



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO 18-22-ESRD

DATE: August 10, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group (formerly Survey & Certification Group)

SUBJECT: Revisions to the State Operations Manual (SOM), Chapter 2, End Stage Renal Disease (ESRD) Program

Memorandum Summary

- The SOM operationalizes the oversight activities of State Survey Agencies (SAs) and Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) for certified Medicare providers and suppliers. Chapter 2 of the SOM includes guidance and instructions on procedures for ESRD facilities.
- CMS has completed a comprehensive update to the SOM Chapter 2, ESRD section to incorporate current Conditions for Coverage (CfC) and CMS policies for ESRD issued previously through memoranda.

Background

The ESRD CfCs set baseline standards that a Medicare certified ESRD facility must meet when furnishing dialysis services to any patient, regardless of payment source. The current ESRD CfC were published in a final rule on April 15, 2008, with an effective date of October 14, 2008 for most of the requirements. The ESRD section of Chapter 2 of the SOM was not updated to include the 2008 CfC or CMS policy changes issued through memoranda since 2008.

Discussion

CMS has completed comprehensive revisions to the SOM, Chapter 2, ESRD section. The revisions incorporate all CMS policy releases, issued through previous Survey and Certification memoranda, and updated CDC recommendations and changes to standards of practice in the community including:

- CMS guidance for ESRD activities related to relocations, addition of stations, expansion of services, and temporary closures (§488.60(a));
- Guidance for dialysis services provided in a nursing home;
- Infection control considerations (§494.30);
- Medical Director waiver considerations (§494.140(a)(2)).

Contact: Any questions pertaining to this matter should be submitted to ESRDQuestions@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment: Advanced Copy - Revisions to the State Operations Manual, Chapter 2, End Stage Renal Disease Program

cc: Survey and Certification Regional Office Management

End Stage Renal Disease (ESRD) Facilities

2270 - Medicare and ESRD

(Rev. 2, XX-XX-18)

The Social Security Act (the Act) designates those providers and suppliers that are subject to Federal health care quality standards. Dialysis facilities are so designated under §1881(b)(1) of the Act.

Note: The terms ESRD facility and dialysis facility are used interchangeably in this document.

ESRD is that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplant to maintain life. *Section 1802 of the Act provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate in Medicare if that institution, agency, or person undertakes to provide that individual such services.*

The ESRD Conditions for Coverage (CfCs) set baseline standards for ESRD facilities to meet when furnishing dialysis services which apply to all patients receiving care from the Medicare-approved facility, not just those who are Medicare beneficiaries. All dialysis patients must receive care that meets or exceeds the CfCs.

2270A – ESRD Conditions for Coverage

(Rev. 1, XX-XX-18)

Social Security Act §1881(b)(1)

Section 1881(b)(1) of the Act requires dialysis facilities to comply with the Conditions for Coverage (CfCs) for End-Stage Renal Disease (ESRD) Facilities in 42 CFR Part 494. These regulations specify the conditions with which facilities must comply to achieve and maintain approval for Medicare reimbursement.

Conditions for Coverage

The current CfCs for ESRD facilities were comprehensively updated through a final rule that was published on April 15, 2008, with an effective date of October 14, 2008 for most of the requirements. The requirement for an isolation room or area for hepatitis B virus positive (HBV+) patients at §494.30 became effective February 9, 2009. Some provisions addressing Life Safety Code (LSC) for ESRD facilities at §494.60 were updated through a final rule (77 FR 29002) that was published May 12, 2012, which became effective on July 16, 2012. The requirement for emergency preparedness at §494.62 became effective November 15, 2016 with an implementation of November 15, 2017.

2270B - ESRD Survey and Certification Communication, Information, Tools

(Rev. 1, XX-XX-18)

In order to foster communication among States Survey Agencies, CMS Regional Offices, and the ESRD community, the following website may be accessed for ESRD information and updates:

[CMS Dialysis Survey and Certification web site](#)

The website contains:

- Hyperlinks to the 2008 Final Rule, Conditions for Coverage for End-Stage Renal Disease Facilities and the Interpretive Guidance (IGs);*
- Frequently Asked Questions (FAQs) submitted by ESRD surveyors and the public since the implementation of the 2008 CfCs. The FAQs are organized by respective Conditions and V-tags in the IGs and are updated periodically with new questions and answers that are noted in red for easy reference;*
- Survey tools and training materials including, but not limited to, the ESRD Core Survey Field Manual, Outline of the ESRD Core Survey Process, ESRD Core Survey Process Triggers, the Measures Assessment Tool (MAT), critical water and dialysate requirements, a list of V-tags and identifiers, information on infection control and requirements for isolation rooms/areas, ESRD personnel requirements including information on organizations that certify dialysis patient care technicians, components of immediate jeopardy, and a list of helpful web sites for ESRD surveyors;*
- ESRD program-related survey and certification memoranda; and*
- Hyperlinks to ESRD-related web sites within and external to CMS.*

2270C – Definitions

(Rev. 1, XX-XX-18)

Dialysis

Dialysis is a process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. There are two types of renal dialysis procedures in common clinical usage: hemodialysis and peritoneal dialysis. Both hemodialysis and peritoneal dialysis are modalities of treatment for ESRD under Medicare and can be performed in a dialysis facility or in the patient’s residence.

Hemodialysis

In hemodialysis (HD), blood from the patient’s body is passed through blood lines and a hemodialyzer (“artificial kidney”) with the use of a hemodialysis machine. Hemodialysis uses osmosis and diffusion to remove waste products and excess fluids. Access to the patient’s blood circulation is required. Through exposure to a prescribed solution called dialysate, the patient’s blood is cleansed and extra fluid is removed. The cleansed blood is returned to the patient’s bloodstream. Hemodialysis is most commonly conducted 3 times a week with each session lasting 3 to 5 hours. It can also be conducted in 4 to 6 shorter sessions per week or in 3 to 6 overnight sessions lasting 6 to 8 hours each. Hemodialysis can be performed in a dialysis facility or at the patient’s home.

Peritoneal Dialysis

Peritoneal dialysis (PD) uses the patient's peritoneal membrane as the filter, and direct access to the patient's blood system is not required. A permanent tube (catheter) is surgically placed through the skin into the peritoneal space to allow introduction of a prescribed solution (dialysate). Waste products pass from the patient's blood through the peritoneal membrane into this fluid, which is drained and exchanged for clean solution periodically. Peritoneal dialysis can be done manually four to five times daily at spaced intervals or may be done using a machine (called a cycler) 7 to 10 hours daily, generally overnight. The length of time, number of exchanges, and content of the dialysate is based on the physician's prescription. PD is usually performed in the patient's home but may be performed in-center for ESRD facilities approved for in-center PD.

Intermittent Peritoneal Dialysis (IPD)

Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions.

Continuous Ambulatory Peritoneal Dialysis Coverage (CAPD)

In CAPD, the patient's peritoneal membrane is used as a dialyzer. CAPD does not require machinery or water supplies since the dialysate comes prepackaged in plastic bags ready for use. CAPD requires implantation of an indwelling catheter to provide access to the peritoneum. The patient connects the 2-liter plastic bag of the dialysate to the catheter, and the fluid infuses into the peritoneal cavity. Four to six hours later, the patient drains the fluid into a new drain bag and refills the peritoneal cavity with fresh dialysate. The procedure is accomplished three to five times daily, with the first exchange made upon arising and the last at bedtime. The procedure not only frees the patient from a machine but also allows scheduling flexibility without many of the restrictions associated with other types of dialysis.

Continuous Cycling Peritoneal Dialysis (CCPD)

CCPD uses an automated peritoneal dialysis machine to infuse a prescribed amount of dialysate into the abdomen and drain it, depending on the prescription. The process is repeated for 8 to 10 hours a day, usually at night while the patient sleeps. The last exchange stays in the abdomen during the day. Thus the patient cycles at night, but continuously dialyzes during the day.

2271 - General Requirements for In-center and Home Dialysis Program

(Rev. 1, XX-XX-18)

In-Center Dialysis:

Approval to provide in-center dialysis includes approval for a specific number of dialysis "stations" for that modality. A dialysis station is an individual patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for routine care and any emergency care indicated. There must be sufficient separation from other dialysis

stations to afford protection from cross-contamination with blood-borne pathogens. A hemodialysis station is equipped with an adjustable chair or bed, a hemodialysis machine, and, depending on the hemodialysis machine being used, access to a purified water source and dialysate concentrates.

Federal regulations do not have space/dimension requirements for in-center dialysis stations or home dialysis training and support areas. Some State regulations may identify space/dimension and other requirements for each in-center dialysis stations and the home dialysis training and support room/area.

Home Training and Support Program:

Approval to provide home training and support services requires the dialysis facility to provide both home training to the patient and/or their care partner in the modality and ongoing support and monitoring of the patient/care partner, as outlined in 42 CFR §494.100. An approved home training and support program must include both training and support services. A dialysis facility that is approved 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 ESRD CfCs.

There are no requirements for a specification of the number of training stations. The expectation for these services is that there will be sufficient space to provide an appropriate learning environment for each patient and care partner, if applicable. The in-facility home dialysis training and support space must be large enough to accommodate the dialysis equipment, routine and emergency care, to afford patient privacy, and to prevent cross-contamination with pathogens.

In accordance with §494.100(c)(1)(vii), facilities which provide only home dialysis training and support must have a plan/arrangement in place to provide emergency back-up dialysis services when there is an interruption, or anticipated interruption, in a patient's routine home dialysis treatment. Situations that may require back-up dialysis services include, but are not limited to, non-functional equipment, power or water outages, availability of a designated care partner and/or a patient's anticipated travel away from their home.

