

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

PRINTED: 11/18/2021

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 11/05/2021
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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: 11/4/2021 to 11/5/2021</p> <p>Facility #: 005980</p> <p>CCN: 152521</p> <p>Stations: 40, includes the isolation room</p> <p>ICHD Patients: 81</p> <p>Home Peritoneal Dialysis patients: 10</p> <p>Total Census: 91</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 visit was a post-condition revisit survey for an ESRD recertification survey conducted on 09/09/2021 - 09/15/2021.</p> <p>Survey Dates: 11/4/2021 to 11/5/2021</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 disclosable 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>Facility: IN005980</p> <p>Provider: 152521</p> <p>Current Census: 91 patients</p> <p>81 Incenter Hemodialysis patients 10 Home Peritoneal Dialysis patients</p> <p>A recertification survey was conducted on 9/9/2021 -9/15/2021 Comprehensive Renal Care - Gary was found to be out of compliance with Conditions of Participation 42CFR 494.80 Patient Assessment. During this survey 1 condition was removed and 3 standards were recited.</p> <p>Quality Review Completed 11/12/2021</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> <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 7 of 10 hand hygiene observations completed. (PCT L, PCT F, PCT G, PCT H)</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</p>	V 0113	<p>V113</p> <p>Facility Administrator (FA) held mandatory in-service for all clinical Teammates (TMs) on 11/15/2021 reviewing Policy & Procedure # 1-05-01: Infection Control for Dialysis Facilities and 11/15/2021 reviewing Policy & Procedure 1-05-01A Use of Alcohol-Based Hand Rubs, 1-05-01B Handwashing. In-service emphasized 1) TMs must wear</p>	12/15/2021

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	<p>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 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</p>		<p>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 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</p>	

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	<p>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. During an observation on 11/4/2021 at 11:05 AM, PCT [patient care technician] L was observed initiating dialysis through the CVC (central venous catheter) for patient #12 at station 15. During this care PCT L cleansed the CVC with antimicrobial swabs, removed her gloves, and removed a new pair of gloves from a box on the cart in the center of the pod. PCT L failed to wash her hands prior to reaching into the box for a new pair of gloves.</p> <p>4. During an observation on 11/4/2021 at 10:30 AM, PCT L was observed initiating dialysis through a fistula (an abnormal connection between an artery and a vein) on patient #17 at station 23. During this care PCT L took labs to the lab refrigerator, sanitized her hands, donned a pair of gloves, and looked over the patient's clip board. PCT L flipped the paper over on the clipboard and hung the clipboard on the IV (intravenous) pole. She removed her gloves and touched one key on the keyboard, failing to wash or sanitize her hands before touching the keyboard. She used hand sanitizer on her palms failing to sanitize all surfaces of her hands and began to type on the keyboard.</p> <p>5. During an observation on 11/4/2021 at 1:15 PM, PCT F was observed discontinuing dialysis for patient #3 at station #25. PCT F sanitized her hands, donned gloves, obtained labs and disconnected the arterial line, then cleansed the</p>		<p>responsible for compliance with this plan of correction</p> <p>Completion date: 12/15/2021</p>				

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	<p>hub. PCT F reinfused the extracorporeal circuit, failing to remove her gloves and wash her hands after reinfusing the extracorporeal circuit. She disconnected the lines cleaned the hub and gave heparin (medication to prevent clotting). PCT F disconnected the syringe and put the end cap on the patient's CVC lines and wrapped her lines in sterile pad and taped the dressing.</p> <p>6. During an observation on 11/4/2021 at 11:21 AM, PCT H was observed initiating dialysis for patient #14 at station #16. PCT H was observed typing on the computer. PCT H donned a pair of gloves after typing on the computer, failing to wash or sanitize his hands prior to donning gloves. After initiation of dialysis PCT H removed his gloves and removed supplies from clean cabinet failing to wash his hands prior to entering the clean cabinet.</p> <p>During an interview on 11/4/2021 at 3:10 PM the administrator indicated when using hand sanitizer teammates are to use friction and rub all surfaces of their hands until their hands are dry. The administrator indicated hands should be washed when going from dirty to clean areas, when initiating treatment, after touching dialysis machine and before and after taking off their gloves.</p> <p>7. During an observation on 11/4/2021 at 11:55 AM, PCT [patient care technician] G was observed touching the dirty pillow and barrier under patient #17's arm without wearing any gloves. PCT G then took two gloves from the box of gloves on the computer cart, placed them on the dirty barrier next to patient #17's arm, performed hand hygiene with alcohol-based hand rub, picked up the gloves from the dirty barrier, and put them on her hands.</p> <p>8. During an observation on 11/4/2021 at 11:58</p>			

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V 0503 Bldg. 00	<p>AM, PCT G was observed touching the top of a dialysis machine with her ungloved left hand. The PCT failed to don a glove on each hand prior to touching the dialysis machine.</p> <p>9. During an observation on 11/4/2021 at 1:25 PM, PCT G was observed touching and moving a clean chair and dialysis machine #4 at station #1 while wearing only one glove on one hand. The PCT failed to don a glove on each hand prior to touching the dialysis machine.</p> <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 record review and interview, the 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 1 of 6 incenter hemodialysis patients. (patient #2)</p> <p>The findings include:</p> <p>An agency document 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>An agency document titled "Pre-Intra-Post Treatment Data Collection, Monitoring and</p>	V 0503	<p>V503</p> <p>FA held mandatory in-service for all clinical TMs on 11/15/2021. 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</p>	12/15/2021

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	<p>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] form the target weight..."</p> <p>Clinical record review on 11/4/2021 for patient #2, start of care 5/1/2014, evidenced an agency document titled "Post Treatment" dated 11/2/2021. This document indicated patient #2's dry weight [a weight without excess fluid] was 76.5 kg. At completion of treatment patient #2's weight was 78.8 kg. This document failed to evidence documentation the nurse and physician were informed patient #2 failed to achieve his dry weight.</p> <p>During an interview on 11/5/2021 at 3:31 PM, the administrator indicated the nurse and the physician need to be notified if the patient was not meeting their target dry weight goal. The PCT (patient care technicians) should notify the nurse if the patient was over or under 1 kg per agency policy.</p>		<p>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 documented in patient's medical record. 4) Patient care staff must obtain and 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. 5) Patient comprehensive assessment criteria includes, but is not be limited to, evaluation of: dialysis prescription, blood pressure, and fluid management needs. Verification of attendance</p>		

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V 0504 Bldg. 00	<p>494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS</p> <p>The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>Blood pressure, and fluid management needs.</p> <p>Based on record review and interview, the dialysis facility failed to ensure patient pre/post and intradialytic blood pressures were being assessed and managed in 4 of 7 incenter hemodialysis records reviewed (#2, #3, #6, #8).</p> <p>The findings include:</p>	V 0504	<p>at in-service will be evidenced by TMs signature on in-service sheet.</p> <p>FA or designee to conduct daily audits on 25% of patient treatment flow sheets x 4 weeks, then 10% 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> <p>Completion date: 12/15/2021</p>	12/15/2021	

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	<p>1. An agency document titled "Hypotension" revised October 2017, stated " ... 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 [millimeter / mercury] or less than 90 mm/Hg Diastolic greater than or equal to 100 mm/Hg Difference of 20 mm/Hg increase or decrease from 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 11/4/2021, for patient #2, start of care 10/29/2015, evidenced an agency document titled "Kardex." This document indicated if the patient's pretreatment systolic [top number] blood pressure was greater than 140 to notify the RN (registered nurse).</p>		<p>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) 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. 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 documented in patient's medical record. Emphasis placed on TMs informing RN when patients target weight not achieved above or below 1 kilogram from the target weight. 4) Patient comprehensive assessment criteria includes, but is not be limited to, evaluation of: dialysis prescription, blood pressure, and</p>	

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	<p>Record review on 11/4/2021 for patient #2, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 10/19/2021. This document evidenced the patient's blood pressure pretreatment was 153/73 (a normal blood pressure reading is 120/80). At the initiation of treatment patient #2's blood pressure was 174/70. During treatment the patient's blood pressure dropped to 80/51. At the end of treatment the patient's blood pressure was 90/59 This document failed to evidence documentation the nurse and physician were notified of the patient's blood pressures.</p> <p>Record review on 11/4/2021 for patient #2, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 10/21/2021. This document evidenced the patient's blood pressure pretreatment was 164/64. At the initiation of treatment patient #2's blood pressure was 174/82. During treatment the patient's blood pressure was 201/94. This document failed to evidence documentation the nurse and physician were notified of the patient's high blood pressures.</p> <p>Record review on 11/4/2021 for patient #2, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 10/26/2021. This document evidenced the patient's blood pressure at the beginning of treatment was 172/73, at the end of treatment patient #2's blood pressure was 93/44. This document failed to evidence documentation the nurse and physician were notified of the patient's blood pressures.</p> <p>Record review on 11/4/2021 for patient #2, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 10/28/2021. This document evidenced the patient's blood pressure pretreatment was 158/75. At the initiation of</p>		<p>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 25% of patient treatment flow sheets x 4 weeks, then 10% 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> <p>Completion date: 12/15/2021</p>		

