be provided whenever there is a change in home dialysis helper, treatment modality, or home dialysis equipment. Retraining may also be indicated if there are problems such as repeated episodes of peritonitis, vascular access infections, or a failure to achieve expected outcomes, including goals for dialysis adequacy and anemia management.

FED - V0583 - H-TRAIN BY CERTIFIED HOME TRAIN FACILITY

Title H-TRAIN BY CERTIFIED HOME TRAIN FACILITY

Type Standard

CFR 494.100(a)(1)

Regulation Definition

The training must-
(1) Be provided by a dialysis facility that is approved to provide home dialysis services;

Interpretive Guideline

For a dialysis facility to provide a home dialysis program, the facility must be certified for home dialysis services including both training and support. The facility may choose to apply for certification for peritoneal dialysis (PD) only, home hemodialysis (HHD) only, or both services. These services may be added to an existing facility. A new facility may apply for home dialysis services in addition to in-center services, or to provide only home dialysis services. The facility application for home dialysis should be directed to the State survey agency.

There are two "methods" of home dialysis delivery:
o Method I: the certified ESRD facility provides both training and all support including equipment and supplies; and
o Method II: the ESRD facility provides training and most support, but a Durable Medical Equipment (DME) supplier provides the home dialysis equipment and supplies. DMEs are not certified for and cannot provide home training.

The CMS-3427 End Stage Renal Disease Application/Notification and Survey and Certification Report should be completed to indicate that the facility is approved for PD and/or HHD training and support.

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FED - V0584 - H-TRAINING CONDUCTED BY QUALIFIED RN

Title H-TRAINING CONDUCTED BY QUALIFIED RN

Type Standard

CFR 494.100(a)(2)

Regulation Definition

The training must-
(2) Be conducted by a registered nurse who meets the requirements of §494.140(b)(2);

Interpretive Guideline

The nurse responsible for home dialysis training must be a registered nurse who meets the practice requirements of the State in which he or she is employed; have at least 12 months experience in providing nursing care; and an additional 3 months of experience working as a nurse in the specific modality (hemodialysis or peritoneal dialysis) for which the nurse will provide patient/helper training. Refer to V685.

While the qualified home training RN(s) is expected to be the primary staff member providing training and support whether training occurs in the dialysis facility or in the patient's home, other members of the clinical dialysis staff may assist in providing the home training, within the scope of practice and expertise/competencies of those staff members. For example, another nurse might reinforce earlier training done by the qualified RN; the dietitian might educate the patient about food and fluid limits based on the type of home dialysis treatment; the social worker might offer suggestions for keeping one's job or coping with any stress potentially created by home treatment; and the biomed staff might coach the patient/helper in troubleshooting equipment. The qualified home training RN is responsible to ensure that the all of the training is in accordance with the requirements listed in this Condition.

Use V685 for the failure to have a qualified nurse; use this tag if the qualified nurse is not primarily responsible for conducting training.

FED - V0585 - H-TRAIN CONTENT INCLUDES ER PREP HOME PTS

Title H-TRAIN CONTENT INCLUDES ER PREP HOME PTS

Type Standard

CFR 494.100(a)(3)

Regulation Definition

The training must-

Interpretive Guideline

The training must be individualized to the needs of each home dialysis patient. Patients/helpers may be trained in

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(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:
(i) The nature and management of ESRD.
(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.
(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.
(iv) Availability of support resources and how to access and use resources.
(v) How to self-monitor health status and record and report health status information.
(vi) How to handle medical and non-medical emergencies.
(vii) Infection control precautions.
(viii) Proper waste storage and disposal procedures.

small groups or individually, as long as the individual patient's needs are identified and addressed. The information provided should be tailored to the patient's/helper's level of understanding. Each of the subject areas listed here should be addressed in the record of the training. Examples for clarification of the subject areas are as follows:

The "full range" of home dialysis techniques would include:
o Specific (step-by step) instructions on how to use the patient's prescribed dialysis equipment (e.g. hemodialysis machine and water treatment components, peritoneal dialysis cycler);
o Specific (step-by step) instructions in home dialysis procedures (e.g. self-cannulation, peritoneal dialysis exchange) to facilitate adequate dialysis as prescribed by the physician; and
o Training in proper storage and administration of ESAs, if applicable. Refer to V548 for anemia management requirements for home patients.

Peritoneal dialysis patients must be taught to recognize, manage and report dialysis complications, including catheter, tunnel or exit site infection; peritonitis; catheter dislodgement; hypotension; hypokalemia; failure of sufficient dialysate to drain from the peritoneal space; protein malnutrition; etc. Home hemodialysis patients must be taught to recognize, manage and report such potential complications as vascular access problems (e.g., difficulty with cannulation, a change in bruit or thrill, bleeding), infections, hypertension or hypotension, hyperkalemia, etc.

Technical problems to be recognized, managed and reported would include power outages, failure of the PD cycler or HD machine, failure of water treatment components (e.g., chlorine/chloramine breakthrough), clotting of the hemodialysis circuit, dialyzer blood leaks, line disconnection, water supply problems or leaks, and problems with supply delivery.

The facility training program should include instruction aimed at enabling patients/helpers to detect, prioritize and report problems and to ensure that they are prepared to recognize and promptly act upon those situations which could present hazards to patient safety.
Training home dialysis patients/helpers to "handle" medical emergencies that may be anticipated (e.g., syncope, significant blood loss, cardiac events) would include immediate responses/actions and methods for contacting emergency medical systems. Refer to V768.

Training for non-medical emergencies may include those related to mechanical/technical equipment failures (as listed above), as well as preparing for natural or man-made disasters that may result in the inability to dialyze at home as scheduled and/or delays in supply delivery. Refer to V412.

Patients need to understand how to contact and use their support resources including their assigned facility staff

coordinator, physician, home training nurse, dietitian, social worker, dialysis equipment suppliers, machine manufacturers, water treatment personnel. As with in-center patients, facilities must provide home dialysis patients with contact information for the applicable ESRD Network and State survey agency.

Training for home patients to monitor their own health status should include the use of equipment to monitor heart rate, blood pressure, temperature, and weight; assessment of vascular or peritoneal dialysis access; recognizing adverse signs and symptoms; and when, how, and whom to contact if they experience problems with their health or treatment. Recording treatment and health status information for home dialysis patients includes documentation of the dialysis process, using hemodialysis or peritoneal dialysis specific treatment records.

The facility must provide home dialysis patients access to resources and assistance 24 hours/day, 7 days/week. This may be through a call system which can be reached by the patient/family/helper by phone, beeper, answering service or similar arrangement. Also refer to V768 under the Condition for Governance.

Training for infection control precautions should include, at a minimum, indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, vascular access or peritoneal catheter care and dressing changes, cleaning and disinfecting dialysis equipment, cleaning and disinfection procedures for spills and splashes of blood or effluent. Patients/helpers must understand how to properly dispose of needles, effluents, disposable items, blood tubing and dialyzers to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and dialysis tubing and other contaminated items in intact plastic bags before discarding.). The training staff must ensure that patients understand local waste management rules.

According to AAMI, as part of their training for home hemodialysis, the patient/helper should be instructed in any water/dialysate sample collection or any water/dialysate quality tests that they will be expected to perform in their homes. AAMI also states that the patient/helper shall be trained how to perform the chlorine analysis and shall be trained regarding what action to take if chlorine is detected above the specified limit. Depending upon the chlorine test used, the patient/helper should be capable of distinguishing between different shades of pink or a digital meter should be used to indicate the chlorine concentration.

Home dialysis training materials should address the training content listed above, at a minimum.

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FED - V0586 - H-PT/CAREGIVER DEMO COMPREHEND TRAINING

Title H-PT/CAREGIVER DEMO COMPREHEND TRAINING

Type Standard

CFR 494.100(b)(1)

Regulation Definition

The dialysis facility must -
(1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

Interpretive Guideline

Medical records should include documentation of the training provided, and evidence that the patient/helper demonstrated competence in performing the home dialysis procedures.

FED - V0587 - H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS

Title H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS

Type Standard

CFR 494.100(b)(2),(3)

Regulation Definition

The dialysis facility must -
(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and
(3) Maintain this information in the patient ' s medical record.

Interpretive Guideline

The dialysis facility must obtain and maintain records on all home patients including at a minimum, treatment records, flow sheets, medications administered, equipment and water treatment system checks, if applicable. The facility is responsible to assure that records of dialysis treatments in the home setting are retrieved and reviewed by the appropriate personnel at least every 2 months. Such review assists staff in monitoring home patients' status by determining if patients are following their treatment plans and/or having problems with their dialysis at home. When home hemodialysis or peritoneal dialysis machines have the capacity for interactive electronic documentation of the treatment data, the facility may obtain these data electronically, if the security of the electronic submission is in accordance with HIPAA privacy regulations, or from the patient, through a disc/card brought to the facility.

Home dialysis patients' medical records must include dialysis treatment records and evidence of their timely review by home dialysis personnel. If the patient or helper has not provided the appropriate records at least every 2 months, reasonable efforts by facility staff to obtain these records must be made and documented. The patient's plan of care should address any problem with adherence to this requirement. The applicable facility staff member (generally either

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the nurse responsible for home training, the attending physician, or a non-physician practitioner [i.e., advanced practice registered nurse, or physician assistant]) is responsible for review upon receipt of such time sensitive information as hospitalization data and radiology, pathology, and laboratory results that cannot wait 2 months for review.

FED - V0588 - H-SUPPORT SERVICES MUST BE PROVIDED

Title H-SUPPORT SERVICES MUST BE PROVIDED

Type Standard

CFR 494.100(c)(1)

Regulation Definition

A home dialysis training facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.

Interpretive Guideline

Whether the home dialysis training facility provides the patients' home dialysis equipment and supplies or the patient contracts with a DME supplier to obtain the equipment and supplies, the dialysis facility must provide all required support services, as listed in the following tags, either directly or by arrangement, to all home dialysis patients. A DME cannot provide home dialysis training or support services; these services must be provided by an ESRD facility certified for home training and support.

A facility that is certified to provide home dialysis services may also apply to be certified to provide dialysis in long-term care facilities. The special requirements for providing this service are detailed in a Survey and Certification Letter.

FED - V0589 - H-MONITOR HOME ADAPT;HOME VISIT=POC

Title H-MONITOR HOME ADAPT;HOME VISIT=POC

Type Standard

CFR 494.100(c)(1)(i)

Regulation Definition

Services include, but are not limited to, the following:
(i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

Interpretive Guideline

To assess a patient's home dialysis environment, a home visit should be conducted at the initiation of home therapy and whenever a problem is identified with either patient health or equipment that could be related to treatment at home. Periodic routine replacement of equipment would not necessarily require a home visit be scheduled. The interdisciplinary team may designate the most appropriate staff member(s) to make the home visit(s).

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Documentation of home visits should be included in the medical record. The number, timing, and frequency of home visits should be based on individual patient need as indicated in the patient's plan of care. Distance from the facility or concerns about staff safety should not preclude home visits. If a patient refuses a home visit, the interdisciplinary team must evaluate his/her refusal and the potential impact it may have on achieving the goals identified in the patient's plan of care as well as discuss alternative ways to assure the patient's health and safety at home.

FED - V0590 - H-COORDINATION OF CARE BY MEMBER OF IDT

Title H-COORDINATION OF CARE BY MEMBER OF IDT

Type Standard

CFR 494.100(c)(1)(ii)

Regulation Definition

Services include, but are not limited to, the following:
(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

Interpretive Guideline

The home training and support facility must identify a specific member of the interdisciplinary team to be responsible for the coordination of each individual home patient's care. "Coordination of care" does not mean that the staff member must deliver all of the care, but that the coordinating staff member is the "contact person" on the interdisciplinary team, is responsible for facilitating communication between the interdisciplinary team and the patient/helper, and ensures oversight/and monitoring of the patients' home dialysis in accordance with the patient ' s plan of care.

All patients should receive coordinated/integrated care no matter which member of the interdisciplinary team coordinates that care.

FED - V0591 - H-HOME PT PLAN OF CARE DEV/UPDATED

Title H-HOME PT PLAN OF CARE DEV/UPDATED

Type Standard

CFR 494.100(b)(1)(iii)

Regulation Definition

Services include, but are not limited to, the following:
(iii) Development and periodic review of the patient's

Interpretive Guideline

This tag should only be cited if there is no systematic care planning for home dialysis patients. While the home patient is expected to play a central role in the development and implementation of the plan of care, the development

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individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in §494.90 of this part.

and review of the home patients' plans of care must meet the same standards as for in-center patients, which are addressed under the Condition for Patient plan of care. Problems with individual plans of care for home patients should be cited at the applicable tags under that Condition.

FED - V0592 - H-PT CONSULTATION WITH IDT MEMBERS PRN

Title H-PT CONSULTATION WITH IDT MEMBERS PRN

Type Standard

CFR 494.100(c)(1)(iv)

Regulation Definition

Services include, but are not limited to, the following:
(iv) Patient consultation with members of the interdisciplinary team, as needed.

Interpretive Guideline

The home dialysis patients must have access to members of the interdisciplinary team (i.e. registered nurse, dietitian, social worker, physician treating the patient, as defined at V501), who must be available to provide clinical services as needed by the patient. The interdisciplinary team must include the staff member who is responsible for the coordination of that patient's care. Contact may be in-person, by phone, by mail or by email with confirmation of patient receipt. The required minimum frequency of contacts may be defined by facility policy, but must meet the individual needs of each patient in accordance with their plan of care.

Note the requirements at V510 for initial and periodic evaluation of all patients by a qualified social worker and at V509 for evaluation by a qualified dietitian.