The home dialysis support services may be provided directly by the ESRD facility or by arrangement with another ESRD facility. If the support services are provided by another ESRD facility, such arrangements should be made at a location as convenient to the patient's home as possible, regardless of facility ownership.

2271A - Dialysis in Nursing Homes

(Rev. 1, XX-XX-18)

Terms Used in This Guidance

The term “nursing home” in this guidance refers to a Skilled Nursing Facility (SNF) or a Nursing Facility (NF). The term “ESRD facility” refers to the certified end-stage renal disease (ESRD) facility that retains overall responsibility for all the dialysis care and services of the patient.

Overview: Dialysis for Nursing Home Residents

Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare.

Nursing homes are not required to accommodate dialysis services on-site. Some State regulations may not allow dialysis services to be provided in a nursing home setting, or may have additional requirements regarding the qualifications of personnel who provide dialysis treatments in a nursing home.

Residents of a nursing home may receive chronic dialysis treatments through two options:

1. In-Center Dialysis:

- Transporting the resident to and from a separately certified ESRD facility that is located off-site of the nursing home for dialysis treatments; or*
- Transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or proximate to the nursing home building.*

2. Home Dialysis in a Nursing Home:

Residents may receive dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for training, and competency verification in 42 CFR 494.100(a) and (b) as also stated in this guidance, and are provided through a written agreement between the nursing home and the ESRD facility.

Mitigating risks for residents receiving dialysis treatments in a nursing home include: 1) ensuring only qualified personnel administer, monitor, and supervise the dialysis treatments; 2) monitoring the dialysis patient’s status before, during, and after the treatments; and 3) ensuring a safe and sanitary environment for the treatments.

The goal of this guidance is to ensure that an ESRD facility, providing home dialysis services to a nursing home resident under a written agreement with the resident’s nursing home, maintains direct responsibility for the dialysis related care and services provided to the nursing home resident(s) consistent with the ESRD Conditions for Coverage (CfC) requirements as well as the terms of an applicable agreement with the nursing home.

ESRD Notification to the State Survey Agency of a New or Additional Contract with a Nursing Home to Provide Dialysis Services On-Site

No additional approval is required from CMS for an ESRD facility to enter into an agreement with a nursing home to provide dialysis services to nursing home residents. However, the ESRD

facility must notify its State Survey Agency (SA) of any such agreement(s). This notification is accomplished through submitting a completed Form CMS-3427 End Stage Renal Disease Application and Survey and Certification Report. Only the following applicable fields of the Form CMS-3427 must be completed for this notification:

- Field: (1) #6 Other*
- Field: (2) Name of Dialysis Facility*
- Field: (3) CCN*
- Field: (4) Street Address of Dialysis Facility*
- Field: (6) City*
- Field: (7) County*
- Field: (9) State*
- Field: (10) Zip Code*
- Field: (12) Telephone Number*
- Field: (22) Dialysis in LTC Facility Field:*
- Field: (26) How is isolation provided in the nursing home?*

Written Agreement between the ESRD Facility and the Long Term Care Facility

The ESRD facility is expected to enter into a written agreement with any individual nursing home for which they will provide dialysis services. The agreement delineates the responsibilities of the ESRD facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments.

The ESRD facility is ultimately responsible for the safe delivery of dialysis to the nursing home resident which would include review of the qualifications, training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home and who provide on-site supervision of dialysis treatments. The ESRD facility is responsible for the quality and safety of the dialysis treatments and the management of the residents' ESRD-related conditions. The ESRD facility is also responsible for providing all equipment necessary for the resident's dialysis treatment and for the maintenance of such equipment.

The nursing home is responsible for providing a safe environment for the dialysis treatments, monitoring the resident before, during, and after dialysis treatments for complications possibly related to dialysis, and provides all non-dialysis related care. Nursing home staff must be prepared to appropriately address and respond to dialysis related complications and provide emergency interventions, as needed. See 42 CFR §483.25(l) and SOM App. PP at tag F698.

Both the ESRD facility and the nursing home are responsible for ensuring the collaboration necessary to provide dialysis care coordination to each nursing home resident receiving dialysis treatments.

The written agreement must be signed by authorized representatives of the Medicare-certified dialysis facility and the nursing home prior to the provision of dialysis care at the nursing home and must:

- 1. Delineate the lines of authority of each party;*

2. *Delineate the responsibilities of each party;*
3. *Describe how coordination between the parties will occur;*
4. *Describes the accountability for the dialysis services provided;*
5. *Be consistent with the written policies and procedures of the ESRD facility and the nursing home;*
6. *Specify the method by which the parties will ensure adherence to the terms of the agreement, communicate as issues arise, and take remedial action when appropriate; and*
7. *Be reviewed at least annually, and updated as needed.*

ESRD Policies and Procedures for Services to Residents Located in a Nursing Home

At a minimum, the ESRD facility, in collaboration with the nursing home, must develop and implement protocols for the delivery of ESRD services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. The protocols must include requirements set forth at 42 CFR 494.30 and 494.80 through 494.100. These protocols include procedures for infection control, patient assessment, patient plans of care, and care of the dialysis patient at home.

Policies and procedures must be reviewed and updated as necessary to be consistent with the most current standards of practice. Timeframes for re-evaluation of policies and procedures should be determined by each ESRD facility.

Dialysis Supervision and Administration

The ESRD facility providing services to a resident in a nursing home must ensure:

1. *Onsite supervision of dialysis by a trained registered nurse (RN) (who has completed a training course approved by the ESRD facility) whenever a resident is receiving hemodialysis (HD) in the nursing home, and by a trained RN or licensed practical/vocational nurse (LPN/LVN) (who has completed a training course approved by the ESRD facility) when a resident is receiving peritoneal dialysis (PD) treatment in the nursing home;*
2. *Qualified/trained dialysis administering personnel are present in the room and maintain direct visual contact with the resident receiving HD throughout the entire duration of the treatment (the supervising nurse may also be the dialysis administering personnel); and*
3. *If a situation occurs where the nursing home is unable to provide dialysis treatments due to reasons such as insufficient trained staff and/or supervision, the ESRD facility is notified and provides the dialysis treatments to avoid a delay or cancellation of treatment.*

Documentation of training and competency verifications for nursing home staff should be maintained by both the ESRD and nursing home facility.

Hemodialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a trained supervising RN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur

during a resident's hemodialysis treatment. The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs who supervise hemodialysis treatments in the nursing home must have successfully completed a training program which:

- Covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii);
- Is approved by the dialysis facility medical director and governing body;
- Is administered under the direction of a home training nurse meeting the qualifications at §494.140(b)(2); and
- Is equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100(b)(1).

Peritoneal Dialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a qualified supervising RN/LPN/LVN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's PD treatment (i.e. automated PD, continuous ambulatory PD). The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and be readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs/LPNs/LVNs who supervise PD treatments in the nursing home must successfully complete a training program that is:

- Specific to PD care and covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii)
- Approved by the dialysis facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100 (b)(1).

Hemodialysis and Peritoneal Dialysis Administration

Qualifications: The personnel who initiate and discontinue dialysis treatments for HD and PD to nursing home residents must be a RN, LPN or LVN who meets the practice requirements in the State in which he or she is employed. A trained nursing home staff member such as a nurse aide or trained caregiver may monitor the patient for the duration of the patient's treatment, but initiation and discontinuation of HD and PD must only be performed by the supervising nurse.

Training: *The dialysis administering personnel, for example RN, LPN/LVN, nurse aide or trained caregiver, must receive adequate training and possess sufficient competency to ensure that the resident on dialysis receives a safe and effective treatment. The training must be:*

- *Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i-viii) and §494.100 (b)(1).*
- *Approved by the ESRD facility medical director and governing body;*
- *Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;*
- *Specific to the dialysis modality. The training program for HD and PD must include at least the subject matter listed at §494.100 (a)(3)(i-viii).*

Ongoing competency for dialysis administering personnel must be verified through visual audits by an ESRD RN who meets the qualifications of home training nurse at §494.140(b)(2). Frequency for competency verification is determined by the ESRD facility. More frequent competency checks may be warranted if problems in care are identified. For example, a concern of poor clinical outcomes, such as frequent infections, may indicate infection control issues and may be an indicator to review dialysis procedures performed by the nursing home staff and possible re-training.

In-Room Presence

To assure resident safety, the ESRD facility and nursing home must ensure that qualified dialysis administering personnel remain in the room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment, in accordance with §494.60(c)(4).

Existing Personal Caregiver

If an existing ESRD facility home dialysis (PD or home HD) patient is admitted to a nursing home and that patient has a trained personal caregiver who administered the dialysis treatments at home, that caregiver may be approved by the ESRD facility and the nursing home to continue to administer the patient's dialysis treatments in the nursing home. The collaborative decision-making process for such situations must be addressed in the written agreement between the ESRD facility and nursing home. If the nursing home and ESRD facility determine that an existing home dialysis caregiver may continue to administer the dialysis in the nursing home, the ESRD facility must assure that the caregiver meets the training requirements at §494.100(a)(3)(i-viii), and the verification of demonstrated competency at §494.100(b)(1). The ESRD facility is responsible for the ongoing monitoring of the competency of the personal caregiver.

Coordination of Care

Communication

The ESRD facility and nursing home must establish procedures for 24/7 communication between the two entities. The ESRD facility must provide to the nursing home an on-call schedule with the names and contact information of physicians and/or ESRD facility RN's to be called for

emergencies. There should be written agreement on a communication process to include how communication and responses will be coordinated and documented between the ESRD facility and nursing home staff.

