

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/12/2021

FORM APPROVED

OMB NO. 0938-039

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/16/2021
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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY	STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408
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E 0000 Bldg. 00	<p>An Emergency Preparedness survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier.</p> <p>Date of survey: 9/9/2021 to 9/16/2021</p> <p>Facility #: 005980</p> <p>CCN: 152521</p> <p>Stations: 40, includes the isolation room</p> <p>ICHD Patients: 88</p> <p>Home Peritoneal Dialysis patients: 11</p> <p>Total Census: 99</p> <p>At this Emergency Preparedness survey, Comprehensive Renal Care-Gary, was found to have been in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62.</p>	E 0000		
V 0000 Bldg. 00	<p>This survey was a Federal Re-certification, a focused Infection Control, and complaint survey.</p> <p>Complaint #: IN00333728: Complaint was</p>	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosed days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V 0113 Bldg. 00	<p>substantiated. Federal deficiencies related to the complaint were cited.</p> <p>Complaint #: IN00302838: Complaint was substantiated. Federal deficiencies related to the complaint were cited.</p> <p>Complaint #: IN00253702: Complaint was substantiated. Federal deficiencies related to the complaint were cited.</p> <p>Complaint #: IN00355496: Complaint was substantiated. Federal deficiencies related to the complaint were cited.</p> <p>Survey Dates: 9/8/2021 to 9/16/2021</p> <p>Facility: IN005980</p> <p>Provider: 152521</p> <p>Current Census: 99 patients</p> <p>88 Incenter Hemodialysis patients 11 Home Peritoneal Dialysis patients</p> <p>Comprehensive Renal Care - Gary was found to be out of compliance with Conditions of Participation 42CFR 494.80 Patient Assessment.</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE 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.</p>			

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	<p>Based on observation, record review and interview, the facility failed to ensure staff had completed appropriate hand hygiene according to hand hygiene policies and procedures in 8 of 10 hand hygiene observations completed. (PCT L, PCT O, PCT N)</p> <p>The findings include:</p> <p>1. An agency policy titled "INFECTION CONTROL FOR DIALYSIS FACILITY" revised October 2021 stated "Purpose to minimize the spread of infection or bloodborne pathogens in the dialysis facilities environment ... 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. Physicians, Non-Physician Practitioners (NPP) and all teammates are to follow the same requirements for glove use and hand hygiene. 2. If hands are not visibly contaminated, use of an alcohol-based hand rub may be substituted for handwashing ... Handwashing will be performed if hands are visibly contaminated with blood or body fluids ... 6. Alcohol-based hand rub maybe used: -in the absence of sink/water -In the event of an emergency (i.e. emergency evacuation) -Before gloving and after glove removal ... 11. Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis training room/station, and will remove gloves and wash hands or perform hand hygiene between each patient and/or station. 12. Gloves should be worn when: -Potential for exposure to blood, dialysate and other potentially infectious</p>	V 0113	<p>Facility Administrator (FA) held mandatory in-service for all clinical Teammates (TMs) on 9/15/2021 reviewing Policy & Procedure # 1-05-01: Infection Control for Dialysis Facilities and 9/27/2021 reviewing Policy & Procedure 1-05-01A Use of Alcohol-Based Hand Rubs, 1-05-01B Handwashing. In-service emphasized 1) TMs must wear disposable gloves appropriately when caring for the patient or touching the patient's equipment at the dialysis station; 2) TMs must remove gloves and perform hand hygiene between dirty and clean tasks with same patient, between each patient and station; 3) TMs must remove gloves and perform hand hygiene before entering clean supply area; 4) TMs must perform hand hygiene every time gloves removed; 5) TMs must instruct and encourage patients every treatment to perform hand hygiene upon entering the treatment floor; and perform hand hygiene prior to leaving the unit after glove removal, and prior to touching any clean supply or area to assist in avoiding the risk of cross contamination. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct infection control audits daily x 4 weeks, weekly x 4 weeks, and</p>	10/16/2021

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	<p>substances ... Administering medications, checking vital signs ... 13. Gloves should be changed when: -When soiled with blood, dialysate or other body fluids -When going from a "dirty" area or task, to a "clean" area or task - When moving from a contaminated body site to a clean body site of the same patient; and -After touching one patient or their dialysis delivery system and before arriving to care for another patient or touching other patients dialysis delivery system...."</p> <p>2. An agency procedure titled "Use of Alcohol-Based Hand Rubs," revised October 2019, stated "1. Follow the manufacturer's recommendations in regards to volume of product to be used 2. Apply the product in the palm of one hand. 3. Rub hands together covering all surfaces of hands and fingers until hand rub has evaporated and hands are dry."</p> <p>3. An agency procedure titled "Handwashing," revised October 2020, stated "1. Turn on and adjust flow and temperature of water. 2. Wet hands and apply antibacterial liquid soap. 3. Cover hands (palms, back of hands, between fingers) and wrist with lather and wash vigorously for a minimum of 15 seconds. 4. Rinse while using running water flowing from the wrist to the fingertips. Fingertips should be below the level of the wrist. 5. Dry hands thoroughly with paper towels. 6. If sink is not pedal operated turn off faucet with elbows or paper towels. 7. Discard paper towels in the trashcan."</p> <p>4. During an observation on 9/9/2021 at 4:03 PM, PCT (Patient Care Technician) L was observed discontinuing dialysis for Patient #5 at station 20. PCT L donned gloves failing to wash or sanitize hands prior to donning the gloves. A clean field</p>		<p>then monthly. FA will review results of all audits with TMs during homeroom meetings and with Medical Director during monthly Facility Health Meeting (FHM), minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>		

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	<p>was placed under the CVC (central venous catheter) ports and the extracorporeal (outside the body) circuit was reinfused. PCT L removed gloves and donned a new pair of gloves failing to wash hands. After discontinuing the dialysis treatment PCT L washed his hands with soap and water for seven seconds failing to follow policy and washing for 15 seconds.</p> <p>5. During an observation on 9/9/2021 at 9:34 PM, PCT P was observed discontinuing dialysis for Patient #23 at station 15. PCT P removed the needles from patient #19's access site. PCT P removed his gloves and donned new gloves failing to wash or sanitize his hands, and proceeded to take all the tubing from the dialysis machine.</p> <p>6. During an observation on 9/13/2021 at 11:37 AM, PCT O was observed performing care of the central venous catheter exit site for patient #15 at station 30. During this care PCT O was observed removing the old dressing and proceeded to clean the area around the exit site and apply a sterile dressing. PCT O failed to change her gloves and perform hand hygiene before cleansing the site and applying the sterile dressing.</p> <p>7. During an observation on 9/13/2021 at 11:48 AM, PCT O was observed initiating dialysis through the central venous catheter for patient #14 at station 30. During this care PCT O was observed initiating dialysis and then proceeded to remove her gloves and write on a clip board. PCT O failed to do hand hygiene after removing gloves and prior to writing on the clipboard.</p> <p>During an observation on 9/9/2021 at 10:00 AM, PCT O was observed accessing the fistula on patient #16 at station 2. During this care PCT O</p>			

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	<p>was observed inserting cannulation (place inside a vein) needles, taping in place, and initiating treatment. PCT O then removed her gloves and documented in the computer. PCT O failed to wash or sanitize her hands after initiating treatment prior to documenting on the computer.</p> <p>8. During an observation on 9/9/2021 at 10:30 AM, PCT N was observed accessing the fistula (an abnormal connection between an artery and a vein) on patient #17 at station 3. During this care PCT N was observed evaluating patient #17's access site, after evaluating the site, which involves palpating the area, PCT N failed to remove her gloves and wash/sanitize her hands after palpating the access site. PCT N proceeded to insert cannulating needles and obtain a blood sample for labs needed for the patient. PCT N took the labs to the lab area came back and connected patient to the dialysis machine and started treatment failing to remove her gloves and perform hand hygiene after obtaining the labs. PCT N washed her hands with soap and water for 4 seconds failing to follow policy and wash for 15 seconds.</p> <p>9. During an observation on 9/9/2021 at 9:44 AM, PCT N was observed discontinuing dialysis for patient #1 at station #5. PCT N was observed donning gloves, failing to do hand hygiene prior to donning gloves. PCT N reinfused the extracorporeal circuit removed her gloves and washed her hands with soap and water for 3 seconds, failing to follow policy and washing for 15 seconds. PCT N wrote on her clipboard on top of the dialysis machine after removing cannulation needle from patient #1 failing to wash her hands after removing her gloves. PCT N donned new gloves failing to wash her hands, then proceeded to remove the second needle from patient #1's</p>			