Stable home dialysis patients are not seen frequently at the dialysis facility. Medicare payment rules do not require a physician visit in order for the physician to receive payment of the monthly capitated payment (MCP) at the rate of two to three visits per month. The requirement V560, which calls for at least monthly evaluation of all patients by a physician, an advanced practice registered nurse or physician assistant, applies to home dialysis patients, as well as in-center patients. The facility must have a policy regarding how the physician will consult with the home dialysis patient to meet this requirement and to assure that the home patient ' s medical supervision is equivalent to in-center patients. Records of patient consultation by the physician must be documented in the patient's medical record at the facility. Because they are not frequently on-site at the facility, home dialysis patients may see their physicians in their offices instead of seeing their physicians at the dialysis facility. If patients see their physicians in the physician's office, there must be a system in place to transfer information related to the care of the home patient from the physician's office to the dialysis facility.

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FED - V0593 - H-MONITOR H20 /DIALYSATE INC ON SITE EVAL

Title H-MONITOR H20 /DIALYSATE INC ON SITE EVAL

Type Standard

CFR 494.100(c)(1)(v)

Regulation Definition

Services include, but are not limited to, the following:
(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation

Interpretive Guideline

At the time of publishing these regulations, several different technologies for home hemodialysis were available. These included conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which used manufacturer packaged, bagged dialysate or which incorporated water treatment and dialysate preparation and delivery into one system; and sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer. All of these, and any future home hemodialysis technologies developed, present the home dialysis facility with both common and unique challenges for monitoring to ensure the continued efficacy and safety of the home hemodialysis patients' treatments. Because of their differences, the "Interpretive Guidance" for the following tags (V593-V598), at times refers to one or more of the above-mentioned home hemodialysis technologies as related to the specific requirements and/or exclusions from certain requirements.

The facility home training staff must conduct on-site evaluations of the home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. There should be evidence the source water to be used meets the minimum requirements specified by the manufacturer of the water treatment components or of the integrated system, if such is in use. If the source water requirements are not met, there must be adequate pre-treatment of the source water to meet those requirements. Each home water treatment system must include either an RO or a DI treatment component or alternate technology that achieves AAMI standards, and a method to remove chlorine/chloramines.

According to AAMI RD52:2004/Annex C: Special considerations for home hemodialysis at C.3.1 Water supply, if the home is served by a small water system (serving less than 3000 persons), or one classified as an economically or socially-disadvantaged system (serving less than 500 persons), the water entering the residence is not regulated by the EPA Safe Drinking Water Act. In addition, any municipal system may have received a variance, which may be given for chemical contaminants by State drinking water programs. If the water is supplied from an individual well, the EPA standard may not be met.

Because of these variables with the regulation of the water supply to a home for safe drinking water standards, annual

analysis of the quality of the product water may not be sufficient, since the quality of water from the well may change over time, and since private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. The additional monitoring might not need to be the full AAMI analysis if only certain contaminants are known to be of concern.

The home patient's record must include review and acknowledgement of any problems with the source water, and a monitoring schedule for the source water. The patient's physician should demonstrate awareness of any issues with the source water, and the plan of care should address any issues with source water for the home HD patient.

The home evaluation should address the storage of supplies, including dialysate concentrate(s). The storage area should provide a year-round environment that meets the manufacturer's recommendations for the storage of supplies.

For home water treatment systems, guidance is found throughout the Condition for Water and dialysate quality at V595, which highlights the recommendations in ANSI/AAMI RD52:2004: Annex C "Special considerations for home hemodialysis.

FED - V0594 - H-PRECONFIG HD SYS-TEST H20/DIALY PER DFU/FDA

Title H-PRECONFIG HD SYS-TEST H20/DIALY PER DFU/FDA

Type Standard

CFR 494.100(c)(1)(v)

Regulation Definition

Services include, but are not limited to, the following:
testing of the water and dialysate system in accordance with-

(A) The recommendations specified in the manufacturers' instructions; and

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.

Interpretive Guideline

The home training and support facility is responsible for monitoring the quality of the water/dialysate used by home hemodialysis patients as required by the hemodialysis system manufacturer's recommendations and AAMI standards. Water treatment systems for home hemodialysis patients must produce water that meets the AAMI standards and the requirements specified in § 494.40(a) of these regulations.

A chemical analysis of the product water must be done at the start of home treatment and at least once a year near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other than the replacement of disposable components), to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded. If chemical analysis is not conducted as described here, refer to V201 for RO systems or to V206 for DI systems. According to AAMI, more frequent than annual analysis may be needed if there are seasonal variations in source water quality or if the source water is supplied from a well, as detailed at V593.

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When any repairs are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if indicated. Note: the requirements for in-center use of preconfigured systems are detailed at V276.

FED - V0595 - H-MEET RD52:2004

Title H-MEET RD52:2004

Type Standard

CFR 494.100(c)(1)(v)

Regulation Definition

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.

Interpretive Guideline

Chlorine/chloramine levels must be tested prior to the start of each treatment (or before use of each new batch of dialysate) in accordance with AAMI guidance and manufacturer's recommendations or instructions. An appropriate volume of water for the testing method in use should be tested for the presence of chlorine/chloramines. For batch systems (integrated systems which prepare enough dialysate for multiple treatments), the chlorine/chloramines testing shall be performed at the worst case scenario, i.e., after the preparation of each batch of dialysate, but before use of that batch from a testing port that meets specifications of the manufacturer to be in compliance with the requirements of AAMI. If the test shows results above AAMI ' s maximum allowable level, then the user must discard that batch, change any applicable components, prepare another batch of dialysate, and test again.

Recognize that systems that use sorbent technology do not produce water: the product of the sorbent cartridge is dialysate, thus the requirements for the chemical, bacteriological and endotoxin testing of water do not apply. With sorbent technology, due to the low volume of exposure of patients to water (i.e. 6 liters per treatment) and the capacity of the single-use sorbent cartridge to remove chlorine and chloramines, testing for chlorines and chloramines is not required. Sorbent system users are expected to perform bacteriological and endotoxin testing on dialysate.

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. The facility must maintain documentation of the medical director ' s review, which should be incorporated as a part of the QAPI program review.

The results of water and dialysate testing for home hemodialysis patients may be included in the patients' medical records or in separate logs. According to AAMI, a log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility.

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The ANSI/AAMI RD52:2004 "Dialysate for Hemodialysis" has been incorporated by reference into these regulations, as stated in §494.40 Condition for Water and dialysate quality. CMS interprets this reference as inclusive of the "Amendment 1 to ANSI/AAMI RD52:2004: Annex C Special Considerations for Home Hemodialysis." This document addresses concerns particular to the home hemodialysis setting. Be aware that many of the provisions of RD52:2004, as outlined in the Condition for Water and dialysate quality at §494.40 pertain to the home hemodialysis setting when conventional water treatment equipment is used for water purification. The review of conventional water treatment equipment should reference the requirements listed in that Condition for the specific components in use in the home setting. Additional pertinent excerpts from ANSI/AAMI RD52:2004 Annex C, which clarify specific home hemodialysis issues, are as follows:

C.3 Utilities
It is recommended that the utility companies providing water and power to the patient's home be notified that home dialysis is being performed at that location and that restoring service after any interruption should be a priority.

C.3.2 Drain
If the home has a septic tank, the septic tank should be able to process the volume of water from a drain [that is one inch or larger in diameter]. It may not be possible to perform nocturnal hemodialysis in a home with a septic tank since this tank may not be able to support the volume of water delivered to it over an extended period (8 hours). Another possible limitation is that the septic system will be exposed to disinfectant chemicals (bleach, peracetic acid, hydrogen peroxide, etc.) which may kill the bacteria needed for the septic tank to function.

C.5.2 Softener
Attention must be paid to setting the time for softener regeneration, particularly when daily nocturnal hemodialysis is being performed.

C.5.3 Carbon adsorption media
At least one carbon adsorption bed or filter should be installed even if the water supply is from a well and no chlorine is present. In addition to chlorine, carbon can remove organic contaminants from ground water, including solvents, pesticides, industrial wastes, and substances leaking from underground storage tanks. When water is obtained from a municipal water supply, two carbon adsorption devices connected in series and providing the equivalent of an empty bed contact time of 10 minutes, or some other process incorporating safety redundancy for chloramine removal, is recommended. A means should be provided to sample the water between the two carbon adsorption devices. If chlorine is not present in the water, the carbon should be changed on a routine schedule.

C.5.4 Reverse osmosis

Since the product flow rate will decrease with decreasing water temperature, a reverse osmosis system installed without a tempering valve to ensure constant feed water temperature may need to be oversized so that it will deliver the quantity of water required by the dialysis machine with the coldest anticipated water temperature.

C.5.5 Deionization
Deionization systems for home hemodialysis are not required to have a mechanism to prevent product water from reaching the point of use if the conductivity of the water is one microsiemen/cm or more (specific resistivity of one megohm-cm or less). However, this feature is strongly recommended, particularly in situations where the water treatment system is not located in the room where dialysis treatments are performed or when nocturnal hemodialysis is being performed. If a diversion system is not installed, the patient must be trained to stop dialysis immediately if the conductivity/resistivity monitoring system alarms.

C.5.6 Treated water distribution
Because systems used for home hemodialysis operate intermittently, the distribution system should be designed and maintained to minimize bacterial proliferation. The reverse osmosis system should be disinfected at least monthly according to the manufacturer's instructions. The dialysis machine should be disinfected following each treatment according to the manufacturer's instructions.

C.6.2 Acid concentrate
The patient/helpers should be trained to know that different hemodialysis machines use different proportioning ratios for concentrate and water and that they should ensure use of the correct acid concentrate for their hemodialysis machine. The acid concentrate used should be documented as part of the treatment record.

C.7 Monitoring
C.7.1 Water and dialysate quality
Sampling for microbiological testing should be performed before disinfecting the water treatment system and dialysis machine. To avoid disconnecting hoses, and opening the system to possible contamination, the system should be designed with the necessary sampling valves.

C.7.2 Equipment
C.7.2.1 General
A log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility. Measurements should be made at least 15 minutes after the water treatment system has been set in operation and before dialysis is initiated. Any alarm associated with a component of the water treatment system should be audible and visible in the patient treatment area.

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If any measure of water treatment system performance is found to be outside its acceptable range, the dialysis center should be notified.

C.7.2.2 Softener
[When a softener is used] the water hardness should be monitored prior to each treatment using a sample obtained through a labeled sample port located between the softener and the reverse osmosis membranes. For hardness tests requiring color differentiation, the person performing the analysis should be able to distinguish between the colors of blue, purple, and red. If the person cannot differentiate these colors, an automated meter should be used.

C.7.2.3 Carbon adsorption media
The chloramine concentration shall be checked prior to each treatment. It may be more convenient to monitor total chlorine instead of chloramine. In that case, the acceptable level for total chlorine shall be 0.1 mg/L, or less. The patient/helper shall be trained how to perform the chlorine analysis, and shall be trained regarding what action to take if chlorine is detected above the specified limit. Depending on the chlorine test used, the patient/helper should be capable of distinguishing between different shades of pink or a digital meter should be used to indicate the chlorine concentration.

C.7.2.4 Reverse osmosis
Prior to each treatment, the performance of the reverse osmosis system should be monitored by checking the product water conductivity and percent rejection.

End AAMI requirements

The facility home hemodialysis staff should be familiar with the recommendations in ANSI/AAMI RD52 Annex C, and the facility policies, procedures and practice must reflect those applicable to the home hemodialysis systems in use.

The microbiological quality of the dialysate should be analyzed quarterly using cultures and endotoxin measurements, or more frequently, if indicated.

If integrated systems are in use, the dialysate should be tested for bacteria and endotoxins near the end of the usability of any disposable water treatment or dialysate components. If the patient uses manufacturer-provided bagged dialysate, cultures of those fluids are not required.

Refer to the Condition for Water and dialysate quality at V178 and V180 for action and maximum allowable culture

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and endotoxin levels in water and dialysate. 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 culture/endotoxin results, physician and medical director notification of any abnormal levels, and a corrective action plan if results are out of range.

Records of results of chemical and microbial testing of home hemodialysis water and dialysate should be available in the home setting and at the dialysis facility providing support; the log of these results may be included the patient's medical record or in a separate record.

FED - V0596 - H-FIX H20/DIALY PROB/ARRANGE BACK-UP TX

Title H-FIX H20/DIALY PROB/ARRANGE BACK-UP TX

Type Standard

CFR 494.100(c)(1)(v)

Regulation Definition

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if-
(1) Analysis of the water and dialysate quality indicates contamination; or
(2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

Interpretive Guideline

If analysis of the water and/or dialysate quality indicates contamination (i.e. microbial "action" levels or maximum level(s) of chemical contaminants are exceeded), the facility should evaluate for possible sample contamination and at minimum, when the threat is low, re-test. If the threat is higher or the re-test remains positive, the facility must correct the water treatment and/or dialysate delivery (machine) system to ensure product water and dialysate meet AAMI standards for chemical levels and microbial counts.

When unable to make such corrections in time to allow home hemodialysis to resume within an acceptable time frame, the dialysis facility must arrange for back-up dialysis until the home system is corrected. If an integrated system is involved and all applicable disposable components are replaced, treatment may continue, with testing to continue per schedule.

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. 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. If such symptoms are present, the facility must notify the patient ' s physician/medical director to determine appropriate action (i.e., culture and treatment).

Facility policies must address, and responsible staff members (e.g., home training nurse, chief technician responsible

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for the home program) must be aware of what responsive and corrective actions they should take if microbial and/or chemical test results were elevated, or should a patient exhibit such clinical symptoms (e.g. referral for immediate patient evaluation and treatment by the patient ' s physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant) and possible arrangement for back-up dialysis, if needed, until the cause of the symptoms is identified and any problems with the home water treatment and dialysate delivery system are resolved).

FED - V0597 - H-PROVIDE ORDERED SUPPLIES/EQUIPMENT

Title H-PROVIDE ORDERED SUPPLIES/EQUIPMENT

Type Standard

CFR 494.100(c)(1)(vi)

Regulation Definition

Services include, but are not limited to, the following:
(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

Interpretive Guideline

The dialysis facility is responsible for the oversight and overall management of the home dialysis patient, including assuring that the patient is provided with functional prescribed equipment and supplies.

