

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

PRINTED: 03/12/2025
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 02/13/2025
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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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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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
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E 0000 Bldg. 00	An Emergency Preparedness Survey was conducted by the Indiana State Department of Health in accordance with 42 CFR 494.62 Survey dates: 02/10/2025, 02/11/2025, 02/12/2025, 02/13/2025 Total Census: 70 At this Emergency Preparedness Survey, Comprehensive Renal Care Gary was found to be in compliance with Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 42 CFR 494.62	E 0000		
V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider. Survey dates: 02/10/2025, 02/11/2025, 02/12/2025, 02/13/2025 Census by Service Type: In Center Hemodialysis: 64 Home Peritoneal Dialysis: 6 Total Census: 70 Isolation Room: 1 Comprehensive Renal Care - Gary was found to be out of compliance with Condition for Coverage 42	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Damian Tomich	Facility Administrator	03/06/2025

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>CFR 494.90 Patient Plan of Care.</p> <p>Abbreviations used in the survey report: RN for Registered Nurse, POC for Plan of Care, and PCT for Patient Care Technician.</p> <p>QR: A1, FEB 20, 2025</p> <p>494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure that PCT 1, PCT 2, PCT 6, and RN 4 performed hand hygiene after glove removal in 2 of 3 central venous catheter [CVC] (large catheter into vein) discontinuations observed (Patient #7 and Patient #8) and in 1 of 4 observations on 02/10/2025 between 11:40AM to 1:15PM.</p> <p>Findings include:</p> <p>1. A revised policy, dated April 2023, titled "Infection Control For Dialysis Facilities", indicated that teammates should perform hand hygiene prior to gloving and immediately after removal of gloves.</p> <p>2. During an observation on 02/10/2025, beginning at 12:44PM, PCT 1, at station #11, discontinued dialysis treatment on Patient #7. During the observation, after reinfusing the extracorporeal circuit (dialysis machine), PCT 1 changed her gloves, and failed to perform hand hygiene before donning new gloves and disconnecting the patient from the dialysis machine.</p> <p>3. During an observation on 02/10/2025, beginning at 12:50PM, PCT 1, at station #14, discontinued</p>	V 0113	The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Surveyor observations were reviewed. Education included a review of Policy 1-05-01 "Infection Control For Dialysis Facilities with emphasis on but not limited to: All teammates will perform hand hygiene prior to gloving and immediately after removal of gloves. Verification of attendance is evidenced by a signature sheet for each in-service. The Facility Administrator or assigned teammate will conduct observational infection control audits specific to hand hygiene daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs	03/14/2025

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	<p>dialysis treatment on Patient #8. During the observation, after reinfusing the extracorporeal circuit (dialysis machine), PCT 1 changed gloves, and failed to perform hand hygiene before donning new gloves and disconnecting the patient from the dialysis machine.</p> <p>4. During an interview on 02/10/2025, beginning at 1:15PM, PCT 1 indicated that hand hygiene should be performed upon initiating discontinuation of dialysis with a CVC, and when discontinuation is complete. PCT 1 indicated that glove changes between those times did not include hand hygiene.</p> <p>5. During an observation on 02/10/2025, beginning at 12:35PM, PCT 6, entered station #12 with Patient #10. During the observation, PCT 6 changed the linen soiled with a red substance, removed her gloves, failed to perform hand hygiene, donned new gloves, and then entered station #11 with Patient #7.</p> <p>6. During an interview on 02/10/2025, beginning at 1:22PM, PCT 6 indicated that hand hygiene should be performed prior to donning new gloves.</p> <p>7. During an observation of care, on 02/10/2025 at 11:40 AM, RN 4 administered what she indicated was Mircera (medication to treat anemia), she removed her gloves, then touched the computer keyboard and the computer mouse, then applied new gloves, and then attached a syringe to Patient's dialysis tubing and administered what RN 4 indicated was Venofer (iron). RN 4 failed to perform hygiene prior to donning gloves and administering an intravenous medication during this observation.</p> <p>8. During an observation of care, on 02/10/2025 at 12:25 PM, PCT 2 stepped away from the dialysis</p>		<p>during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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V 0122 Bldg. 00	<p>station while wearing gloves, touched papers at a desk outside of the station, applied labels to 2 syringes and returned to the station. PCT 2 then attached a syringe, which PCT 2 indicated was heparin (a medication used to prevent blood clots) to Patient 2's dialysis tubing. PCT 2 failed to remove their gloves and perform hand hygiene after leaving the station, before touching and applying labels to the medication syringes, upon reentry to the station, and prior to administering intravenous medication.</p> <p>9. During an observation of care, on 2/10/2024 at 1:15 PM, PCT 2 stepped out of the dialysis station while wearing gloves, picked up a multi-use vial off of the nurse's desk, drew up liquid from the vial into a syringe, and attached the syringe to Patient #20's dialysis tubing. PCT 2 indicated the medication was heparin. PCT 2 failed to remove their gloves and perform hand hygiene upon exiting the station, before withdrawing medication from the vial, and prior to administering intravenous medication.</p> <p>10. On 02/10/2025, at 1:15 PM, PCT 2 indicated gloves should be removed and then hand sanitizer and new gloves applied before touching the patient and dialysis machine/tubing.</p> <p>494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL Based on observation, record review, and interview, the dialysis facility failed to ensure PCT 1 and PCT 4 cleaned the dialysis station in accordance with standard infection control precautions in 2 of 3 dialysis stations cleaning observed (PCT 1, PCT 4); and failed to ensure PCT 4 decontaminated medical equipment in 3 of 3 hemodialysis [HD](a process to filter the blood of</p>	V 0122	The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples. Education included a review of Policy 1-05-01 "Infection Control	03/14/2025

