

- Facility failed to provide an effective pain management treatment per the resident's choice and preference. A resident request a hot shower on the evening shift as an effective intervention for back pain. The staff member assigned to her informed her that she would not be able to be showered until later in the evening. A staff member who understood what the resident was experiencing quickly intervened and gave her a hot shower relieving her back pain.
- The facility staff failed to consistently evaluate the effectiveness of regularly scheduled pain medication on a resident. The resident was receiving the pain medication on a routine basis; however, the record did not reflect the resident's response to the administration of the pain medication. In interviews, the resident stated that her pain was being managed for the most part, but that staff did not ask her if she received relief from the medication. She stated that occasionally, she would not attend an activity due to discomfort, but this did not routinely occur. When she mentioned it to staff, they would tell her to lie down for a while and would check on her later. However, she stated that they usually did not recheck her. Staff interviewed stated they didn't have the time to go back, check, and record the resident's response, but, if she complained, they would recheck her and see if she needed anything else.

Level 1, *no* actual harm with potential for minimal harm:

The failure of the facility to provide appropriate care and services related to pain management places the resident at risk for more than minimal harm. Therefore Severity 1 does not apply for this regulatory requirement.

F698

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§483.25(l) Dialysis.

The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

INTENT: §483.25(l)

The intent of this requirement is that the facility assures that each resident receives care and services for the provision of hemodialysis and/or peritoneal dialysis consistent with professional standards of practice including the:

- Ongoing assessment of the resident's condition and monitoring for complications before and after dialysis treatments received at a certified dialysis facility;

- Safe administration of hemodialysis at the bedside and/or peritoneal dialysis in the nursing home provided by qualified trained staff/caregivers, in accordance with State and Federal laws and regulations;
- Ongoing assessment and oversight of the resident before, during and after dialysis treatments, including monitoring the resident’s condition during treatments, monitoring for complications, implementing appropriate interventions, and using appropriate infection control practices; and
- Ongoing communication and collaboration with the dialysis facility regarding dialysis care and services.

DEFINITIONS: §483.25(l)

“End-Stage Renal Disease (ESRD)” - The stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life. (42 CFR, Part §405 - §405.2102)

“Dialysis” - A process by which dissolved substances are removed from a patient’s body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis (HD) and peritoneal dialysis (PD). (§405.2102)

“Dialysis facility” - means an entity that provides outpatient maintenance dialysis services or home dialysis training and support services, or both. (§494.10 Definitions)

“Home Dialysis” - Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in §494.100(a) of this part.

NOTE: For the purposes of this guidance the term “nursing home” refers to a long-term care facility and dialysis facility refers to a Medicare certified dialysis facility. Home hemodialysis will be referenced as HHD.

INTERPRETIVE GUIDANCE: §483.25(l)

There is no requirement that a nursing home must offer dialysis services. If the nursing home has an arrangement with a dialysis facility for the provision of dialysis services, the nursing home must inform each resident before or at the time of admission, and periodically thereafter during the resident’s stay, of dialysis services, if available in the nursing home.

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

- **Medicare Certified Dialysis Facility:** This may involve either:

- Transporting to and from an off-site certified dialysis facility for dialysis treatments; or
- Transporting to a location within or proximate to the nursing home building which is dedicated for and separately certified as a dialysis facility providing in-center dialysis; and/or
- **Dialysis in a Nursing Home:** Receive home hemodialysis (HHD) or peritoneal dialysis (PD) treatments in the nursing home, by trained and qualified staff who have received training and competency from the dialysis facility.

If a current resident has been identified as meeting the criteria for HHD/PD by the dialysis facility team, and the nephrologist or the physician prescribing dialysis, and chooses to receive either HHD/PD, and the nursing home does not allow for these onsite services, the nursing home must assist the resident with the transfer to a nursing home or in the relocation to a setting (e.g. private home, or residential/assisted living facility) of his/her choice that provides HHD/PD services.

NOTE: The long-term care survey team does not have the authority under Federal nursing home regulations to review the care and services provided directly within a Medicare-certified dialysis facility located either on or offsite. If at any time during the survey, a concern or issue arises regarding the dialysis services provided to a sampled resident by the dialysis facility, the survey team should report this as a complaint to the State Agency survey unit responsible for oversight of the Medicare certified ESRD entity. The survey team must identify the specific resident(s) involved and the concerns identified.

Responsibilities for the Provision of Dialysis Care/Services

If the nursing home has made the decision to provide dialysis care and services according to the options above, there must be, in accordance with current standards of practice, coordination and collaboration between the nursing home and the dialysis facility to assure that:

- The resident's needs related to dialysis treatments are met;
- Only trained and qualified staff/caregivers administer the dialysis treatments;
- The provision of the dialysis treatments and care of the resident meets current standards of practice for the safe administration of the dialysis treatments;
- Documentation requirements are met to assure that treatments are provided as ordered by the nephrologist, attending practitioner and dialysis team; and
- There is ongoing communication and collaboration for the development and implementation of the dialysis care plan by nursing home and dialysis staff.