The dialysis facility or a DME supplier may be responsible for purchasing, leasing, renting, delivering, installing, and maintaining home dialysis supplies and equipment. If the dialysis facility or patient contracts with a DME supplier, there must be a written agreement between the DME supplier and the dialysis facility, specifying the responsibilities of each. The dialysis facility is always responsible for oversight of the patient and the dialysis process.

Machines and equipment must be repaired and routine preventive maintenance completed in accordance with the manufacturer's recommendations. The facility should maintain records of preventive maintenance and repairs, even if performed by a DME supplier. If the facility staff members are responsible for performing the maintenance and repair on the home dialysis equipment, personnel file review should show evidence of training and competency verification for all of the different systems the facility maintains.

Some manufacturers use a system for exchange of malfunctioning equipment in lieu of maintenance. If so, documentation should detail what was done to refurbish the equipment used in exchange. This documentation might be a form or letter for each piece of equipment, or could be in the form of a policy or manual from the manufacturer detailing the extent of refurbishing done at each exchange. The facility should keep a log of the serial numbers of all equipment in use at patients' homes; these logs should be updated to reflect any exchange of equipment.

The preventative maintenance and repair logs for the equipment in use at patients' homes should verify the

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manufacturer's directions were adhered to for periodic preventative maintenance.

FED - V0598 - H-PLAN FOR ER BACK-UP DIALYSIS

Title H-PLAN FOR ER BACK-UP DIALYSIS

Type Standard

CFR 494.100(c)(1)(vii)

Regulation Definition

Services include, but are not limited to, the following:
(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

Interpretive Guideline

The dialysis facility is responsible for identifying a plan and arranging for timely emergency back-up dialysis whenever needed by the home dialysis patient. Examples of when back-up dialysis may be necessary include (but are not limited to) when the patient's home dialysis equipment is non-functional, the water quality is not within AAMI standards, the patient's medical conditions warrant a change in modalities, a PD patient requires peritoneal catheter replacement and temporary HD. Back-up dialysis should also be available in the event of the need for respite of either the patient or the helper.

The facility should assist each home dialysis patient in developing a personal disaster plan that identifies actions to take in the event of a natural or other disaster affecting his/her home treatment.

The dialysis facility must inform each patient/helper of the availability and location of back-up dialysis if equipment fails or if dialysis at home is not possible. The "back-up dialysis" plan should provide dialysis services that are equivalent to a certified facility.

FED - V0599 - H-RECORDKEEPING SYSTEM

Title H-RECORDKEEPING SYSTEM

Type Standard

CFR 494.100(c)(2)

Regulation Definition

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical

Interpretive Guideline

The facility must maintain a centralized recordkeeping system for home dialysis patients, which includes documentation of patient assessments and plans of care, training and competency verification, patient monitoring, and records of machine and water treatment/dialysate delivery systems, the latter of which may be in a separate log.

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equipment (DME) suppliers referred to in §414.330(a)(2) of this chapter.

Both the dialysis facility and DME supplier must have recordkeeping systems that are HIPAA-compliant and effective in assuring continuity of care. The regulations for DME suppliers at §414.330(a)(2) require the DME to report all data for each patient regarding services and items furnished to the home patient to the supporting ESRD facility every 45 days, thus there should be no issue with the DME supplier providing records within the 2 months allowed by these regulations.

Use this tag if deficient practices in the content or maintenance of home dialysis patients' records are identified. For major issues related to the home patient records, refer to V731.

FED - V0625 - CFC-QAPI

Title CFC-QAPI

Type Condition

CFR 494.110

Regulation Definition

Interpretive Guideline

This Condition 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.

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:
o Absence of an effective QAPI program;
o Failure to recognize and prioritize major problems that threaten the health and safety of patients; or
o Failure to take action to address identified problems.

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FED - V0626 - QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL

Title QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL

Type Standard

CFR 494.110

Regulation Definition

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. 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.

Interpretive Guideline

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. This facility-based team is led by the medical director, who may also serve as the physician representative of the IDT. Each team member must meet the qualifications outlined in the Condition for Personnel qualifications for their respective disciplines. The interdisciplinary team must have effective communications and must produce effective quality assessment and performance improvement activities which positively influence their patient's outcomes. There must be an operationalized, written plan describing the QAPI program scope, objectives, organization, responsibilities of all participants, and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving activities.

The scope of the QAPI program must be facility wide: all services provided must be included in the review (e.g. in-center, home hemodialysis, home peritoneal dialysis, reuse, central reprocessing, self-care). Data on current professionally-accepted clinical practice standards must be used to track health outcomes, and the program must allow for identification, prevention and reduction of medical errors, mortality and morbidities. Refer to the Measures Assessment Tool (MAT) which lists the expected outcomes based on these standards and CMS Clinical Performance Measures (CPMs).

The MAT is a reference for community-accepted standards and values for listed elements of QAPI. Within their individual QAPI program, facilities are expected to use the community-accepted standards and values associated with clinical outcomes as referenced on the MAT. Facilities are expected to use CROWNWeb and Dialysis Facility Reports to determine comparison or "average" values associated with clinical outcomes.

If a facility has areas of QAPI that do not meet target levels (per MAT) or areas where the facility performance is below average (per data reports), the facility is expected to take action toward improving those outcomes.

The important aspects of the QAPI program are appropriately monitoring data/information; prioritizing areas for improvement; determining potential root causes; developing, implementing, evaluating, and revising plans that result

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in improvements in care.

Records of QAPI activities including minutes or another method of demonstrating this analysis and action must be available for review.

FED - V0627 - QAPI-ONGOING;USES INDICATORS=IMPROVEMENT

Title QAPI-ONGOING;USES INDICATORS=IMPROVEMENT

Type Standard

CFR 494.110(a)(1)

Regulation Definition

The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

Interpretive Guideline

An "ongoing" program continuously looks at indicators as they are available, trends outcomes and develops an improvement plan when indicated. Generally this would require at least monthly review of indicators, since prescribed patient indicators are typically evaluated with laboratory results monthly and this serves as a functional time frame for trending of data within the facility.

"Indicators" or "performance measures" include at least those specified in this Condition, as well as measures of water and dialysate quality and safety, and safe machine maintenance. Performance expectations are based on current professionally-accepted clinical practice standards. Refer to the Measures Assessment Tool (MAT) provided which lists these and the CMS Clinical Performance Measures (CPMs).

FED - V0628 - QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS

Title QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS

Type Standard

CFR 494.110(a)(2)

Regulation Definition

The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or

Interpretive Guideline

The facility's QAPI program monitors the assessment and improvement of care in the facility.
CMS-generated data reports, including the Dialysis Facility Reports (DFR) and other Consolidated Renal Operations in a Web-enabled Network Web (CROWNWeb) provided data reports, are and will be distributed to facilities to help them focus their QAPI improvement programs. Each facility should be comparing their performance with

relate to the desired outcomes or be the outcomes themselves.

community-based standards and with other facilities in their State, their Network and the U.S. and working to improve their outcomes where needed. This comparative data is readily available to all facilities, whether they are corporate owned or independent.

QAPI requires the use of aggregate patient data to evaluate the facility patient outcomes. Hemodialysis patients and peritoneal dialysis patients should be reviewed separately since factors affecting their clinical outcomes may be different; both groups of patients must be reviewed on an ongoing basis.

Data related to patient outcomes, complaints, medical injuries and medical errors (e.g., clinical variances, occurrences, and adverse events) should be used to identify potential problems and to identify opportunities for improving care.

Data should be analyzed by the interdisciplinary team (IDT) on an ongoing basis. Based upon the data review, the IDT should discuss the areas which need improvement and develop, implement, and evaluate a plan for such improvement. The facility must use broadly accepted, community-developed standards (e.g., CMS CPMs, NKF KDOQI, AAMI) as performance measures. Those standards which are expected to be measured and tracked are detailed on the Measures Assessment Tool (MAT). Where minimum outcome values have been determined, facilities are expected to provide care directed at achievement of at least the minimum outcome value by all patients. The IDT must work with individual patients who do not reach the target; this work must be reflected in the patient's plan of care for that outcome. Refer to the applicable tag under the Condition for Plan of care for individual patient issues.

FED - V0629 - QAPI-INDICATOR-ADEQUACY OF DIALYSIS

Title QAPI-INDICATOR-ADEQUACY OF DIALYSIS

Type Standard

CFR 494.110(a)(2)(i)

Regulation Definition

The program must include, but not be limited to, the following:
(i) Adequacy of dialysis.

Interpretive Guideline

The intent of QAPI in addressing adequacy of dialysis is to maximize the number of patients who achieve the goals for adequate dialysis, which include both successful fluid volume management and clearance of toxins.

To identify opportunities for improvement and track progress in adequacy of dialysis for its hemodialysis and peritoneal dialysis population the IDT must:
o Review aggregate patient data;
o Identify any commonalities among patients who do not reach the minimum expected targets;

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o Develop a plan to address those causes;
o Implement the plan;
o Monitor the effectiveness of the plan; and
o Adjust portions of the plan that are not successful.

The IDT must use current professionally-accepted clinical practice standards as target values. Refer to the Measures Assessment Tool (MAT) provided which lists these standards.

If a data report shows that the facility ' s ranking for hemodialysis adequacy is below the expected average, the facility must demonstrate QAPI review of global factors that might affect adequacy, e.g. missed/shortened treatments, less-efficient dialyzers, and failure to achieve the ordered blood flow rates.

FED - V0630 - QAPI-INDICATOR-NUTRITIONAL STATUS

Title QAPI-INDICATOR-NUTRITIONAL STATUS

Type Standard

CFR 494.110(a)(2)(ii)

Regulation Definition

The program must include, but not be limited to, the following:
(ii) Nutritional status.

Interpretive Guideline

The intent of QAPI in addressing nutritional status is to maximize the number of patients who achieve the goals for this area.

Serum albumin is a valid and useful measure of protein-energy nutritional status in maintenance dialysis patients. Serum albumin levels are commonly and extensively used to evaluate the nutritional status of ESRD patients; low albumin levels are highly predictive of mortality risk. Refer to the Measures Assessment Tool (MAT) provided, which lists current professionally-accepted clinical practice standards in this and other areas.

Serum albumin is affected by inflammation and other factors as well as by diet. The IDT may not be able to have a majority of its patients achieve the desired goal for this area, but should be actively intervening on actionable factors.

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FED - V0631 - QAPI-INDICATOR-CKD-MBD

Title QAPI-INDICATOR-CKD-MBD

Type Standard

CFR 494.110(a)(2)(iii)

Regulation Definition

The program must include, but not be limited to, the following:
(iii) Mineral metabolism and renal bone disease.

Interpretive Guideline

The intent of QAPI in addressing management of CKD mineral and bone disorder is to maximize the number of patients who achieve the goals for this area. Refer to the Measures Assessment Tool (MAT), which lists the current professionally-accepted clinical practice standards in this and other areas.

Since this area is heavily influenced by patient diet, it is critical that patient education, encouragement, and support be included in improvement plans for this indicator. The IDT should evaluate the efficacy of any standardized CKD mineral and bone disorder guideline or algorithm in use if facility QAPI goals in this area are not achieved over consecutive evaluation periods and other factors (e.g., transfers, new admissions, hospitalizations, discharges, recent access surgeries, or acutely ill patients) are not responsible

FED - V0632 - QAPI-INDICATOR-ANEMIA MANAGEMENT

Title QAPI-INDICATOR-ANEMIA MANAGEMENT

Type Standard

CFR 494.110(a)(2)(iv)

Regulation Definition

The program must include, but not be limited to, the following:
(iv) Anemia management.

Interpretive Guideline

The intent of QAPI in addressing management of anemia is to maximize the number of patients who achieve the goals for this area. Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical practice standards and CMS CPMs in this and other areas.

For anemia management, factors which should be tracked monthly for the facility patient population as a whole include laboratory values for hemoglobin and hematocrit. If facility QAPI goals for anemia management are not achieved over consecutive evaluation periods, the facility IDT should conduct a review of transferrin saturation (TSAT) levels, ferritin levels, and other iron indices; erythropoietin stimulating agent (ESA) doses and response to

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those doses; and any evidence of blood loss, such as repeated episodes of insufficient rinseback of red blood cells or prolonged bleeding post treatment.

If the facility uses a standardized anemia management guideline or algorithm, the IDT should evaluate the efficacy of this tool if facility QAPI goals for anemia management are not achieved over consecutive evaluation periods.

Home and in-center patient outcomes may need to be reviewed separately by the facility in this area as the factors to be addressed may be different. For example, a home peritoneal patient may be reluctant to inject himself/herself with an ESA, resulting in lower values for this measure in the home population.

FED - V0633 - QAPI-INDICATOR-VASCULAR ACCESS

Title QAPI-INDICATOR-VASCULAR ACCESS

Type Standard

CFR 494.110(a)(2)(v)

Regulation Definition

The program must include, but not be limited to, the following:
(v) Vascular access.

Interpretive Guideline

The intent of QAPI in addressing vascular access is first, to improve the rate of use and preservation of fistulas; second, to decrease the inappropriate use of catheters; and finally, to improve the care provided for all types of vascular access.

To identify opportunities for improvement and track progress in management of vascular access for its hemodialysis population, the IDT must use a standard that has achieved broadly accepted use in the ESRD community. Refer to the Measures Assessment Tool (MAT), which lists the current professionally-accepted clinical practice standards and CMS CPMs for this and other areas.

Fistula survival may be affected by:
o Cannulation technique problems such as frequent infiltrations related to training issues or individual personnel difficulties;
o Episodes of hypotension or hypovolemia; and
o Differences in surgical outcomes.

The QAPI program should include efforts to reduce the use of catheters and to reduce the incidence of infection related to catheter use. Requirements related to the care of catheters can be found under the Condition for Infection control, at V146, V147 and V148.