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	<p>a patient whose kidneys do not work normally) Phoenix meter testing observed (PCT 4), and failed to ensure clamp and acid wand were cleaned per policy in 1 of 1 observation of a 1:10 bleach solution on 02/10/2025 between 10:00 AM and 2:20 PM.</p> <p>Findings include:</p> <p>1. A revised policy dated April 2023, titled, "Infection Control For Dialysis Facilities," indicated at the end of each treatment, the dialysis station and surfaces would be cleaned and disinfected to include all surfaces in contact with the patient or their belongings such as the dialysis chair, tray table, blood pressure cuffs, dialysis machine, touchscreens and countertops. The policy indicated non-disposable items are to be disinfected after each patient use, prior to removal from the treatment area/station and if contaminated between uses, and if an item cannot be cleaned and disinfected it would be dedicated for use on a single patient. The policy indicated hemostats [blood line clamps] would be in the open position and fully submerged in an appropriate disinfectant solution. The policy indicated clean areas should be clearly designated for unused supplies and equipment and clean areas would be separately from contaminated areas where used supplies and equipment are handled.</p> <p>2. During an observation on 02/10/2025, beginning at 10:25 AM, PCT 1 was cleaning HD station #18. During the observation, PCT 1 cleaned the HD station, a clamp was not cleaned on the intravenous [IV] pole, PCT 1 exited station #18; and PCT 4 entered station #18 and hung a new saline bag on the IV pole, and the clamp remained at the station. PCT 1 failed to remove or</p>		<p>For Dialysis Facilities" with emphasis on but not limited to the following at the end of each treatment, the dialysis station will be cleaned and disinfected. Surfaces to disinfect include all surfaces in contact with the patient or their belongings such as the dialysis chair, tray table, blood pressure cuffs, dialysis machine, touchscreens and countertops. Non- disposable items are to be disinfected after each patient use, prior to removal from the treatment area/station and if contaminated between uses. If an item cannot be cleaned and disinfected it would be dedicated for use on a single patient. Hemostats [blood line clamps] should be in the open position and fully submerged in an appropriate disinfectant solution. Clean areas should be clearly designated for unused supplies and equipment. Clean areas should be separate from contaminated areas where used supplies and equipment are handled. Verification of attendance is evidenced by a signature sheet for each in-service. The Facility Administrator on 2/12/2025 Created Dedicated Clean & Dirty Disinfect Containers for Acid Wands and on 2/12/2025 Created Dedicated Clean & Dirty Disinfect Containers for Hemostats (Blue Clamps). The Facility Administrator or assigned teammate will conduct</p>	

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	<p>clean the clamp prior to PCT 4 hanging the saline on the IV pole or setting up the HD machine saline.</p> <p>During an interview on 02/10/2025, beginning at 11:22 AM, PCT 4 indicated the clamp should have been removed from the station prior to setting up for the next patient.</p> <p>During an interview on 02/10/2025, beginning at 11:30 AM, PCT 1 indicated clamps should be cleaned with a 1:10 bleach solution and returned to the IV pole and she could not recall if the clamp was cleaned but should have been cleaned prior to set up of the station for the next patient.</p> <p>3. During an observation on 02/10/2025, beginning at 12:50 AM, PCT 4 cleaned HD station #17. During the observation, PCT 4 failed to clean the IV pole, clamp on the IV pole, counter behind the station and the mounted tv, PCT 4 exited station #17 retrieved a new saline bag and tubing set up and reentered station #17 and PCT 4 hung the saline bag on the IV pole and the clamp remained on the IV pole. PCT 4 failed to remove the clamp prior to hanging the saline on the IV pole or setting up the HD machine saline.</p> <p>During an interview on 02/10/2025, beginning at 2:10 PM, PCT 4 indicated a station cleaning should be done with a 1:100 bleach solution and include all surfaces, HD machine, chair, keyboard, tv and counter.</p> <p>4. During an observation on 02/10/2025, beginning at 11:15 AM, an unsubmerged clamp and acid wand was observed in a 1:10 bleach solution with cleaning wipes.</p> <p>During an interview on 02/10/2025, beginning at</p>		<p>observational infection control audits specific to disinfection of equipment and surfaces daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audits to verify compliance.</p> <p>Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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	<p>11:15 AM, PCT 1 indicated the acid wand, and the clamp should not be in the 1:10 bleach solution.</p> <p>During an interview on 02/12/2025, beginning at 10:45 AM, RN 1 indicated acid wands are to be cleaned with 1:100 bleach solution and put in a dry container, the clamps are to be disinfected at the station or can be cleaned in a 1:10 bleach solution.</p> <p>During an interview on 02/12/2025, beginning at 4:50 PM, the Administrator (Administrative Staff 1) indicated he would need to check how clamps and acids wands are to be stored and cleaned.</p> <p>5. During an observation on 02/10/2025, beginning at 10:50 AM, PCT 4 was at station #18 with Patient #15 present. PCT 4 obtained the phoenix meter from top of a cabinet, centrally located at the pod, that had new saline bags, wrapped tubing on top of the cabinet, conducted the test on the HD machine, returned the meter to the top of the cabinet with new saline bags and tubing present and failed to clean the meter prior to returning to the top of the cabinet.</p> <p>6. During an observation on 02/10/2025, beginning at 11:30 AM, PCT 4 was at station #15 with Patient #12 present. PCT 4 obtained the phoenix meter from top of a cabinet, centrally located at the pod, that had new saline bags, wrapped tubing on top of the cabinet, brought the phoenix meter to station #16, conducted the test on the HD machine, returned the meter to the top of the cabinet with new saline bags and tubing present and failed to clean the meter prior to returning to the top of the cabinet.</p> <p>7. During an observation on 02/10/2025, beginning at 1:35 PM, PCT 4 was at station #17</p>			