Interdisciplinary Team (IDT) Coordination between ESRD Facility and Nursing Home Staff

The dialysis facility IDT team must coordinate with the nursing home staff for the development and implementation of an individualized care plan based on the patient's assessment. Both the nursing home staff and ESRD facility staff are responsible for monitoring and addressing any medical or non-medical needs that are identified. Any identified barriers or issues that are preventing residents from meeting the established ESRD facility goals identified through a patient assessment and/or defined in the plan of care, should be promptly communicated between the ESRD facility IDT and the nursing home IDT. Any barriers experienced by a dialysis patient will require re-assessment and an updated plan of care by both teams.

Emergency Plans

The dialysis facility maintains overall responsibility to prepare the nursing home to address all emergencies related to the dialysis needs of the resident receiving treatments in the nursing home. The following emergency plans must be clear and communicated to nursing home staff in a manner that allows for the continuity of care and be incorporated into the written agreement between the two entities:

1. Emergency Staffing

When the nursing home staff are functioning as the caregiver for the nursing home resident and providing the dialysis treatment for the resident, it is the responsibility of the nursing home staff to notify the ESRD facility of any delays or interruptions in the provision of the prescribed dialysis treatment. The ESRD facility is responsible for ensuring that a backup plan is in place to ensure the resident receives the treatment.

2. Emergency Care

Nursing Home residents receiving dialysis may have complications which require treatment with emergency medications or equipment. The physician treatment orders for the ESRD patient should include what emergency medications are to be kept on hand.

3. Equipment Failure

The ESRD facility must provide nursing home staff with:

- Adequate and appropriate education for possible equipment failures and risk(s) associated with equipment failures;*
- Troubleshooting techniques; and*
- Contact information for assistance in resolving issues with equipment failure.*

Any equipment that is non-functional must be replaced or restored by the ESRD facility to avoid interruption of a patient's dialysis treatment.

4. Emergency Supplies

Nursing homes should maintain all necessary medication and supply inventories to prevent any delays or interruptions to a resident's prescribed dialysis treatment. The ESRD facility and the nursing home should ensure a reserve of supplies to be available in emergency circumstances. The emergency supply reserve is in excess of the routine supply inventory and generally includes at least five (5) days of emergency supplies for each resident.

To assist with the inventory, the ESRD facility should provide nursing homes with medications, equipment, and dialysis related supplies through routine deliveries. Plans must be in place for the safe delivery of additional supplies in the event of an emergency.

2271B - Dialysis in Hospitals

(Rev. 1, XX-XX-18)

A department/unit of a hospital (other than a psychiatric hospital) may, as permitted under State law, provide either inpatient or outpatient dialysis services.

In certain situations dialysis services may be provided in a hospital department/unit for non-ESRD patients requiring temporary dialysis or for ESRD patients who are admitted to the hospital for other diagnoses or injuries. These dialysis services are referred to as "acute dialysis." A department /unit of a hospital that provides acute dialysis services must provide those services in compliance with the hospital Conditions of Participation (CoP) and are not subject to the ESRD CfCs.

Hospitals that provide outpatient dialysis services must be certified as a hospital-based ESRD facility.

2272 - ESRD Facility Classification

(Rev. 2, XX-XX-18)

Hospital-Based ESRD Facility

A hospital-based ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and that meets the ESRD CfCs at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital (CAH) and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CMS certification number (CCN).

A hospital-based ESRD facility is discussed at 42 CFR §413.174(c) and meets the following criteria:

- The ESRD facility and hospital have a common governing body and are subject to the bylaws and operating policies of this body. All management authority flows from this governing body which has final administrative responsibility over both entities. The common governing body approves all personnel actions, appoints medical staff, and*

- carries out similar management functions;*
- There is a clearly established line of authority between the ESRD facility administrator and the hospital chief executive officer wherein the administrator is under the supervision of the chief executive officer. The ESRD facility administrator reports to the common governing body through the hospital's chief executive officer;*
 - ESRD facility personnel policies and practices conform to those of the hospital;*
 - Administrative functions of the ESRD facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and*
 - The ESRD facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the ESRD facility through the required step-down methodology.*

Hospital-based ESRD facilities are assigned CCNs from the 2300-2499 series.

Satellite Renal Dialysis Facility (Hospital-Based)

A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the campus of the hospital. A single hospital may have several satellite renal dialysis facilities. Each satellite facility is separately certified and surveyed; must independently meet the ESRD CfCs from other facilities owned by that hospital; and is assigned its own CCN.

Satellite renal dialysis facilities (Hospital-Based) are assigned CCNs in the 3500-3699 series.

Independent Renal Dialysis Facility

An independent renal dialysis facility is any ESRD facility that does not meet the definition of a hospital-based renal dialysis facility or satellite renal dialysis facility as described in the paragraphs above. An independent renal dialysis facility may be physically located on a hospital campus, but is not owned and/or administered by the hospital.

Independent renal dialysis facilities are assigned CCNs in the 2500-2899 series.

Special Purpose Renal Dialysis Facility (SPRDF) (§494.120)

This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e. up to 8 months in any 12 month period) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area.

The RO must clearly specify the limited nature of the SPRDF certification, the time period covered by the certification, and the automatic termination of payment on the last day of the certification period in its notifications.

The special locations for SPRDF fall into two categories:

Vacation Camps

Vacation camps serve dialysis patients temporarily residing there. A vacation camp SPRDF would allow campers to receive hemodialysis at the camp site, avoiding

interruption of the camping experience. Vacation camps may be approved for the duration of the camp, but up to a maximum of 8 months in any 12-month period.

Emergency Circumstance SPRDFs

These locations are set up to provide dialysis services to those ESRD patients who would otherwise be unable to obtain such services in their geographical area as a result of a natural or man-made disaster or a need for a greater capacity to dialyze patients who may have been evacuated from another location.

The RO may extend the time period in emergency SPRDF approvals, where necessary, beyond the standard eight-month period based upon the termination of the emergency condition.

In emergency situations, the RO should coordinate with the applicable State Health Department to assist the ESRD Network to relocate all patients to permanent facilities prior to the scheduled closing date of the emergency circumstance SPRDF.

Special purpose renal dialysis facilities are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities.

2273 – Dialysis Modalities and Dialysis Related Services

(Rev. 1, XX-XX-18)

Dialysis is a treatment option for end stage renal disease. Under the Medicare program, ESRD facilities may apply for and be approved to provide a variety of specific dialysis modalities and dialysis-related services. The dialysis modalities and dialysis-related services are listed below.

Dialysis Modalities

In-center Hemodialysis:

Under this modality, in-center hemodialysis patients receive their treatments at the ESRD facility, usually 2-5 times per week for varying lengths of time, generally from 3-5 hours as prescribed by their physician.

In-center Nocturnal Hemodialysis

This modality is a type of in-center hemodialysis where patients receive longer treatments overnight. In-center nocturnal hemodialysis stations usually include a reclining chair or bed to accommodate patient comfort.

In-center Hemodialysis- Self-dialysis

“Self-dialysis” is defined in the ESRD CfCs at 42 CFR 494.10 as “dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part.” Self-dialysis refers to an individual patient's preference for performing self-care in the outpatient dialysis facility setting. In contrast to “home dialysis” which is also defined at §494.10, CMS considers the self-dialysis patient as an in-center dialysis patient (or their personal care partner) who wishes to

self-administer most or all of their dialysis treatment without professional help in one of the approved in-center dialysis stations of the certified ESRD facility rather than in their home. There is no separate approval for facilities that offer “self-dialysis” so long as they are approved for in-center dialysis.

The ESRD CfCs include requirements related to the training of self-dialysis patients and/or care partners. The patient or care partner must successfully complete a course of training that covers at least the subject matters listed at § 494.100(a)(3). The training must be conducted by a qualified self-care/home care dialysis training nurse (who meets the requirements pursuant to § 494.140(b)(2)), be provided by an ESRD facility which is approved to provide home dialysis services (§ 494.100(a)(1)). The facility must verify the competency of the patient/care partner in the administration of the dialysis treatments, and document the verification in the patient's medical record (§ 494.100(b)(1)).

In-center dialysis patients who wish to self-administer a minor portion of their treatments, such as inserting their own needles, or taking their own blood pressures do not meet the definition of “self-dialysis.”

In-center Peritoneal Dialysis (PD)

Although PD is primarily a home dialysis therapy, there may be situations when a patient is receiving PD at the dialysis facility on a temporary basis while training for home PD, or prior to switching to hemodialysis. In-center PD generally requires a patient to come to the dialysis facility for PD treatment for eight or more hours per treatment as prescribed by their physician.

Home Hemodialysis Training and Support

The patient and/or care partner is trained to perform routine hemodialysis treatments at the patient's place of residence by a home training nurse who meets the qualifications at 42 CFR 494.140(b)(2). The home dialysis training and support facility staff, inclusive of the interdisciplinary team, provides ongoing monitoring and support services to the patient for their home hemodialysis treatments.

Staff-Assisted Dialysis in the Home

The dialysis facility may provide qualified staff members in the patient's home to assist them in performing their home dialysis treatments. The dialysis staff member functions in the role of the patient's caregiver and monitors the patient throughout the dialysis treatment. The dialysis facility maintains overall responsibility and oversight to ensure appropriate, qualified staff are assigned and trained and provides supervision of staff members as indicated. Employees performing staff assisted dialysis must meet the personnel qualification requirements at §494.140.