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FED - V0634 - QAPI-INDICATOR-MEDICAL INJURIES/ERRORS

Title QAPI-INDICATOR-MEDICAL INJURIES/ERRORS

Type Standard

CFR 494.110(a)(2)(vi)

Regulation Definition

The program must include, but not be limited to, the following:
(vi) Medical injuries and medical errors identification.

Interpretive Guideline

The intent of QAPI in addressing medical injuries and identification of medical errors is to minimize the number of occurrences and limit the number of patients and staff who are adversely affected by such occurrences.

The facility must compile and the QAPI team must review reports and complaints related to any patient or staff injuries, and treatment or medication errors. Part of the QAPI activity is to trend any injuries or errors to identify the prevalence of occurrences, commonalities, and causes.

An example of medical injury is a patient fall, which may occur post-dialysis treatment. Information to allow identification of any trends and to detail facility response in terms of risk assessment and precautions in place to prevent future falls should be in evidence.

Similarly, occurrences such as treatment prescription errors, intradialytic morbidities, and staff needle sticks should be identified, reviewed and trended. "Intradialytic morbidities" is any adverse symptom that occurs during the dialysis treatment to include but not be limited to seizures, chest pain, hypotension and cardiac arrest. Other events which should be tracked include hospitalizations, deaths, acute allergic-type reactions, blood loss >100 ml, and patient transfers by ambulance from the dialysis facility to a hospital emergency room.

The facility should collect and aggregate data regarding adverse occurrences, and there should be a mechanism to ensure all adverse events are recorded as soon as possible after they occur. The QAPI committee should analyze both isolated and repeated events in their review. In September, 2008, the Renal Physicians' Association launched a new website "Keeping Kidney Patients Safe" to serve as a repository for ESRD patient safety best practices. In collaboration with the Forum of ESRD Networks, the following areas were identified through patient and professional surveys as the top five areas of focus for adverse patient safety events:

"1. Hand hygiene: Accumulation and transmission of germs on hands are transmitted by touching one's self, patients and surfaces in the patient environment. Infections are a serious problem in healthcare facilities and many infections are transmitted on the hands of healthcare personnel. Hand hygiene practices - the use of alcohol-based hand rubs or

use of soap and water before and after patient contact, removal of gloves and contact with the immediate patient care environment - protect both healthcare personnel and patients from contact with infectious agents. Failure to practice hand hygiene may be caused by lack of equipment; low staffing ratios; allergies to hand washing products; insufficient knowledge about risks posed by not practicing hand hygiene; time required; or casual attitude by staff towards hand hygiene. Proper hand hygiene breaks the chain of infection transmission and minimizes microorganisms acquired by contact with infected surfaces.

2. Patient falls: Patient falls are defined as any untoward event in which the patient comes to rest unintentionally on the floor. Falls are largely preventable occurrences that injure patients, cause hospitalizations, and significantly increase healthcare costs. Most ESRD patients who fall indicate they fall following dialysis treatment, and they fall because they feel dizzy or weak. Additional attention to post-dialysis blood pressure levels, assistance as patients initially stand up coupled with queries about their steadiness, and removal of physical obstacles to patient navigation could all serve to reduce patient falls.

3. Incorrect dialyzer or dialyzing solution: The wrong dialyzer or dialyzing solution being set-up for a patient is a dangerous event that can result in great harm to patients. Feasible remedies for ensuring that initial set-up errors do not result in patient harm range from patient and professional education to procedural safeguards such as technician checklists and rules for set-up procedures. Increasing patient involvement in their dialysis care and safety issues may provide another approach to safeguarding against dialyzer solution errors.

4. Medication omissions or errors: Medication errors include giving a patient the wrong medication, giving medication at the wrong time, being given the wrong dose of a medication, or a patient failing to receive one of his/her medications. The consequence of each occurrence of a medication error, particularly omitting a patient's medication, can be quite significant and result in medical harm particularly when one considers that dialysis patients take large numbers of different medications each day; most take between 6 and 10 medications per day (based on the patient survey). Patients ascribe infection transmission and minimizes microorganisms acquired by contact with infected surfaces.

5. Non-adherence to procedures: Failure to adhere to procedures, including the performance of routine completion of pre- and post-dialysis tasks such as taking patients' weight and blood pressure, leads to medical errors, increased risk of hospitalization and mortality. Non-adherence may also include failing to follow procedures regarding trouble with needle insertion and failure to complete event reports when medical errors occur. Non-adherence may also include patients' skipping or shortening dialysis treatments thereby increasing their odds of mortality. Non-adherence problems may reflect issues with procedural guidance, training, and/or enforcement.

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Definitions:
"Error" is defined as the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission (Institute of Medicine, 2004).

"Medication error" is defined as any error occurring in the medication-use process (Bates et al., 1995). Examples include wrong dosage prescribed, wrong dosage administered for a prescribed medication, failure to give (by the provider) or take (by the patient) a medication, or administration of a drug to which the patient is known to be allergic.

"Adverse drug event" is defined as any injury due to medication (Bates et al., 1995). Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.

FED - V0635 - QAPI-INDICATOR-HD REUSE PROGRAM

Title QAPI-INDICATOR-HD REUSE PROGRAM

Type Standard

CFR 494.110(a)(2)(vii)

Regulation Definition

The program must include, but not be limited to, the following:
(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

Interpretive Guideline

If a facility has a dialyzer reuse program, it must be compliant with the quality assurance requirements specific to reuse, located at V360-368. These requirements outline periodic reuse process and practice audits which must be conducted and documented to ensure the reuse program remains safe and effective. Refer to the Measures Assessment Tool (MAT) for quality indictors related to the reuse of hemodialyzers.

The QAPI meeting minutes should demonstrate oversight of the reprocessing/reuse program and include at least summaries of the required reuse audits.

This tag is used to cite major problems related to quality assessment and performance improvement for the Condition for Reuse. Use individual tags in the Condition for Reuse of hemodialyzers for citations of specific or isolated issues in the required audits for quality assurance (V360-V368).

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FED - V0636 - QAPI-INDICATOR-PT SATIS & GRIEVANCES

Title QAPI-INDICATOR-PT SATIS & GRIEVANCES

Type Standard

CFR 494.110(a)(2)(viii)

Regulation Definition

The program must include, but not be limited to, the following:
(viii) Patient satisfaction and grievances.

Interpretive Guideline

The intent of QAPI in this area is to use patient satisfaction surveys and patient grievance investigations as a means to identify opportunities to improve care. The survey should be non-threatening and be conducted in a manner to protect the patient's identity. QAPI discussion of patient satisfaction survey results and patient grievance information should focus on the use of data to inform the care delivery system. If needed changes are identified, there should be evidence of action taken to implement those changes.

Facilities must monitor and track patient grievance reports and outcomes as required at V765; use that tag for issues related to responding to individual grievances.

An In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey instrument, which is a standardized experience of care assessment tool appropriate for in-center hemodialysis patients, is available for use. Effective 4/1/2008, CMS endorsed the use of this tool to measure in-center hemodialysis patient satisfaction as a CPM. As other measures of patient satisfaction are standardized, refer to the Measures Assessment Tool (MAT) for the current standard of practice.

FED - V0637 - QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT

Title QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT

Type Standard

CFR 494.110(a)(2)(ix)

Regulation Definition

The program must include, but not be limited to, the following:
(ix) Infection control; with respect to this component the

Interpretive Guideline

The intent of QAPI in addressing infection control is to minimize the number of patients and staff who are exposed to or acquire infectious diseases at the facility.

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facility must-
(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;
(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and
(C) Take actions to reduce future incidents.

The facility must record and follow up on all patient infections and serious adverse events. The occurrence of these events should be recorded using a centralized log book or other tracking mechanism and regularly reviewed, with documentation of actions taken. Surveillance information available for review should include, but not be limited to, patients' vaccination status (hepatitis B, pneumococcal pneumonia, and influenza vaccines); viral hepatitis serologies and seroconversions for HBV(and HCV and ALT, if known); bacteremia episodes; pyrogenic reactions; vascular access infections; and vascular access loss due to infection.

Surveillance information must include at a minimum, the date of infection onset, site of infection, full identification of infecting organism(s), and antimicrobial susceptibility results.

Responsible staff must review the results of all routine and diagnostic testing (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. It is important to identify the method of transmission whenever possible as well as the immune status of affected and at risk patients. Appropriate State or local publichealth officials should be notified of viral hepatitis seroconversions and other infectious diseases, and clusters of adverse events that occur among patients in the facility.

The analysis of patient infection incidence during the periodic QAPI meetings may not be sufficiently timely for identification of an outbreak of infections. Tracking of infections and serious adverse events must be done on an ongoing basis to ensure the safety of the patients.

Actions taken by the facility must be appropriate to the degree of risk to patients and staff. Actions could include in-service training in infection control; implementation of different protocols for cleaning equipment between uses; and audits of practice regarding infection control precautions for dialysis settings.

Information in this area may be recorded separately or incorporated into the QAPI documents; either method is acceptable, as long as review and analysis of the information collected is apparent.

As infection control indicators are developed, refer to the Measures Assessment Tool (MAT) for the current standard of practice.

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FED - V0638 - QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE

Title QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE

Type Standard

CFR 494.110(b)

Regulation Definition

The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

Interpretive Guideline

"Continuously monitor" requires that outcome data, achievement of treatment goals, adverse events, infections, falls, errors, etc. be monitored as this data is available or these events occur. Tracking and trending, analysis of root causes, development of improvement plans, implementation of those plans, evaluation of the success of the plan, and revision of the plan must occur as indicated.

Once improvement is made, the facility must have a mechanism to ensure that improvement is sustained. This could include practice audits, review of records, or repeat patient satisfaction surveys, etc.

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. 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. The minutes of the governing body or the minutes of the QAPI committee should demonstrate communication between the governing body and the medical director.

Refer to V756 for the requirements related to the responsibilities of the governing body for QAPI.

FED - V0639 - QAPI-PRIORITIZING IMPROVEMENT ACTIVITIES

Title QAPI-PRIORITIZING IMPROVEMENT ACTIVITIES

Type Standard

CFR 494.110(c)

Regulation Definition

The dialysis facility must set priorities for performance improvement, considering prevalence and severity of

Interpretive Guideline

The facility must incorporate CMS-generated data reports, along with data reports that the facility produces to identify all areas needing improvement and to prioritize these, ranking those which have potential to affect patient

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identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.

health and safety as more urgent than those that do not have such potential. In setting priorities, the prevalence and severity of the identified problems must be considered.

FED - V0640 - QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES

Title QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES

Type Standard

CFR 494.110(c)

Regulation Definition

The facility must immediately correct any identified problems that threaten the health and safety of patients.

Interpretive Guideline

Examples of conditions which could pose a threat to the health and safety of dialysis patients and require immediate correction include but are not limited to:
o Dangerous levels of contaminants in product water;
o Unsafe levels of electrolytes in dialysate;
o Failure to conduct an accurate pre-assessment
o Setting an inaccurate fluid removal rate
o Failure to provide adequate observation of patient, patient vascular access, patient equipment;
o Defective clinical equipment;
o Failure to adequately disinfect reprocessed dialyzers;
o Failure to reduce residual germicides in reprocessed dialyzers to safe levels;
o Lack of qualified staff to perform crucial tests or to meet critical patient needs;
o Evidence that staff assigned to perform crucial tests or to meet critical patient needs are not competent;
o Potential for cross-contamination between infected and non-infected patients; and
o Failure to use machine-provided safety devices (muting machine alarms, bypassing the air detector, etc.).

The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety.

FED - V0660 - CFC-SPECIAL PURPOSE RENAL DIALYSIS FACILITIES

Title CFC-SPECIAL PURPOSE RENAL DIALYSIS FACILITIES

Type Condition

CFR 494.120

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Regulation Definition

Interpretive Guideline

This Condition 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.

This Condition only applies to SPDF; it provides information about the availability of this special certification and defines which of the regulatory requirements included in the other Conditions for Coverage are required to be met by each type of SPDF. Deficiencies would be cited under each of the applicable Conditions and Standards that are outlined for either the vacation camp or the emergency circumstance facility. This Condition would be cited in the event a facility that applied as an SPDF did not meet the requirements for that designation. Other Conditions and Standards would also be cited in that situation.

FED - V0661 - SPDF-SPECIAL PURPOSE-TWO CATEGORIES

Title SPDF-SPECIAL PURPOSE-TWO CATEGORIES

Type Standard

CFR 494.120

Regulation Definition

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

Interpretive Guideline

"Vacation camp" SPDFs are temporary vacation locations that provide (and bill for) outpatient hemodialysis treatments at the camp site. Camps that transport hemodialysis patients to local certified out-patient facilities for dialysis are not considered SPDF and do not need to be certified separately to accept the campers as transient patients. Camps that provide only peritoneal dialysis on-site are not required to be certified as the treatment provided would be considered a "home" treatment. "Emergency circumstances" for SPDF applies to a natural or man-made disaster that prevents the use of established dialysis facilities, and applies to a patient or group of patients who can not otherwise be served in an area. The most common use of certification as an emergency SPDF is when the usual treatment facility(ies) are incapacitated by weather-related emergencies causing disruption to electrical service, water supplies, or vehicular access. However, a hospital, long-term care facility, or other provider could request SPDF certification to provide dialysis to one or more patients that are denied outpatient dialysis by all dialysis facilities within reasonable driving distance because of medical complications (morbidly obese, bedbound, respirator-dependent, tracheotomy requiring frequent suctioning, etc.) or a history of disruptive or threatening behaviors.

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In the event a new ESRD facility which has not yet been certified is granted an emergency SPDF status, that facility would need to undergo an initial survey for full certification within the 8 month SPDF certification period in order to continue service and to expand its census beyond those patients who could not otherwise be served in that geographic locality.