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V 0126 Bldg. 00	<p>with Patient #13 present. PCT 4 obtained the phoenix meter from top of a cabinet, centrally located at the pod, that had new saline bags, wrapped tubing on top of the cabinet and brought the phoenix meter to station #17 conducted test on the HD machine, returned the meter to the top of the cabinet with new saline bags and tubing present and failed to clean the meter prior to returning to the top of the cabinet.</p> <p>8. During an interview on 02/10/2025, beginning at 2:10 PM, PCT 4 indicated the phoenix meters are cleaned in the morning before the start of patient care and are not cleaned throughout the day.</p> <p>9. During an interview on 02/10/2025, beginning at 10:35 AM, PCT 1 indicated there were 4 phoenix meters on the floor and 1 for the water room and each pod on the observation floor had a phoenix meter. PCT 1 indicated the phoenix meter should be cleaned with 1:100 bleach solution after being brought to a station for HD machine tests.</p> <p>494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF</p> <p>Based on record review and interview, the dialysis facility failed to ensure Hepatitis B (liver infection) surveillance was conducted in 7 of 7 Hepatitis B susceptible (with a Hepatitis B antibody less than 10) patients that did not have documentation of a refusal to receiving the Hepatitis B vaccine, was in the series of receiving the Hepatitis B vaccine, or was considered a non-responder (Patient #4, Patient #9, Patient #20, Patient #22, Patient #23, Patient #24, Patient #25).</p> <p>Findings include:</p> <p>1. A revised policy dated April 2024, titled,</p>	V 0126	The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples. Education included a review of Policy: 1-05-02 HEPATITIS B SURVEILLANCE, VACCINATION, INFECTION CONTROL MEASURES AND ISOLATION GUIDANCE with emphasis on but not limited to the following: indicated to test all vaccinated	03/14/2025

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	<p>"Hepatitis B Surveillance, Vaccination, Infection Control Measures and Isolation Guidance," indicated to test all vaccinated patients for the Hepatitis B surface antibody 1 to 2 months after the last dose of the full series, adequate response was defined as greater than or equal to 10. The policy indicated if a Hepatitis B surface antibody was less than 10 the patient was considered susceptible and the patient should be revaccinated with an additional full series. The policy indicated annual retesting of immune patients due to vaccination, Hepatitis B surface antibody less than 10 would require a booster dose of the Hepatitis B vaccine with a nephrologist order.</p> <p>2. A Vaccinations and Surveillance Report, for Patient #20, indicated Patient's Hepatitis B surface antibody, dated 03/14/2023, was less than 3, and received 3 doses of the Hepatitis B vaccine on 04/11/2023, 05/11/2023, and 08/31/2023. The Report failed to evidence documentation of a repeat of the Hepatitis B surface antibody after 03/14/2023.</p> <p>During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator (Administrative Staff 1) indicated Patient #20 should have had the Hepatitis B antibody rechecked.</p> <p>3. A Vaccinations and Surveillance Report, for Patient #4, indicated Patient's Hepatitis B surface antibody, dated 04/03/2024, was less than 3. The Report failed to evidence documentation of a Hepatitis B vaccination being offered, received or refused.</p> <p>During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator indicated Patient #4 should have been offered the Hepatitis B vaccine.</p>		<p>patients for the Hepatitis B surface antibody 1 to 2 months after the last dose of the full series, adequate response was defined as greater than or equal to 10. If a Hepatitis B surface antibody was less than 10 the patient was considered susceptible and the patient should be revaccinated with an additional full series. The policy indicated annual retesting of immune patients due to vaccination, Hepatitis B surface antibody less than 10 would require a booster dose of the Hepatitis B vaccine with a nephrologist order. The Facility Administrator or assigned Registered Nurse will complete the following 1) Audit 100% of patients HBV serological status. 2) All permanent patients including AKI patients will have HBV serologic testing drawn during the first full week of March 2025 (depending on treatment schedule) 3) Results will be reviewed to determine status and next steps per Admission Screening Table 4) Obtain orders for routine surveillance testing per Routine Surveillance Testing Table 5) An order will be obtained for hepatitis B vaccination. The patient is provided the Vaccination Information Sheet (VIS) and a consent form (included in Patient Registration Packet found in Reggie). The patient will consent to the vaccination or will decline.</p>	

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	<p>4. A Vaccinations and Surveillance Report, for Patient #22, indicated Patient received Hepatitis B vaccines on 11/29/2023, 12/29/2023, 01/29/2024, and 05/08/2024. Patient had a Hepatitis B surface antibody, dated 04/03/2024, of 4. The Report failed to evidence documentation of a repeat Hepatitis B surface antibody after 04/03/2024 or after completion of the Hepatitis B vaccination series.</p> <p>During an interview on 02/11/2025, beginning at 4:00 PM, the Administrator indicated Patient should have had a Hepatitis B surface antibody repeat blood test 1 month after the completion of the vaccination series.</p> <p>5. A Vaccinations and Surveillance Report, for Patient #23, indicated a Hepatitis B surface antibody of less than 3 on 04/25/2024, and received a Hepatitis B vaccination on 07/12/2024, and 08/24/2024. The Report failed to evidence documentation of the reason Patient did not receive the full Hepatitis B vaccination series or a repeat antibody test after 04/25/2024.</p> <p>During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator indicated there was no further documentation related to Patient #23's Hepatitis B vaccination series or antibody test.</p> <p>6. A Vaccinations and Surveillance Report, for Patient #24, indicated a Hepatitis B surface antibody of 4, on 10/28/2024, and received a series of Hepatitis B vaccination on 04/27/2021, 05/25/2021, 06/29/2021 and 10/27/2021. The Report failed to evidence documentation of a Hepatitis B repeat vaccination series or booster offered after the 10/28/2024 surface antibody result.</p>		<p>The completed form will be kept in the patient's health record. 6) Vaccinate patients per manufacturers guidelines. 7) Test all vaccinated patients for HBsAb one (1) to two (2) months after the last dose of the full vaccine series (adequate response is defined as greater than or equal (=) 10 mIU/mL). a. If hepatitis B surface antibody (HBsAb) is less than (<) 10 mIU/mL, consider the patient susceptible, revaccinate with an additional full series, and retest for HBsAb one (1) to two (2) months after the last dose of the second series. i. No additional doses of vaccine are warranted for those patients who do not respond to a full second series. ii. Such patients are considered vaccine non-responders. They remain susceptible to hepatitis B infection and monthly hepatitis B surface antigen (HBsAg) testing is required. 8) If the hepatitis B surface antibody (HBsAb) is greater than or equal to (>) 10 mIU/mL, consider patient immune, and retest annually for HBsAb. 9) On annual retesting of immune patients due to vaccination, HBsAb less than (<) 10 mIU/mL, with nephrologist order, administer a booster dose of vaccine. i. Retest for HBsAb one (1) to two (2) months after the booster dose ii. If HBsAb is greater than or equal (=) 10 mIU/mL continue to retest annually for HBsAb. b. If the</p>	