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	<p>access site.</p> <p>During an interview on 9/16/2021 at 3:43 PM, the facility administrator indicated staff should be washing their hands when they enter the treatment floor, in-between patients, before initiating treatment, when changing gloves, and before and after keyboard usage.</p> <p>10. During an observation on 9/9/2021 at 3:51 PM, PCT O was observed discontinuing dialysis for patient #9 at station #17. PCT O performed hand hygiene, donned gloves, swabbed each CVC (central venous catheter) port with an alcohol wipe for two seconds, and then placed a cap on each port. PCT O then placed a clean gauze dressing over the CVC ports, secured them with tape, then removed her gloves and performed hand hygiene. PCT O failed to change her gloves and perform hand hygiene before applying a sterile dressing to the CVC site.</p> <p>11. During an observation on 9/13/2021 at 11:06 AM, PCT O was observed checking the blood pressure of patient #15 at station #29, prior to starting dialysis. PCT O donned gloves without performing hand hygiene and placed the blood pressure cuff on the right arm of patient #15,</p>			

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	<p>picked up a clipboard and pen from the computer next to the treatment chair, wrote on the clipboard, placed the clipboard back onto the computer, removed her gloves, and then performed hand hygiene. PCT O then began typing on the computer. She then put gloves on without performing hand hygiene, performed a water test on the dialysis machine, laid the tester on a counter top holding multiple patient supplies, took her gloves off, and performed hand hygiene. She typed on the computer, donned gloves without hand hygiene first, entered information on the dialysis machine, took her gloves off, and performed hand hygiene. She typed in the computer, did hand hygiene and donned new gloves. PCT O laid a clean barrier over patient #15's shirt and around the CVC site. She then removed the existing tape and gauze dressing from the CVC and used two swabs to clean the area, and used alcohol wipes around the area to clean as well. PCT O then placed clean gauze and new tape on top of CVC site. She then removed the old dressing material from the CVC port ends, removed the caps, wiped them with an alcohol wipe, placed a saline flush on both, unclamped each one, flushed and pulled back to verify blood return, and reclamped them. PCT O then took one syringe of saline off and replaced it with a syringe of heparin (a drug used to help prevent clot formation) without cleaning the port first, and administered the heparin. She then attached the ports to the blood lines and removed her gloves. She then donned one glove only, pushed buttons on the dialysis machine, unclamped tubing attached to the dialysis machine, removed the glove, then without performing hand hygiene, typed on the computer. An alarm started to sound at station #32 in the treatment pod, and PCT O donned one glove, silenced the alarm, then donned a second glove and continued to help the</p>			

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V 0116 Bldg. 00	<p>patient #18 at station #32. PCT O failed to perform hand hygiene between patients.</p> <p>During an interview on 9/15/2021 at 11:49 AM, when queried about her training in infection prevention and control, PCT O indicated her training was "kind of lost in the rush." PCT O confirmed her training was rushed due to lack of staffing.</p> <p>494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT</p> <p>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.</p> <p>-- 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.</p> <p>-- 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.</p> <p>Based on observation, record review and interview, the End Stage Renal Dialysis staff failed to ensure medical equipment was cleaned and disinfected in between patients in 1 of 1 observations of an assessment. (PCT N)</p> <p>The findings include:</p> <p>1. An agency policy titled "INFECTION CONTROL FOR DIALYSIS FACILITIES" revised October 2020 stated "Stethoscopes will be</p>	V 0116	<p>FA held mandatory in-service for all clinical TMs on 9/15/2021. In-service included but was not limited to: review of Policy & Procedure # 1-05-01: Infection Control for Dialysis Facilities emphasizing items taken to dialysis station should be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before</p>	10/16/2021	

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V 0122 Bldg. 00	<p>disinfected with 1:100 bleach solution and if they are visibly contaminated with blood or bodily fluid should be disinfected with a 1:10 (one to ten) bleach solution...."</p> <p>2. During an observation on 9/9/2021 10:30 AM, PCT (patient care technician) N was observed assessing patient #17's access site. PCT N used the stethoscope to listen for Bruit (sound of blood flow) failing to clean the stethoscope prior to use. PCT N was observed placing the stethoscope on the supply counter failing to sanitize the stethoscope after using it on patient #17.</p> <p>During an interview on 9/16/2021 at 3:42 PM, the facility administrator indicated all stethoscopes should be disinfected before and after use.</p> <p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing-</p>		<p>returning to clean area or used on another patient. 1) Stethoscopes disinfected with 1:100 bleach solution and if they are visibly contaminated with blood or bodily fluid should be disinfected with 1:10 bleach solution. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct infection control audits daily x 4 weeks, weekly x 4 weeks, and then monthly. FA will review results of all audits with TMs during homeroom meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>	

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	<p>(4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-]</p> <p>(ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review and interview, the facility failed to ensure staff had completed appropriate disinfection of dialysis stations in 2 of 2 disinfection of stations observed. (station #15, #23)</p> <p>These findings include:</p> <p>1. An agency policy titled INFECTION CONTROL FOR DIALYSIS FACILITIES" revised October 2020 stated " ... Equipment including the dialysis delivery system and work station, 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 patients and teammates, facility wheel chairs, outside of sharps containers, IV poles, as well as all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedures, before being used on another patient, after spills of blood, throughout the work day, and after each treatment...."</p> <p>2. During an observation on 9/9/2021 at 3:15 PM, PCT O was observed at station #15 cleaning the station after patient use. PCT O was observed cleaning the chair. During the cleaning process PCT O failed to fully recline the chair, and failed to clean the side of the seat to ensure all surfaces of the chair were disinfected.</p> <p>2. During an observation on 9/13/2021 at 12:35</p>	V 0122	<p>FA held mandatory in-service for all clinical TMs on 9/15/2021 and 9/27/2021. In-service included but was not be limited to: review of Policy & Procedure # 1-05-01: Infection Control for Dialysis Facilities emphasizing proper procedure for disinfection with bleach solution between patient treatments of machine, chair and surrounding equipment. 1) TMs must fully clean machine including top, front, sides, and bottom lip. TMs must completely recline chair, open footrests, and side arms if applicable in order to thoroughly clean all crevasses of chair. Tables on chairs will be lowered and wiped with bleach solution between patients; 2) TMs instructed they must remove, empty, disinfect prime containers between each patient treatment; 3) All other equipment including TVs, TV arms, blood pressure cuffs, and IV poles must be wiped with a bleach solution between patients; 4) TMs instructed on proper use for 1:10 vs. 1:100 bleach solutions for cleaning and disinfection tasks emphasizing for visible blood or gross blood spills a 1:10 bleach solution must be utilized. After blood is cleaned</p>	10/16/2021	