FED - V0662 - SPDF-APPROVAL PERIOD-8 MONTHS

Title SPDF-APPROVAL PERIOD-8 MONTHS

Type Standard

CFR 494.120(a)

Regulation Definition

The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12-month period.

Interpretive Guideline

The maximum period of certification is 8 months in any 12-month period. A vacation camp SPDF may be operational for as little as one to two weeks, and the same facility may reapply for certification in the following (or any subsequent) year.

Facilities applying for an SPDF "emergency designation in order to accommodate longer term dialysis for patients who are unable to be placed in an outpatient facility must recognize the time-limited nature of this certification and the fact that admissions are limited to those patients who were unable to obtain outpatient dialysis elsewhere in the area. This type SPDF may also reapply for certification in the following (or any subsequent) year.

FED - V0663 - SPDF-SERVICE LIMITATIONS

Title SPDF-SERVICE LIMITATIONS

Type Standard

CFR 494.120(b)

Regulation Definition

Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain

Interpretive Guideline

An SPDF is to provide care that would not otherwise be available in that geographic area. In the case of vacation camps, the "geographic locality" factor is related to minimizing the time that the patient would be away from camp activities. There may be a dialysis facility within driving distance, but dialysis treatment would take the camper away from the camp activities.

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treatments in the geographic locality served by the facility.	In the case of emergency circumstance facilities, the intent is to temporarily provide service until permanent arrangements are possible. An SPDF established to provide care to patients with medical or psychosocial needs which cannot be met in a standard outpatient dialysis setting should define the population it intends to serve in its admission criteria and include in those criteria the lack of outpatient dialysis service for these patients within the geographic area.

FED - V0666 - SPDF-PHYSICIAN CONTACT

Title SPDF-PHYSICIAN CONTACT

Type Standard

CFR 494.120(d)

Regulation Definition	Interpretive Guideline
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 (described in §494.90).	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. 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.

FED - V0667 - SPDF-RECORDS TRANSFERRED WITHIN 30 DAYS

Title SPDF-RECORDS TRANSFERRED WITHIN 30 DAYS

Type Standard

CFR 494.120(e)

Regulation Definition	Interpretive Guideline
All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.	Care in any SPDF should be documented at the time it is delivered and sent to the patient's permanent facility within 30 days of the last treatment provided by the SPDF. Additional time may be needed for the transfer of documentation of care in the event of a natural disaster. For example, if a patient's original facility was destroyed and not rebuilt, the documentation transfer may be delayed or even impossible.

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Hospitals or skilled nursing facilities that obtain an "emergency circumstance" SPDF designation to care for patients with medical or psychosocial needs that cannot be met in a standard outpatient dialysis facility may choose to maintain the original record of care at the SPDF and forward copies of requested portions of the record to another treatment setting that will be receiving the patient for care. In this case, the records would be expected to be transferred within one working day. Refer to V733.

FED - V0675 - CFC-LABORATORY SERVICES

Title CFC-LABORATORY SERVICES

Type Condition

CFR 494.130

Regulation Definition

Interpretive Guideline

This Condition describes the requirements for clinical laboratory services required to meet the needs of ESRD patients.

Compliance with this Condition is determined by clinical record review and if indicated, staff interviews and review of agreements.

Examples of Condition level non-compliance include, but are not limited to:
o The laboratory being used is not CLIA approved; or
o Serious and pervasive problems persist in the methods for collecting and handling the specimens drawn for laboratory analysis.

FED - V0676 - LAB-CLIA LABS/MEET NEEDS OF PTS

Title LAB-CLIA LABS/MEET NEEDS OF PTS

Type Standard

CFR 494.130

Regulation Definition

Interpretive Guideline

The dialysis facility must provide or make available, laboratory services (other than tissue pathology and

Under Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratory services can only be provided by an appropriately certified laboratory. Arrangements with these providers must be in writing and signed and should

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histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

specify the types of laboratory tests to be performed; methods for collection and handling the specimen(s); and delivering results, including a timeline for reporting of "alert" (sometimes called "panic") values to a responsible person.

Many facilities have agreements with distant laboratories for routine services; there should also be a provision for service from a local laboratory for time-sensitive testing.

The dialysis facility may provide some testing directly. Generally this is limited to CLIA-waivered tests, such as for blood glucose determinations obtained by blood glucose monitoring devices cleared by FDA specifically for home use; and for stool testing for occult blood.

HLA Laboratories performing Panel Reactive Antibody (PRA) testing for patients on the transplant waitlist must have a "regular" CLIA certificate or certificate of accreditation which allows the laboratory to perform high-complexity testing.

Laboratory reports should be included in facility records and should include the patient's name and identifier, the date and time the specimen was taken, and the name and address of the laboratory performing the test. Facility policies should address methods for specimen collection, especially pertaining to post-dialysis samples for dialysis adequacy testing to ensure accurate results.

FED - V0680 - CFC-PERSONNEL QUALIFICATIONS

Title CFC-PERSONNEL QUALIFICATIONS

Type Condition

CFR 494.140

Regulation Definition

Interpretive Guideline

This Condition defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs.

Compliance with this Condition is determined primarily by review of medical staff and personnel credential files, educational programs, policies and procedures for determining "competency" of the various staff members. Facilities must maintain current documentation to demonstrate personnel meet the basic requirements of their assigned roles, including any State specific requirements. When patient or staff interviews or observations of practice raise concerns about competency, the survey process may become more focused to ensure staff members are competent to perform

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assigned duties and to fulfill their roles in providing safe and effective patient care.

Examples of Condition level noncompliance would include, but not be limited to:
o Required interdisciplinary team member(s) do not meet the qualifications listed,
o Serious or pervasive problems with qualifications and/or competency of the direct care staff, including the patient care technicians.

FED - V0681 - PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY

Title PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY

Type Standard

CFR 494.140

Regulation Definition

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

Interpretive Guideline

All dialysis facility staff, including non-physician practitioners (whether employee, contractor, or credentialed as a member of the medical staff), must meet the applicable qualifications; scope of practice; and board and licensure requirements in effect in the State in which they are employed. All staff members are expected to practice within the licensure and/or certification requirements for their degree, practice setting, and scope of practice as defined by their individual State.

All facility staff must be able to demonstrate competency required to serve the complex needs of dialysis patients and must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions. Each facility is expected to determine how each staff member will "demonstrate" competency. Specific competencies expected to be able to be demonstrated by staff assigned to these tasks include, but are not limited to, skills at testing for chlorine/chloramine levels; operating reuse equipment; following infection control practices designated for dialysis facilities by CDC; identifying and treating intradialytic morbidities, and monitoring patients and equipment alarms during treatment.

FED - V0682 - PQ-MED DIRECTOR-BD CERT+12 MO DIALYSIS EXP

Title PQ-MED DIRECTOR-BD CERT+12 MO DIALYSIS EXP

Type Standard

CFR 494.140(a)(1)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

(1) 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.

Interpretive Guideline

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.

According to the websites of the American Board of Internal Medicine (ABIM) and the American Board of Pediatrics (ABP), a physician does not need to maintain certification in internal medicine or general pediatrics to recertify in nephrology or pediatric nephrology. Therefore, a medical director may maintain current certification in nephrology or pediatric nephrology or current certification in internal medicine or general pediatrics. 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.

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.

FED - V0683 - PQ-MED DIRECTOR EXCEPTION (CMS APPROVAL)

Title PQ-MED DIRECTOR EXCEPTION (CMS APPROVAL)

Type Standard

CFR 494.140(a)(2)

Regulation Definition

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.

Interpretive Guideline

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.

FED - V0684 - PQ-NURSE MANAGER-12 MO RN+6 MO DIALYSIS

Title PQ-NURSE MANAGER-12 MO RN+6 MO DIALYSIS

Type Standard

CFR 494.140(b)(1)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

(1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must-
(i) Be a full time employee of the facility;
(ii) Be a registered nurse; and
(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

Interpretive Guideline

"Responsible for nursing services" means the nurse manager provides oversight and direction to all direct care staff that provide dialysis and nursing care in the facility, including input into hiring, evaluating, and terminating these staff. Two or more qualified nurses may share this responsibility, but the facility must designate one of these nurses as primarily responsible.

The nurse manager is the only staff person who must be a direct employee of the facility rather than a contracted employee.

"Full-time" means the nurse manager is available to work in the dialysis facility the number of hours that the facility is open or as facility policy requires for full-time employment. For example, a dialysis facility that is only open for 24 hours a week, would need to employ the nurse manager for 24 hours a week to satisfy this requirement. If the facility is open 6 days a week or provides nocturnal dialysis, the nurse manager would need to be available to work at least 40 hours a week, and provide on-call coverage, in rotation with other qualified staff, all hours that the facility is open, including night and weekend hours.

"Employee" means a person for whom the facility files a W-2 Tax Form. A "contract" staff person is not considered an "employee."

The nurse manager must be registered and licensed to practice in the applicable State. He/she must have at least 12 months experience as a registered nurse, plus 6 months experience as a registered nurse providing clinical nursing care to dialysis patients, in either a chronic or acute setting.

The same registered nurse(s) who meets these requirements may fulfill multiple nursing roles in the dialysis facility as long as the facility has an adequate number of qualified nurses present while patients are dialyzing to meet patients' clinical needs for the level of dialysis care provided. Refer to V758.

FED - V0685 - PQ-SELF/HOME TRG RN-12 MO RN+3 MO MODALITY

Title PQ-SELF/HOME TRG RN-12 MO RN+3 MO MODALITY

Type Standard

CFR 494.140(b)(2)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

(2) Self-care and home dialysis training nurse. The nurse responsible for self-care and/or home care training must-
(i) Be a registered nurse; and
(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

Interpretive Guideline

"Responsible for ...training" means that the registered nurse must be in charge of and provide self-care and home dialysis training for dialysis patients and/or their caregivers. Although some portions of the training may be delegated to other trainers with required specialty knowledge, the "nurse responsible" must provide major portions of the training and coordinate and oversee the program.

The registered nurse responsible for self-care and the home dialysis training must have at least 12 months experience as a registered nurse, plus 3 months experience as a registered nurse in the specific modality of hemodialysis (HD) and/or peritoneal dialysis (PD). If one registered nurse is responsible for both the HD and PD programs, that nurse must have 12 months experience as a nurse plus at least three months experience in each respective modality. The self-care and home dialysis training nurse position may be filled by an employee or a contracted nurse who meets these qualifications. This position is not required to be full-time. However, if the position is part-time, the facility must have personnel experienced in all home modalities provided to respond to patients' concerns and to troubleshoot problems when the home training nurse is unavailable.

FED - V0686 - PQ-CHARGE NURSE-12 MO NURSING+3 MO DIALYSIS

Title PQ-CHARGE NURSE-12 MO NURSING+3 MO DIALYSIS

Type Standard

CFR 494.140(b)(3)(i)-(ii)

Regulation Definition

The charge nurse responsible for each shift must-
(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;
(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis;

Interpretive Guideline

There must be one or more "charge nurse" designated as responsible each shift. If the charge nurse is a registered nurse, he/she must be registered and licensed to practice in the applicable State. If the person functioning in the charge role is a licensed practical nurse or licensed vocational nurse, he/she must be legally authorized to practice as a licensed practical or vocational nurse (LPN. or LVN) in that State.

A charge nurse must have a minimum of 9 months of nursing experience, and an additional 3 months of specialized experience (to total 12 months) providing clinical nursing care to dialysis patients, in either a chronic or acute setting. The charge nurse position may be filled by a full-time or part-time employee or a contracted nurse who meets these qualifications.

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FED - V0687 - PQ-RN/LPN CHARGE SUPERVISION

Title PQ-RN/LPN CHARGE SUPERVISION

Type Standard

CFR 494.140(b)(3)(iii)

Regulation Definition

The charge nurse responsible for each shift must-
(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

Interpretive Guideline

Recognize that a licensed practical/vocational nurse cannot be in charge of a dialysis facility without specific authority from the applicable State board of nursing. CMS did not intend for, and State boards of nursing may prohibit, a licensed practical/vocational nurse supervising a registered nurse.
An LPN/LVN cannot be the only licensed person in a dialysis facility while patients are on dialysis. Refer to V759 which requires a registered nurse to be present whenever in-center patients are being treated.

FED - V0688 - PQ-STAFF NURSE-MEET STATE REQUIREMENTS

Title PQ-STAFF NURSE-MEET STATE REQUIREMENTS

Type Standard

CFR 494.140(b)(4)

Regulation Definition

Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

Interpretive Guideline

Each nurse must have the required State license (refer to V681), and meet any practice requirements for the applicable State.

FED - V0689 - PQ-DIETITIAN-RD

Title PQ-DIETITIAN-RD

Type Standard

CFR 494.140(c)(1)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition	Interpretive Guideline
The facility must have a dietitian who must- (1) Be a registered dietitian with the Commission on Dietetic Registration;	The Commission on Dietetic Registration is the credentialing agency for the American Dietetic Association. Dietitians working in dialysis must have evidence of registration with that organization.

FED - V0690 - PQ-DIETITIAN-1 YEAR EXPERIENCE AFTER RD

Title PQ-DIETITIAN-1 YEAR EXPERIENCE AFTER RD

Type Standard

CFR 494.140(c)(2)

Regulation Definition	Interpretive Guideline
The facility must have a dietitian who must- (2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian;	

FED - V0691 - PQ-SW-MSW;GRANDFATHER IF HIRED BEFORE 1976

Title PQ-SW-MSW;GRANDFATHER IF HIRED BEFORE 1976

Type Standard

CFR 494.140(d)

Regulation Definition	Interpretive Guideline
The facility must have a social worker who- (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under §494.140 (d)(1).	The social worker must have a master's degree in social work from a college or university that is accredited by the Council on Social Work Education (CSWE). The CSWE website database lists accredited masters level social work degree programs. The Association of State Boards of Social Work website has links to State regulations and rules for social work practice in each State. The curriculum of masters-level programs in schools accredited by the CSWE includes courses in human behavior, family dynamics, diagnosis, mental health treatment, conflict management, and ethics. Therefore, any one whose degree is from a school accredited by the CSWE is presumed to have a "specialization in clinical practice."