In order to provide staff-assisted home dialysis, a dialysis facility must be approved to provide Home Training & Support services. Staff-assisted home dialysis does not require additional approval.

Home Peritoneal Dialysis (PD) Training and Support

The patient and/or designated care partner are trained to perform peritoneal dialysis at the patient's place of residence by a home training nurse who meets the qualifications at 42 CFR 494.140(b)(2). The home dialysis training and support staff, inclusive of the interdisciplinary team, provides ongoing monitoring and support services to the patient for their PD at home. Home PD may include Intermittent Peritoneal Dialysis (IPD), Continuous Ambulatory Peritoneal Dialysis (CAPD), or Continuous Cycling Peritoneal Dialysis (CCPD). A dialysis facility must have an approved Home Training & Support program to offer IPD, CAPD, or CCPD. IPD, CAPD and CCPD do not require additional approval.

Urgent Start Peritoneal Dialysis (PD) in the ESRD Facility

Urgent start peritoneal dialysis is the initiation of peritoneal dialysis as early as two weeks following catheter placement and is an option to avoid central line insertion for patients interested in home dialysis but requiring initiation of dialysis. Urgent start PD allows the facility to support the patient's dialysis related needs until the patient's catheter is healed and training is completed. Typically, patients will receive peritoneal dialysis treatments in the facility up to five days/week over eight hours. This process usually lasts between two to four weeks and after this period the patient will begin routine home PD independently in their home.

In order to perform urgent PD, the facility must have an approved in-center PD and Home Training & Support program. No separate approval is required.

Pre-Configured Systems

*ESRD CfCs applicable to preconfigured hemodialysis systems are located at 42 CFR 494.40 (e), "Standard: In-center use of preconfigured hemodialysis system. **Follow FDA labeling.**" This requires that the system's FDA approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality. Because this system does not share the same design or configuration of a traditional in-center hemodialysis water system, all the requirements of §494.40 Water and Dialysate Quality will not be applicable. Accordingly, for purposes of surveying water and dialysate quality with preconfigured hemodialysis machines, the surveyor determines whether the facility follows the FDA and manufacturer's labeling for the machine. If that is confirmed, the surveyor may conclude that the preconfigured machine meets the requirements of 42 CFR 494.40(e) and the AAMI requirements at RD52. Maximum levels for contaminants including chlorine, bacteria and endotoxins in water and dialysate recommended by AAMI apply to both traditional in-center hemodialysis water systems and preconfigured systems.*

Portable Reverse Osmosis (RO) Systems

A central water treatment and delivery system remains the traditional method for water purification for multiple hemodialysis machines in a dialysis facility. However, improvements in the manufacturing of small portable water treatment devices (i.e. portable reverse osmosis units) have created changes in options for water treatment in small chronic dialysis facilities. The use

of portable RO units in small chronic dialysis facilities is an alternative method of delivering AAMI quality water to the point of use (hemodialysis machine), if the portable RO units are appropriately constructed, monitored, and maintained. The portable RO unit must produce the water quality defined in American National Standard Institute (ANSI)/AAMI RD52:2004, as incorporated by reference in 42 CFR 494.40 “Condition: Water and dialysate quality.” The portable RO unit must be operated in accordance with manufacturer’s directions for use.

Pursuant to §494.40, monitoring of each portable RO unit must include testing for total chlorine before each treatment, monthly microbiological monitoring of cultures and endotoxins, and at least annual testing of chemical quality of the product water. Monitoring must also include daily function monitoring and recording of the portable RO unit for percent rejection and the water quality produced by conductivity or total dissolved solids (TDS). Surveyors should follow the guidance of the ESRD Core Survey process and tools, expanding their review for the above-mentioned specific requirements, when reviewing a facility using portable RO units. During an initial certification survey, the surveyor should confirm that the facility’s policies address all of these requirements.

Dialysis-related Services

Dialyzer Reprocessing and Reuse

A hemodialyzer (artificial kidney) is a medical device which may be manufactured for single use, or constructed so that it may be reprocessed and reused for hemodialysis following specific safety guidelines. Reusable hemodialyzers are:

- Assigned to an individual patient;*
- Labeled with the patient’s unique identifying information;*
- Rinsed/cleaned;*
- Tested for efficiency;*
- Disinfected after each hemodialysis treatment and rinsed, and*
- Tested for any residual disinfectant chemicals.*

The processes for safe and effective dialyzer reprocessing and reuse are established by the AAMI, which are adopted by reference into the ESRD CfCs at 42 CFR 494.50.

Some dialysis facilities opt to transport patient dialyzers to an off-site location for reprocessing. This is known as a centralized reprocessing location. Guidance for review of centralized dialyzer reprocessing is included in SOM section 2285, “Specialized Areas of ESRD Oversight.”

Many dialysis facilities do not reuse hemodialyzers. At these facilities, single-use dialyzers are prescribed to individual patients by type and are discarded in a biohazard receptacle after a single hemodialysis session.

2274 - ESRD Survey and Certification Forms

(Rev. 2, XX-XX-18)

2274A - Form CMS 855A: “Medicare Enrollment Application: Institutional Providers

(Rev. 1, XX-XX-18)

The ESRD supplier completes the Form CMS-855A and submits it directly to the applicable Medicare Administrative Contractor (MAC). The MAC will process the Form CMS-855A and will send a copy of any approved application to the SA and the CMS Regional Office. Updates to the Form CMS 855A must be submitted to the MAC when there are changes to the information already submitted.

2274B - Form CMS-3427: “End Stage Renal Disease Application and Survey and Certification Report”

(Rev. 1, XX-XX-18)

In addition to the CMS-855, an ESRD facility must submit the completed Form CMS-3427 for:

- An initial application for participation by prospective ESRD facilities;*
- A request to expand or add in-center dialysis stations for approved modalities;*
- Change in location/relocation;*
- Change in ownership (CHOW);*
- For addition or elimination of a dialysis modality/service (s) provided, including:*
 - In-center hemodialysis*
 - In-center nocturnal hemodialysis*
 - In-center peritoneal dialysis*
 - Home hemodialysis training and support*
 - Home peritoneal dialysis training and support*
 - Dialysis in the Nursing Home setting*
 - Dialyzer reprocessing and reuse*

After the completion of a survey or review, the SA must complete and upload Part II of the form and denote the type of survey conducted. Instructions for completing the Form-CMS 3427 are included on the last page of the form.

2274C - Form CMS 670: “Survey Team Composition and Workload Report”

(Rev. 1, XX-XX-18)

The Form CMS-670 is completed by the survey team members for each onsite ESRD survey activity to capture surveyor resources utilized. For instructions on completion of Form CMS-670, refer to the State Operations Manual, Chapter 2, the Certification Process, Section 2705.

2274D - Form CMS-2567: “Statement of Deficiencies and Plan of Correction”

(Rev. 1, XX-XX-18)

The Form CMS-2567:

- Is the official report of survey findings;
- Is the document which is disclosed to the public;
- Details the facility's deficient practices identified during the survey; and
- Contains the facility's plan for correction.

For more general information about the Form-CMS 2567, refer to the State Operations Manual, Chapter 2 the Certification Process, Section 2728. For ESRD surveys, specific instructions regarding documentation on the Form CMS-2567 for the following V-tags are provided:

Use of Tag V000

This tag should be used to document the type of survey conducted (e.g., complaint, initial, revisit).

Additionally, Tag V000 should include an explicit statement indicating the facility's compliance, or level of non-compliance with the CfCs, as result of the survey findings.

Finally, Tag V000 may also be used to list a glossary of technical terms and abbreviations. If listed at V000, the terms and abbreviations may be used throughout that CMS-2567 without further explanation.

Use of Tags V100, 101: State and Local Law

The State determines compliance with its State licensure requirements. Tags V100 and V101 may not be used to cite noncompliance with State licensure requirements unless the state licensure finding has been completely adjudicated and is final, i.e., the finding has been upheld through the State appeals process or has not been appealed and is a final state action.

Do not use V100 or V101 to cite deficiencies related to Occupational Safety & Health Administration (OSHA), the Americans with Disabilities Act (ADA), or the Food and Drug Administration. CMS is not the designated entity to survey for those requirements. Refer concerns in these areas to the applicable CMS Regional Office for referral to and notification of the appropriate oversight entity.

2274E - Form CMS 2567B: “Post Certification Revisit Report”

(Rev. 1, XX-XX-18)

The Form CMS-2567B is completed by the SA after a revisit survey to document verification of correction of deficiencies cited on the recertification survey.

2274F - Form CMS 1539: “Medicare/Medicaid Certification and Transmittal”

(Rev. 1, XX-XX-18)

The SA uses Form CMS-1539 to communicate findings to the CMS Regional Office with respect to a facility’s compliance with health and safety requirements. Form CMS-1539 is also a transmittal cover sheet for the certification packet. The SA completes Part I of the form and the Regional Office completes Part II. For instructions on completion of Form CMS-1539, refer to the State Operations Manual, Chapter 2 the Certification Process, Section 2762.

2276 - SA Control of Form CMS-3427

(Rev. 2, XX-XX-18)

The SA date-stamps all Form CMS-3427s (“*End Stage Renal Disease Application and Survey and Certification Report*”) and application-related correspondence *received* and reviews the forms and documentation for accuracy and completeness.

The SA forwards the original and one copy of Form CMS-3427, Part I, and the related materials to the RO within 3 days, using the “Medicare/Medicaid Certification and Transmittal,” Form CMS-1539 *to forward their recommendation to the RO*.