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	<p>treatment patient #2's blood pressure was 180/80. During treatment the patient's blood pressure dropped to 82/47. At the end of treatment the patient's blood pressure was 92/52 This document failed to evidence documentation the physician was notified of the patient's blood pressures.</p> <p>Record review on 11/4/2021 for patient #2, start of care 10/29/2015, evidenced an agency document titled "Post Treatment" dated 10/30/2021. This document evidenced the patient's blood pressure pretreatment was 169/79. During treatment the patient's blood pressure was 191/84. At the end of treatment the patient's blood pressure was 96/56. This document failed to evidence documentation the physician was notified of the patient's blood pressures.</p> <p>During an interview on 11/4/2021 at 3:26 PM, the administrator indicated the policy says to notify the nurse if the systolic blood pressure is over 180 pretreatment. She indicated the note to notify the nurse of any systolic blood pressure above 140 should be a trigger in the system to alert the staff.</p> <p>During an interview on 11/4/2021 at 3:30 PM, RN I indicated the physician had the patient holding his blood pressure medications until after his dialysis treatments.</p> <p>4. Record review on 11/4/2021 for patient #3, start of care 9/5/2019, evidenced an agency document titled "Post Treatment" dated 10/21/2021. This document evidenced the patient's blood pressure at 10:58 AM, was 192/129. At 11:33 AM, the patient's blood pressure was 200/173. This document failed to evidence documentation the nurse notified the physician of the high blood pressures.</p>				

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCY (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	<p>During an interview on 11/5/2021 at 3:24 PM, the administrator indicated the patient was discussed for non compliance. She indicated this patient had been a peritoneal dialysis patient and switched to incenter due to non compliance and trying to self treat. The administrator indicated the physician was aware of the patient's blood pressures.</p> <p>5. Record review on 11/5/2021 for patient #6, start of care 2/19/2020, evidenced an agency document titled "Post Treatment" dated 10/21/2021. This document evidenced the patient's blood pressure at 11:01 AM, was 133/83. At 11:32 AM, the patient's blood pressure was 93/61. This document failed to evidence documentation the nurse was notified of the drop in blood pressure.</p> <p>During an interview on 11/5/2021 at 3:31 PM, employee B (regional director), indicated the technicians were to notify the nurse of any blood pressure drop of 20 points.</p> <p>6. Record review on 11/5/2021 for patient #8, start of care 11/23/2012, evidenced an agency document titled "Post Treatment" dated 10/27/2021. This document evidenced the patient's blood pressure at 3:57 PM, was 127/82. At 4:27 PM, the patient's blood pressure was 159/88. At 5:57 PM, the patient's blood pressure was 181/89 and at 6:12 PM, the patient's blood pressure was 160/95. This document failed to evidence documentation the nurse was notified of the changes in the patients blood pressure, and failed to evidence documentation the physician was notified of the high blood pressures.</p> <p>Record review on 11/5/2021 for patient #8, start of care 11/23/2012, evidenced an agency document titled "Post Treatment" dated 11/1/2021. This</p>			

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

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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 11/05/2021
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>document evidenced the patient's blood pressure at 7:58 PM, was 174/96. At 8:28 PM, the patient's blood pressure was 180/98. At 9:45 PM, the patient's blood pressure was 184/94, and at the end of treatment the patient's blood pressure was 186/96. This document failed to evidence documentation the nurse notified the physician of the high blood pressures.</p> <p>Record review on 11/5/2021 for patient #8, start of care 11/23/2012, evidenced an agency document titled "Post Treatment" dated 11/3/2021. This document evidenced the patient's blood pressure at 6:32 PM, was 185/95. At 7:33 PM, the patient's blood pressure was 201/106. This document failed to evidence documentation the nurse notified the physician of the high blood pressures.</p> <p>During an interview on 11/5/2021 at 3:26 PM, RN I indicated the physician was aware of the patient's high blood pressures and had seen him in the dialysis center. She indicated the patient has been non compliant at times with treatments and he has let his work interfere with getting appropriate health care.</p>				