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V 0401 Bldg. 00	<p>PM, PCT N was observed at station #23 cleaning the station after patient use. PCT N failed to recline the chair, disinfect the back of the machine, failed to disinfect the television, blood pressure cuff and the pillow.</p> <p>During an interview on 9/16/2021 at 2:44 PM, the facility administrator indicated staff should clean all surfaces of the machine, the chair should be fully reclined so it can be cleaned in all the crevices, the television, blood pressure cuff and anything at the station should be disinfected after patient use.</p> <p>494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation, record review and interview, the agency failed to ensure they provided a comfortable, sanitary environment for patients while undergoing dialysis, in 1 of 1 dialysis facility.</p> <p>The findings include:</p>	V 0401	<p>with 1:10 bleach solution TMs must use new disposable towel soaked with 1:10 bleach solution and clean a second time. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct infection control audits daily x 4 weeks, weekly x 4 weeks, and then monthly. FA will review results of all audits with TMs during homeroom meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>	10/16/2021

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		X3) DATE SURVEY COMPLETED 09/16/2021
NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY			STREET ADDRESS, CITY, STATE, ZIP CODE 4802 BROADWAY GARY, IN 46408		
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	<p>1. An agency policy titled "Infection Control for Dialysis Facilities," revised October 2020 stated "Purpose to minimize the spread of infection or bloodborne pathogen's in the dialysis facilities environment ... Teammates will monitor for the occurrence of residue/buildup, or bubbling/splashing or drainage backup in the wall boxes and report to the Facility Administrator and Biomedical Services for advanced drain care option. The presence of flies (drain flies, sink flies, filter flies or sewer gnats which are small true flies with short, hairy bodies and wings giving them a "fuzzy" moth- like appearance will prompt a report to the Facility Administrator and Biomedical Services for advanced drain care options...."</p> <p>2. During an observation on 9/9/2021 at 9:36 AM, flies were observed flying around the treatment floor near station 15.</p> <p>3. During an observation on 9/9/2021 at 9:30 AM, paper, tape and empty alcohol prep pad wrappers were observed on the floor near station 19.</p> <p>4. During an observation on 9/9/2021 at 12:39 PM, a fly was flying around the office the surveyors were working in at the end stage renal dialysis facility.</p> <p>5. During an observation on 9/9/2021 at 3:06 PM, ripped up paper towels and a white powdery substance were observed on the floor between Pods E and F.</p> <p>6. During an observation on 9/9/2021 at 3:25 PM, there was a rip that was taped with white medical tape observed on the chair at station 39.</p> <p>7. During an observation on 9/9/2021 at 3:26 PM,</p>		<p>placed with Champion to repair.</p> <p>FA to contact Terminix Exterminator Service to set up treatments to remove flies. Biomedical Services will conduct weekly manual Drain Cleaning until Elimishield Drain Pumps installed. Installation completed by 11/15/2021. Monthly Biomedical Audits to verify all drain pumps wall boxes are properly working, solutions, and supplies in stock or available for use are checked for expiration.</p> <p>FA conducted mandatory in-service for all clinical TMs on 9/15/2021. In-service included but was not limited to: review of Policy & Procedure # 1-05-01 Infection Control for Dialysis Facilities emphasizing all TMs are responsible for providing a sanitary and safe environment in the treatment area, and throughout facility. Dialysis facility maintained to provide dialysis patients, teammates, and public a safe, functional, and comfortable treatment environment. 1) Facility must remain clean, organized; 2) TMs must clean up spills; facility floors must remain clean and free of debris or trash; 3) Review of Wall Box and Drain /Water Line Care and Maintenance. Teammates will monitor the occurrence of residue/buildup, or bubbling/splashing of drainage</p>		

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	<p>there were used chlorine test strips observed on the counter behind station 39 and 40 in the isolation room. There was also a blood pressure cuff laying in the sink next to station 40.</p> <p>8. During an observation on 9/9/2021 at 3:34 PM, there was a 3 shelf cart sitting outside of the isolation room. There was white powdery residue observed on the top shelf of the cart and the cart was wet.</p> <p>9. During an observation on 9/9/2021 at 3:42 PM, there were used chlorine strips in the dirty sink by POD C.</p> <p>10. During an observation on 9/9/2021 at 3:15 PM, water was observed on the floor under the chair and between the chair and dialysis machine at station 15. There were paper and small pieces of debris on the floor.</p> <p>11. During an observation on 9/10/2021 at 9:16 AM, used chlorine test strips were observed on the shelf behind dialysis stations 39 and 40.</p> <p>12. During an observation on 9/10/2021 at 12:31 PM, flying insects were noted flying in the office where the surveyors were working.</p> <p>13. During an observation on 9/14/2021 at 11:41 AM, patient #5 was observed waving her hands and smacking them together. Patient #5 indicated there was a fly at the station that kept flying by her head.</p> <p>14. During an observation on 9/14/2021 at 3:21 PM, there were used chlorine test strips observed on the counter of station 39 and 40.</p> <p>15. During an observation on 9/15/2021 at 2:43</p>		<p>backup in the wall boxes and report to the Facility Administrator and Biomedical Services for the advanced drain care. The presence of flies (drain flies, sink flies) will be promptly reported to Facility Administrator and Biomedical Services for advanced drain care; 4) Any chairs identified in need of repair reported to FA and Biomedical Technician for evaluation, replacement parts ordered, repaired/replaced accordingly; 5) Dialysis Station Management and cleaning of Dialysis Station reviewed; 6) Expiration date must be checked on supplies before opening, and once opened TMs must label with signature and date and properly discard after use. TMs must verify all facility medications, solutions, and supplies are checked for expiration dates and discarded per Policy and Procedure if found. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct infection control audits daily x 4 weeks, weekly x 4 weeks, and then monthly. FA will review results of all audits with TMs during homeroom meetings and with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to</p>		

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	<p>PM, flying insects were noted flying in the office the surveyors are working.</p> <p>16. During an observation on 9/16/2021 at 4:01 PM, flying insects were noted flying in the office the surveyors are working.</p> <p>During an interview on 9/9/2021 at 4:05 PM, the Alternate Facility administrator indicated the dialysis center has a contract with Terminex, he indicated they come quarterly for a problem they have had with bed bugs.</p> <p>During an interview on 9/16/2021 at 10:20 AM, the facility administrator indicated they have a contract with Terminex, she indicated they received monthly service from them.</p> <p>17. During an observation on 9/9/2021 at 9:54 AM, small flying insects were observed in the dialysis treatment area near stations #21-26.</p> <p>18. During an observation on 9/9/2021 at 10:08 AM, liquid was on the floor next to machine #23 at station #20.</p>		<p>monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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	19. During an observation on 9/9/2021 at 10:08 AM, liquid was on the floor next to machine #34 at station #19.			
	20. During an observation on 9/9/2021 at 10:05 AM, small flying insects were observed in the dialysis treatment area near stations #21-26 by the walkway.			
	21. During an observation on 9/9/2021 at 10:08 AM, liquid was on the floor next to machine #43 at station #18.			
	22. During an observation on 9/9/2021 at 3:06 PM, a paper towel was observed to be laying on the floor at station #20 in the treatment area, and pieces of garbage were laying on the floor by the sink between station #26 and station #27.			
	23. During an observation on 9/13/2021 at 10:32 AM, loud music could be heard playing in the treatment area near station #32 and could be heard throughout the whole pod.			
	24. During an observation on 9/14/2021 at 12:30 PM, a spider was crawling on the floor in the nurse's station area, and two dead spiders were observed laying on the floor between the door to the treatment area and the outside door.			
	25. During an observation on 9/15/2021 at 11:35 AM, a dried white substance was on the floor behind machine #4 at station #33.			
	During an interview on 9/14/2021 at 3:49 PM, when queried about the insect problem, employee B confirmed the facility has a service agreement with a pest control company. Employee B also confirmed that bedbugs have been a big problem			