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Licensure requirements for master-prepared social workers in clinical practice vary from state to state. The masters prepared social worker must meet the licensure requirements in the state of practice. Refer to V681.

Staff without master's degrees in social work, including bachelor's prepared social workers, may function as assistants under the supervision of the qualified social worker and provide services such as assisting with transportation arrangements; providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care; and locating resources to assist in payment for adequate nutrition, housing, and medications. Only masters-prepared social workers may do assessments, develop psychosocial plans of care, provide counseling to patients and families, and participate as the social worker in the facility's QAPI program.

The grandfather clause at (2) applies to very few social workers, as it only applies to those social workers who have worked in dialysis or transplant facilities since September 1, 1975 and who had at least two years of social work experience on September 1, 1976 when the original ESRD Conditions for Coverage became effective. The social worker who "qualifies" as a social worker through this grandfather clause must have a "consultative relationship" with a qualified social worker. A "consultative relationship" requires a written agreement outlining the supervision that will be provided by the masters-prepared social worker. Since the professional responsibility for services lies with the masters-prepared social worker, this agreement needs to be consented to and signed by both parties. Having the masters-prepared social worker co-sign social service medical record entries made by the other social worker is not sufficient to meet the consultative relationship requirement.

FED - V0692 - PQ-PCT-STATE REQUIREMENTS & HS DIPLOMA

Title PQ-PCT-STATE REQUIREMENTS & HS DIPLOMA

Type Standard

CFR 494.140(e)(1),(2)

Regulation Definition

Patient care dialysis technicians must-
(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and
(2) Have a high school diploma or equivalency;

Interpretive Guideline

A "patient care (dialysis) technician" (PCT) means any person who provides direct care to patients and who is not classified as another professional, e.g., nurse, dietitian, or social worker. A biomedical technician or dialysis assistant would be classified as a PCT if he/she has responsibility for direct patient care or to set up machines for patient use. A technician who maintains or "takes down" machines after use without direct patient contact is not considered a PCT under these regulations.

Patient care (dialysis) technicians must meet requirements of the applicable State for education and training to provide patient care in dialysis facilities, including any State requirements related to practice standards, certification

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or registration.

CMS recognizes there are some experienced PCTs working in dialysis facilities as of the effective date of these rules who may not have evidence of a high school diploma or equivalency. PCTs with greater than 4 years work experience in dialysis as of 10/14/08 who lack evidence of a high school diploma may use that work experience in lieu of the requirement for high school diploma.

FED - V0693 - PQ-PCT-COMPLETE TRAINING PROGRAM

Title PQ-PCT-COMPLETE TRAINING PROGRAM

Type Standard

CFR 494.140(e)(3)

Regulation Definition

Patient care dialysis technicians must-
(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients.

Interpretive Guideline

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. 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.

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.

For "experienced" PCTs, meaning those PCTS who have been employed as a PCT for more than 2 years as of the effective date of these regulations, who do not have documentation of having completed a training program covering the listed content, competency may be demonstrated by successful completion of a facility ' s written exam(s) over the required content and a skills checklist completed by observation of the PCT's skills by a registered nurse. Successful completion of these exam(s) and competency testing would not negate the need for these experienced PCTs to achieve certification within the specified time period.

Facility policies and procedures should define the curriculum; length of training course; and the method for determining successful completion of the course.

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FED - V0694 - PQ-PCT-TRAINING PROGRAM CONTENT

Title PQ-PCT-TRAINING PROGRAM CONTENT

Type Standard

CFR 494.140(e)(3)

Regulation Definition

The training program must include the following subjects:
(i) Principles of dialysis.
(ii) Care of patients with kidney failure, including interpersonal skills.
(iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.
(iv) Possible complications of dialysis.
(v) Water treatment and dialysate preparation.
(vi) Infection control.
(vii) Safety.
(viii) Dialyzer reprocessing, if applicable.

Interpretive Guideline

The training program must include the content referenced in the regulation, at a minimum.

FED - V0695 - PQ-PCT CERTIFIED

Title PQ-PCT CERTIFIED

Type Standard

CFR 494.140(e)(4)

Regulation Definition

Patient care dialysis technicians must-
(4) Be certified under a State certification program or a national commercially available certification program, as follows-
(i) For newly employed patient care technicians, within 18

Interpretive Guideline

Certification can occur under the aegis of either a national commercially-available program or a State program.

At the time of publication of these regulations, there were three national commercially-available certification programs: the Certified Clinical Hemodialysis Technician (CCHT) examination offered by the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners for Nursing and Technology (BONENT)

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months of being hired as a dialysis patient care technician; or (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.

exam, and the National Nephrology Certification Organization (NNCO) exam. CMS has approved these three national certification programs for ESRD patient care technician certification. Additional national programs that are interested in offering a certification program may apply to CMS for approval.

These national commercially-available certification programs require a patient care dialysis technician to successfully pass a standardized certification examination in a proctored environment, and maintain certification through current work experience and continuing education.

State certification programs which have a formal certification and competency program (including standardized tests, which reflect the content listed in the regulation, administered in a proctored environment by an independent examiner) that is specific to patient care dialysis technicians, can satisfy this requirement. A "standardized test" is one developed and tested to validly and reliably measure the knowledge required to demonstrate competency in the area. If the state requires certification by a national commercially-available certification program, this regulation expects continued certification under the requirements of the national commercially-available program.

Patient care dialysis technicians working on October 14, 2008, who are not yet certified under an approved program, must be certified before April 15, 2010. Patient care technicians hired after October 14, 2008 must be certified within 18 months of their hire date as a patient care technician. If a patient care technician who is not certified changes jobs from one dialysis facility to another, the time he/she was employed in the first facility will count toward the 18-month deadline for certification unless he/she had a gap in employment as a patient care technician of more than 18 months.

A reuse technician or a water treatment technician who does not provide direct patient care does not require certification as a patient care dialysis technician. The training curriculum for persons performing hemodialyzer reprocessing is delineated under the Condition for Reuse of hemodialyzers and bloodlines at V308. The training for persons responsible for operating and testing the water treatment and dialysate preparation systems is addressed under the Condition for Water and dialysate quality at V260. If a reprocessing technician or water treatment technician changes positions to become a patient care technician, he/she must be certified in 18 months from the date he/she begins the new PCT position.

FED - V0696 - PQ-H20 TREATMENT SYSTEM TECHS TRAINING

Title PQ-H20 TREATMENT SYSTEM TECHS TRAINING

Type Standard

CFR 494.140(f)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

Interpretive Guideline

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.

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.

FED - V0710 - CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR

Title CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR

Type Condition

CFR 494.150

Regulation Definition

Interpretive Guideline

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.

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.

Examples of Condition level non-compliance include, but are not limited to:
o Serious and/or pervasive problems/trends identified in the quality of care delivery, quality assurance and performance improvement activities;
o 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.

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FED - V0711 - MD RESP-MED DIR QUAL/ACCOUNTABLE TO GOV BODY

Title MD RESP-MED DIR QUAL/ACCOUNTABLE TO GOV BODY

Type Standard

CFR 494.150

Regulation Definition

The dialysis facility must have a medical director who meets the qualifications of §494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients.

Interpretive Guideline

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. The position of medical director may not be shared by several physicians. 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.

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.

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).

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.

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 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.

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FED - V0712 - MD RESP-QAPI PROGRAM

Title MD RESP-QAPI PROGRAM

Type Standard

CFR 494.150(a)

Regulation Definition

Medical director responsibilities include, but are not limited to, the following:
(a) Quality assessment and performance improvement program.

Interpretive Guideline

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 the QAPI program. Operational responsibility includes review of quality indicators related to 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; and participating in the evaluation of the effectiveness of performance improvement plans/activities.

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

FED - V0713 - MD RESP-STAFF ED, TRAINING & PERFORM

Title MD RESP-STAFF ED, TRAINING & PERFORM

Type Standard

CFR 494.150(b)

Regulation Definition

Medical director responsibilities include, but are not limited to, the following:
(b) Staff education, training, and performance.

Interpretive Guideline

The medical director is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities.

"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

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services), and follow facility policy regarding expected performance.

Refer to other Conditions in these regulations for specific requirements for staff education, training and/or competency:
o V132 in Infection control;
o V260 in Water and dialysate quality;
o V308, 309 in Reuse;
o V409, V410, V411 in Physical environment;
o V693, V694, V696 in Personnel qualifications; and
o V760 in Governance.
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.

FED - V0714 - MD RESP-DEVELOP, REVIEW & APPROVE P&P

Title MD RESP-DEVELOP, REVIEW & APPROVE P&P

Type Standard

CFR 494.150(c)(1)

Regulation Definition

The medical director must-
(1) Participate in the development, periodic review and approval of a "patient care policies and procedures manual" for the facility;

Interpretive Guideline

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.

There must be evidence that the medical director reviewed and approved the patient care policies and procedures and any revisions as they are made. Corporate-owned or corporate-managed facilities may use standard policies and procedures developed by the corporation. 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.

Policies are expected to be adequate, accurate and up to date.

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FED - V0715 - MD RESP-ENSURE ALL ADHERE TO P&P

Title MD RESP-ENSURE ALL ADHERE TO P&P

Type Standard

CFR 494.150(c)(2)(i)

Regulation Definition

The medical director must-
(2) Ensure that-
(i) 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 nonphysician providers;

Interpretive Guideline

The medical director is responsible for the implementation of the policies and procedures by all staff. 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. 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.

The medical director is responsible for ensuring that the facility has an established policy regarding admissions to the facility. 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 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.

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:
o Neurologic: level of alertness/mental status, orientation, identification of sensory deficits
o Subjective Complaints
o Rest and comfort: pain status
o Activity: ambulation status, support needs, fall risk
o Access: assessment
o Respiratory: respirations description, lung sounds
o Cardiovascular: heart rate and rhythm; presence and location of edema

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o Fluid gains, blood pressure and temperature pre-treatment
o Integumentary: skin color, temperature and as needed, type/location of wounds
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.

FED - V0716 - MD RESP-ENSURE IVD P&P FOLLOWED

Title MD RESP-ENSURE IVD P&P FOLLOWED

Type Standard

CFR 494.150(c)(2)(ii)

Regulation Definition

The medical director must-
(2) Ensure that-
(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in §494.180(f).

Interpretive Guideline

The medical director must monitor and review each 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.

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.

FED - V0725 - CFC-MEDICAL RECORDS

Title CFC-MEDICAL RECORDS

Type Condition

CFR 494.170

Regulation Definition

Interpretive Guideline

This Condition 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.

Compliance with this Condition is determined by observation and review of medical records.

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Condition level non-compliance should be considered when there are serious and/or pervasive problems identified with the accuracy, completion, accessibility, and/or protection of patients' medical record information.

FED - V0726 - MR-COMPLETE, ACCURATE, ACCESSIBLE

Title MR-COMPLETE, ACCURATE, ACCESSIBLE

Type Standard

CFR 494.170

Regulation Definition

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

Interpretive Guideline

In ESRD, the term "medical records" includes printed or electronic information such as, but not limited to consents, histories and physicals, medication reports, radiology reports, laboratory reports, dialysis treatment orders, patient assessments, patient plans of care, treatment records, and progress notes regarding the condition and care of the patient. Each patient's medical record, whether hard copy, electronic, or a combination of both, should include complete and pertinent information about the condition of the patient, assessments by the interdisciplinary team, updated plans of care, all interventions and treatments prescribed and delivered, and details of any events occurring with the patient during the course of treatment. No matter what format, the record of care must be readily accessible to every authorized member of the healthcare team so that care can be coordinated to best meet the needs of the patient.

The facility must create and maintain a complete and accurate record of care for every patient that is unique for that patient. Each patient's medical record should clearly portray the patient, the care provided by the facility personnel, and the outcomes of that care.

V731 in this Condition and V599 under the Condition for Care at home also address the records of home patients.

FED - V0727 - MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL

Title MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL

Type Standard

CFR 494.170(a)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

The dialysis facility must-
(1)Safeguard patient records against loss, destruction, or unauthorized use; and
(2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:
(i) The transfer of the patient to another facility.
(ii) Certain exceptions provided for in the law.
(iii) Provisions allowed under third party payment contracts.
(iv) Approval by the patient.
(v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.

Interpretive Guideline

The medical record system must protect the privacy and security of all patients' medical record information. The medical records system must ensure that records are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security, controlled accessibility and protection of the records.

Electronic medical records systems must be designed to prevent accidental loss or destruction of medical record information (e.g., have an automated backup system), and have safeguards to prevent alteration of entries without notation of the alteration (e.g., a late entry must be indicated as such). Facility personnel should have sufficient knowledge of electronic system functions to assure their ability to safeguard records on that system in the event of a problem, including backup of electronic medical records and restoring data. Staff members should be aware of the facility's plan to ensure uninterrupted maintenance of the patient's medical record in the event of a computer failure. Staff members should be able to provide a printed copy of requested portions or the complete current medical record without significant delay (e.g., less than one hour for a portion of the record, less than four hours for the complete current record).

The accumulation of records for a patient treated several times a week for years can become voluminous. The current working chart may contain recent treatment records, and a year of patient assessments, plans of care, progress notes, orders, lab reports, etc. Older records of current patients may be stored in a convenient and secure location where they can be readily accessed as needed. Electronic storage of records is permissible if a secure means to protect the integrity of the record and the privacy of the patient is provided.

The facility policy for stored medical records must ensure prompt retrieval. Facility policy should address how staff members access records that are stored offsite, and the expected time to retrieve them.
In the event of loss of medical records due to unavoidable circumstances, (i.e., natural or man-made disaster) there should be evidence in the QAPI documentation of the event, what records were lost/destroyed, and what steps were taken to prevent similar losses in the future. The facility must have a plan for protecting medical records in an emergency (e.g. transport, secure in place, redundant backup, continuous automatic off-site backup), and for minimizing loss.