The nursing home remains responsible for the overall quality of care the resident receives and must provide the same services to a resident who is receiving dialysis as it furnishes to its residents who are not. This includes the ongoing provision of assessment, care planning and provision of care. There must be a coordinated plan for dialysis treatments developed with input from both the nursing home and dialysis facility. The resident should not experience any lack of nursing home services or care because of his or her dialysis status. The nursing home staff must be aware and identify changes in resident's behavior, especially for a cognitively impaired resident, that may impact the safe administration of dialysis, including, resistance to care, and pulling on tubes/access sites and inform the attending practitioner and dialysis facility of the changes. This requires more frequent and increased observations and monitoring for this resident before, during (if dialysis is provided by nursing home staff/caregivers or the resident) and after dialysis treatments.

NOTE: The nursing home may wish to designate a staff person to coordinate activities and communications with each dialysis facility that they have arrangements with to provide dialysis services.

The dialysis facility is responsible for the medical management for the end stage renal disease including dialysis treatments, performed offsite or onsite. It is the responsibility of the dialysis facility to provide all necessary equipment and supplies for the provision of the dialysis treatments, including maintenance and repair as needed, testing/monitoring water and dialysate quality for the dialysis treatment, and for the training of individuals providing the HHD/PD.

Shared Communication between the Nursing Home and the Dialysis facility

It is essential that a communication process be established between the nursing home and the dialysis facility to be used 24-hours a day. The care of the resident receiving dialysis services must reflect ongoing communication, coordination and collaboration between the nursing home and the dialysis staff. The communication process should include how the communication will occur, who is responsible for communicating, and where the communication and responses will be documented in the medical record, including but not limited to:

- Timely medication administration (initiated, administered, held or discontinued) by the nursing home and/or dialysis facility;
Physician/treatment orders, laboratory values, and vital signs;
- Advance Directives and code status; specific directives about treatment choices; and any changes or need for further discussion with the resident/representative, and practitioners;
- Nutritional/fluid management including documentation of weights, resident compliance with food/fluid restrictions or the provision of meals before, during and/or after dialysis and monitoring intake and output measurements as ordered;

- Dialysis treatment provided and resident's response, including declines in functional status, falls, the identification of symptoms such as anxiety, depression, confusion, and/or behavioral symptoms that interfere with treatments;
- Dialysis adverse reactions/complications and/or recommendations for follow up observations and monitoring, and/or concerns related to the vascular access site/PD catheter;
- Changes and/or decline in condition unrelated to dialysis. This would include communication related to care concerns such as a resident who is at risk for or who has a pressure ulcer, receiving appropriate interventions; and
- The occurrence or risk of falls and any concerns related to transportation to and from the dialysis facility.

Coordination of Physician Services between the Nursing Home and Dialysis facility

For a resident receiving dialysis, the nursing home staff must immediately contact and communicate with the attending physician/practitioner, resident/resident representative, and designated dialysis staff (i.e., nephrologist, registered nurse) regarding any significant changes in the resident's status related to clinical complications or emergent situations that may impact the dialysis portion of the care plan. (Refer to F580 – Notification of Changes in condition) These situations may include but are not limited to changes in cognition or sudden unexpected decline in condition, dialysis complications such as bleeding, hypotension, or adverse consequences to a medication or therapy, or other situations.

Any changes in the resident's care initiated by the dialysis facility must be communicated to the resident's nursing home attending physician/practitioner.

Hospital Transfer

The dialysis facility must ensure access to a hospital for emergency services that has the capacity to provide emergency dialysis care (ESRD Conditions for Coverage (CfC) at V770 - §494.180). In order to assure that the dialysis needs of the resident are met in the case of an emergency, the care plan should identify acute care settings that would be able to meet the resident's need for dialysis.

In case of the need to transfer to an acute care facility to manage dialysis complications or other care concerns, the nursing home must have ongoing communication with the dialysis facility and have knowledge of the location and how to access the hospital that has the capacity to provide emergency dialysis care, as identified by the dialysis facility.

NOTE: According to the ESRD regulations at V770 - §494.180 - The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and

emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must: (i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed. (ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

Resident Care Policies and Staffing Specific to Dialysis Care and Services

Some State licensure rules don't allow for the provision of HHD in a nursing home and/or a State's nurse practice act or scope of practice may preclude certain health care workers from performing HHD treatments. Some State licensing rules may have specific regulations related to the provision of HHD/PD in a nursing home, such as specifying patient to staff ratio requirements. The nursing home must identify who is allowed to provide HHD/PD treatments to a resident, such as a licensed nurse or nurse aide. The dialysis facility is responsible for providing training and assuring the competency of staff or individuals that are allowed to initiate, access and discontinue dialysis treatments. The nursing home must maintain documentation of completion of training/competency for staff or other individuals providing the dialysis treatments.