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V 0407 Bldg. 00	<p>in the past and the pest control company will do extra visits for those types of pests.</p> <p>During an interview on 9/9/2021 at 10:12 AM, patient #12 confirmed bugs are often seen flying and crawling around the treatment area. A flying insect was observed flying near the patient's face during the interview.</p> <p>494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). Based on observations, record review and interview, the facility failed to ensure patient safety and the visualization of patient access sites were unobscured during 3 of 6 survey observation days.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. An agency document titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" revised April 2021. The policy stated " ... c. The vascular access site, blood line connections and the patient's face should be visible throughout the dialysis treatment...." 2. During an observation on 9/9/2021 at 2:59 PM, there was no staff observed in POD C with two patients receiving dialysis treatment. The facility failed to ensure patients were being monitored during hemodialysis treatments. 3. During an observation on 9/10/2021 at 9:31 AM, patient #21 at station 15 was observed with a 	V 0407	<p>FA held mandatory in-service for all clinical Teammates (TMs) on 9/27/2021. In-service will review of Policy & Procedure # 1-04-11 Vascular Access Monitoring and Surveillance, emphasizing vascular access sites must remain visible at all times during patient treatment to ensure or minimize the risk of needle dislodgement during treatment. TMs must visualize patient's vascular access at a minimum of every 30 minutes, documenting if access is visible or not, and if access is not visible, document action taken including re-educating the patient and requesting that the patient uncover the access, involving Social Worker and MD as necessary. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p>	10/16/2021	

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	<p>blanket covering his access site during hemodialysis treatment.</p> <p>4. During an observation on 9/14/2021 at 11:45 AM, patient #24 at station 5 was observed with access site covered with a blanket during hemodialysis treatment.</p> <p>During an interview on 9/16/2021 at 3:21 PM, the facility administrator indicated the patient's access site should always be in view. She also indicated there should always be someone in the POD watching over the patients.</p> <p>5. In an observation on 9/9/2021 at 9:05 AM, patient #19 at station #21 had their access site covered during treatment. It remained covered when observed at 9:51 AM. The end stage renal dialysis facility failed to ensure visualization of patient's access site during hemodialysis treatment.</p> <p>6. In an observation on 9/10/2021 at 9:17 AM, patient #20 at station #26 had their CVC [central venous catheter] access site covered during hemodialysis treatment.</p> <p>7. In an observation on 9/10/2021 at 9:17 AM, patient #21 at station #25 had their access site covered during hemodialysis treatment.</p> <p>8. In an observation on 9/10/2021 at 9:17 AM, patient #22 at station #24 had their access site covered during hemodialysis treatment.</p>		<p>Clinical Coordinator will re-educate the importance of access visibility with patients and provide educational sheet on uncovering access by 10/16/2021. Acknowledgement of education placed in patient medical record.</p> <p>FA or designee will conduct observational audits weekly x 4 weeks, then monthly. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>		

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V 0500 Bldg. 00	<p>494.80 CFC-PATIENT ASSESSMENT</p> <p>Based on observation, record review and interview the dialysis center failed to ensure the interdisciplinary team assessed patient needs and met the needs of patients, failed to ensure the appropriateness of dialysis prescriptions related to achieving dry weight (see tag 503), and failed to ensure blood pressure and fluid management needs were met (see tag 504).</p> <p>The cumulative effect of these systemic problems has resulted in the dialysis center's inability to ensure provision of quality health care in a safe environment for the condition of participation 42CFR 494.80 Patient Assessment.</p>	V 0500	<p>DaVita Comprehensive Renal Care Gary takes the conditions of coverage very seriously; immediate steps taken to verify patient care management and safety. These actions outlined in depth in the plan of correction for V503, and V504.</p> <p>Governing Body meeting held to review the deficiencies received as result of CMS survey concluded on 9/16/2021. Members of the GB including Medical Director, FA, and ROD have agreed to meet weekly to monitor facilities ongoing progress towards compliance including but not limited to: 1) Verifying patients receive treatment as prescribed, patients are assessed and receive a comprehensive skilled RN assessment of current health status when not meeting prescribed treatment and/or experiencing intradialytic complications with blood pressure and fluid management needs; 2) Verify TMs obtain and document basic data on each patient post dialysis, compare to pre dialysis findings. If abnormal findings or concern is identified post treatment, licensed nurse notified, assesses the patient and collects additional data needed prior to discharge. Licensed Nurse uses</p>	10/16/2021
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V 0503 Bldg. 00	<p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription, Based on observation, record review and interview, the dialysis facility failed to ensure the nurse and physician were aware of changes to patient conditions and ability of the patient to achieve their dry weight to establish appropriateness of the dialysis prescriptions in 5 of 10 in-center hemodialysis patients. (patient #1, #4, #7 #8, #9)</p>	V 0503	<p>clinical judgement based on individual patient needs to determine if any clinical intervention or notification of physician is necessary prior to discharge. GB will review FHM minutes to verify action plans are evaluated for effectiveness, new plans developed as applicable. Once compliance achieved, plan of correction monitored during GB meeting at a minimum of quarterly. This plan of correction also reviewed during monthly FHM and FA will report progress, as well as any barriers to maintaining compliance, supporting documentation included in the meeting minutes.</p> <p>FA held mandatory in-service for all clinical TMs on 10/8/2021. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment, Policy & Procedure #1-14-01 Interdisciplinary Team</p>	10/16/2021

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	<p>The Findings include:</p> <p>1. An agency document received on 9/14/2021, titled "Interdisciplinary Team (IDT) Patient Assessment and Plan of Care" revised October 2020, stated " ... In addition if the expected outcome is not achieved, the interdisciplinary team (or individual IDT member) will adjust the patient's plan of care to achieve the specific goal.... "</p> <p>2. An agency document received on 9/14/2021, titled "Cramps" revised October 2020, stated " ... 1. Assess the patient to determine if symptoms are caused by fluid deficiency. ... 3. Discontinue ultrafiltration rate ... 6. If signs/symptoms of cramping persist contact the nephrologist 7. Document event, orders, and patient response in the patients medical record."</p> <p>3. An agency document titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" revised April 2021, stated " ... Members of the patient care team should report ANY changes in patient conditions or concerns of patient well-being immediately to the nurse at any time Any weight loss from the last post weight ... removal goal not to exceed maximum Ordered by physician ... If patient is above or below 1 kg [kilogram] from the target weight..."</p> <p>4. Clinical record review on 9/15/2021 for patient #1, start of care 3/23/2015, evidenced an agency document titled "Post Treatment" dated 9/9/2021. This document indicated patient #1's pre-treatment blood pressure was 147/72 [average blood pressure is 120/80]. At 9:31 AM, patient #1's blood pressure was evidenced as 92/60, PCT (patient care technician) N documented patient #1</p>		<p>Patient Assessment and Plan of Care emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for verifying patients receive prescribed dose of dialysis and physician orders are followed; 2) Treatment monitoring must be completed at a minimum of every 30 minutes during treatment, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing. TMs must report and document any significant changes or indicators outside of ordered parameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response documented in patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 100% of patient treatment flow sheets x 4 weeks, then 25% weekly x 4 weeks, and</p>	

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	<p>was cramping so the ultra filtration was turned off. This document failed to evidence the nurse was notified of the patient cramping and the ultrafiltration was turned off by PCT N.</p> <p>5. Clinical record review on 9/15/2021 for patient #7, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 9/11/2021. This document indicated patient #7's dry weight [a weight without excess fluid] was 96.5 kg. At completion of treatment patient #7's weight was 97.7 kg. This document failed to evidence patient #7 achieved her dry weight target. This document failed to evidence the nurse and physician were informed patient #7 failed to achieve her target dry weight.</p> <p>6. Clinical record review on 9/15/2021 for patient #8, start of care 5/14/2016, evidenced an agency document titled "Post Treatment" dated 9/4/2021. This document indicated patient #8 demanded to be taken off of treatment due to severe cramping. This document failed to evidence the physician was notified of the cramping and shortened treatment.</p> <p>7. Clinical record review on 9/15/2021 for patient #4, start of care 2/28/2008, evidenced an agency document titled "Post Treatment" dated 9/11/2021. This document indicated patient #7's dry weight was 96.5 kg. At completion of treatment patient #7's weight was 88 kg. This document failed to evidence patient #7 achieved her dry weight target. This document also failed to evidence the nurse and physician were informed patient #4 failed to achieve her target dry weight.</p> <p>During an interview on 9/16/2021 at 3:32 PM, the facility administrator indicated the PCT can give a fluid bolus up to 200 milliliters, but should notify</p>		<p>then monthly on 10% of treatment sheets to verify compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>	