2278 - ESRD Survey Procedures

(Rev. 1, 05-21-04)

2278A - Facility Withdraws Application Prior to Survey

(Rev. 2, XX-XX-18)

If *the surveyor arrives onsite and the* facility states it no longer wishes to be considered for ESRD program participation, the SA requests that the facility *immediately* submit a statement of voluntary withdrawal *electronically to the SA*. *The surveyor should remain at the facility until the SA receives the request and instructs the surveyor to terminate the survey.*

2278B - Certificate of Need (CON)

(Rev. 2, XX-XX-18)

Each application, except for a SPRDF, must be accompanied by evidence of a CON in all States where it is required by State law.

The SA returns applications that do not include the CON on the basis of an incomplete application, using the model letter in [Exhibit 30](#).

2278C - Initial RO Approval

(Rev. 2, XX-XX-18)

In order to be certified in the Medicare program as an ESRD facility, a facility must:

- *Complete Part I of Form CMS-3427A, “End Stage Renal Disease Application and Survey and Certification Report;”*
- Have provided care to a minimum of one patient per modality; and*
- Be in compliance with all federal requirements including the ESRD Conditions for Coverage*
- A certificate of need (CON), where required by State law, must be submitted by the facility unless it is a Special Purpose Renal Dialysis Facility (SPRDF).*

The SA forwards its recommendation for certification or for denial of certification to the CMS RO. The RO will forward the final determination to the facility. If the facility is approved for certification, the RO assigns the ESRD facility a CMS Certification Number (CCN) number and sends a Form CMS-2007 (Exhibit 156) to the MAC. The RO completes the certification in ASPEN.

2278D - Expansion or Addition of Services – SA/RO Procedures

(Rev. 2, XX-XX-18)

When a facility submits a request for expansion of services, per form CMS-3427, this generally relates to the addition of dialysis stations. The SA/RO will request and review a facility floor plan, with the proposed additional stations shown, to determine whether there are concerns regarding inadequate space for each station or infection control concerns due to inadequate space. Since there are no square footage requirements for each station, the review must ensure that each station has adequate space to provide for patient privacy and sufficient space for safety such as providing the need for the patient to exit if necessary or for emergency care to be provided if necessary.

If the review confirms there is adequate space for the expansion or addition of services, no on-site review is required. The SA should notify the provider of the approval of the additional stations.

When a facility submits a request for addition of a modality or service through the form CMS-3427:

1. *On-site survey must be performed for: (All applicable regulations for the service/modality requested should be reviewed.)*
 - *Addition of In-center Hemodialysis; (Survey confirms that the facility has provided HD to at least one patient.)*
 - *Addition of Home Training and Support Modality; (Survey must confirm that the facility has provided home training a support to a minimum of one patient.)*

- *Addition of In-Center PD, if no approval for Home Training and Support; and*
 - *Addition of Reuse*
2. *On-site survey is not required for the following changes in modalities or services:*
- *Addition of In-Center Nocturnal HD; (Provider must provide documentation how the water system will be maintained.)*
 - *Addition of In-Center PD, if facility already approved for Home Training and Support; and*
 - *Addition of HD or PD in a Long Term Care Facility, if already approved for Home Training and Support.)*

The SA notifies the facility of its decision regarding approval or denial of the expansion or addition. If approval is recommended, the SA forwards a CMS-1539 to the CMS RO with a recommendation. The RO forwards a CMS-2007 (Exhibit 156) to the MAC denoting any changes in services.

2279 - ESRD CMS Certification Numbers

(Rev. 1, XX-XX-18)

The CMS Certification Number (CCN) is assigned to the ESRD facility after all certification requirements have been met. Assignment of the ESRD facility CCN should be in accordance with the guidelines contained in Chapter 2 of the State Operations Manual, section §2779.A.1. The RO forwards Form CMS-2007 to the MAC upon issuance of the CCN.

ESRD facilities and their CCN series are as follows:

- 2300-2499 Hospital-Based Renal Dialysis Facilities*
- 2500-2899 Independent Renal Dialysis Facilities*
- 2900-2999 Independent Special Purpose Renal Dialysis Facilities*
- 3500-3699 Satellite Renal Dialysis Facilities*
- 3700-3799 Hospital-Based Special Purpose Renal Dialysis Facilities*

2280 - ESRD Survey Activities

(Rev. 2, XX-XX-18)

State Licensure Requirements

An entity applying for certification as an ESRD facility must be in compliance with any applicable State Licensure requirements, in addition to the Federal requirements for each type of survey described below. Although State licensure requirements may include State Certificate of Need (CON) for ESRD facilities, Special Purpose Renal Dialysis Facilities (SPRDFs) may be exempt from CON requirements.

Initial Certification Application and Survey

Application

To request initial certification under Medicare, the applicant must notify the SA of their intent in writing, and submit Form CMS 3427: End Stage Renal Disease Application and Certification Report. The SA will communicate with the applicant regarding all required documents that must be submitted for enrollment and certification and inform the applicant that the facility must have provided services to at least one patient for each modality or service for which they are applying. CMS will not accept the transfer of an already trained home dialysis patient or “borrowing” qualified home dialysis staff from another certified ESRD facility for initial approval of a Home Dialysis Training & Support program.

The applicant must also submit Form CMS 855A: Medicare Enrollment Application: Institutional Providers to the Medicare Administrative Contractor (MAC). Once the MAC reviews and approves the CMS-855A, it will notify the SA/RO that a survey may be scheduled.

Prioritization of Initial Surveys

The priority of initial certification surveys of prospective ESRD facilities is specified annually in the Survey and Certification Mission and Priority Document (MPD).

Initial ESRD Certification Survey Process

The ESRD initial survey should follow the ESRD Core Survey Process as discussed in Appendix H of the SOM. The ESRD survey process for initial certification includes a review of all ESRD Standards within the Conditions for Coverage.

Initial Certification Determination

The applicable CMS Regional Office is responsible for the initial certification determination of a new ESRD facility.

Denial of Initial Certification

If the initial certification survey identifies Condition-level non-compliance during an initial survey, the SA must notify the CMS Regional Office of the recommendation for denial of Medicare certification. The State survey team must prepare the Form CMS 2567 detailing the survey findings. The CMS Regional Office reviews the findings and makes the final certification determination and then communicates its decision to the dialysis facility and to the SA, as well as notifies the MAC of the denial via Form CMS-2007.

Reapplication after Initial Certification Denial or Voluntary Withdrawal

In the case of voluntary withdrawal of a request for initial certification or a denial of certification, the facility may reapply in the future. To reapply, the facility must resubmit a new Form CMS-3427 to the SA and a new CMS-855A to the MAC. An initial survey will also be required.

Recertification Survey

Prioritization of Recertification Surveys

Prioritization for recertification surveys of ESRD facilities is specified annually in the CMS Survey and Certification (MPD).

Recertification Survey Process

ESRD recertification surveys should follow the ESRD Core Survey Process as discussed in Appendix H of the SOM.

Revisit Survey

The SA must conduct a revisit survey prior to the termination date for any ESRD survey with findings of Condition-level non-compliance. It is at the discretion of the SA/RO as to whether a revisit is performed when only Standard level deficiencies are identified. The revisit survey is conducted to substantiate that the facility is back in substantial compliance with the applicable ESRD CfCs. The SA schedules a revisit survey after the last date of correction provided in the approved plan of correction. The information reviewed at the revisit is drawn from records and other evidence dated since the original survey. It is the intent of the revisit survey to review compliance with requirements which were cited as being deficient on the prior recertification survey. However, the surveyor(s) is required to cite any deficient practices identified in the course of determining correction of previously cited deficiencies,

Temporary Closures

A temporary closure may occur as a planned event (either voluntary or as the result of survey findings) to allow repair or remodeling, or as an unplanned event due to damage from a natural or man-made disaster. The facility is required to notify the SA in writing of any temporary closure of the facility which extends greater than one day of operation. Prior to reopening, the facility must submit to the SA a description of the changes or modifications to the facility which occurred during the closure and must submit the results of product water quality testing performed after the restart of the water treatment system. This documentation must include chemical analysis, cultures, and endotoxin levels. The SA will make a determination as to whether an on-site review is required based upon the submitted documentation. In situations where the dialysis facility has damages caused by a natural or man-made disaster which affects, or has the potential to affect the structural integrity of the facility, an on-site survey shall be performed prior to re-opening.

The SA must review the facility-submitted information and determine whether the water testing results (if applicable) are within acceptable limits, as detailed in the ESRD CfCs at 42 CFR 494.40(a) (see V177, V178 and V180), and notify the facility administrative personnel whether or not the water testing results are within the requirements of the regulation and may reopen to treat patients.

If, in the course of repair or remodeling during a temporary closure, the facility determines that it is more expedient to relocate, the facility must immediately communicate this request to the SA. The SA must evaluate the request and determine whether the ESRD facility will retain their participation at the new location. The SA would then follow the relocation process described below.

A temporarily closed facility may not retain its Medicare participation indefinitely. At the time of the temporary closure, the facility provides a projected date for resumption of services. The projected time frame for closure must be consistent with the repairs or renovation required.

Depending on the duration, closure may be viewed as a cessation of business (voluntary termination of the Medicare CCN). The facility may be asked to submit periodic progress reports to the SA as to whether the projected re-opening remains the same.

Relocation Survey

Generally, a relocation survey is not required when an ESRD facility relocates to a new physical location but is still serving the same patients and employing the same staff, changes its location on a campus or changes its location within the original address. However, the ESRD facility must submit the following information to the SA and an on-site survey may be performed if indicated by the information submitted:

Prior to the move, the ESRD facility must inform the SA how patients will continue to receive dialysis treatments uninterrupted during the relocation.