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (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 02/11/2025, beginning at 4:00 PM, the Administrator indicated Patient should have been an offered a Hepatitis B booster vaccine.</p> <p>7. A Vaccinations and Surveillance Report, for Patient #25, indicated Patient had received a Hepatitis B vaccination 04/12/2023, 05/12/2023 and 08/09/2023. The Report failed to evidence documentation of a Hepatitis B surface antibody blood test result completed.</p> <p>During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator indicated there was no further information for Patient #25 related to the reason Patient did not finish the Hepatitis B vaccine series and the Hepatitis B surface antibody was not rechecked.</p> <p>8. A Vaccinations and Surveillance Report, for Patient #9, indicated a Hepatitis B surface antibody of less than 3, on 06/19/2023. The Report indicated Patient received a Hepatitis vaccine on 08/04/2023. The Report failed to evidence documentation of a repeat Hepatitis B surface antibody or the reason Patient did not receive the full Hepatitis B vaccination series.</p> <p>9. During an interview on 02/11/2025, beginning at 4:00 PM, the Administrator indicated Hepatitis B surface antibodies should be completed 30 days after the Hepatitis B vaccine series was completed. The Administrator indicated Hepatitis B antibodies should be checked annually.</p> <p>10. During an interview on 02/12/2025, beginning at 11:15 AM, the Administrator indicated no further Hepatitis B surveillance patient documentation was available.</p>		<p>HBsAb is less than (<) 10 mIU/mL following the booster dose, no subsequent/future doses of vaccine will be provided. Patient will be considered a non-responder and managed as a susceptible patient. ii. There is no limit to the number of annual boosters although future doses should be discontinued if at any time, the patient fails to respond with HBsAb greater than or equal (=) 10 mIU/mL. Verification of attendance is evidenced by a signature sheet for each in-service. The Facility Administrator or assigned RN will conduct Hepatitis B Vaccination and Surveillance audits weekly for four (4) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the Hepatitis B Vaccination and Surveillance audit review to verify compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>		

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V 0146 Bldg. 00	<p>11. During an interview on 02/13/2025, beginning at 1:30 PM, the Medical Director indicated Hepatitis B antibodies should be checked per the facility's protocol and after a patient received the full Hepatitis B vaccine series.</p> <p>494.30(c)(2) IC-CATHETERS:GENERAL</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure central venous catheter [CVC] (catheter into large vein) standard infection control precautions were implemented by PCT 1, PCT 2, and PCT 4 to prevent catheter related infections in 3 of 3 CVC initiations observed (Patient #4, Patient #12, Patient #15) and in 2 of 3 CVC discontinuations observed (Patient #7, Patient #8, Patient #22) of in-center hemodialysis [HD] [process to filter the blood of a patient whose kidneys do not work normally] patients.</p> <p>Findings include:</p> <p>1. A revised policy, dated October 2024, titled, "Central Venous Catheter [CVC] With Clearguard HD Antimicrobial End Caps Procedure," indicated the procedure for cleaning of the CVC hub would include scrubbing of each CVC hub for 15 seconds with an alcohol prep pad. The policy indicated the exit site of a CVC would be cleaned with a chlorhexidine (disinfectant) swab applying in a back and forth pattern progressing from the insertion site to the periphery and if the site was not free of exudates to repeat the step with a new chlorahexidine swab.</p> <p>2. During an observation on 02/10/2025, beginning</p>	V 0146	The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Education included a review of Policy 1-04-02 "Central Venous Catheter (CVC) Care" and Procedure: 1-04-02B CENTRAL VENOUS CATHETER (CVC) WITH CLEARGUARD HD ANTIMICROBIAL END CAPS PROCEDURE. Teammates were instructed using surveyor observations as examples with emphasis on but not limited to the following: One at a time, disinfect each CVC hub with a new alcohol prep pad. Scrub each CVC hub for 15 seconds. Clean exit site with 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol swab for a minimum of 30 seconds, apply to the CVC exit site in a "back and forth" pattern, using gentle friction progressing from the insertion site to the periphery using both sides of the swab. If site is not free of exudates, repeat this step with new 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol swab. Then wait 60 seconds for air	03/14/2025