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V 0504 Bldg. 00	<p>the nurse of cramping, She indicated they will monitor the dry weight and ensure there was not a need to change the target weight for the patient who was not achieving their target weight goal.</p> <p>8. Clinical record review on 09/15/2021 for patient #9, admit date 12/12/2017, evidenced facility documents titled "Post Treatment" which failed to evidence the correct blood flow rate (BFR) of 400 mL [milliliters]/min [minute] prescribed by the physician. The facility document dated 08/31/2021 indicated the BFR was 340mL from 12:06 PM until 1:02 PM. Then this document indicated the BFR was increased to 350 mL/min from 1:02 PM until the termination of hemodialysis at 3:26 PM. The facility document dated 09/02/2021 indicated the BFR was 350 mL/min from 11:31 AM until the termination of hemodialysis at 2:48 PM. The facility document dated 9/4/2021 indicated the BFR was 350 mL/min from 11:53 AM until the termination of hemodialysis at 2:41 PM. The facility documents failed to evidence a reason for the changes to the patient's BFR prescription.</p> <p>During an interview on 9/16/2021 at 1:00 PM, employee C confirmed changes to the prescribed BFR should be documented.</p> <p>494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/16/2021
NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY			STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408		
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	<p>must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>Based on observation, record review and interview, the end stage renal dialysis facility failed to ensure patient pre/post and intradialytic blood pressures were being assessed and managed in 10 of 10 in-center hemodialysis records reviewed (Patient #1, #4, #5 #6, #7, #8, #9, #10, #11, #12)</p> <p>The findings include:</p> <p>1. An agency document titled "Hypotension" revised October 2017, indicated special considerations should be taken to prevent hypotensive events from occurring. Take vital signs, decrease or turn of the ultrafiltration rate depending on the patient's condition. Administer normal saline bolus of 100-200 milliliters for severe hypotensive symptoms, Patient care technician can administer up to 200 milliliter and will inform nurse of intervention. continue to monitoring the blood pressure, if the patient continue to show hypotension symptoms notify the physician...."</p> <p>2. An agency document titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" revised April 2021, stated " ... Members of the patient care team should report ANY changes in patient conditions or concerns of patient well-being immediately to the nurse at any time removal goal not to exceed maximum Ordered by physician ... If patient is above or below 1 kg from the target weight .. systolic greater than 190 mm/Hg or less than 90 mm/Hg Diastolic greater than or equal to 100 mm/Hg Difference of 20 mm/Hg increase or decrease from</p>	V 0504	<p>FA held mandatory in-service for all clinical TMs on 10/8/2021. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment, Policy & Procedure #1-14-01 Interdisciplinary Team Patient Assessment and Plan of Care emphasizing 1) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for verifying patients receive prescribed dose of dialysis and physician orders are followed; 2) TMs must obtain and document basic data on each patient at a minimum of pre-treatment, every 30 minutes during treatment, and post treatment; 3) TMs must report and document any significant changes or indicators outside of ordered parameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in patient's medical record. 4) Patient care staff must obtain and document basic data on each</p>	10/16/2021	

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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY	STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408
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	<p>patients last intradialytic treatment reading ... standing systolic BP (blood pressure) is greater than 140 mmHg or less than 90 mmHg standing diastolic BP is greater than 90 mmHg or less than 50 mmHg ... sitting systolic BP greater than 90 mmHg or less than 90 mmHg sitting diastolic BP greater than 90 mmHg or less than 50 mmHg...."</p> <p>3. Record review on 9/15/2021 for patient #1, start of care 3/23/2015, evidenced an agency document titled "Post Treatment" dated 8/28/2021. This document indicated patient #1's pre-treatment blood pressure was 133/64 (a normal blood pressure is 120/80). At 8:29 AM, patient #1's blood pressure was 92/63, at 8:59 AM, patient #1's blood pressure was 87/57, at 9:01 AM, patient #1's blood pressure was 84/60, and when treatment was terminated at 9:36 AM, the patient's blood pressure was 94/50. This document failed to evidence the nurse was notified of patient #1's low blood pressure during treatment.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/28/2021. This document indicated patient #1's target weight was 97 kg (kilograms). Post treatment data collection evidenced patient #1's weight at the end of the treatment was 95.9 kg. This document failed to evidence the physician was notified of the patient being 1.1 kg under target weight.</p> <p>Record review on 9/15/2021 for patient #1, evidenced an agency document titled "Post Treatment" dated 9/11/2021. This document indicated patient #1's pre-treatment blood pressure was 133/68. At 7:29 AM, patient #1's blood pressure was 87/58, at 7:31 AM, patient #1's blood pressure was 93/61, at 7:59 AM, patient #1's blood pressure was 78/53. This document failed to evidence the nurse was notified of patient #1's</p>		<p>patient post dialysis and compare to pre dialysis findings. If abnormal finding or concern identified, post treatment including if patient is above or below 1 kg from the target weight, this needs reported to the licensed nurse. The licensed nurse will assess the patient prior to discharge. Licensed nurse will use his/her clinical judgment based on individual patient needs to determine if any clinical interventions or notification of physician is necessary prior to discharge of the patient from the facility. All findings, interventions and patient response documented in patient's medical record. 5) Patient comprehensive assessment criteria includes, but is not limited to, evaluation of: dialysis prescription, blood pressure, and fluid management needs. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 100% of patient treatment flow sheets x 4 weeks, then 25% weekly x 4 weeks, and then monthly on 10% of treatment sheets to verify compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed</p>	

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	<p>low blood pressure.</p> <p>4. Record review on 9/14/2021 for patient #7, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 9/9/2021. This document evidenced the patients blood pressure at the beginning of treatment was 117/59, at the end of treatment patient #7's blood pressure was 158/78. This document failed to evidence the physician was notified of the patient's high systolic blood pressure.</p> <p>Record review on 9/14/2021 for patient #7, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 9/7/2021. This document evidenced the patients blood pressure at the beginning of treatment was 128/62, during treatment patient #7's blood pressure was elevated to 160/78, there failed to be evidence the nurse was notified of the elevated blood pressure. At the end of treatment patient #7's blood pressure was 158/78. This document failed to evidence the physician was notified of the patient's high systolic blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/4/2021. This document indicated patient #7's blood pressure at the completion of treatment was 170/76 and the patient was instructed to take blood pressure medication. This document failed to evidence the physician was notified of the high systolic blood pressure.</p> <p>5. Record review on 9/14/2021 for patient #6, start of care 7/28/2015, evidenced an agency document titled "Post Treatment" dated 8/23/2021. This document evidenced patient #6's blood pressure at the end of treatment was 150/81. This document failed to indicate the nurse was notified of the</p>		<p>during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 10/12/2021
FORM APPROVED
OMB NO. 0938-039

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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY	STREET ADDRESS, CITY, STATE, ZIP CODE 4802 BROADWAY GARY, IN 46408
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	<p>elevated blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 9/3/2021. This document evidenced patient #6's blood pressure, sitting at the end of treatment was 155/84, and standing blood pressure was 156/83. This document failed to evidence the nurse was notified of the elevated blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 9/6/2021. This document evidenced patient #6's standing blood pressure was 145/82. This document failed to evidence the nurse was notified of the elevated blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 9/13/2021. This document indicated patient #6's blood pressure at the end of treatment was 150/65. This document failed to evidence the nurse was notified of the elevated systolic blood pressure.</p> <p>6. Record review on 9/15/2021 for patient #8, start of care 5/14/2016, evidenced an agency document titled "Post Treatment" dated 9/14/2021. This document evidenced patient #8's pre treatment sitting blood pressure was 221/105 and standing was 232/112 at 6:35 AM, treatment was initiated with blood pressure 197/93, at 7:00 AM, patient #8's blood pressure was 220/108. At the completion of treatment patient #8's blood pressure was 195/104. This document failed to evidence the physician was notified of the patient's high blood pressure at the completion of treatment.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/11/2021.</p>			