Immediately upon the relocation the ESRD facility must submit evidence to the SA that water testing was performed and determined to be within acceptable ranges.

The ESRD facility must also submit a revised floor plan to the SA to confirm adequate space for stations.

Criteria for Relocations

If a dialysis facility permanently relocates, it must remain essentially the same operation at its new location. CMS makes the determination that the facility is serving the same patients with the same staff.

Process for Relocations

A dialysis facility must notify the SA prior to its relocation and notify the Medicare contractor (MAC) via a revised CMS-855A within 90 days following the move. The facility must submit a revised Form CMS-3427 to the SA. The facility must immediately inform the SA of any changes to the relocation date.

Prior to the relocation of any patients, the facility must provide reports to the SA demonstrating acceptable results of product water quality testing, including chemical analysis and reports of acceptable results from testing for bacteria and endotoxin at the new location. If additional or replacement dialysis machines will be used in the new location, documentation must be submitted to confirm that baseline dialysate, bacteria and endotoxin have been completed on those machines. The facility must provide a floor plan to confirm sufficient space and privacy for each station. The facility must also attest to compliance with the Life Safety Code requirements. The SA reviews the reports and the floor plan to ensure the results are within acceptable limits, as detailed in the ESRD CfCs at §494.40(a) (see V177, V178 and V180). Once the SA accepts these water and dialysate quality reports and completes any indicated on-site review, the SA notifies the facility that it may open and operate the same number of treatment stations approved at its previous location and relocate its patients. If the facility requests additional stations concurrent with the relocation, see instructions below for Expansions.

In the event that the ESRD facility relocates without notifying the SA and does not submit the above referenced documentation and information to the SA before relocating patients, the SA

should conduct an immediate jeopardy complaint investigation to ensure that water testing has been done appropriately, there is adequate space for the stations, and Life Safety Code requirements are met.

If the ESRD facility requests approval for an additional service or modality simultaneously with a relocation, refer to SOM Section 2278D regarding “Expansions and Change in Services” to determine whether an on-site review is required.

Certification at the New Location

If an ESRD facility relocates to another state, it is considered a voluntary termination and the facility’s Medicare CCN is terminated. The relocated facility must seek Medicare participation as an initial applicant in the new State. The ESRD facility would be certified as a new ESRD facility and have a new CCN once it demonstrates compliance with all federal requirements.

If an independent ESRD facility relocates within the same state, the CMS RO will determine if the facility will retain its Medicare agreement and CCN after the relocation, or whether the move will be treated as a cessation of business (voluntary termination) of the first location and an initial certification of a prospective ESRD facility at the new location. The RO will base its decision on whether the ESRD facility continues to serve the original community and utilizes the same staff after the relocation as it served at the previous location.

If a hospital-based ESRD facility relocates to an off-campus location but continues to serve the same community and utilizes the same staff at this new location, its CCN will be retired and the facility will be assigned a new CCN that corresponds to renal satellite facilities. This is not a voluntary termination.

Expansions and Change in Modalities and Services

Expansion: Addition of In-Center Dialysis Stations

When a dialysis facility wishes to increase the number of its approved in-center dialysis stations, it must submit a new Form CMS-3427 ESRD Application and Survey and Certification Report to the applicable SA. The dialysis facility must specify the number of additional stations requested and include: evidence that adequate space is available for the stations in consideration of safety and infection control; and a summary explanation of any building renovations that will be necessary for the addition of stations.

Voluntary elimination of approved modalities/services

When a dialysis facility wishes to discontinue providing an approved dialysis modality or dialyzer reprocessing/reuse, it must file a new Form CMS 3427 reflecting the modalities/service that it plans to provide after the elimination along with a written explanation of the change(s). When received, the SA must review the information and contact the facility with any concerns or additional information required, such as plans for appropriate transition of patients who rely upon the discontinued service.

To assure patient access to care in the community served by the dialysis facility, when a facility wishes to eliminate a dialysis modality, the change should not inconvenience patients. If a

facility has one or more patients in their patient census who is using the dialysis modality it plans to eliminate, the facility must:

- *Assess each patient who will be affected by the change (§494.80(a));*
- *Inform the affected patients of the plan to eliminate the modality, and of their options for continuing treatment (e.g. transfer to a facility that offers the modality, switch to a different modality offered by the current facility) (§494.70(a), §494.70(b));*
- *Include the affected patients in the decision-making process, giving weight to the patient's preferences for their continued care (§494.80(a)(9)); and*
- *Arrange for orderly transfer of those patients who opt to transfer to another facility. The facility must report to the applicable ESRD Network any patient transfer when the patient(s) feels that he/she was transferred without their consent (involuntary transfer).*

The SA must also communicate with the applicable ESRD Network to confirm that the facility gave the affected patients sufficient (30 days) notice that the service was to be discontinued and that the patients are relocated to other ESRD facilities in consideration of patient preferences and with minimal disruption. If the SA identifies concerns with any of the above protections, a deficiency may be cited at §494.70(a) and/or §494.70(b).

Addition of dialysis modalities or services

When a facility wishes to add a dialysis modality or service, it must file a revised Form CMS-3427 with the applicable SA office. Upon receipt of the form, the SA must review the facility file, if available, for current or past quality concerns, the current FY State Outcomes List, and must contact the applicable ESRD Network. The SA should utilize this information to assist with an on-site review, where required. Refer to section 2278D for guidance on addition of dialysis modalities or services. The SA informs the facility that it must have at least one patient on census using each dialysis modality for which it is applying to allow the SA to review care.

For approval of each home dialysis modality for which the facility is applying, there must be at least one patient and/or their caregiver, on census who is in the process of being trained or has been trained by that facility. CMS will not accept the transfer of an already trained home dialysis patient or “borrowing” qualified home dialysis staff from another certified facility. Such a practice does not constitute evidence that the facility meets the requirements to demonstrate that it will continue to provide safe and effective care for these patients on an ongoing basis.

Complaint Survey

When investigating complaint allegations or the circumstances of a self-reported event in an ESRD facility, the ESRD surveyor should use all applicable survey tasks or portions of tasks from the ESRD Core Survey process at Appendix H of this SOM. See Chapter 5 of the SOM for additional instructions on complaint investigations.

Extension of a Complaint Investigation into Recertification Survey

When the findings from a complaint survey are determined to be at Condition-level or the surveyor identifies an Immediate Jeopardy situation, the SA must extend the complaint survey into a full recertification survey.

Change of Ownership (CHOW)

Refer to SOM Section 3210

2281 - Waivers

(Rev. 1, XX-XX-18)

2281A - Isolation Room Waiver

(Rev. 1, XX-XX-18)

The ESRD CfCs at §494.30(a)(1)(i) refer to the requirements for the treatment of hemodialysis patients who are positive for hepatitis B (HBV+). Every certified ESRD facility must have the capacity to treat one or more HBV+ patients in an isolation room or isolation area, or have an approved waiver under §494.30(a)(1)(ii).

*An **isolation room** is a separate room with walls and a door to contain any spatter of blood, body fluids or other contaminants. The door does not need to remain closed, except as indicated to contain contaminants. The walls do not need to reach the ceiling, but should be a least six feet in height and must fully contact the floor to contain blood spills. The walls must allow for continuous visualization of the patient(s) in the room. Plexiglas (or similar) walls are acceptable.*

*An **isolation area** is an area or space separated from other dialysis stations by a space equivalent to the width of a hemodialysis station.*

***Sufficient capacity** takes into account the availability of dialysis facilities with isolation rooms in the proximate geographic area. The proximate area must not create an undue hardship on the patient to have to relocate to the proximate facility.*

ESRD facilities certified prior to February 9, 2009 may have an isolation area, an isolation room or apply for an isolation room waiver to provide isolation services. In those instances where a patient already being served by the ESRD facility develops the need for isolation, the ESRD facility must have written arrangements in place to affect the safe transfer of the patient to another local ESRD facility which does provide isolation services.

Facilities certified after February 9, 2009 must have either an isolation room or apply for an isolation room waiver to provide isolation services. In those instances where a patient already being served by the ESRD facility develops the need for isolation, the ESRD facility must have written arrangements in place to affect the safe transfer of the patient to another local ESRD facility which does provide isolation services.

Waiver Process

Under §494.30(a)(1)(i), a new or expanding dialysis facility may be eligible for a waiver of the isolation room requirement if isolation rooms for HBV+ patients in other ESRD facilities are available and the available HBV+ isolation rooms sufficiently serve the needs of the HBV+ patients in the geographic area.

The facility must update the CMS-3427 form by completing Field 26 to annotate the waiver request.

The facility must submit a written request for an isolation room waiver to the applicable SA. The written request must include information about the geographical proximity of facilities with isolation rooms and identifies any barriers to accessibility for the patients.

The SA makes a recommendation via Form CMS-1539 to the RO for approval or denial of an isolation room waiver request. Document in the “Remarks” section the request for a waiver of the isolation room requirement. The CMS RO will review the information, make the decision whether to grant the waiver, and inform the facility and the SA of its decision.

Criteria for Consideration of the Isolation Room Waiver:

- 1) Other facilities in the local area that provide isolation services (review CMS-3427 Forms to verify if the facility provides isolation services);*
- 2) Communications with the ESRD Network regarding geographical availability of isolation services, quality of care concerns involving isolation, etc.;*
- 3) Complaints received by the SA regarding lack of isolation services provided.*

2281B - Medical Director Waiver

(Rev. 1, XX-XX-XX)

The ESRD CfCs at §494.140(a)(1) require dialysis facilities to have a qualified medical director and specifies the qualification criteria. A qualified medical director must have completed a board-approved training program in nephrology; have 12 months of experience providing care to dialysis patients; be licensed to practice in the State; and be board certified in internal medicine or pediatrics.