NOTE: Anecdotally, it has been reported that some nursing homes provide dialysis for multiple residents at a time in a single area/den setting. The facility must assure that compliance is maintained for providing dialysis in a location that promotes dignity, individual privacy during treatments, sufficient staff, access to a call system and hand washing facilities, availability of emergency equipment and supplies, secured medication storage and preparation area, including a refrigerator as necessary, soiled utility area, disposal of equipment and supplies, and based upon professional standards of practice, the maintenance of effective infection control practices and measures. This includes ensuring that a resident who is hepatitis B+ is not dialyzed in the same location as resident who is not hepatitis B+. Consideration should be given to implementing appropriate infection control practices related to care of a resident who is hepatitis B+, such as using dedicated staff, a dedicated machine, equipment, instruments, and supplies that will not be used by other resident's including a resident who is not hepatitis B+.

If PD treatments are provided, the treatments may only be administered by an individual trained by the qualified dialysis trainer from the certified dialysis facility. An LPN/LVN may administer the PD treatment if not in conflict with the States Nurse Practice Act/Scope of practice.

A nursing home, that provides dialysis treatments, in collaboration with the nursing home medical director and the dialysis facility, must develop dialysis specific policies/procedures, based upon current standards of practice. This includes the care of a resident receiving dialysis services whether in the facility or at an offsite location. (Refer to F841 – Responsibilities of Medical Director.) At a minimum, these policies must include, but are not limited to the following:

- The identification of all staff or contracted individuals who are allowed to provide HHD/PD and the training required. An RN, LPN/LVN, a nurse aide or a trained technician can provide dialysis treatments if not in conflict with the States Nurse Practice Act/Scope of practice and only if the individual has received training from a qualified dialysis trainer from a certified dialysis facility for the individual resident receiving HHD/PD;
- The documentation of training and competency requirements for individuals providing dialysis treatments;
- If the facility allows a resident/family member or other individual to provide HHD or PD treatments, documentation that training and competency was provided by the certified dialysis facility;
- Procedures for the initiation, administration and discontinuation of HHD/PD treatments, type of monitoring required before, during and after the treatments, including documentation requirements;
- Procedures for methods of communication between the nursing home and the dialysis facility including how it will occur, with whom, and where the communication and responses will be documented;
- The development and implementation of a coordinated comprehensive care plan(s) that identifies nursing home and dialysis responsibilities and provides direction for nursing home staff; and
- The development and implementation of interventions, based upon current standards of practice including, but not limited to documentation and monitoring of complications, pre-and post-dialysis weights, access sites, nutrition and hydration, lab tests, vital signs including blood pressure and medications;
- Management of dialysis emergencies including procedures for medical complications, and for equipment and supplies necessary;
- The provision of medications on dialysis treatment days;
- Procedures for monitoring and documenting nutrition/hydration needs, including the provision of meals on days that dialysis treatments are provided;
- Assessing, observing and documenting care of access sites, as applicable, such as:
 - Auscultation/palpation of the AV fistula (pulse, bruit and thrill) to assure adequate blood flow;
 - Significant changes in the extremity when compared to the opposite extremity (edema, pain, redness);

- Steal Syndrome (pain, numbness, discoloration, or cold to touch in the fingers or hand indicating inadequate arterial flow);
- Skin integrity (waxy skin, ulcerations, drainage from incisions);
- Bruising/hematoma;
- Collateral vein distension (veins in access arm close to AV fistula becoming larger);
- Complaints of pain or numbness; or
- Evidence of infection at the surgical site, such as drainage, redness, tenderness at incision site, fever.
- Safe and sanitary care and storage of dialysis equipment and supplies;
- Responsibility for reporting adverse events, including who to report to, investigating the event and correcting identified problems;
- Response and management of technical problems related to HHD and/or PD treatments, such as power outages or:
 - For PD, how to recognize impaired flow and drainage or failure of the PD cyclers;
 - For failure of HHD machines: clotting of the hemodialysis circuit, dialyzer blood leak, or line disconnection; and
 - For HHD/PD: how and when to stop dialysis and/or seek help when there are significant issues.

NOTE: The dialysis facility is responsible for the overall provision and maintenance of the dialysis equipment and monitoring source water. The nursing home staff should be aware of any issues with the source water, and the care plan should address these issues. The nursing home trained and qualified staff responsible for providing the dialysis treatment, must know how to use the dialysis equipment and identify if there are issues in order to provide safe treatments.

- Dialysis specific infection control policies, including but not limited to:
 - Transmission based precautions including blood borne precautions, placement/location (cohorting), staff/visitor personal protection equipment (PPE) requirements, indications for the use of gloves, masks, and hand hygiene;

- Potential health care associated infections (HAI) including Hepatitis B and tuberculosis;
- Restrictions for visitors/roommate, if any, during provision of HHD/PD;
- Handling, using, and disposing of equipment/supplies, medications or other products in accordance with manufacturer's instructions, and in accordance with all applicable Federal, State and local laws and regulations;

NOTE: Nursing home staff who have been trained to provide dialysis treatments for a resident, must understand how to properly dispose of needles, effluents, disposable items, blood tubing and dialyzers to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and dialysis tubing and other contaminated items in specific biohazard container(s) or bag(s) before discarding.