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	<p>This document evidenced patient #8's pre treatment sitting blood pressure was 235/113 and standing blood pressure was 225/113. At the completion of treatment patient #8's blood pressure was 186/82. This document failed to evidence the physician was notified of the patient's high blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/7/2021. This document evidenced patient #8's pre treatment sitting blood pressure was 198/88 and standing blood pressure was 199/92. At the completion of treatment patient #8's blood pressure was 214/97. This document failed to evidence the physician was notified of the patient's high blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/31/2021. This document evidenced patient #8's pre treatment sitting blood pressure was 232/107 and standing blood pressure was 193/101. At the completion of treatment patient #8's blood pressure was 193/87. This document failed to evidence the physician was notified of the patient's high blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/28/2021. This document indicated patient #8's pre treatment sitting blood pressure was 224/100 and standing blood pressure was 229/109. At the completion of treatment patient #8's blood pressure was 210/94. This document failed to evidence the physician was notified of the patient's high blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/26/2021.</p>			

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	<p>This document indicated patient #8's pre treatment sitting blood pressure was 189/89 and standing blood pressure was 201/92. At the completion of treatment patient #8's blood pressure was 184/92. This document failed to evidence the physician was notified of the high blood pressure.</p> <p>7. Record review on 9/14/2021 for patient #4, start of care 2/28/2008, evidenced an agency document titled "Post Treatment" dated 9/1/2021. This document evidenced patient #4's pre treatment sitting blood pressure was 72/46 and standing blood pressure was 78/50. Patient #4's blood pressure at 6:32 AM was 81/54, at 7:02 AM, blood pressure was 70/46, at 7:32 AM, blood pressure was 70/44, at 8:03 AM, blood pressure was 73/42, at 8:33 AM, blood pressure was 68/47, at 8:59 AM blood pressure was 78/44, at 9:02 AM, blood pressure was 77/40, at 9:32 AM, blood pressure was 69/46 and at the termination of treatment at 10:02 AM, the blood pressure was 78/52. There was a note evidenced in the document which indicated patient #4 forgot to bring midodrine [medication used to treat low blood pressure] for blood pressure. This document failed to evidence the physician was notified of the patient's low blood pressure throughout the treatment.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/6/2021. This document evidenced patient #4's pre treatment sitting blood pressure was 80/56 and standing blood pressure was 77/46. At the termination of treatment, patient #4's blood pressure was 78/44. There was a note evidenced in the document which indicated patient #4 forgot to bring midodrine for blood pressure. This document failed to evidence the physician was notified of the patient's low blood pressure.</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/16/2021
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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY	STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408
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	<p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/13/2021. This document indicated patient #4's pre treatment sitting blood pressure was 71/44 and standing blood pressure was 73/52. At the termination of treatment patient #4's blood pressure was 78/44. There was a note evidenced in the document which indicated patient #4 forgot to bring midodrine for blood pressure. This document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 9/3/2021. This document evidenced patient #4's blood pressure when treatment was initiated was 74/49. At the termination of treatment patient #4's blood pressure was 64/43. This document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/20/2021. This document indicated patient #4's blood pressure when treatment was initiated was 73/45. At the termination of treatment patient #4's blood pressure was 85/62. This document failed to evidence the physician and nurse were notified of the patient's low blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/23/2021. This document indicated patient #4's blood pressure, when treatment was initiated, was 84/58. At the termination of treatment patient #4's blood pressure was 74/57. This document failed to evidence the physician was notified of the patient's low blood pressure.</p>			

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	<p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/25/2021. This document indicated patient #4's blood pressure, when treatment was initiated, was 66/47. At the termination of treatment patient #4's blood pressure was 74/57. This document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/27/2021. This document indicated patient #4's blood pressure, when treatment was initiated, was 66/46. At the termination of treatment patient #4's blood pressure was 68/41. This document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>Record review on 9/15/2021, evidenced an agency document titled "Post Treatment" dated 8/29/2021. This document indicated patient #4's blood pressure, when treatment was initiated, was 80/53. At the termination of treatment patient #4's blood pressure was 70/46. This document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>8. Record review on 9/14/2021 for patient #5, start of care 2/18/15, evidenced an agency document titled "Post Treatment" dated 9/7/2021. This document evidenced patient #5's blood pressure at the initiation of treatment, at 10:54 AM, was 139/66, at 11:32 AM, patient #5's blood pressure was 176/117, and at 11:36 AM, blood pressure was 165/114. This document failed to evidence the physician was notified of the patient's high blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 9/7/2021.</p>						

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 09/16/2021
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	<p>Patient #5 had a pre-treatment blood pressure of 119/82. The document indicated patient #5's blood pressure had dropped to 63/45. The document failed to evidence the nurse was notified of the low blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 9/2/2021. Patient #5 had a pre-treatment blood pressure of 130/89. This document indicated patient #5's blood pressure had dropped to 72/56. The document failed to evidence the nurse was notified of the patient's low blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 8/26/2021. Patient #5 had a pre-treatment blood pressure of 98/59. This document indicated patient #5's blood pressure had dropped to 74/57. The document failed to evidence the nurse was notified of the patient's low blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 8/28/2021. Patient #5 had a pretreatment blood pressure of 136/91. The document indicated patient #5's blood pressure had dropped to 74/57. The document failed to evidence the nurse was notified of the patient's low blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 8/24/2021. Patient #5 had a pretreatment blood pressure of 151/101. This document indicated patient #5's blood pressure had dropped to 79/58. The document failed to evidence the physician was notified of the patient's low blood pressure.</p> <p>Record review on 9/14/2021, evidenced an agency document titled "Post Treatment" dated 8/21/2021.</p>				

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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	<p>Patient #5 had a pretreatment blood pressure of 118/83. This document indicated patient #5's blood pressure had dropped to 69/54. The document failed to evidence the nurse was notified of the patient's low blood pressure.</p> <p>During an interview on 9/16/2021 at 1:22 PM, the facility administrator indicated the nurse would need to assess the patient and use nursing judgement on calling the physician. The facility administrator also indicated they have documented blood pressure issues and they have improved, but they need to be more consistent.</p> <p>9. Clinical record review on 09/15/2021 for patient #11, admit date 03/23/2018, evidenced a facility document titled "Post Treatment" dated 09/10/2021. This document indicated the patient's blood pressure at 10:00 AM, was 45/35 and at 10:20 AM the blood pressure was documented as 84/47. The very low blood pressure recorded at 10:00 AM (45/35), failed to be re-assessed for 20 minutes by the registered nurse. The registered</p>			