Facility policy and practices must reflect the requirements of the Health Insurance Portability and Accountability Act (HIPAA) requirements for paper and electronic medical records. HIPAA allows release of protected health information (PHI) in certain emergency circumstances, and for the continuity of health care. Also refer to the Condition for Patients' rights at V455.

Facility policy should address the release of patient's protected health information to third parties.

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

FED - V0728 - MR-OBTAIN WRITTEN PERMISSION FOR RELEASE

Title MR-OBTAIN WRITTEN PERMISSION FOR RELEASE

Type Standard

CFR 494.170(a)

Regulation Definition

The dialysis facility must-
(3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.

Interpretive Guideline

Medical records must contain written authorization for health information release prior to release of any medical records that require the patient's/designee's authorization to release.

42 CFR §494.170(a)(2)(v) gives state surveyors and ESRD Networks rights to access and review patient records, including taking copies of medical records offsite for official purposes.

FED - V0729 - MR-COMPLETE RECORDS PROMPTLY

Title MR-COMPLETE RECORDS PROMPTLY

Type Standard

CFR 494.170(b)(1)

Regulation Definition

(1) Current medical records and those of discharged patients must be completed promptly.

Interpretive Guideline

"Completed promptly" for current (active) patient records means that each clinical event is recorded as soon as possible after its occurrence, care interventions are recorded when provided, and other pertinent patient health information (e.g. assessments, plans of care, progress notes, medication administration, labs, radiology reports, medical orders) is recorded in a timeframe that provides other interdisciplinary team members with an up-to-date picture of the status of the patient at all times.

Facility policy must identify timeframes for the completion of medical records (e.g. signing of verbal orders, completion of discharged patients' records). The medical record system must have a method for identification of the author, date and time of each entry. The author's identification may be by written signature, initials, computer key, or other code. If initials or computer codes are used as signatures, there must be a means to identify the author of the entry. Rubber stamp signatures are not permitted.

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

FED - V0730 - MR-CENTRALIZE ALL INFO;IDT HAS ACCESS

Title MR-CENTRALIZE ALL INFO;IDT HAS ACCESS

Type Standard

CFR 494.170(b)(2)

Regulation Definition

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

Interpretive Guideline

"Centralized" means that the patient's health information is maintained in a common location, such as a "chart" or electronic record system. At the time of publishing of these regulations, many facilities had a combination of hard copy and electronic records. If part or all of the record is maintained electronically, each member of the interdisciplinary team must be familiar with and able to access those areas of the patient record he/she would need to use to stay current with the patient's plan of care. The system in place must allow the members of the interdisciplinary team to promptly access the most current information about the patient and their treatment.

Dialysis treatment records (i.e., "flow sheets") are the primary means of documenting the daily care of hemodialysis patients. These records should contain complete information about the treatment, such as pre and post treatment assessments, vital signs, vascular access in use, pre and post treatment weights, machine parameters and safety checks (e.g. alarm tests, dialysate pH and conductivity, dialysis prescription delivered (i.e. dialyzer, dialysate components, blood and dialysate flow rates, length of treatment), medications given, any clinical events that occurred during the treatment, actions taken and response.

FED - V0731 - MR-MAINTAIN HOME PT RECORDS

Title MR-MAINTAIN HOME PT RECORDS

Type Standard

CFR 494.170(b)(3)

Regulation Definition

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

Interpretive Guideline

The facility should have a system to maintain and regularly review treatment records kept by all home patients (including those whose equipment and supplies are furnished by a durable medical equipment (DME) supplier) and to incorporate those records into the patient ' s medical record.

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Refer to V599 if deficient practices in the content or maintenance of individual home dialysis patients' records are identified. Use this tag if there are facility-wide issues related to the records for multiple home patients.

FED - V0732 - MR-RETAIN ALL RECORDS 6 YEARS P DC/DEATH

Title MR-RETAIN ALL RECORDS 6 YEARS P DC/DEATH

Type Standard

CFR 494.710(c)

Regulation Definition

In accordance with 45 CFR §164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer or death.

Interpretive Guideline

Note that some states have more stringent requirements for medical record retention. Retention requirements begin after the patient is no longer on census at the facility.

These retention requirements also apply to the records of machine maintenance, dialyzer reprocessing/reuse, water treatment and dialysate preparation as each of these records is part of the medical record for the patients on service at the time those records were completed. Documentation of these processes is retained in logs rather than individual patient records. Since many patients are treated on the equipment each day, determination of the retention period may be difficult. Facility policy should address retention of these records.

FED - V0733 - MR-TRANSFER REQ RECORDS IN 1 WORKING DAY

Title MR-TRANSFER REQ RECORDS IN 1 WORKING DAY

Type Standard

CFR 494.170(d)

Regulation Definition

When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

Interpretive Guideline

The facility is responsible for transfer of requested medical record information to the receiving facility within 1 working day. The intent is to maintain continuity of care whenever patients leave the facility temporarily (e.g., vacation, business, hospitalization), or transfer permanently to a new facility.

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FED - V0750 - CFC-GOVERNANCE

Title CFC-GOVERNANCE

Type Condition

CFR 494.180

Regulation Definition

Interpretive Guideline

This Condition 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.
Compliance with this Condition is determined by patient and staff interview, observations, and review of records. Because the governing body is responsible for the total operation of the facility, the responsibility of the governing body must be considered when serious problems in other Conditions are identified.

Examples of Condition-level non-compliance include but are not limited to:
o Major problems with care and safety of patients, patient rights, or operations;
o Failure to follow the requirements for involuntary patient discharge;
o Failure to respond to Network requests for corrective action plans for problems identified by the Network;
o Failure to submit required data electronically; and
o Non compliance with another Condition for Coverage if the governing body has some responsibility for the deficient practices.

FED - V0751 - GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS

Title GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS

Type Standard

CFR 494.180

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients ' personal and property rights, and to the general operation of the facility.

Interpretive Guideline

" Identifiable " means that the individual or individuals that are responsible for the conduct and oversight of the operations of the facility are identified in writing. This may be demonstrated in governing body bylaws or minutes, or in ownership documents.

Terminology related to ownership:
· " Hospital-based " means owned and operated by and located in a hospital. A facility physically located inside a hospital but owned by another entity, such as a dialysis corporation, would not be considered " hospital-based. "
· " Satellite facility " means owned and operated by a hospital but located away from the central hospital campus. A satellite facility is surveyed separately and has its own CMS certification number (CCN).
" Corporate entity " means owned by a group, individual or · company; generally these facilities are part of a multi-facility group numbering from several to hundreds of facilities.
· " Physician-owned " means owned by a physician through a sole proprietorship, limited liability company, or corporation; may be one or multiple facilities.

The governing body bylaws should clearly define the ownership of the facility. In some cases, the owner has a contract with another entity for management of the facility. If so, this relationship should be clear in the governing body records of the facility.

Facilities that are part of a dialysis organization with multiple widespread facilities must have a local governing body designated to guide the day-to-day operation of the facility. The governing body may consist of one person or a group of persons. It should be clear in the governing body records who constitutes the governing body and who has the legal authority and responsibility for the governance and operation of the facility.

FED - V0752 - GOV-APPOINT CEO/ADMINISTRATOR

Title GOV-APPOINT CEO/ADMINISTRATOR

Type Standard

CFR 494.180(a)

Regulation Definition

The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility

Interpretive Guideline

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. The governing body or its designee must appoint the selected individual to this role. This position may be held by a

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for the management of the facility and the provision of all dialysis services,

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.

FED - V0753 - GOV-ADM RESP FOR STAFF APPOINTMENTS

Title GOV-ADM RESP FOR STAFF APPOINTMENTS

Type Standard

CFR 494.180(a)(1)

Regulation Definition

The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-
(1) Staff appointments;

Interpretive Guideline

The governing body, through the CEO or administrator, is responsible for the appointment of medical staff including physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician assistants). These appointments must be documented either in governing body minutes or in the applicable credential file.

FED - V0754 - GOV-ADM RESP FOR FISCAL OPERATIONS

Title GOV-ADM RESP FOR FISCAL OPERATIONS

Type Standard

CFR 494.180(a)(2)

Regulation Definition

The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-
(2) Fiscal operations;

Interpretive Guideline

The governing body, through the CEO or administrator, is responsible for maintaining sound fiscal operations. Issues which could indicate problems with fiscal operations include (but are not limited to) missed doses due to a lack of prescribed medications, broken equipment, deterioration of the physical plant, or insufficient staff.

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FED - V0755 - GOV-ADM RESP FOR RELATIONSHIP W/ESRD NW

Title GOV-ADM RESP FOR RELATIONSHIP W/ESRD NW

Type Standard

CFR 494.180(a)(3)

Regulation Definition

The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-
(3) The relationship with the ESRD networks;

Interpretive Guideline

The ESRD Networks are CMS contractors assigned responsibilities via a Statement of Work to:
o Collect and analyze data on ESRD patients and their outcomes of care, including the information that allows patients to be enrolled into the ESRD Medicare benefit program
o Provide education and oversight to improve the quality of care delivered to dialysis and kidney transplant patients
o Support facilities in developing and maintaining an effective QAPI program
o Respond to complaints and grievances

At the time of publishing these regulations, there were 18 ESRD Networks, each covering a specified geographic area.

A signed agreement between the facility and the applicable Network is required prior to the initial certification survey. The CEO or administrator is responsible to receive and act on correspondence from the ESRD Network and to promptly respond to any request from the applicable Networks.

Additional requirements related to Networks are found at V772.

FED - V0756 - GOV-ADM RESP FOR RESOURCES FOR QAPI

Title GOV-ADM RESP FOR RESOURCES FOR QAPI

Type Standard

CFR 494.180(a)(4)

Regulation Definition

The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief

Interpretive Guideline

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

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executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-
(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in §494.110.

be considered. 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 identified and their causes, and provide guidance and support for proposed needed corrections.

FED - V0757 - GOV-STAFF # & RATIO MEET PT NEEDS

Title GOV-STAFF # & RATIO MEET PT NEEDS

Type Standard

CFR 494.180(b)(1)

Regulation Definition

The governing body or designated person responsible must ensure that-
(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;

Interpretive Guideline

There must be sufficient numbers of qualified and trained staff on duty while patients are on dialysis in-center to meet the individualized needs of the patients. Consideration should be given to the acuity and care needs of patients, staff experience and areas of expertise when evaluating the adequacy of staffing. Sufficient numbers of staff must be present in the treatment area to be able to see every patient during treatment (including lunch breaks, shift change, etc. [refer to V407]); to deliver routine care, patient assessment and monitoring per facility policy; and to promptly respond to and address patient needs (such as changes in physical or mental condition) and machine alarms. Staffing assignments and schedules should demonstrate a pattern of sufficient staff coverage to ensure safe patient care.

Facilities are expected to meet any applicable State regulations that identify specific patient-to-staff ratio requirements. Failure to comply with those State requirements may be cited at this tag.

FED - V0758 - GOV-RN, MSW, & RD AVAIL TO MEET PT NEEDS

Title GOV-RN, MSW, & RD AVAIL TO MEET PT NEEDS

Type Standard

CFR 494.180(b)(1)

Regulation Definition

The governing body or designated person responsible must

Interpretive Guideline

The governing body is expected to make diligent efforts to promptly fill vacant positions. If the nurse manager, social

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ensure that-
The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

worker, dietitian or other required or necessary position is vacant for more than a month, the governing body must make some provision for temporary coverage. If the facility "shares" the social worker or dietitian with multiple clinics or requires professional staff to perform non-clinical tasks, it must not negatively impact the time available to provide the clinical interventions required to achieve the goals identified in the patient's plan of care. The facility CEO or administrator is responsible to assure the professional support staff members have sufficient time available in the facility to meet the clinical needs of in-center and home dialysis patients.

FED - V0759 - GOV-RN PRESENT AT ALL TIMES

Title GOV-RN PRESENT AT ALL TIMES

Type Standard

CFR 494.180(b)(2)

Regulation Definition

The governing body or designated person responsible must ensure that-
(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

Interpretive Guideline

There must be a registered nurse (RN) on duty and available at all times when in-center dialysis patients are being treated. This requirement is based upon data in the nursing literature which demonstrates a positive correlation between the availability of professional nursing service and patient outcomes.

If only one RN is on duty, that RN is expected to spend the majority of his/her time on the treatment floor. Short personal breaks away from the treatment floor are acceptable. An RN must be on-duty whenever patients are present, including the beginning and end of the treatment day.

In some cases, the RN who is on duty may not be qualified under these regulations as a " charge nurse " See V686-V687. In those instances, if allowed under the applicable State nurse practice act, a qualified licensed practical nurse or qualified licensed vocational nurse may function in the charge role.

FED - V0760 - GOV-GB RESP FOR STAFF ORIENTATION

Title GOV-GB RESP FOR STAFF ORIENTATION

Type Standard

CFR 494.180(b)(3)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition	Interpretive Guideline
The governing body or designated person responsible must ensure that- (3) 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.

FED - V0761 - GOV-STAFF HAVE ACCESS TO CONTINUING ED

Title GOV-STAFF HAVE ACCESS TO CONTINUING ED

Type Standard

CFR 494.180(b)(4)

Regulation Definition	Interpretive Guideline
The governing body or designated person responsible must ensure that- (4) All employees have an opportunity for continuing education and related development activities	Continuing education programs should be offered to all staff to help them maintain and improve their knowledge, skills, and licensure, if applicable. "Continuing education" includes internal training programs, as well as external professional educational programs. These regulations also include specific requirements regarding the provision of staff in-services and continuing education relating to Infection control at V132; Water & dialysate quality at V260; Physical environment at V409; and Personnel qualifications at V693, V694, and V696. Those tags should be considered (rather than this tag) if the deficient practice identified is related to one of those specific areas.