- Obtaining and reviewing dialysis facility monitoring for the dialysis water and dialysate quality, including total chlorine testing and at least quarterly testing of water and dialysate bacterial and endotoxin as applicable to the HHD equipment in use;
- Types of furnishings allowed (such as a recliner used during the dialysis treatment), based on infection control standards and the cleaning/sanitizing of these furnishings that have the potential to become contaminated with blood/blood products;
- Access to clean sink for hand washing, in addition, disposal needs to be addressed for dialysis by-products from the dialysis treatment;
- Housekeeping/laundry policies for cleaning/sanitizing the location(s) where treatments are provided, including linen handling and waste disposal;
- Vascular access or peritoneal catheter care and dressing changes; and
- Cleaning and disinfecting dialysis equipment, including procedures for spills and splashes of blood or effluent on furnishings, equipment, floors and supplies.

NOTE: For information regarding home dialysis guidance see ESRD CFR §494.100 – V580 Care at Home. This condition also provides information regarding the provision of home dialysis including water treatment and quality testing and other requirements of the ANSI/AAMI RD52:2004. For information related more specifically to water testing and treatment refer to:

- V-253 -ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR §494.40 (a)7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/frequency. Culture ...dialysate fluid weekly for new

systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution; and

- V 278 - In-center preconfigured HD: quarterly cultures/LALs Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

Some portable dialysis machines may have a self-check system and more stringent requirements may need to be followed as recommended by the manufacturer.

Dialysis Provided at a Medicare Certified Dialysis Facility Located Offsite or Onsite

A resident may choose to receive dialysis at a dialysis facility located off site or in a separately certified dialysis unit located within the facility. The choice of the dialysis provider is made by the resident/resident representative. The nursing home must assist the resident to assure that arrangements are provided for safe transportation to and from the dialysis facility. (See F745 – Social Services).

The nursing home staff must provide immediate monitoring and documentation of the status of the resident's access site(s) upon return from the dialysis treatment to observe for bleeding or other complications. The nursing home and dialysis facility dietitians should coordinate the nutritional care including monitoring, documenting, and deciding how and when to address weight changes and nutrition issues. This includes identifying weight fluctuations due to fluid retention between dialysis sessions, possible fluid volume depletion in the immediate post-dialysis period or associated with anorexia which may be due to renal failure. Staff must weigh the resident and document the findings based on orders. If weight loss occurs, the facility must notify the attending practitioner and dialysis facility practitioner regarding the management for causes of anorexia and weight loss other than fluid loss that might present.

Home Hemodialysis provided by Nursing Home Staff

The nursing home must continue to meet the nursing home requirements found throughout 42 CFR Part §483 to assure the residents health, safety and well-being. The facility must be able to demonstrate in collaboration with the dialysis facility, the arrangements in place in order to provide safe HHD/HPD through qualified trained staff/caregivers and assure that the resident receives the dialysis treatments as ordered. The nursing home is responsible for the ongoing coordination of dialysis care in collaboration with the Medicare certified ESRD entity. The nursing home resident who receives dialysis is entitled to the same rights, services, and efforts to achieve expected outcomes as a person receiving dialysis at a dialysis facility.

NOTE: According to 42 CFR §494.100 - V581, a dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that

home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions part 494. This does not imply that the nursing home surveyor surveys to or applies ESRD regulations.

- Provision of HHD Treatments

The nursing home and the dialysis facility must have ongoing communication to coordinate the care and manage any changes/issues that arise. The nursing home staff must use appropriate infection precautions, including blood-borne precautions, for all aspects of dialysis care. In addition, if the HHD is provided in a semi-private resident room, adherence to the right of privacy during treatment is required. The nursing home staff must have specific written guidance for identifying and handling complications and emergencies before, during and after the provision of HHD.

The nursing home must have a system in place for staff to contact the dialysis facility immediately with any concerns/issues regarding dialysis. This includes who to communicate with, such as the dialysis staff, attending practitioner, or nephrologist regarding HHD. The nursing home must have dialysis facility contact numbers readily accessible to licensed nursing home staff that assures the on-call dialysis qualified licensed professional staff is available by phone 24 hours a day 7 days a week.

HHD may be performed by either the resident (if physically and cognitively capable) or an individual, such as a family member (if allowed by the nursing home), nursing home staff or a contracted individual, such as a licensed nurse or dialysis technician, who has completed training/competency by a qualified trainer from a Medicare certified dialysis facility in accordance with State licensure, Scope of Practice for Nursing. The required training for staff providing HHD (and PD) treatments in nursing homes must be individualized and **resident specific** and provided directly by the Medicare certified dialysis facility that is responsible for the provision of the resident's overall dialysis care. This training cannot be provided by nursing home staff even if they have previously received the training for dialysis by this or another dialysis facility for another resident. The nursing home must have documentation of the completion of resident specific dialysis training by the dialysis facility for each nursing home staff member providing dialysis treatments for the resident. While a nursing home may allow a resident and/or a dialysis trained caregiver to provide the dialysis treatment, the nursing home nonetheless remains responsible for the resident's care and services.

The facility must maintain documentation of the required ongoing dialysis training in order to assure qualified staff/caregivers are capable of providing the HHD treatments. (Refer to F658) Training based upon current standards of practice must include, but not be limited to, the following:

- Specific (step-by step) instructions on how to use the resident's prescribed dialysis equipment (e.g. hemodialysis machine and water treatment components);

- Specific (step-by step) instructions in home dialysis procedures to facilitate adequate dialysis as prescribed by the physician;
- Training in proper storage and administration of Erythropoiesis-Stimulating Agents (ESAs), if applicable and in accordance with State laws and State scope of practice. ESAs are medications that may be used to treat anemia in a resident with a diagnosis of ESRD;
- How to identify/recognize medical emergencies, implement immediate responses/actions and methods for contacting emergency medical systems. Medical emergencies may include, but are not limited to, cardiac arrest, air embolism, drug reactions, suspected pyrogen reactions, profound hypotension or hypertension and significant blood loss;
- How to recognize, manage and report such potential complications as vascular access problems such as difficulty with cannulation, a change in bruit or thrill, or bleeding, and infections, hypertension or hypotension, hyperkalemia, etc;
- Infection control practices, including indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, vascular access and dressing changes, cleaning and disinfecting dialysis equipment, cleaning and disinfection procedures for spills and splashes of blood or effluent;
- Identifying symptoms associated with water and dialysate contamination that cannot be readily attributed to other causes. Clinical symptoms may include, but are not limited to, chills, shaking, fever, vomiting, headache, dizziness, muscle weakness, skin flushing, itching, diarrhea, hyper/hypotension, hemolysis and anemia. If such symptoms are present, the facility must notify the attending practitioner and dialysis team to determine appropriate action; and
- Recognizing, managing and reporting power outages, failure of the HD machine, failure of water treatment components (e.g., chlorine/chloramine breakthrough), clotting of the hemodialysis circuit, dialyzer blood leaks, line disconnection, water supply problems or leaks, and problems with supply delivery.

The nursing home must have orders for the provision of the dialysis treatments, including individualized dialysis prescription such as, at a minimum, the number of treatments per week, length of treatment time, the type of dialyzer, and specific parameters of the dialysis delivery system (e.g., electrolyte composition of the dialysate, blood flow rate, and dialysate flow rate), anticoagulation, and the resident's target weight.

The resident's care plan must, based on standards of practice, identify the resident specific parameters for blood pressure, weights and other vital signs. The resident's blood pressures must be monitored pre, during, and post treatment and abnormal values must be addressed. Excessively high or low blood pressure measurements during treatment without evidence of assessment and action to address those values would

indicate the care plan for this parameter was either not developed or not implemented. The nursing home staff must provide ongoing assessment of the resident during dialysis, including vital signs, level of consciousness, muscle cramping, itching and comfort or distress; and must report identified or suspected complications to the attending practitioner and identified dialysis staff to enable timely interventions. In addition, staff must ensure that a resident who is hepatitis B+ is not dialyzed in the same location as resident who is not hepatitis B+. Consideration should be given to implementing appropriate infection control practices related to care of a resident who is hepatitis B+, such as using dedicated staff, a dedicated machine, equipment, instruments, and supplies that will not be used by other resident's including a resident who is not hepatitis B+.

NOTE: According to the interpretive guidelines at ESRD regulation V581 - CFR §494.100 Condition: Care at Home – “Home dialysis patients are considered part of the census of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected patient outcomes as the in-center dialysis patients of the facility.”

After receiving dialysis, staff must obtain vital signs, assess the resident's stability and monitor for post-dialysis complications and symptoms such as but not limited to dizziness, nausea, vomiting, fatigue or hypotension.

The resident receiving HHD must be under direct observation of the trained caregiver who must be physically present in the room with the resident throughout the entire HHD treatment in the immediate location where the HHD is being provided.

NOTE: Nursing home staff assigned to provide an HHD treatment, must not have assignments for additional residents throughout the duration of the HHD treatment and after completed until the resident is determined stable according to accepted standards of practice.

The resident's vascular access site and bloodline connections must be able to be seen by the trained caregiver throughout the dialysis treatment. Allowing a resident to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes. The medical record should reflect the care and monitoring of the access site, including but not limited to examining the arteriovenous fistula (AV fistula) and/or surgical incisions to detect problems that require immediate notification of the attending practitioner.

Peritoneal Dialysis (PD) Provided by Nursing Home Staff

If the nursing home provides PD on site, it is responsible for the ongoing coordination of dialysis care in collaboration with the Medicare certified dialysis facility. The nursing home staff must have specific written guidance for the provision of treatments, and handling complications and emergencies during the provision of PD. The nursing home must have contact information available for staff to assure that dialysis qualified licensed

professional staff is available by phone 24 hours a day 7 days a week, including who to communicate with regarding PD related issues.

PD may be performed by either the resident (if physically and cognitively capable) or an individual, such as a family member (if allowed by the nursing home), nursing home staff or a contracted caregiver who has completed training/competency by a qualified trainer from a Medicare certified dialysis facility. While a nursing home may allow a resident and/or a dialysis trained caregiver to provide the dialysis treatment, the nursing home nonetheless remains responsible for the resident's care and services.

The facility must maintain documentation of the required ongoing dialysis training in order to assure qualified staff/caregivers are capable of providing the PD treatments. (Refer to F658 – Meeting professional standards) Training based upon current standards of practice must include, but not be limited to, the following:

- Specific (step-by step) instructions on how to use the resident's prescribed dialysis equipment (e.g. peritoneal dialysis cycler) and instructions in home dialysis procedures for PD to facilitate adequate dialysis as prescribed by the practitioner;
- Training in proper storage and administration of Erythropoiesis-Stimulating Agents (ESAs), if applicable;
- How to identify/recognize medical emergencies, implement immediate responses/actions and methods for contacting emergency medical systems. Medical emergencies may include, but are not limited to, cardiac arrest, drug reactions, suspected pyrogen reactions, profound hypotension or hypertension and significant blood loss;
- How to recognize, manage and report dialysis complications, including catheter, tunnel or exit site infection; peritonitis; catheter dislodgement; hypotension; hypokalemia; failure of sufficient dialysate to drain from the peritoneal space; protein malnutrition;
- Indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, peritoneal catheter care and dressing changes, cleaning and disinfecting dialysis equipment, cleaning and disinfection procedures for spills and splashes of effluent;
- How to properly dispose of needles, effluents, disposable items, and tubing and to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and tubing in intact plastic bags before discarding.); and
- Recognizing, managing and reporting power outages, failure of the PD cycler.

Provision of PD Treatment

PD may be provided via the following modalities:

- **Continuous ambulatory peritoneal dialysis (CAPD)** is a treatment in which dialysis solution is introduced through a catheter into the abdomen via gravity and the bag is disconnected. After a specified period of time, the catheter is reconnected and drains the solution containing wastes back into the bag. CAPD does not require a machine; the process uses gravity to fill and empty the abdomen. CAPD may be provided during three or four exchanges during the day and one overnight. A mini-cycler machine may be used to exchange the dialysis solution overnight as the resident sleeps; or
- **Continuous cycler-assisted peritoneal dialysis (CCPD)** uses a machine to fill and empty the abdomen three to five times during the night. In the morning, the last fill remains in the abdomen with a dwell time that is individualized according to the resident's needs. In some cases, an additional exchange is done in the mid-afternoon to increase the amount of waste removed and to prevent excess fluid absorption.

For a resident receiving PD, the practitioner orders for the individualized prescription must include at least the number of exchanges or cycles to be done during each dialysis session, the volume of fluid with each exchange, duration of fluid in the peritoneal cavity, the concentration of glucose or other osmotic agent to be used for fluid removal, and the use of an automated, manual, or combined techniques.

Before, during and after receiving the PD, nursing home staff must, based on practitioner's orders and professional standards of practice, obtain vital signs, weights, assess the resident's stability level of consciousness, and comfort or distress; and monitor for post-dialysis complications and symptoms such as but not limited to dizziness, nausea, fatigue or hypotension. The staff must report identified or suspected complications immediately to the attending practitioner and dialysis staff to enable timely interventions. The resident's record must include documentation of ongoing evaluation of the peritoneal catheter, including assessment of catheter related infections (For example, exit site acute and chronic infections) and tunnel for condition, monitoring for patency, leaks, infection, and bleeding at the site. In addition, staff should be monitoring for complications such as peritonitis (For example, abdominal pain/tenderness/distention, cloudy PD fluid, fever, nausea and vomiting).

NOTE: For more information related to PD related infections, refer to <https://www.cdc.gov/disasters/icfordialysis.html>

Interim and Emergency Medications for Residents Receiving Dialysis

Nursing homes must have access to medications and treatments such as antibiotics and intravenous fluids to treat common complications of dialysis. The nursing home staff must collaborate with the medical director, consultant pharmacist and dialysis facility to develop policies and procedures to address common complications and to ensure access to needed medications.

The attending practitioner and dialysis team may have prescribed Erythropoiesis-Stimulating Agents (ESAs), which are medications that may be used to treat anemia in a resident with a diagnosis of ESRD. These medications act similarly to erythropoietin to stimulate the production of red blood cells and are administered either intravenously or subcutaneously. Commonly used ESAs include Epogen (epoetin alfa) 2 and Aranesp (darbepoetin alfa). Other causes of anemia unrelated to kidney disease (e.g., hemolytic anemia and blood loss anemia) may also occur in individuals with ESRD. Additionally, many anemic individuals with ESRD are also treated with iron supplements because iron is necessary for the production of red blood cells. These include iron supplements such as Venofer (iron sucrose) and Ferrlecit (sodium ferric gluconate complex) to treat iron-deficiency anemia.

NOTE: ESAs were approved by the FDA starting with Epogen for the treatment of anemia in 1989 and Aranesp in 2001. Since the approval, the product labeling for this class of medications has been updated several times to incorporate new safety information. The FDA approved-new labeling for both drugs in March 2007 that included a warning that ESAs can increase the risk for death and serious cardiovascular events (including myocardial infarction, stroke, heart failure) when they are dosed to achieve a target hemoglobin of greater than 12 g/dL. For individuals with chronic kidney disease on dialysis, FDA approved labels for ESAs now recommend that health care professionals initiate ESA treatment when the hemoglobin level is less than 10 g/dL and that the dose be reduced or interrupted if the hemoglobin approaches or exceeds 11 g/dL,. Ongoing monitoring is mandated to ensure efficacy as well as safety and reimbursement of the medication(s).

<http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109375.htm>

Depending on the dialysis method and the resident's comorbidities, medication administration may need to be modified. The attending practitioner and nephrologist determine which medications are to be administered during dialysis, which are to be held prior to dialysis (e.g., because of excessive hypotension during dialysis), whether any specific medications are to be given prior to dialysis and any medications (such as antibiotics or ESA's) that are to be given by dialysis staff. All such medication administration must be coordinated, communicated and documented between dialysis staff, nursing home staff, and practitioners. (For issues related to medications and or pharmacy review, refer to F757 Unnecessary Medications, and/or F755 Pharmacy Services and/or F756 – Pharmacy Review.)

Canceling or Postponing Dialysis (Either HD, HHD and/or PD)

The nephrologist/dialysis team, the resident's attending practitioner must be notified of the canceled or postponed dialysis treatment and responses to the change in treatment must be documented in the resident's medical record. If dialysis is canceled or postponed, the nursing home and dialysis staff should provide or obtain ongoing monitoring and medical management for changes such as fluid gain, respiratory issues, review of relevant lab results, and any other complications that occur until dialysis can be rescheduled based on resident assessment, stability and need.

- **Lack of sufficient trained and qualified staff to provide treatments**

In the event circumstance do not allow dialysis to be provided by the designated trained and qualified individual, the nursing home must immediately notify the dialysis facility in order to make arrangements to assure that no dialysis treatments are missed.

- **Equipment Failure for HHD/PD**

Dialysis may be stopped, postponed, or delayed due to dialysis equipment failure. If this happens during dialysis, the staff and practitioner must assess the resident immediately to assure that urgent medical needs are met, identify and manage any consequences, contact the dialysis facility and reschedule the dialysis as appropriate and/or transport the resident to the off-site certified dialysis facility to receive the required dialysis treatments. The staff must check the equipment and supplies to identify what happened, and why, and arrange with the dialysis facility for the repair/replace the equipment and supplies as necessary.

- **Resident Declines or Acute Illness, Or Resident Complications**

Dialysis may be stopped, postponed or delayed due to a resident's declines of the dialysis treatment or the presence of acute illness or complications to the resident before, during, after, and in between dialysis sessions. As part of care coordination between the nursing home and the dialysis facility, there must be a systematic approach to handling situations where the resident has a condition change and/or becomes ill or unstable during dialysis. This approach includes knowing who is to be contacted, who decides whether to stop dialysis, who documents the situation, under what circumstances dialysis may be terminated and when the dialysis treatment may be restarted or the next treatment scheduled. The record must reflect the how the missed treatments will be addressed in order to prevent an avoidable decline and/or potential complications. If a resident wants to decline the dialysis treatment(s), the nursing home and dialysis facility social workers, should coordinate services to assess psychosocial concerns related to the resident's desire to discontinue dialysis treatments.

The nursing home and dialysis staff must coordinate their approaches in order to provide immediate care for possible emergencies and complications, such as cardiac arrest during dialysis. Any orders related to cardio-pulmonary resuscitation (CPR) and any documents

that might be needed (e.g., practitioner orders for life-sustaining treatment, advance directives including code status) must be available for both the nursing home and the dialysis staff. Knowledge of existing advance directives, including specific directives about treatment choices and code status, must be communicated between dialysis and nursing home staff to ensure that there is a uniform approach, consistent with State laws and regulations. (Refer to F678 – Advance Directives)

ADMINISTRATIVE REVIEW OF NURSING HOME PRACTICES

As appropriate, the administrator, nursing director, medical director, and pharmacist, and the QAA committee should review the nursing home's dialysis care and services on an ongoing basis including:

- The communication, training, supervision and care coordination between the nursing home and the participating dialysis facility;
- Whether policies and procedures for the types of dialysis that are provided in the nursing home are consistent with current standards of practice and are being followed consistently;
- Any complications associated with dialysis provision, such as those associated with potential breeches in infection control, those resulting in hospitalization and those due to equipment, technique, process failures, or supplies;
- Provision of ongoing staff training which is individualized to meet the needs of each HHD/PD resident. Staff training must be provided by qualified dialysis facility instructors and include how to address emergencies; and
- Communication and coordination between the nursing home and the dialysis facility in sharing data about outcomes and processes and reviewing quality indicators and care issues.

Investigative Summary for Dialysis Care and Services

Use

Use the Dialysis Critical Element (CE) Pathway, along with the interpretive guidelines when determining if the facility meets the requirements for providing care and services for a resident receiving dialysis services, in accordance with professional standards of practice, and the comprehensive person-centered care plan,

Summary of Investigative Procedure

Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has recognized, assessed, provided interventions and implemented care and services according to professional standards of practice in order to meet the resident's dialysis care needs under investigation. This information will

guide observations and interviews to be made in order to corroborate concerns identified. In addition, investigate to assure that there are sufficient numbers of trained, qualified and competent staff to provide the interventions identified for a resident receiving dialysis care and services.

If the resident has been in the facility for less than 14 days (before completion of all the Resident Assessment Instrument (RAI) is required), review the baseline care plan which must be completed within 48 hours to determine if the facility is providing appropriate care and services based on information available at the time of admission. In addition, review to determine whether the comprehensive care plan is evaluated and revised based on the resident's response to interventions.

NOTE: Always observe for visual cues of psychosocial distress and *consider whether psychosocial harm has occurred when determining severity level* (See guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide *located in the Survey Resources zip file located at <https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/nursing-homes>*). In addition, if noncompliance at this tag demonstrates a pervasive disregard for the resident's quality of life, consider investigating concerns at F675 – Quality of Life.

OTHER TAGS, CARE AREAS (CA) AND TASKS TO CONSIDER:

Dignity CA (F550); Right to be informed and make treatment decisions (F552); Right to refuse (F578); Advance Directives CA (F561); Notification of change (F580); Accommodation of needs, call system (Environment task & F558); Be provided by qualified persons (F659); Pressure ulcer CA (F686); Nutrition CA(F692); Hydration CA (F692); Sufficient and Competent Staffing (Task & F725); Unnecessary Medications CA (F757); Infection Control (Task & F880); Medical director (F841); Resident Records (F842); and QA&A QAPI (Task F868);

DEFICIENCY CATEGORIZATION

NOTE: The death or transfer of a resident, who was harmed as a result of nursing home practices, does not remove a finding of immediate jeopardy. The nursing home is required to implement specific actions to correct the deficient practices which allowed or caused the immediate jeopardy.

Examples that demonstrate severity at Level 4 include, but are not limited to:

- The nursing home failed to ensure that the nursing home staff provided adequate monitoring for a resident after returning from receiving an offsite HHD treatment at an ERSD unit. The resident was found to have pulled out the hemodialysis catheter and was found by staff over an hour later to be profusely bleeding which led to death.

- The nursing home failed to ensure that nursing home staff providing the HHD monitored and identified complications during a dialysis treatment. The resident's vital signs were not monitored during the dialysis treatment and as a result, the resident experienced serious hypotensive complications resulting in an emergency transfer and admission to the hospital.
- The nursing home failed to ensure that the nursing home staff monitored the PD catheter site for complications. The nursing home staff providing the PD treatments, failed to monitor the condition of the PD catheter site and identify signs of infection. As a result of the infection at the catheter site, the resident required medical intervention for removal of the catheter and initiation of hemodialysis.

Examples that demonstrate severity at Level 3 may include, but are not limited to:

- The nursing home failed to notify the attending practitioner and dialysis team of changes in a resident's behavior and failed to assure the treatments were provided according to the orders. A cognitively impaired resident was observed during a HHD treatment to exhibit combative and resistive behaviors, such as pulling at the tubing and access site. The resident had a history of previously dislodging the catheter, causing bleeding. The resident was observed trying to remove his/her shoes and trying to stand up from the dialysis chair and requires constant supervision during the treatment. The staff attributed the behavioral symptoms to dementia and administered a benzodiazepine to try to sedate the resident. Due to the behavioral symptoms, the HHD treatment had to be discontinued but the practitioner wasn't contacted regarding discontinuing the treatment. This had occurred several times, however the nursing home staff failed to contact the practitioner, identify underlying causes, such as delirium or medication side effects and did not attempt to consider environmental or other non-pharmacological measures to try to reduce the restlessness during dialysis. As a result of the treatments being discontinued early, the resident had electrolyte imbalance and fluid retention.

Examples that demonstrate Severity Level 2 include, but are not limited to:

- The nursing home failed to ensure that the nursing home staff provided PD treatments as ordered. The nursing home staff providing the PD failed to follow the orders for the duration of fluid in the peritoneal cavity however, the resident's status was stable.
- The nursing home failed to ensure that the nursing home staff provided PD treatments as ordered. The nursing home staff failed to identify a recent change in a resident's dialysis order for an increase in the number of daily PD treatments; however, the resident's status was stable.