If a qualified physician is not available to serve as the medical director of a certified dialysis facility, the ESRD CfCs at §494.140(a)(2), provide that another physician may direct the services subject to the approval of the Secretary.

Waiver Process

Waiver of the medical director requirement is not available for initial certifications.

For existing facilities, if a physician who meets the required qualifications at §494.140(a)(1) is no longer available to serve as medical director of a certified dialysis facility, a facility may request a waiver to appoint another physician to serve as the medical director. This request must be reviewed and approved by CMS.

The facility request for waiver consideration, along with a brief resume of the alternate physician and an explanation as to why a physician who meets the requirements is not available should be submitted to the applicable SA.

The SA forwards the waiver request along with their recommendation for approval or denial via CMS-1539 to the RO. The CMS RO makes the final determination on approval/denial.

Criteria for Consideration of the Medical Director Waiver:

- 1) Facility ranking on the most recent confidential outcomes list, i.e. is the facility ranked at or above the national five percent threshold?;*
- 2) Lack of qualified providers in the geographical area;*
- 3) Impact of a waiver denial on patient access to care;*
- 4) Candidate's previous experience in the care of dialysis patients;*
- 5) Continuing efforts of the facility to secure a qualified medical director.*

Waivers should be reviewed by the RO on an annual basis. The RO requests the facility to submit updated information addressing 1-5 of the considered criteria above for the annual review.

The CMS RO will review the request, make the decision, and inform the facility and the SA of its decision regarding the waiver request.

The current Master list of approved ESRD facility waivers can be found on the CMS [Quality Certifications and Oversight Reports \(QCOR\)](#) web site under "Resources" in the menu bar, and listed under "ESRD Waivers Tracking Worksheets MASTER." ([QCOR](#))

2281C – Life Safety Code Waiver

(Rev. 1, XX-XX-18)

Limited LSC Applicability – Exemption for certain ESRD Facilities

Effective July 16, 2012, pursuant to §494.60 (d)(1), compliance by certified ESRD facilities with the applicable requirements of the 2000 edition of the National Fire Protection Association (NFPA) Life Safety Code 101 is limited to those ESRD facilities that are located adjacent to high hazardous occupancies and those facilities that do not exit to the outside at grade level from the patient treatment area.

“Exit to the Outside at Grade Level from the Patient Treatment Area Level”:

The phrase “exit to the outside at grade level from the patient treatment area level” applies to ESRD facilities that are on the ground or grade level of a building where patients do not have to traverse up or down stairways within the building to evacuate to the outside. Accessibility ramps in the exit area that provide an ease of access between the patient treatment level and the outside ground level are not considered stairways. Compliance with the structural requirements of

NFPA LSC 101 for ESRD facilities that pose a higher risk for life safety from fire is still required. Such higher risk ESRD facilities include those that do not have a readily available exit to the outside at grade level for swift, unencumbered exit and those facilities that are located adjacent to an “industrial high hazardous” occupancy, as defined by NFPA 101 at section A.3.3.134.8.2, Annex A.

Defining Adjacent to an Industrial High Hazardous Occupancy:

An “industrial high hazardous occupancy” is based upon the definition in the NFPA LSC 101, 2000 Edition at section A.3.2.134.8.2, Annex A as: “occupancies where gasoline and other flammable liquids are handled, used, or stored under such conditions that involve possible release of flammable vapors; where grain dust, wood, or plastic dusts, aluminum or magnesium dust, or other explosive dusts are produced; where hazardous chemicals or explosives are manufactured, stored, or handled; where cotton or other combustible fibers are processed or handled under conditions that might produce flammable flyings; and where other situations of similar hazard exist.” Being adjacent means an ESRD facility shares a common wall, floor, or ceiling with that occupancy.

The ESRD facility administrator may submit an attestation to the applicable SA that the facility meets the requirements for an exemption to compliance with NFPA LSC 101. Those facilities that do not submit an attestation claiming exemption will be considered a non-exempt facility and will continue to be surveyed for compliance with chapters 20 and 21 of the NFPA 101 LSC, 2000 Edition.

2282 - RO Use of Provider Tie-In Notice, Form CMS-2007, for Suppliers of ESRD Program Services (Exhibit 156)

(Rev. 2, XX-XX-18)

Form CMS-2007 serves as the official notice to the MAC of program actions affecting ESRD facilities that supply Medicare program services. The RO must forward a CMS-2007 to the MAC for all initial certifications/denials, voluntary and involuntary terminations, and CHOWs. The addition of a new service or modality must be communicated with the MAC and may be forwarded through either the CMS-2007 or electronic mail.

2283 - Termination Procedures

(Rev. 2, XX-XX-18)

See [SOM Chapter 3](#).

2284 - Specialized Areas of ESRD Oversight
(Rev. 1, XX-XX-18)

2284A - Centralized Dialyzer Reprocessing

(Rev. 1, XX-XX-18)

Centralized dialyzer reprocessing refers to a process of transporting used hemodialyzers from multiple facilities to a central location for reprocessing. When centralized reprocessing services are used, the certified dialysis facility retains responsibility for the dialyzer reprocessing, is expected to actively communicate and coordinate with the centralized reprocessing entity, and incorporate the activities of the centralized reprocessing location into the dialysis facility's Quality Assessment and Performance Improvement (QAPI) oversight of the dialyzer reprocessing/reuse program.

On-site visits to centralized reprocessing sites are done as a part of the survey of any dialysis facility using a reprocessing site, since there is no separate Federal certification for centralized reprocessing sites. Some States may have licensing requirements for these sites. The ESRD CfC requirements at 42 CFR 494.50 for the dialyzer reprocessing area, reprocessing procedures, environmental control, safety standards, and training of staff are the same for the centralized reprocessing site as for on-site dialyzer reprocessing at the ESRD facility. An on-site review of the reprocessing center must be included in every initial and recertification survey.

When a facility utilizes a central reprocessing service, there must be clear policies to guide the transporting of the dirty (i.e., used) dialyzers to the reprocessing site and returning the reprocessed dialyzers to the dialysis facility for clinical use. The system for transportation of the dirty dialyzers must protect patients' dialyzers from damage and microbiological contamination. Temperature controls must be in place to prevent microbiological growth, container temperatures monitored during transit, and steps taken to prevent cross-contamination between dialyzers during transport (§ 494.50(b)(1) at V319, V331, and V345). Safety checks must be in place to assure that reprocessed dialyzers are returned to the correct ESRD facility for use. Culture and endotoxin testing must be conducted at least monthly at the centralized reprocessing site and results monitored and retained at user dialysis facilities (§ 494.40(a) at V178; § 494.50(b)(1) at V314). User dialysis facilities must include oversight of the centralized reprocessing location outcomes, equipment maintenance, staff competency verifications, and other applicable Reuse Quality Assurance audits in their QAPI program (§ 494.110(a)(2)(vii); § 494.50(b)(1) at V360-368).

Deficiencies Identified at the Centralized Reprocessing Location

During the on-site visit to a centralized reprocessing location, the surveyor obtains a list of the names and CCNs of all Medicare certified dialysis facilities currently using the center. If any deficiencies are cited during the on-site visit at the reprocessing center, the SA must secure corrective action from all ESRD facilities within their jurisdiction. Each ESRD facility, including the ESRD facility under survey, is immediately notified of the findings and the need for a corrective action plan. The SA must contact the affected ESRD facilities not under survey by electronic mail or telephone the day the finding is made. The findings are then cited on a CMS-2567 for all facilities within the SA's jurisdiction that utilize the center. Upon return to the SA, the finding is entered into ACTS as a complaint against all ESRD facilities not under survey and a CMS-2567 is issued to each facility with a plan of correction requested.

The SA notifies the applicable State Health Department of the findings as required by Revised S&C 14-36.

When survey findings at a reprocessing center identify ESRDs from other states utilizing the center, the SA should notify their RO that will in turn notify the other ROs for the affected states

and the associated SAs will prepare the CMS-2567s.

2285B - ESRD Services across State Lines

(Rev. 1, XX-XX-18)

There are instances when a certified dialysis facility will provide home hemodialysis or home peritoneal dialysis services to patients or nursing home residents who reside within close proximity of state lines (which in some cases may be across the street). No special approval or agreement is required for a dialysis facility to provide home training and support services to patients in a bordering states.

2286 – ESRD Network Participation and Data Submission

(Rev. 1, XX-XX-18)

2286A – ESRD Network Participation

(Rev. 1, XX-XX-18)

There are 18 geographically-defined ESRD Networks (NW) across the United States. Every dialysis facility is located within the service area of an ESRD NW. ESRD facilities must cooperate with their assigned NW and participate in NW activities.

ESRD NWs are contracted by CMS to advance quality improvement in dialysis facilities through monitoring and supporting facility-based participation in quality improvement activities which ensure safe, effective care. CMS expects ESRD NWs to address and attempt to resolve patient grievances and to facilitate clinical data submission and analysis. To ensure the cooperation of dialysis facilities in achieving the CMS goals assigned to ESRD NWs, each facility is required to sign a NW/Facility agreement as part of their initial certification.

CMS expects SAs and ESRD NWs to establish an ongoing relationship focused on the provision of quality care and the advancement of quality improvement in the ESRD facilities. The relationship should include regular communication and coordination between the SA and the ESRD NW regarding routine quality improvement activities as well as ad hoc communication and collaboration as indicated when individual facilities have serious quality concerns that could impact the health and safety of patients.