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	<p>at 11:00 AM, PCT 4 was initiating HD treatment of Patient #15 at station #18. During the observation, PCT 4 removed the cap to the hub (end of the CVC that connects to the blood lines or caps) of the blue line and cleaned the hub for 11 seconds with an alcohol swab, and PCT 4 removed the cap to the hub of the red line and cleaned the hub for 9 seconds with an alcohol prep pad.</p> <p>3. During an observation on 02/10/2025, beginning at 12:00 PM, PCT 4 was initiating HD treatment of Patient #12 at station #16. During the observation, PCT 4 removed the cap to the hub of the blue line and cleaned the hub for 7 seconds with an alcohol swab, PCT 4 removed the cap to the hub of the red line and cleaned the hub for 6 seconds with an alcohol prep pad.</p> <p>4. During an observation on 02/10/2025, beginning at 10:25 AM, PCT 1 discontinued HD treatment of Patient #22 at station #16. During the observation, PCT 1 cleaned the red and blue hubs for 3 seconds with an alcohol prep and inserted syringes into the hubs.</p> <p>5. During an interview on 02/10/2025, beginning at 2:10 PM, PCT 4 indicated the CVC hubs should be cleaned for 15 seconds with an alcohol pad.</p> <p>6. During an observation on 02/10/2025, beginning at 12:44 PM, PCT 1 discontinued HD treatment of Patient #7 at station #11. During the observation, PCT 1 cleaned the red and blue hubs for 2 seconds with an alcohol prep and inserted syringes into the hubs.</p> <p>7. During an observation on 02/10/2025, beginning at 12:50 PM, PCT 1 discontinued HD treatment of Patient #8 at station #14. During the observation, PCT 1 cleaned the red and blue hubs</p>		<p>dry time. Verification of attendance is evidenced by a signature sheet for each in-service. The Facility Administrator or assigned teammate will conduct observational audits for CVC care daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audit. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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V 0402 Bldg. 00	<p>for 2 seconds with an alcohol prep and inserted syringes into the hubs.</p> <p>8. During an observation of care, on 02/10/2025 at 12:17 PM, PCT 2 was observed cleansing the CVC access site for Patient #4. PCT 2 was observed cleansing the surrounding skin and the top of the catheter hub and then cleansing the insertion / access site.</p> <p>9. On 02/13/2025, at 2:09 PM, the Medical Director indicated the expectation for CVC care was that the area would be cleaned from clean to dirty and not cleaning the insertion site after cleaning the surrounding skin.</p> <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY</p> <p>Based on observation, record review, and interview, the dialysis facility failed to ensure the safety of the patients was maintained by properly storing medications in 1 of 1 observation.</p> <p>The findings include:</p> <p>A review of a policy titled "Infection Control for Dialysis Facilities" with a revised date of April 2023 indicated patients would not have access to supplies.</p> <p>During an observation, on 02/10/2025 from 10:55 AM to 12:14 PM, 2 vials with clear liquid labeled "heparin" (a medication used to prevent blood clots) were left unattended on top of a desk that was not enclosed and was left unsecured as patients walked from the lobby to/from the stations on the treatment floor.</p> <p>On 02/10/2025, at 12:14 PM, RN 1 indicated the</p>	V 0402	The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting 2/13/2025. Surveyor observations were reviewed as examples. Education included a review of Policy 1-05-01 INFECTION CONTROL FOR DIALYSIS FACILITIES with emphasis on but not limited to: Supplies will be stored in a manner that maintains their integrity. a. Patient and visitors should not access the supplies and Policy: 1-06-01 MEDICATION POLICY with emphasis on but not limited to: All refrigerated medications, for example erythropoietin stimulating agents (ESA) and vaccines are to be locked at the close of each business day or if not under supervision by the licensed	03/14/2025	

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	<p>facility failed to evidence the Phoenix meter maintenance was completed to include calibration and disinfection per the Phoenix meter disinfection and calibration facility policy for January 2025 to include: 11 of 27 days for B-Pod Meter, 2 of 27 days for C-Pod Meter, 2 of 27 days for D-Pod Meter, 2 of 27 days H-Pod Meter and 3 of 27 days for Bicarb Meter; and for December 2024 to include: 4 of 25 days for B-Pod, 2 of 25 days for C-Pod, 7 of 25 days for D-Pod, and 12 of 25 days for Bicarb Meter.</p> <p>Findings include:</p> <p>1. A revised policy dated October 2024, titled, "Phoenix Meter Disinfection and Calibration Verification," indicated 1:100 bleach solution was to be mixed with dialysis quality water daily, the phoenix meter was to be disinfected and verified prior t daily use. The policy indicated after disinfection the phoenix meter calibration would be verified prior to daily use or whenever inaccurate readings are suspected. The policy indicated the outside of the phoenix meter must be disinfected after use prior to returning the meter to the storage location.</p> <p>2. A Phoenix XL Meter Log for January 2025 evidenced the following:</p> <p>A. B-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 01/02/2025 to 01/04/2025, 01/07/2025, 01/11/2025, 01/14/2025, 01/18/2025, 01/25/2025, 01/27/2025, 01/28/2025, and 01/30/2025.</p> <p>B. C-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was</p>		<p>held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples. Education included a review of on Procedure: 1-21-13 PHOENIX XL METER DISINFECTION, CALIBRATION VERIFICATION AND STORAGE PROCEDURES and Procedure: 1-21-13A pPhoenix XL Meter Log with emphasis on but not limited to the following: Draw a 1% bleach solution through the measurement module and into the syringe. Seal the measurement module with the air-tight luer end cap. Note: Bleach solution is prepared fresh daily. Bleach provides low level disinfection of liquid-contacting surfaces. A 1:100 dilution of bleach solution with dialysis quality water is used. Allow 1% bleach solution to remain in instrument for 10 minutes. Expel the bleach solution. Thoroughly rinse the 1% bleach solution from the syringe and measurement module by rapidly flushing with dialysis quality water at least three times. Document disinfection step on the pPhoenix XL meter log. Bleach must be rinsed from the pPhoenix XL Meter prior to introducing conductivity standard or pH buffer solutions. Test for residual bleach. See Residual Bleach Testing using RPC E-Z Chek Residual Chlorine</p>	

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	<p>completed on 01/03/2025 and 01/07/2025.</p> <p>C. D-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 01/03/2025 and 01/07/2025.</p> <p>D. H-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 01/03/2025, 01/07/2025 and 01/13/2025.</p> <p>E. Bicarb Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 01/03/2025, 01/07/2025 and 01/25/2025.</p> <p>3. A Phoenix XL Meter Log for December 2024 evidenced the following:</p> <p>A. B-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 12/05/2024 to 12/07/2024, 12/10/2024, and 12/31/2024.</p> <p>B. H-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 12/05/2024 to 12/07/2024.</p> <p>C. C-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 12/05/2024 to 12/07/2024.</p> <p>D. D-Pod Phoenix meter failed to evidence the meter was disinfected with bleach, checked for</p>		<p>(Bleach) Test Strips or Residual Bleach Testing using Serim Residual Chlorine (Bleach) Test Strips. Document the results of the residual bleach test on the pHoenix XL log. Clean the exterior of the meter with a 1%bleach solution. Verification of attendance is evidenced by a signature sheet for each in-service The Facility Administrator or approved teammate will conduct observational infection control audits and observational Phoenix Meter Log Adherence audits daily for two (2) weeks and then weekly for two (2) weeks to verify compliance with facility policy. Ongoing compliance will be verified monthly during the internal infection control audits to verify compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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V 0540 Bldg. 00	<p>bleach residual, conductivity and PH was completed on 12/02/2024 to 12/07/2024 and 12/26/2024.</p> <p>E. Bicarb Phoenix meter failed to evidence the meter was disinfected with bleach, checked for bleach residual, conductivity and PH was completed on 12/02/2024 to 12/07/2024, 12/14/2024, 12/16/2024 to 12/18/2024, 12/26/2024 and 12/27/2024.</p> <p>4. During an interview on 02/12/2025, beginning at 10:35 AM, PCT 1 indicated there were 4 Phoenix meters in use on the dialysis floor and 1 Phoenix meter in use in the water room. PCT 1 indicated there was 1 Phoenix meter per Pod, the Phoenix meter was to be bleached and checked for residual every morning by the PCT staff.</p> <p>5. During an interview on 02/13/2025, beginning at 1:00 PM, the Administrator (Administrative Staff 1) indicated there were 4 Phoenix meters in use on the dialysis floor and 1 in the water room, the dialysis facility was open 6 days per week Monday through Saturday, the Phoenix meters should have bleach drawn up daily, checked for residual and documented on the log. The Administrator indicated there were holes in the Phoenix Meter disinfection schedule log. The Administrator indicated Pod B was not in use daily and he would need to check the schedule to see when Pod B was in use, upon exit of the survey on 02/13/2025 no further information was provided.</p> <p>494.90 CFC-PATIENT PLAN OF CARE</p> <p>Based on observation, record review and</p>	V 0540	CRC Gary Dialysis takes the Conditions for Coverage very	03/14/2025
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V 0543 Bldg. 00	<p>interview, the dialysis facility failed to provide the necessary care to manage mineral metabolism to prevent or treat renal bone disease (See V546) and failed to provide documentation patients' plan of care were reviewed or signed by the patient (See V556).</p> <p>The cumulative effect of the systemic problem has resulted in the dialysis facility inability to ensure the provision of quality health care in a safe environment for the condition for coverage at 494.90 Patient Plan of Care.</p> <p>494.90(a)(1) POC-MANAGE VOLUME STATUS</p> <p>Based on record review and interview, the dialysis facility failed to provide the necessary care and services to manage the patient's volume status in 1 of 1 in center hemodialysis patient with a lower extremity central venous catheter [CVC] (large catheter into vein) clinical records reviewed (Patient #7).</p>	V 0543	<p>serious. Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the Plan of Correction (POC). Immediate steps were taken to ensure compliance with Patient Plan of Care. These actions are outlined in depth in the plan of correction under V546 and V556 that are not met as well as other standards and contain specifics of corrective action plans. The Governing Body will meet weekly to ensure compliance with the POC. Further compliance to the POC will be reviewed during monthly QAPI/Facility Health Meeting (FHM) and reported to the Governing Body. Once compliance is reached the GB will review and provide oversight no less than semi-annually. The Facility Administrator (FA) representing the GB will be responsible for implementation and ongoing compliance with this POC.</p> <p>The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples. Education included a review of</p>	03/14/2025

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	<p>Findings include:</p> <p>1. A revised policy, dated 11/15/23, titled "ICHD Fluid Management Protocol Rev. 1.0," indicated that if a patient's post weight is above the target weight by 1.0 kilogram [kg] or more for 2 treatments, then interventions would include target weight adjustment weekly until no longer meeting criteria.</p> <p>2. In center Hemodialysis Treatment Prescriptions dated 12/28/2024, 02/03/2025, 02/04/2025, 02/07/2025, 02/08/2025, and 02/10/2025 indicated prescribed target weight was 36.0kg for Patient #7.</p> <p>Treatment Detail Reports, dated 01/13/2025 through 2/10/2025 evidenced the following:</p> <ul style="list-style-type: none"> a. 01/13/2025 post weight was 37.3kg b. 01/22/2025 post weight was 38.1kg c. 01/24/2025 post weight was 37.5kg d. 01/27/2025 post weight was 38.8kg e. 01/29/2025 post weight was 38.6kg f. 01/31/2025 post weight was 38.2kg g. 02/03/2025 post weight was 38.0kg h. 02/05/2025 post weight was 37.6kg i. 02/07/2025 post weight was 37.6kg j. 02/10/2025 post weight was 38.7kg <p>The Treatment Detail Reports failed to evidence the target weight was adjusted after Patient #7 was above target weight.</p> <p>3. During an interview, on 2/13/2025 beginning at 3:05PM, the Medical Director indicated that the physician should be notified of a post weight of 1.0kg or more above target weight for more than 2 consecutive treatments.</p>		<p>Policy: 1-03-08 PRE-INTRA-POST TREATMENT DATA COLLECTION, MONITORING AND NURSING ASSESSMENT with emphasis on but not limited to: ABNORMAL FINDINGS Unless other abnormal parameters are established by the facility Governing Body and documented in the Governing Body Meeting minutes, the following are considered abnormal findings and should be reported to the licensed nurse and documented in the patient's medical record. Fluid Status: Post-treatment: • If patient is above or below 1 kg from the target weight.</p> <p>Verification of attendance is evidenced by a signature sheet for each in-service. Protocols (ICHD Fluid Management Protocol) is a tool and process to identify and manage patients whose fluid status could benefit from immediate intervention; ultimately, to optimize fluid management status and prevent fluid – related hospitalizations. Protocols are approved by the Medical Director and governed in for use. Each Nephrologist has the ability to “order the protocol” or provide individual orders. If the Protocol is ordered: The nurse will monitor and enter orders per direction given in the protocol. With scope and entitlements, other licensed teammates (i.e. RDs) can monitor and enter Target Weight orders</p>	

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			<p>per direction given in the protocol in coordination with the nurse. • Target Weight should not be adjusted under this protocol more than once every 5 days unless the patient meets conditions for every 2 treatments. • Once treatment is initiated, all TW changes per this protocol will be effective the following treatment. • Consult with the physician/NPP before decreasing TW per this protocol for patients with frequent intradialytic hypotension and/or increasing TW for patients with frequent pre-dialysis hypertension. The CRC Gary Governing Body met and reviewed the above V-Tag and developed a Target Weight Assessment Plan Titled: Fluid Management RN & RD Fluid Advisors. The Facility Administrator along with the Governing Body will oversee the RN & RD Fluid Advisors and their roles and responsibilities. The Facility Administrator, RN/RD Fluid Advisors or other licensed nurse will meet weekly to review 100% ICHD Patients Target Weights (TW) Utilizing CWOW report: Fluid and BP Management Report. Ongoing compliance will be verified with monthly review of the CWOW report: Fluid and BP Management Report and number of patient outliers. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of</p>	

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V 0546 Bldg. 00	<p>494.90(a)(3) POC-MANAGE MINERAL METABOLISM</p> <p>Based on record review and interview, the dialysis facility failed to provide the necessary care to manage mineral metabolism to prevent or treat renal bone disease in 2 of 2 patients with elevated Phosphorus blood levels above 6 (normal phosphorus level 2.8 to 4.5 milligrams per deciliter) (Patient #3, Patient # 4).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A lab monitoring protocol, dated December 2017, titled, "MBD [mineral bone disorder] Monitoring Protocol," indicated Phosphorus labs would be drawn monthly. 2. A nephrologist (kidney doctor) note, titled, "Comprehensive Encounter," dated 10/16/2024, indicated Patient #3's phosphorus level was elevated at 7.7 and needed binders (medication to help lower the phosphorus level in the body). <p>A nephrologist note, titled, "Comprehensive Encounter," dated 11/11/2024, indicated Patient #3's phosphorus level was elevated at 7.8 and</p>	V 0546	<p>all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction. 3/14/2025</p> <p>The Facility Administrator (FA) held mandatory in-service(s) for all RD's on MBD Lab Monitoring Protocol (Revision 1.0) and the completed Governing Body Titled: Mineral Bone Disease Management Team Developed (MBDMT) which was formed to closely and timely monitor and review patient MBD related lab results and medications on 2/13/2025. Teammates were instructed using surveyor observations as examples with emphasis on but not limited to the following: Protocol Purpose • The MBD Lab Protocol guides the timing and frequency of calcium (Ca), phosphorus (P), and parathyroid hormone (PTH) lab draws, to aid in the assessment of intervention and dosing of phosphate binders, active vitamin D, and calcimimetics. Phosphorus</p>	03/14/2025

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	<p>needed binders.</p> <p>A nephrologist note, titled, "Limited Encounter," dated 12/16/2024, indicated Patient #3's phosphorus level was elevated at 10.8 and needed binders (medication to help lower the phosphorus level in the body).</p> <p>A nephrologist note, titled, "Comprehensive Encounter," dated 01/20/2025, indicated Patient #3's phosphorus level was elevated at 6.7 and needed binders.</p> <p>The patient's clinical record failed to evidence documentation binders were prescribed, the patient received the binders, the patient was aware of added binders, or the RD discussed binders with the patient.</p> <p>A Mineral Bone Disorder Report indicated Patient's phosphorus level 09/04/2024 was 5.8, 10/11/2024 was 7.7, 11/06/2024 was 7.8, 12/06/2024 was 10/8, and 01/15/2025 was 6.7.</p> <p>A Medication List, last updated 01/20/2025, failed to evidence a phosphorus binder medication.</p> <p>3. During an interview on 02/13/2025, beginning at 1:30 PM, the Medical Director indicated he prescribed medication through a system called Entity 1, an electronic medical record prescription ordering program, that staff were not able to access and would tell the nurse a new medication was to be added.</p> <p>4. During an interview on 02/13/2025, beginning at 2:20 PM, the Registered Dietician [RD] indicated in January of 2025 some insurance companies began to bundle HD patients' medications through Entity 1, a pharmacy partnered with the</p>		<p>lab draws will occur monthly. Education also included a review of policy 3-02-03 Physician Orders for Patient Care with emphasis on but not limited to: PROTOCOL: 18. Refers to a specific set of instructions (an algorithm) for the determination of the dose (dosage and frequency), if any, of a specific medication to be administered to the patient based on current laboratory or other objective data. Protocols are drafted so that the exact dose (dosage and frequency) that has been ordered for the patient can be determined, verified and replicated without requiring or allowing the exercise of discretion on the part of center teammates or requiring further confirmation or additional input from the physician or Non-Physician Practitioner (NPP). Protocols are not simply practice guidelines, they are patient specific and when ordered by a physician or NPP, the protocol becomes part of the order. If the physician orders deviate from the protocols the order source should not be protocol but one of the other order source options defined by this policy. Registered Nurses, NPPs (per DaVita policy), and Registered Dietitians unless expressly prohibited by state law may write orders for medication/treatment changes based on patient-specific</p>	