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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	<p>nurse failed to notify the patient's physician of the low blood pressures.</p> <p>Clinical record review on 9/15/2021 for patient #11, admit date 3/23/2018, evidenced a facility document titled "Post Treatment" dated 08/27/2021. This document indicated the patient's blood pressure at 8:32 AM was 126/75, at 9:02 AM was 91/66, at 9:32 AM was 111/40, and at end of treatment at 10:27 AM was 93/59. There failed to be any evidence in the clinical record that the registered nurse or physician were notified of the 20 point decrease in blood pressure in accordance with the facility policy.</p> <p>10. Clinical record review on 9/15/2021 for patient #12, admit date 5/28/2020, evidenced a facility document titled "Post Treatment" dated 9/2/2021. This document evidenced the patient's blood pressure at 8:01 AM was 175/92, and at 8:31 AM it was 130/75. There was no documentation from a Registered Nurse until 10:01 AM. There failed to be evidence of notification of a 20 point decrease in blood pressure for 90 minutes.</p> <p>Clinical record review on 9/15/2021 for patient #12, admit date 5/28/2020, evidenced a post treatment sheet dated 8/28/2021. This document evidenced the patient's blood pressure at 8:30 AM was 178/91, at 9:01 AM was 149/81, at 9:30 AM was 169/93, at 10:00 AM was 194/95, and at 10:31 AM was 171/101. There failed to be evidence the registered nurse was notified of a 20 point blood pressure increase in accordance with the facility policy.</p> <p>11. Clinical record review on 9/15/2021 for patient #9, admit date 12/12/2017, evidenced a facility document titled "Post Treatment" dated 8/19/2021. This document evidenced the patient's blood</p>			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 152521	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/16/2021
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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY	STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408
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V 0543 Bldg. 00	<p>pressure at 3:01 PM was 132/75. At 3:31 PM the patient's blood pressure was 103/71. There failed to be evidence the registered nurse was notified of a 20 point blood pressure decrease in accordance with the facility policy.</p> <p>12. Clinical record review on 9/15/2021 for patient #10, admit date 11/24/2017, evidenced a facility document titled "Post Treatment" dated 9/3/2021. This document evidenced the patient's blood pressure at 6:30 PM was 137/56. At 7:00 PM the patient's blood pressure was 108/57. There failed to be evidence the registered nurse was notified of a 20 point blood pressure decrease in accordance with the facility policy.</p> <p>Clinical record review on 9/15/2021 for patient #10, admit date 11/24/2017, evidenced a facility document titled "Post Treatment" dated 8/30/2021. This document evidenced the patient's blood pressure at 6:32 PM was 161/81. At 7:02 PM the patient's blood pressure was 130/66. There failed to be evidence the registered nurse was notified of a 20 point blood pressure decrease in accordance with the facility policy.</p> <p>494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; Based on observation, record review and interview, the end stage renal dialysis facility failed to ensure the patients volume status was managed per policy and physician orders in 3 of 10 in-center hemodialysis clinical records reviewed (patients #1, #5, #7), and failed to ensure</p>	V 0543	FA held mandatory in-service for all clinical TMs on 10/8/2021. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing	10/16/2021

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NAME OF PROVIDER OR SUPPLIER COMPREHENSIVE RENAL CARE- GARY			STREET ADDRESS, CITY, STATE, ZIP COD 4802 BROADWAY GARY, IN 46408		
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	<p>a post treatment assessment was completed in 1 of 10 in-center hemodialysis clinical records reviewed. (patient #10)</p> <p>1. An agency document titled "Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment" revised April 2021 stated " ... Members of the patient care team should report ANY changes in patient conditions or concerns of patient well-being immediately to the nurse at any time removal goal not to exceed maximum Ordered by physician ... The nursing assessment will be performed and documented by a licensed nurse or if permitted by law a Licensed Practical Nurse ... A physical assessment of the patient which includes: Apical heart rate and rhythm ... Evaluation of volume status including edema Post treatment Data Assessment the PCT or nurse will obtain and document basic data on each patient post dialysis and compare to pre dialysis findings."</p> <p>2. An agency policy titled "Fluid Removal Calculations" revised October 2019 stated "Materials required Electronic treatment record Calculator (optional) conversion table 1 Kg (Kilogram) =1000 ml (milliliter) 1 lb (pound) = 453 ml Procedure 1. Determine the patient intradialytic fluid removal by subtracting the estimated target weight from the pre dialysis weight Convert to fluid equivalents. 2. Add the total amount of fluids to be received (e.g. prime, rinse back, and oral fluids and IV meds) to the intradialytic weight removal goal to determine the total amount of fluid to be removed. 3. For Volumetric Controlled Fluid removal Dialysis delivery systems: Program the amount to be removed and the treatment length in the ultrafiltration controller/calculator. Example 1. Pre dialysis weight 46 kg - 43 kg = 3 kg x 1000</p>		<p>Assessment and Policy & Procedure #1-14-01 Interdisciplinary Team Patient Assessment and Plan of Care emphasizing 1) The interdisciplinary Team must provide necessary care and services to manage patients Target Weight and verify patients post treatment assessment is completed; 2) TMs must verify patient dialysis prescription, and set all treatments as prescribed. Nurses are responsible for verifying patients receive prescribed dose of dialysis and physician orders are followed; 3) Treatment monitoring must be completed at a minimum of every 30 minutes during treatment, evaluation and documentation must include at a minimum patient's blood pressure, heart rate, blood and dialysate flows, arterial & venous pressures, fluid removal and/or replacement, vascular access status, line connections, patient status and subjective wellbeing. TMs must report and document any significant changes or indicators outside of ordered parameters to licensed nurse, licensed nurse must take appropriate action, contact physician if warranted, and follow physician orders. All findings, interventions and patient response will be documented in patient's medical record. 4) Patient care staff must obtain and</p>		

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	<p>ml/kg = 3000 ml 2. Fluid gain 3000ml saline prime 200 ml rinse back 200 ml oral fluids 250 ml IV meds 150 ml 3800 total fluid to be removed."</p> <p>3. Clinical record review on 9/15/2021 for patient #1, start of care 3/23/2015, evidenced an agency document titled "Post Treatment" dated 9/2/2021. This document indicated patient #1 arrived with 1.7 kg (kilograms) above target weight. Patient #1 requested an additional 300 milliliters of fluid to be removed, goal was set for a total of 2.5 liters. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/15/2021 for patient #1, evidenced an agency document titled "Post Treatment" dated 9/11/2021. This document indicated patient #1 arrived with 2.3 kg (kilograms) above target weight. Patient #1 requested an additional 700 milliliters of fluid to be removed for a total of 3.5 liters. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/15/2021 for patient #1, evidenced an agency document titled "Post Treatment" dated 9/14/2021. This document indicated patient #1 arrived with 2.1 kg (kilograms) above target weight. Patient #1 requested an additional 1 Liter of fluid to be removed for a total of 3.1 liters. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>4. Clinical record review on 9/14/2021 for patient #7, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 8/26/2021. This document indicated patient #7 arrived 1.5 kg above target weight, 2.0 liters was removed per patient request. Patient #7 left 0.4 kg under dry</p>		<p>document basic data on each patient post dialysis and compare to pre dialysis findings. If abnormal finding or concern identified, post treatment including if patient is above or below 1 kg from the target weight, this needs reported to the licensed nurse. The licensed nurse will assess the patient prior to discharge. Licensed nurse will use his/her clinical judgment based on individual patient needs to determine if any clinical interventions or notification of physician is necessary prior to discharge of the patient from the facility. All findings, interventions and patient response documented in patient's medical record. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 100% of patient treatment flow sheets x 4 weeks, then 25% weekly x 4 weeks, and then monthly on 10% of treatment sheets to verify compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>	

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	<p>weight. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #7 evidenced an agency document titled "Post Treatment" dated 9/2/2021. This document indicated patient #7 arrived 1.0 kg above target weight, Patient #7 requested an additional 500 milliliter to be removed, goal was set at 2.0 liters. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #7 evidenced an agency document titled "Post Treatment" dated 8/24/2021. This document indicated patient #7 arrived 1.9 kg above target weight, 2.1 liters was removed per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #7 evidenced an agency document titled "Post Treatment" dated 9/4/2021. This document indicated patient #7 arrived 1.9 kg above target weight, 2.5 liters was removed per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #7 evidenced an agency document titled "Post Treatment" dated 9/9/2021. This document indicated patient #7 arrived 0.9 kg above target weight, 1.5 liters were removed per patient request. Patient #7 left 0.3 kg under dry weight. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #7 evidenced an agency document titled "Post</p>			

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	<p>Treatment" dated 9/7/2021. This document indicated patient #7 arrived 1.4 kg above target weight, 2.0 liters was removed per patient request. Patient #7 left 0.7 kg under dry weight. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>5. Clinical record review on 9/14/2021 for patient #5, start of care 2/18/2015, evidenced an agency document titled "Post Treatment" dated 8/24/2021. This document indicated patient #5 arrived 2.9 kg above target weight, goal set at 3.5 Liters per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #5 evidenced an agency document titled "Post Treatment" dated 8/21/2021. This document indicated patient #5 arrived -0.9 kg above target weight, goal set at 2.5 Liters per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #5 evidenced an agency document titled "Post Treatment" dated 9/4/2021. This document indicated patient #5 arrived 0.7 kg above target weight, goal set at 1.6 Liters per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #5 evidenced an agency document titled "Post Treatment" dated 9/7/2021. This document indicated patient #5 arrived 1.4 kg above target weight, goal set at 2.5 Liters per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p>			

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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FORM APPROVED

OMB NO. 0938-039

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	<p>Clinical record review on 9/14/2021 for patient #5 evidenced an agency document titled "Post Treatment" dated 8/31/2021. This document indicated patient #5 arrived -0.2 kg above target weight, goal set at 2.6 Liters per patient request. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>Clinical record review on 9/14/2021 for patient #5 evidenced an agency document titled "Post Treatment" dated 9/9/2021. This document indicated patient #5 arrived 0.8 kg above target weight, goal set at 2.0 Liters per patient request. Patient #5 was 0.7 kg under dry weight post treatment. The document failed to evidence the nurse had an order from the physician to remove extra fluid.</p> <p>During an interview on 9/16/2021 at 3:23 PM indicated when the fluid removal is programmed they include 200 ml for prime and 300 ml for rise back the nurse should be calling the physician and obtaining an order to remove any extra fluid the patient would want removed.</p> <p>5. Clinical record review on 9/15/2021 for patient #10, admit date 11/24/2017, evidenced facility documents titled "Post Treatment" dated 8/16/2021 - 9/10/2021. Record review evidenced a</p>			

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V 0587 Bldg. 00	<p>post treatment sheet dated 9/6/2021. This document evidenced the absence of a post-treatment assessment by the Registered Nurse.</p> <p>494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS The dialysis facility must - (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record.</p> <p>Based on record review and interview, the end stage renal dialysis facility failed to obtain self-care medical records from all home care patients in 1 of 2 home peritoneal dialysis patients, at least every 2 months. (Patient #3)</p> <p>The findings include:</p> <p>An agency policy titled "Pre-Intra-Post Treatment Collection, Monitoring and Nursing Assessment" revised April 2021 stated "Purpose to obtain and document baseline and ongoing information about the patient before, during and after dialysis treatment through data collection and nursing assessment. This information will be used in planning an documenting the patient's dialysis treatment...."</p> <p>Clinical record review for patient #3 on 9/14/2021, evidenced an untitled agency document dated 3/2/2021, which had a note that stated "Patient did not bring treatment records" signed by RN (Registered Nurse) R.</p> <p>Clinical record review for patient #3 on 9/14/2021,</p>	V 0587	<p>Interdisciplinary Team (IDT) will meet with home patient #3 on 10/15/2021; Nephrologist along with other IDT members to re-educate patient necessity of completing Daily Home treatment records to provide continuity of care, patient instructed to complete documentation of each treatment procedure on the Daily Home Treatment Record and provide to PD RN during clinic visits, Patient placed on Clairia Home Choice all treatments cross over to Baxter portal for RN review documentation of meeting and re-education placed in patient's medical record.</p> <p>FA to hold mandatory in-service for home TMs to review Policy & Procedure #5-01-29 Daily Home Treatment Record. TMs instructed that all Daily Home Treatment</p>	10/16/2021

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	<p>failed to evidence treatment records for the month of April.</p> <p>Clinical record review for patient #3 on 9/14/2021, evidenced an untitled agency document dated 5/27/2021, which had a note that stated "Patient did not bring records" signed by RN (Registered Nurse) R.</p> <p>Clinical record review for patient #3 on 9/14/2021, evidenced an untitled agency document dated 6/9/2021, which had a note that stated "Patient to bring tx [treatment] records to visit with Doctor" signed by RN (Registered Nurse) R.</p> <p>Clinical record review for patient #3 on 9/14/2021, evidenced an untitled agency document dated 8/4/2021, which had a note that stated "Patient brought in, but no treatments were uploaded for the month of August" signed by RN (Registered Nurse) R.</p> <p>During an interview on 9/16/2021 at 12:10 PM, the facility administrator indicated patient #3 has been going through a lot and they have had a difficult time with compliance with this patient.</p>		<p>Records must be maintained as a part of the patient's medical record and reviewed for accuracy. Patients must bring completed records to each clinic visit and TMs must review, evaluate, initial the data recorded on the Daily Home Treatment Record and document findings the medical record. In the absence of Home Records, the licensed nurse TM must review importance of home records, the patient's responsibility to provide them, and issue new record sheets. Educational attempts documented in the medical record. Plans of care for identified non-compliant patients established to address adherence issues. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee will conduct flow sheet audits monthly on 10% of PD patient daily home treatment records.</p> <p>FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>		

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V 0726 Bldg. 00	<p>494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.</p> <p>Based on record review and interview, the end stage renal dialysis facility failed to ensure clinical records were accurate in 2 of 10 in-center dialysis records reviewed (Patient #5, #7)</p> <p>The findings include:</p> <p>1. Record review on 9/14/2021 for patient #7, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 8/24/2021. This document evidenced patient #7's dry weight was 98.2 kg (kilograms), at the end of treatment patient #7's weight was 98.2. There was a subsection titled "POSTTREATMENT COLLECTION DATA AND ASSESSMENT" completed by RN (registered nurse) I which stated "PT [patient] BELOW DRY WEIGHT NO DISTRESS NOTED." The nurse failed to ensure the document contained accurate information regarding the patient #7's post treatment weight.</p> <p>2. Record review on 9/14/2021 for patient #5, start of care 2/16/2015, evidenced an agency document</p>	V 0726	<p>FA held mandatory in-service for all clinical TMs on 9/15/2021. In-service included review of Policy & Procedure #1-03-08 Pre-Intra-Post Treatment Data Collection, Monitoring and Nursing Assessment emphasizing 1) TMs must obtain and document basic data on each patient at a minimum of pre-treatment, every 30 minutes during treatment, and post treatment. 2) All entries in medical record must be accurate; document accurately, concisely, and completely. Documentation must be complete, accurate for treatment and services provided as well as patient responses to care. Verification of attendance at in-service will be evidenced by TMs signature on in-service sheet.</p>	10/16/2021

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	<p>titled "Post Treatment" dated 8/24/2021. This document evidenced patient #7's dry weight was 91.5 kg (kilograms), the patient's pre-treatment weight was documented as 36.3 kg at the end of treatment patient #7's weight was 91.7 kg. This document indicated the calculated target removal was 55.20 kg and the patients weight gain was 56.10 kg. This document failed to evidence the correct pre-treatment weight.</p> <p>During an interview on 9/16/2021 at 3:27 PM, the facility administrator indicated all records should be complete and accurate. She indicated the nurse may have looked at the temperature line when she wrote the note. She also indicated patient #7's weight was most likely a typing error.</p>		<p>FA or designee to conduct daily audits on 100% of patient treatment flow sheets x 4 weeks, then 25% weekly x 4 weeks, and then monthly on 10% of treatment sheets to verify compliance. FA will review results of audits with Medical Director during monthly FHM, minutes will reflect. FHM minutes and activities reviewed during Governing Body meetings to monitor ongoing compliance.</p> <p>FA & Medical Director are responsible for compliance with this plan of correction</p>		