Surveyors should contact the ESRD Networks prior to beginning a survey to gather facility information, but only after entering the ESRD facility and beginning the survey to ensure the survey remains unannounced. Surveyors should contact the NW before initiation of the facility Environmental “Flash” Tour. Surveyors should inquire whether the NW has information to share regarding quality concerns, patient complaints, involuntary discharges, and/or involuntary transfers. It is important that surveyors observe the protocols designed to ensure that surveys are unannounced and unpredictable, while also gathering information important to the survey process.

2286B - Furnishing Data and Information for ESRD Program Administration (42 CFR 494.180(h))

(Rev. 2, XX-XX-18)

All certified, participating ESRD facilities must furnish data and information to CMS as specified by the Secretary, pertaining to its ESRD patient care activities and costs. The national End-Stage Renal Disease Program Management and Medical Information System (ESRD-PMMIS) collects information from each participating ESRD facility.

2286C – Using ESRD Data

(Rev. 1, XX-XX-18)

Surveyors are expected to use Dialysis Facility Reports (see below) to inform the ESRD survey process. This report provides aggregate data regarding laboratory values, demographic information, mortality rates, hospitalizations, infections, etc. which may assist the surveyors during the review of patient medical records.

2286C.1 - Dialysis Facility Reports and Outcomes Lists

(Rev. 1, XX-XX-18)

Each SA and CMS RO assigns a Master Account Holder to control access to the State-specific data which are available on the CMS ESRD Dialysis Facility Reports website. The State Master Account Holder is responsible for accessing the State-specific data at the beginning of each fiscal year. ESRD data reports on this site include:

- A **State Profile**, which provides an overview of the State-specific outcomes and general information such as the number of facilities and number of patients receiving dialysis in the State;*
- An **Outcomes List**, which includes all certified dialysis facilities in the State ranked according to selected outcomes, with the facility which has the poorest outcomes listed first;*
- A **Dialysis Facility Report (DFR)** for each dialysis facility in the State; and*
- An **ESRD Core Survey Pre-survey DFR Extract Report** for each dialysis facility in the State, which lists key data elements to facilitate pre-survey preparation.*

Each SA must:

- Review the State profile to determine specific problem areas in each State, including but not limited to failure to meet expectations regarding infection control practices;*
- Use the State rank-ordered Outcomes List and the data profiles, in conjunction with other information, to select the facilities to be surveyed;*
- Use the facility-specific Dialysis Facility Reports before each survey to inform survey activities; and*
- Use the ESRD Core Survey Pre-survey DFR Extract Report to facilitate surveyor review*

of key facility outcomes and trends for comparison to national benchmarks in preparation for surveys regarding potentially problematic clinical areas in that facility.

The CMS Dialysis Facility Reports web site has a section that is open to the public and a section that is password protected. No password is required to access the list of Master Account Holders and sample reports (Dialysis Facility Report, Supplemental Report, and State/Regional Profile) and guides to those reports. The password protected section of the web site is:

- For surveyors,*
- Controlled by Master Account Holders for each State/Region, and*
- Contains the Dialysis Facility Report and DFR Extract Report for each dialysis facility; the Outcomes List for each State; and the State/Regional Profiles.*

2286C.2 - Dialysis Facility Compare

(Rev. 1, XX-XX-XX)

Dialysis Facility Compare is a site intended for public use and includes a tool for locating and comparing dialysis facilities in an area. This site offers information about Medicare-certified dialysis facilities and other resources for patients and family members who want to learn more about chronic kidney disease and dialysis, or to compare the services available in area dialysis facilities, and the quality of care that those facilities provide. Dialysis Facility Compare uses the same data sources as the Dialysis Facility Reports and provides additional information and resources for patients and families.

2287 – ESRD Patient Care Technician (PCT)

(Rev. 1, XX-XX-18)

2287A - PCT Certification

(Rev. 1, XX-XX-18)

Per §494.140(e), PCTs hired prior to October 14, 2008, should have attained their PCT certification by April 15, 2010. PCTs hired after October 14, 2008 must attain the PCT certification within 18 months of their date of hire. CMS counts all PCT work experience, regardless of changes in employer, in determining the 18-month time period allowed for completion of PCT certification. An approved leave of absence (medical/military/other) extends the period by the number of full or partial months of the leave of absence. If a PCT does not work as a PCT in any dialysis facility for 18 months or more, the 18-month time period allowed for completing certification begins anew.

2287B - Definition of a PCT

(Rev. 1, XX-XX-18)

The CMS requirement for PCT certification applies to unlicensed individuals providing direct patient care. PCTs may be described in a variety of terms, including “biomedical technician”

and “dialysis assistant.” For purposes of CMS technician certification requirements, a dialysis PCT is any unlicensed staff member who has responsibility for direct patient care. “Direct patient care” is defined as any aspect of healthcare for a patient provided personally by a staff member, including but not limited to collecting data (e.g., vital signs, weights, symptoms since last treatment), setting up the dialysis machine, testing reprocessed dialyzers for the presence or absence of germicide, initiating/terminating treatment, care of the dialysis access, delivering any aspect of the hemodialysis or peritoneal dialysis process, responding to machine alarms, and administering medications as allowed by State practice acts. A person who only reprocesses dialyzers and/or maintains or “takes down” dialysis machines (removes dialyzer and lines from the machine after use) and who has no direct patient care responsibilities is not considered a PCT by CMS.

2287C - Certification and Additional Requirements

(Rev. 1, XX-XX-18)

In addition to being certified by a nationally recognized certification organization program, PCTs must meet applicable Federal and State requirements for education, training, and competency to provide patient care in dialysis facilities. This includes any State requirements related to practice standards, certification, credentialing, licensure, or registration.

ESRD CfC requirements at 42 CFR 494.140(e), which became effective on October 14, 2008, requires that the PCT have a high school diploma or equivalency (GED). Recognizing that there were PCTs with extensive experience working in dialysis facilities as of the effective date of the ESRD CfC who may not have verification of a high school diploma or GED, PCTs with greater than four years of PCT work experience in dialysis as of the effective date were permitted to use that work experience in lieu of the requirement for a high school diploma or GED until April 15, 2010. Any PCT applying for certification after April 15, 2010 must have a proof of high school diploma or GED.

CMS also requires that PCTs complete an RN-directed, medical director-approved, job-specific training program which includes the curricula prescribed by the ESRD CfC at 42 CFR §494.140(e)(3) before independently providing care to dialysis patients.

2287D - State and National Certification Programs for PCTs

(Rev. 1, XX-XX-18)

PCT certification can occur under the aegis of either a State or National PCT certification organization. Usual components of the State and National programs include:

- A qualifying standardized test;*
- An independently proctored and protected testing environment;*
- Ongoing re-certification.*

There are currently three recognized National organizations providing commercially-available PCT certification programs: the Board of Nephrology Examiners for Nursing and Technology (BONENT), the Nephrology Nursing Certifying Commission (NNCC); and the National

Nephrology Certification Organization (NNCO).

2288 - Infection Control Considerations

(Rev. 1, XX-XX-18)

Saline Flush Syringes

Under 42 CFR §494.30(b)(2), ESRD facilities must follow aseptic technique when preparing and administering intravenous medications; including the filling of syringes with sterile saline for use during the dialysis procedure.

Pursuant to current recommendations from the Centers for Disease Control (CDC), ESRD facilities may not fill syringes with saline from the single dose saline bag or IV tubing connected to the patient at the dialysis station. To comply with recommended safe injection practices, the facility may acquire pre-filled syringes or may prepare saline syringes for an individual patient in a clean area away from the patient treatment area. When saline syringes are required for vascular access care or to flush medications, ESRD facilities should obtain syringes pre-filled with sterile saline from a manufacturer, Food and Drug Administration (FDA) registered outsourcing facility, or pharmacy whenever possible. However, when saline syringes must be prepared in an ESRD facility for administration, the following safe injection practices must be followed:

- Fill syringes with sterile saline for an individual patient in a dedicated clean area removed from the patient treatment area. Although not required, a clean room separate from the patient treatment area is the preferred location.*
- Prepare syringes for an individual patient as close as possible to the time of administration to prevent compromised sterility or stability.*
- Use aseptic technique for disinfection of saline vials prior to entry and follow the suggested standards from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Institute for Safe Medication Practices (ISMP) when preparing saline flushes including:*
 - Medication containers labeled single-dose or single-use (e.g., saline bags, single-dose vials, ampules) may not be used to prepare more than one syringe for vascular access care or to flush medications. Any unused saline in the opened single-dose or single-use container must be discarded and may not be stored for future use on the same patient.*
 - If multi-dose vials are used to prepare saline flush syringes, they must be dated upon opening and discarded within 28 days unless the manufacturer specifies a different date for that vial. The beyond-use date should never exceed the manufacturer's expiration date.*

Cleaning the Dialysis Station

According to current recommendations from the CDC, to prevent cross-contamination between dialysis patients, it is important that the previous patient completely vacate the dialysis station before the ESRD staff begins cleaning and disinfection of the station and set up for the next patient. Surveyors should cite 42 CFR §494.30(a)(4)(ii) if noncompliance with cleaning and

disinfection of the dialysis station is identified during the survey. It is important to note that all dialysis patients must be clinically stabilized (i.e., stable blood pressure, vascular access hemostasis) following their dialysis treatments before being moved from the dialysis station. If a patient is not sufficiently stable to be moved from the dialysis station, cleaning and disinfection of the equipment at the station and preparations for the next patient must be delayed until the patient is able to be safely moved outside the station.