FED - V0762 - GOV-GB RESP FOR MED STAFF CREDENTIALING

Title GOV-GB RESP FOR MED STAFF CREDENTIALING

Type Standard

CFR 494.180(c)(1)

Regulation Definition	Interpretive Guideline
The governing body- (1) Is responsible for all medical staff appointments and	Privileges for physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician's assistants) are granted by the facility's governing body based on the individual practitioner's qualifications and

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credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners and clinical nurse specialists;

performance. The facility must define the requirements for practice at the facility in accordance with any applicable State laws. The medical staff credential files must include evidence the individual meets those requirements, including current licensure in the applicable State. Refer to V681 for issues related to professional licensing.

If the State has more stringent licensure requirements for ESRD facilities regarding medical staff appointments and those requirements are not met, those findings may be cited at this tag.

FED - V0763 - GOV-GB INFORMS MED STAFF OF P&P/QAPI PROG

Title GOV-GB INFORMS MED STAFF OF P&P/QAPI PROG

Type Standard

CFR 494.180(c)(2),(3)

Regulation Definition

The governing body-
(2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in §494.110.
(3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients.

Interpretive Guideline

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. 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.

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.

FED - V0764 - GOV-SERVICES FURNISHED ON THE MAIN PREMISES

Title GOV-SERVICES FURNISHED ON THE MAIN PREMISES

Type Standard

CFR 494.180(d)

Aspen Federal Regulation Set: V 11.01 END STAGE RENAL DISEASE

Regulation Definition

The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under §494.100).

Interpretive Guideline

Each separate physical location for dialysis services must be certified separately, and all approved services for a particular facility must be provided on the premises of that location. Hospital-based facilities may be located on the same campus of the hospital, with various services (e.g., home training vs. in-center dialysis) being provided in different rooms or areas, but sharing the same address on that campus.

All services provided by the facility must be under the direction of the same professional staff and governing body.

Training and support for home dialysis must be provided by a facility certified for those services. On occasion, some home training may be provided in the patient's home to meet the needs of the patient and/or helper. Training for care at home is discussed at V582 through V585. Home patients may see their physicians or a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) in their offices instead of seeing these practitioners at their dialysis clinics. In-center patients may, on occasion, see their practitioner in their offices, while periodically seeing their practitioner during treatment at the dialysis facility. This requirement can be found under the Condition for Patient plan of care at V560.

FED - V0765 - GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED

Title GOV-INTERNAL GRIEVANCE SYS ID/IMPLEMENTED

Type Standard

CFR 494.180(e)

Regulation Definition

The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services.

The grievance process must include-
(1) A clearly explained procedure for the submission of grievances.
(2) Timeframes for reviewing the grievance.
(3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.

Interpretive Guideline

The facility's policies and procedures must describe all available grievance procedures to the patient. The facility must inform the patient and/or the patient's designated representative (also called "designee") of its internal grievance process. Refer to the requirement at V465 under the Condition for Patients ' rights.

Each facility must implement a process to ensure that there will be no reprisal or denial of services for any patient who files an internal grievance and the grievance procedure will be clearly explained to patients. The existence of grievances should not be viewed negatively, as this would be an indication that patients understand the internal grievance process and believe that filing a grievance will not result in reprisal or denial of services. Lack of grievances does not indicate a lack of an internal grievance process.
The facility's grievance process should assure those grievances involving situations or practices that place patients or staff members in immediate danger (e.g. the patient's grievance brings attention to hazardous environmental

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conditions) are resolved immediately.

The facility's process must include clearly defined timeframes for a grievance to be acknowledged, investigated, and addressed. Timeframes should be sufficient to conduct an investigation yet ensure that the grievance is addressed in a timely manner.

The patient/designee should be informed of the status of the investigation periodically, and when resolution is attained or considered attained by the facility. Each grievance should demonstrate a completed cycle of reviewing the grievance and reporting back to the patient.

FED - V0766 - GOV-GB&MED DIR RESP STAFF FLW DC/TRANSFER P&P

Title GOV-GB&MED DIR RESP STAFF FLW DC/TRANSFER P&P

Type Standard

CFR 494.180(f)(1)-(3)

Regulation Definition

The governing body must ensure that all staff follow the facility's patient discharge and transfer policies and procedures.

The medical director ensures that no patient is discharged or transferred from the facility unless -
(1) The patient or payer no longer reimburses the facility for the ordered services;
(2) The facility ceases to operate;
(3) The transfer is necessary for the patient's welfare because the facility can no longer meet the patient ' s documented medical needs;

Interpretive Guideline

Involuntary discharge or transfer should be rare and preceded by demonstrated effort on the part of the interdisciplinary team to address the problem in a mutually beneficial way. The facility must have and follow written policies and procedures for involuntary discharge and transfer.

If any patients have been involuntarily discharged or transferred since the latter of either the effective date of these rules (October 14, 2008) or the facility's last survey, surveyors will review those patients' medical records to ensure compliance with these regulations and facility policy. See also requirements under Conditions for Patients' rights at V468 and V469.

The medical director must be informed of and approve any involuntary discharge or transfer of a patient. A facility may involuntarily discharge or transfer a patient only for those reasons listed here and at V767. The medical director must ensure that the reasons for any involuntary discharge or transfer are consistent with this requirement.

If a facility involuntarily discharges or transfers a patient for nonpayment of fees, there must be evidence in the patient's medical record that the facility staff (e.g., billing personnel, financial counselor, social worker) made good faith efforts to help the patient resolve nonpayment issues.

In the event a facility ceases to operate, the governing body must notify CMS, the State survey agency, and the

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applicable ESRD Network. The facility's interdisciplinary team must assist patients to obtain dialysis in other facilities.

If the discharge or transfer is necessary for the patient's welfare, the patient's medical record must include documentation of the medical need and reasons why the facility can no longer meet that need.

FED - V0767 - GOV-INVOL DISCHARGE PROCESS REQUIREMENTS

Title GOV-INVOL DISCHARGE PROCESS REQUIREMENTS

Type Standard

CFR 494.180(f)(4)

Regulation Definition

The medical director ensures that no patient is discharged or transferred from the facility unless -
(4) 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-
(i) Documents the reassessments, ongoing problems(s), and efforts made to resolve the problem(s), and enters this documentation into the patient's medical record;
(ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;
(iii) 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;
(iv) Contacts another facility, attempts to place the patient there, and documents that effort; and
(v) Notifies the State survey agency of the involuntary transfer or discharge.
(5) In the case of immediate severe threats to the health and

Interpretive Guideline

Patients should not be discharged for failure to comply with facility policy unless the violation adversely affects clinic operations (e.g., violating facility rules for eating during dialysis should not warrant involuntary discharge). Patients should not be discharged for shortened or missed treatments unless this behavior has a significant adverse affect on other patients' treatment schedules. A facility may evaluate the patient (who shortens or misses treatments) for any psychosocial factors that may contribute to shortening or missing treatments; for home dialysis; or, as a last resort to avoid inconveniencing other patients, may alter the patient's treatment schedule or shorten treatment times for patients who persistently arrive late. Patients should not be discharged for failure to reach facility-set goals for clinical outcomes. Facilities are not penalized if a patient or patients do not reach the expected targets if the plan of care developed by the IDT is individualized, addresses barriers to meeting the targets, and has been implemented and revised as indicated.

In the event facility staff members believe the patient may have to be involuntarily discharged, the interdisciplinary team must reassess the patient with an intent to identify any potential action or plan that could prevent the need to discharge or transfer the patient involuntarily. The reassessment must focus on identifying the root causes of the disruptive or abusive behavior and result in a plan of care aimed at addressing those causes and resolving unacceptable behavior.

Evidence must be on file to substantiate that the patient received notification at least 30 days prior to involuntary discharge or transfer and that the ESRD Network was also notified at that time. While the early notice to the State agency is not required, facilities may choose to notify the patient, Network and the State agency at the same time. A 30-day notice is not required in the case of imminent severe threat to safety of other patients or staff. The State agency and Network would need to be notified immediately if the use of the abbreviated involuntary discharge

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safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

procedure is necessary.

There must be a written order in the patient's medical record, signed by the attending physician and the medical director for the facility to involuntarily discharge or transfer a patient. If the reason for discharge is the physician's determination to no longer care for a particular patient and there is no other physician on staff available or willing to accept the patient, generally the state practice boards for physicians require the patient be given some notice to avoid a charge of patient abandonment. The facility would need to follow this regulation as to reassessment, 30 day notice, attempts for placement, etc. during the physician's period of notice to the patient.

Because the goal of contacting another dialysis facility is for continuity of care, the HIPAA privacy rule does not require patient consent to contact that other dialysis facility. However, it does limit sharing of protected health information to medical records requested by the other provider and prohibits sharing information obtained through hearsay. Good faith efforts should be made to find the closest facility to the patient's residence that will accept the patient in transfer. The applicable patient's medical record must include evidence of those placement efforts.

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.

At the time of publication of these rules, each facility had received a copy of an interactive program developed by the ESRD Networks on Decreasing Dialysis Patient Provider Conflict (DPC) that addresses proactive techniques to resolve such issues before progression to involuntary discharge.

FED - V0768 - GOV-GB GUIDE PTS/STAFF RE ER MED CARE

Title GOV-GB GUIDE PTS/STAFF RE ER MED CARE

Type Standard

CFR 494.180(g)(1)

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Regulation Definition	Interpretive Guideline
(1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.	The facility must provide information to all patients, including home patients, regarding who to call and how to obtain emergency medical care when away from the dialysis facility. The patients should be able to contact a call service for a responsible staff member, physician, or on call staff for dialysis-related emergencies 24 hours a day, 7 days a week. In cases of need for emergent medical care (e.g., severe chest pain, loss of consciousness, or uncontrollable bleeding), patients should be instructed to call "911" for immediate medical care.

FED - V0769 - GOV-PHYSICIAN ROSTER AVAILABLE

Title GOV-PHYSICIAN ROSTER AVAILABLE

Type Standard

CFR 494.180(g)(2)

Regulation Definition	Interpretive Guideline
(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.	There must be a listing available of physicians' names and contact numbers and a call schedule if physicians rotate this responsibility. Every facility must have a written plan for physician coverage during illness, vacations, and holidays.

FED - V0770 - GOV-TRANSFER AGREEMENT W/HOSP FOR INPT CARE

Title GOV-TRANSFER AGREEMENT W/HOSP FOR INPT CARE

Type Standard

CFR 494.180(g)(3)

Regulation Definition	Interpretive Guideline
(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must: (i) Ensure that hospital services are available promptly to the	There must be an agreement with a hospital to provide inpatient dialysis care. This could be in the form of a letter from the hospital acknowledging their agreement to this requirement or a more formal document signed by both the dialysis facility and hospital representatives. This hospital does not have to be certified as an ESRD provider, but must be able to provide hospital dialysis treatment as well as emergency and inpatient treatment and other hospital services.

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dialysis facility ' s patients when needed.
(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

It is not required or expected that every patient admission would be to the hospital with whom the agreement is signed.

FED - V0771 - GOV-ELECTRONIC DATA SUBMISSION REQUIRED

Title GOV-ELECTRONIC DATA SUBMISSION REQUIRED

Type Standard

CFR 494.180(h)

Regulation Definition

(8) Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment.

The data and information must-
(1) Be submitted at the intervals specified by the Secretary;
(2) Be submitted electronically in the format specified by the Secretary;
(3) Include, but not be limited to-
(i) Cost reports;
(ii) ESRD administrative forms;
(iii) Patient survival information; and
(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

Interpretive Guideline

Beginning February 1, 2009, all dialysis facilities must electronically submit data to allow patient enrollment in and disenrollment from the ESRD benefit program, assessment of clinical outcomes, and claims processing.

The facility must electronically submit required information at the specified intervals, which vary depending on the data element. Data required to be submitted electronically includes cost report data; administrative data (such as changes in key staff and changes in patient treatment modality); forms such as the CMS 2728 and 2746; and clinical performance data on all patients regardless of payment source, at the frequency determined by CMS. The clinical performance measures required to be submitted are determined by the Secretary of HHS, and any changes to these will be developed by a standardized process.

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FED - V0772 - GOV-RESPONDS TO NW REQUEST/WORKS TOWARD GOALS

Title GOV-RESPONDS TO NW REQUEST/WORKS TOWARD GOALS

Type Standard

CFR 494.180(i)

Regulation Definition

The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

Interpretive Guideline

The ESRD facility must respond promptly within any specified deadlines to requests for information, data, or corrective action plans from its ESRD Network. The facility must participate in Network projects and activities aimed at addressing identified needs and improving quality of care in the individual facility or the Network-wide area. Facilities may easily obtain copies of their Network's goals and objectives as each Network is required to post their annual report on their website. These reports include the individual Network's goals and activities.

At the time of publication of these regulations, the goals of ESRD Networks were to:
o Improve the quality and safety of dialysis-related services provided for individuals with ESRD.
o Improve independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through encouragement of transplantation, use of self-care modalities (e.g., home peritoneal dialysis, home hemodialysis, and in-center self care), as medically appropriate, through the end of life.
o Encourage and support collaborative activities to ensure achievement of these goals through the most efficient and effective means possible, with recognition of the differences among providers (e.g., independent, hospital-based, member of a group, affiliate of an organization) and the associated possibilities/capabilities.
o Improve the collection, reliability, timeliness, and use of data to: measure processes of care and outcomes; maintain the patient registry; and support the ESRD Network program

FED - V0773 - GOV-DISCLOSURE OF OWNERSHIP

Title GOV-DISCLOSURE OF OWNERSHIP

Type Standard

CFR 494.180(j)

Regulation Definition

In accordance with § 420.200 through § 420.206 of this

Interpretive Guideline

The governing body of the ESRD facility must report to the State survey agency a full and complete listing of any

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chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

individuals with ownership of 5% or more of the facility.

Any change in ownership must be reported in a timely manner to the State survey agency.

FED - V9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline