

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 012501	(X3) Date Survey Completed 06/30/2021
Name of Provider or Supplier Gadsden Dialysis	Street Address, City, State 409 South First Street, Gadsden, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
E0000	Based on the recertification survey conducted on 6/28/21 to 6/30/21, Gadsden Dialysis was found to be in substantial compliance with the Conditions of Participation for Emergency Preparedness.
V0000	(Core) A recertification survey was conducted on 6/28/21 to 6/30/21 with standard level deficiencies cited.
V0111	<p>IC-SANITARY ENVIRONMENT CFR(s): 494.30</p> <p>The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of facility policy and procedure and interviews, it was determined the facility failed to ensure the staff: followed the facility policy for the initiation of a dialysis treatment with an arteriovenous fistula (AVF). This affected 1 of 2 observations conducted and did affect Patient Identifier (PI) # 2 and had the potential to negatively affect all patients served by the facility. Findings include: Title: AV (Arteriovenous) Fistula or Graft Cannulation With Nipro or Medisystems Safety Fistula Needles (SFN) and Administration of Heparin Loading Dose. Policy Number: 1-04-01E Revised Date: April 2019 Procedure: 8. Locate and palpate the needle cannulation sites prior to skin preparation... 10. While maintain aseptic technique, prep each planned needle site by applying a 70% alcohol prep pad to each site using a circular rubbing motion, center out... 13. Do not palpate insertion site once area has been prepped... 1. During observations of care on 6/28/21 at 9:11 AM the surveyor observed Employee Identifier (EI) # 7, Certified Clinical Hemodialysis Technician, prepping the sites with an antiseptic for cannulation of PI # 2 at station 19. After the</p>

sites were prepped EI # 7 then palpated/touched both sites with his/her fingers without repeating skin antiseptics before cannulation, thus leading to potential contamination. An interview was conducted on 6/28/21 at 11:50 AM with EI # 1, Facility Administrator, who verified staff failed to follow the facility policy for accessing of an AV Fistula.

V0113

IC-WEAR GLOVES/HAND HYGIENE

CFR(s): 494.30(a)(1)

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

This STANDARD is not met as evidenced by:

Based on observations, review of facility policy and procedure, and staff interviews, it was determined, the staff failed to: 1. Perform hand hygiene before and between glove changes, patient and/or stations as directed per the facility policy. 2. Perform hand hygiene before touching the ChairSideSnappy keyboard. 3. Perform hand hygiene after removing gloves and obtaining clean supplies. 4. Perform hand hygiene after removing needles and removing gloves. 5. Remove gloves and performed hand hygiene per facility procedure when performing Central Venous Catheter (CVC) exit site care. 6. Perform hand hygiene after removing gloves and obtaining medications. This did affect 1 of 3 observations conducted to discontinue dialysis on patients with an AVF/AVG (arteriovenous fistula/graft), 1 of 3 observations conducted to initiate dialysis and perform exit site care on patients with a CVC, and 1 of 3 observations conducted to initiate dialysis and perform exit site care on patients with a CVC. This did affect Patient Identifier (PI) #5, PI # 7, PI # 6, PI #10 and 5 unsampled patients and had the potential to negatively affect all patients served by this facility. Findings include: Policy: Infection Control For Dialysis Facilities Policy Number: 1-05-01 Revised Date: October 2020 Purpose: To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. Policy: The centers for Disease Control (CDC) recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients (Dialysis Precautions) will be followed when caring for all patients... Teammate Hygiene 1. Hand hygiene is to be performed upon entering the patient treatment area, prior to gloving, after removal of gloves, after contamination with blood or other infectious material, after patient and dialysis delivery system contact, between patients even if the contact is casual, before touching clean areas such as supplies and on exiting the patient treatment area... Teammate/Patient Safety 11. Teammates will wear disposable gloves when caring for patient or touching the patient's equipment at the dialysis station, and will remove gloves and wash hands or perform hand hygiene between each patient and/or station. 13. Gloves should be changed when: ...When going from a "dirty" area or task to a "clean" area or task. ...After touching one patient or their dialysis delivery system and before arriving to care for another patient or touch another patient's dialysis delivery system. ChairsideSnappy Terminal and Cart 71. The ChairSideSnappy cart, monitor and keyboard are considered clean areas. 72. Gloves are to be removed and hands washed or alcohol based hand rubs used before and after touching the keyboard. Title: Central Venous Catheter (CVC) with Clearguard HD (Hemodialysis) Antimicrobial End Caps Procedure Procedure Number: 1-04-02B Origination Date: April 2019 Procedure: 4. Remove old dressing and discard. 5. Observe site for signs and symptoms of infection ... 7. Remove gloves and discard. Perform hand hygiene per procedure and re-glove. 8. ...clean exit site with 2% (percent) Chlorhexidine

Gluconate 70% Isopropyl Alcohol swab for a minimum 30 seconds... 1. During observations of care on 6/28/21 at 7:50 AM, the surveyor observed Employee Identifier (EI) # 5, Registered Nurse (RN), at station 1 attempt to stop bleeding around PI # 5's access site, doff gloves and don new gloves without performing hand hygiene as directed per the facility policy. 2. During observations of care on 6/28/21 at 8:30 AM the surveyor observed EI # 6, Certified Clinical Hemodialysis Technician (CCHT), apply a glove to his/her right hand and silence the alarm on the hemodialysis machine of an unsampled patient at station 20. EI # 6 then removed his/her glove, reapplied gloves and proceeded to an unsampled patient at station 21 and touched the dialysis machine without performing hand hygiene. EI # 6 failed to perform hand hygiene between glove changes as directed per the facility policy. 3. An observation was conducted on 6/28/21 at 8:59 AM to observe EI # 6 initiate dialysis on PI # 7 at station 6 with an AVF/AVG. EI # 6 removed his/her gloves and proceeded to the clean supply drawer and retrieved clean supplies without performing hand hygiene as directed per the facility policy. 4. During observations of care on 6/28/21 at 10:00 AM the surveyor observed EI # 4, RN wearing gloves and obtaining the vital signs of an unsampled patient at station 24. EI # 4 then proceeded to station 23 and wearing the same gloves, unlocked the dialysis chair with his/her gloved hand. EI # 4 failed to remove his/her gloves between each patient and/or station. After unlocking the dialysis chair, EI # 4 removed his/her gloves and began typing on the ChairSideSnappy keyboard without performing hand hygiene as directed per the facility policy. 5. During observations of care on 6/28/21 at 10:20 AM the surveyor observed EI # 6 discontinuing dialysis on an unsampled patient at station 25. EI # 6 removed the needle and removed his/her gloves without performing hand hygiene. EI # 6 then proceeded to the ChairSideSnappy cart at station 5 and began typing on the keyboard without performing hand hygiene as directed per the facility. 6. An observation was conducted on 6/28/21 at 10:29 AM to observe EI # 4 perform exit site care and initiate dialysis on PI # 6 with a CVC at station 23. EI # 4, performed hand hygiene, donned clean gloves, removed the old dressing and discarded the old dressing and then, without performing hand hygiene, cleaned area around CVC exit site with antiseptic. Upon completion of the exit site care, EI # 4 connected sterile syringes to each port then removed his/her gloves and proceeded to the medication drawer and obtained two syringes of Heparin without performing hand hygiene as directed per the facility. 7. During observations of care on 6/28/21 at 10:45 AM, the surveyor observed EI # 8, CCHT, doff gloves, gown and face shield prior to exiting the dialysis unit. On re-entry to the dialysis unit, EI # 8 donned gown, face shield and gloves without performing hand hygiene and proceeded to secure a dressing to the left arm of an unsampled patient at station 14. EI # 8 failed to follow the facility policy for hand hygiene. 8. During observations of care on 6/29/21 at 7:50 AM, the surveyor observed EI # 4, RN provide CVC exit site care to PI # 10. EI # 4, performed hand hygiene, donned clean gloves, removed old dressing and discarded old dressing and then, without removing gloves and without performing hand hygiene, cleaned area around CVC exit site with antiseptic. An interview was conducted on 6/30/21 at 11:50 AM with EI # 1, Facility Administrator, who verified the staff failed to follow the facility policy for hand hygiene and gloving. 42144

V0114

IC-SINKS AVAILABLE
CFR(s): 494.30(a)(1)(i)

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

This STANDARD is not met as evidenced by:
Based on observations, review of policy, and interview, it was determined the facility failed to ensure the staff followed their own policy for hand washing sinks. This had the potential to negatively affect all patients dialyzing in this facility. Findings include: Facility Policy Title: Infection Control For Dialysis Facilities Policy: 1-05-01 Revision Date: October 2020 "Facility Hygiene 39. ...Clean sinks should be dedicated to clean activities such as hand washing and remain clean. Avoid placing, cleaning or draining dirty items in clean hand washing sinks. Used or contaminated items should be handled in designated utility sinks". 1. During observations of care on 6/28/21 at 9:04 AM the surveyor observed Employee Identifier (EI) # 7, Certified Clinical Hemodialysis Technician (CCHT), perform the dialysate pH and conductivity testing for dialysis machine preparation with a Myron L meter at station 6. After completing the conductivity testing EI # 7 rinsed the Myron L meter with RO (Reverse Osmosis) solution and emptied the dirty solution in the clean hand washing sink. EI # 7 did not follow the policy for the use of hand washing sinks. An interview was conducted on 6/30/21 at 11:50 AM with EI # 1, Facility Administrator, who verified the staff failed to follow the facility policy for hand washing sinks.

V0116

IC-IF TO STATION=DISP/DEDICATE OR DISINFECT
CFR(s): 494.30(a)(1)(i)

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

This STANDARD is not met as evidenced by:
Based on observations, review of facility policy and interview, it was determined the facility failed to ensure the staff cleaned and disinfected equipment before returning it to a common clean area or being used on another patient. This did affect 1 of 2 observations conducted for preparation of the hemodialysis machine and perform conductivity testing using the Myron L meter and 1 of 3 observations conducted for initiation of dialysis and exit site care of patients with a Central Venous Catheter (CVC). This did affect Patient Identifier (PI) # 7, PI # 1, and 1 unsampled patient. This had the potential to negatively affect all patients served by this facility. Findings Include: Policy: Infection Control for Dialysis Facilities Policy Number: 1-05-01 Date Revised: October 2020 Purpose: To minimize the spread of infections or bloodborne pathogens in the dialysis facility environment. ...Teammate/Patient Safety ...25. Non-disposable items are to be disinfected between patients. 26. Stethoscopes will be disinfected with alcohol prep pad and/or 1:100 (one to one hundred) bleach solution... ..Dialysis Station Management ...65. Items taken into the dialysis station will be... cleaned and disinfected before taken to a common area or used on another patient... 66. Teammates will thoroughly wipe down all non-disposable items and equipment... with an appropriate disinfectant... Chairsidesnappy Terminal and Cart 71. The ChairSideSnappy cart, monitor and keyboard are considered clean areas. 1. An observation was conducted on 6/28/21 at 8:15 AM to observe Employee Identifier (EI) # 6, Certified Clinical Hemodialysis Technician (CCHT) prepare the dialysis machine and perform the conductivity using the Myron L meter for PI # 7 at station 6.

EI # 6 obtained the Myron L meter from the clean supply countertop and proceeded to station 6. EI # 6 obtained the dialysate solution from the dialysis machine and then placed the Myron L meter on PI # 6's flowsheet which was lying on top of the ChairSideSnappy cart. After performing the conductivity testing PI # 6 retrieved the Myron L meter and returned the meter to the clean supply countertop without cleaning the meter after use as directed per the facility policy. 2. During observations of care on 6/28/21 at 10:10AM the surveyor observed EI # 6 retrieve the thermometer from the ChairSideSnappy cart at station 22 and proceed to an unsampled patient at station 20. EI # 6 obtained the unsampled patient's temperature at station 20 then proceeded to station 5. EI # 6 placed the thermometer on the ChairSideSnappy cart at station 5 without cleaning the thermometer after use as directed per the facility policy. 3. An observation was conducted on 6/28/21 at 10:42 to observe EI # 5, Registered Nurse, perform exit site care and initiate dialysis on PI # 1 with a CVC at station 21. EI # 5 retrieved the thermometer from the clean supply countertop and obtained PI # 1's temperature. EI # 5 then placed the thermometer on the ChairSideSnappy cart without cleaning the thermometer after use as directed per the facility policy. EI # 5 then performed a pre-assessment with a stethoscope on PI # 1. EI # 5 hung the stethoscope around his/her neck and failed to disinfect the stethoscope after use as directed per the facility policy. An interview was conducted on 6/30/21 at 11:50 AM with EI # 1, Facility Administrator, who confirmed the staff failed to clean and disinfect equipment before returning it to a common clean area or before being used on another patient.

V0122

IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL
CFR(s): 494.30(a)(4)(ii)

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

This STANDARD is not met as evidenced by:
Based on 1 of 2 observations of cleaning and disinfection of the hemodialysis stations, review of facility policy and interview, it was determined the facility failed to ensure staff cleaned and disinfected the dialysis station after patient treatments. This had the potential to negatively affect all patients in this facility. Findings Include: Policy: Infection Control for Dialysis Facility Policy Number: 1-05-01 Revision Date: October 2020 Purpose: To minimize the spread of infection or bloodborne pathogens in the dialysis facility environment. Facility Hygiene ...46. Equipment including the dialysis delivery system, the interior and exterior of the prime container, the dialysis chair and side tables including opening the chair to reach crevices, blood pressure equipment, television arms and control knobs or remote control devices if accessible to patient and teammates...as well as work surfaces will be wiped clean with bleach solution of the appropriate strength...before being used on another patient ..., and after each treatment. Dialysis Station Management ...66. Teammates will thoroughly wipe down all non-disposable items and equipment such as the blood pressure cuff, the inside and outside of the prime container, ... and the dialysis delivery systems, with an appropriate disinfectant after every treatment... 1. During observations of care on 6/28 /21 at 8:40 AM the surveyor observed Employee Identifier (EI) # 6, Certified Clinical Hemodialysis Technician, clean and disinfect dialysis station 20. EI # 6 failed to clean and disinfect the dialysate hoses and Hansen connectors on the side of the dialysis machine as directed per the facility policy. An interview was conducted on 6/30/21 at

11:50 AM with EI # 1, Facility Administrator, who verified the staff failed to follow the facility policy for cleaning and disinfection after patient treatments.

V0250

DIALYS PROPORT-MONITOR PH/CONDUCTIVITY
CFR(s): 494.40(a)

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

This STANDARD is not met as evidenced by:

Based on observations, review of facility procedure and interview with facility staff, it was determined the staff failed to follow the facility procedure for testing dialysate conductivity prior to treatment initiation. This affected 1 of 2 observations, including Patient Identifier (PI) # 7 and had the potential to negatively affect all patients who dialyze at this facility. Findings include: Title: Operation of Portable Myron L Conductivity Meter (D-1) Procedure: 2-08-01 B Revision Date: April 2019 Material required: Myron L dialysate meter ...Dialysis quality water obtained fresh daily Procedure 10. When you are finished...RINSE thoroughly with dialysis quality water... 1. An observation was conducted on 6/28/21 at 8:15AM to observe Employee Identifier (EI) # 6, Certified Clinical Hemodialysis Technician, perform conductivity testing at station 6 prior to arrival of PI # 7. After conductivity testing was complete EI # 6 failed to rinse the meter thoroughly with dialysis quality water after use as directed per the facility policy. An interview was conducted on 6/30/21 at 11:50 AM with EI # 1, Facility Administrator, who verified the staff failed to follow the facility procedure for testing dialysate conductivity prior to treatment initiation.

V0544

POC-ACHIEVE ADEQUATE CLEARANCE
CFR(s): 494.90(a)(1)

Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

This STANDARD is not met as evidenced by:

Based on review of medical records (MR), facility policy, and interviews with staff, it was determined the facility failed to ensure the staff followed the physician orders for the Blood Flow Rate (BFR). This affected 3 of 5 MR's reviewed including Patient Identifier (PI) # 1, PI # 2, PI # 3 and had the potential to negatively affect all patients who dialyze at this facility. Findings Include: Policy Number: 1-03-08 Title: Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment Revision Date: April 2021 Purpose: To obtain and document baseline and ongoing information about the patient before, during and after the dialysis treatment through data collection and nursing assessment... Policy: 1. Patient data will be obtained and documented by the patient care technician (PCT) or a licensed nurse. a. Data collection includes but is not necessarily limited to: 3. Patient...prescription and machine settings are verified by teammate prior to initiation of treatment with the exception of blood flow rate which is verified and documented when the ordered rate is obtained after onset of treatment... Prescription components include but are not necessarily limited to: ... f. Blood flow rate Intradialytic Data Collection/Assessment 9. Intradialytic treatment

monitoring and data collection which may be performed by the PCT or licensed nurse includes: ...b. At a minimum, obtain and document the following: iii. Blood and dialysate flows, arterial and venous pressures 10. If the dialysis prescription is not being met (including dialysis flow rate or change to / inability to obtain prescribed blood flow rate) the reason will be documented and the licensed nurse informed... 1. PI # 1 was admitted to the facility on 5/7/21 with a primary diagnosis of End Stage Renal Disease (ESRD). Review of the hemodialysis orders dated 6/9/21 revealed a BFR of 400. Review of the Post Treatment Sheet dated 6/11/21 revealed the BFR was decreased to 350 from 10:01 AM until the end of treatment at 1:23 PM. There was no documentation why the BFR was not at the ordered rate of 400. Review of the Post Treatment Sheet dated 6/14/21 revealed the BFR was decreased to 350 at 3:02 PM. Then at 3:31 PM the BFR was decreased to 300 until the end treatment at 4:12 PM. There was no documentation why the BFR was not at the ordered rate of 400. Review of the Post Treatment Sheet dated 6/18/21 revealed the BFR was decreased to 350 from 9:59AM until the end of treatment at 1:43 PM. There was no documentation why the BFR was not at the ordered rate of 400. Review of the Post Treatment Sheet dated 6/25/21 revealed the BFR was run at 300 from 10:31 AM to 1:42 PM. Then the BFR was increased to 350 until the end of treatment at 1:42 PM. There was no documentation why the BFR was not at the ordered rate of 400. An interview was conducted on 6/30/21 at 11:40 PM with Employee Identifier (EI) # 1, Facility Administrator, who confirmed the BFR was not run at the ordered rate. 2. PI # 2 was admitted to the facility on 6/5/18 with a primary diagnosis of ESRD. Review of the hemodialysis orders dated 2/19/21 revealed a BFR of 350. Review of the Post Treatment Sheet dated 6/23/21 revealed the BFR was run at 300 from initiation of treatment at 9:39 AM until 12:35 PM. There was no documentation why the BFR was not at the ordered rate of 350. An interview was conducted on 6/30/21 at 11:42 PM with EI # 1 who confirmed the BFR was not run at the ordered rate. 42144 3. PI # 3 was admitted to the facility on 4/3/19 with a primary diagnosis of ESRD. Review of the hemodialysis orders dated 5/17/21 revealed a BFR of 450. Review of the Post Treatment Sheet dated 6/18/21 revealed the BFR was run at 400 from 8:01 AM until 11:02 AM. There was no documentation why the BFR was not at the ordered rate of 450. Review of the Post Treatment Sheet dated 6/25/21 revealed the BFR was run at 375 from 8:01 to 10:48. There was no documentation why the BFR was not at the ordered rate of 450. An interview was conducted on 6/30/21 at 11:40 AM with EI # 1 who confirmed the BFR was not run at the ordered rate.

V0547

POC-MANAGE ANEMIA/H/H MEASURED Q MO
 CFR(s): 494.90(a)(4)

The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.

This STANDARD is not met as evidenced by:
 Based on the review of medical records (MR) and interviews, it was determined the facility failed to provide anemia management for 2 of 5 medical records of patients receiving Venofer. This did affect Patient Identifier (PI) # 1, PI # 3, and had the potential to negatively affect all patients served by this facility. Findings include: 1. PI # 1 was admitted to the facility on 5/7/21 with a primary diagnosis of End Stage Renal Disease (ESRD). Review of the hemodialysis orders dated 5/11/21 revealed, "Venofer /Iron Sucrose 50.0 mg (milligrams) IV (Intravenous) qw (every week)". Review of the

MR revealed PI # 1 dialyzed on 6/23/21 and 6/25/21. There was no documentation PI # 1 was administered Venofer 50 mg IV the week of 6/21/21 to 6/25/21 as ordered. An interview was conducted on 6/30/21 at 11:40 PM with Employee Identifier (EI) # 1, Facility Administrator, who confirmed PI # 1 did not receive his/her Venofer for anemia management the week of 6/21/21. 42144 2. PI # 3 was admitted to the facility on 4/3/19 with a primary diagnosis of ESRD. Review of the hemodialysis orders dated 10/21/2020 revealed, "Venofer/Iron Sucrose 50.0 mg IV Push qw." Review of the MR revealed PI # 3 dialyzed on 6/23/21 and 6/25/21. There was no documentation PI # 3 was administered Venofer 50 mg IV the week of 6/21/21 to 6/25/21 as ordered. An interview was conducted on 6/30/21 at 11:40 AM with EI # 1, who confirmed PI # 3 did not receive his/her Venofer for anemia management the week of 6/21/21.