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	<p>dialysis facility's corporation. The RD indicated that the nephrologist would prescribe through entity 2, a pharmacy partner with the dialysis facility. The RD indicated entity 1's prescription program did not communicate with the dialysis facility's electronic medical records system, and she was unable to see if phosphorus binders were ordered by the physician.</p> <p>5. During a follow up interview on 02/13/2025, beginning at 3:52 PM, the RD indicated she reached out to entity 2 and Patient #3 and Patient #4 were not enrolled in entity 2's prescription program and did not receive binders. The RD indicated there was a gap in patients' receiving phosphorus binders as ordered by the physician due to physicians only had access to the prescribing system. The RD indicated there were no phosphorus binder medications prescribed for Patient #3 or Patient #4. The RD indicated she did reach out to the medical director and Patient #3 and Patient #4 were prescribed to start Renvala (a phosphorus binder).</p> <p>6. During an interview on 02/13/2025, beginning at 4:00 PM, the Administrator (Administrative Staff 1) indicated there were no binders prescribed on Patient #3's or Patient #4's medication list.</p> <p>7. A clinical record review for Patient #4 evidenced a Comprehensive Encounter electronically signed by the physician dated 12/11/2024 which indicated their phosphorous (mineral) level in the blood was 7.8 was indicated to be abnormally high. The comprehensive encounter indicated the physician sent an order for phosphorous binders (medication to lower the phosphorous in the blood) to the pharmacy.</p> <p>The Comprehensive Encounter electronically was signed by the physician, dated 2/10/2025,</p>		<p>protocols. Such protocols have been assigned to the patient by the attending physician and approved by the facility Governing Body. All verbal/telephone orders will be transcribed upon receipt into the patient's electronic health record by the licensed nurse teammate or Registered Dietitian receiving the orders and will include all of the following: a. Date and time order was given b. New order or change in existing order c. Name and credentials of physician giving order d. Name and credentials of licensed teammate receiving the order.</p> <p>Education also included a review of policy 1-14-04 Provision of Nutrition Services with emphasis on but not limited to: A comprehensive assessment and periodic reassessments of nutritional status. • Participation in the development of patient Plan(s) of Care (POC) based on the Interdisciplinary team (IDT) patient assessment/reassessment(s) and IDT patient POC meetings. Design, in collaboration with the attending physician, individualized diets and supplement recommendations to meet the patient's nutritional needs. Assure individualized diet order for each patient is entered in computer systems and updated as needed.</p> <p>• Monitor nutrition status and laboratory values to assess adherence and response to</p>	

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	<p>indicated the phosphorous level was abnormally high at 6.6 and indicated the physician sent phosphorous binders to the pharmacy. The review failed to evidence the phosphorous binder was included in the patient's medication list and failed to evidence the patient had been instructed to begin taking phosphorous binders.</p> <p>8. On 02/23/2025, at 2:22 PM, the RD indicated the phosphorous binders were not included in the patient's medication list and indicated the physician must have ordered the binders in one ordering system that did not electronically upload the order into the facility's electronic medical record.</p>		<p>prescribed nutrition therapy and nutrition-related medications. Collaborate with the physician and IDT to evaluate patient outcomes and identify factors that may contribute to undesirable results. Coordinate the monthly distribution of the Nutrition and Blood Test Results report. • Individualized education of patient and/or caregiver on diet guidelines, nutritional issues and nutrition related medications. Coordinate care with extended care facilities where appropriate. Verification of attendance is evidenced by a signature sheet for each in-service. At minimum, the MBDMT will consist of the Registered Dietician (RD) and Medical Director (MD). Other members of the IDT (MSW, CC, RN, FA) may also participate in the meetings. The MBDMT will meet in-person on or around the third full week of each month. The goals & objectives are subject to change as applicable to meet the following: The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time. MBD Manager (Facility's RD) will utilize DaVita's step therapy approach to MBD Management to minimize the potential risks/challenges to MBD</p>	

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			therapies. On or around the 3rd full week of each month the MBDMT will meet to review Monthly MBD Management following the Step Therapy Approach as outlined in the protocol. Facility Administrator, MBDMT or Registered Dietitian will conduct audit on all currently active patients by 3/15/2025 to ensure 1) monthly MBD labs are available, 2) MBD Protocol ordered as applicable 3) binders are prescribed, the patient received the binders, the RD discussed binders with the patient 4) patient binder medication(s) are listed on Home Medication List 5) Bundle eligible patients are enrolled in WellDyne. The Facility Administrator or approved Licensed teammate will review MBD labs on 25% current patients with elevated phosphorus weekly x 4 weeks during core team meeting to ensure RD is addressing patient needs, orders obtained are in place and adherence is documented in patients EMR, and then Monthly for ongoing compliance. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting	

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V 0556 Bldg. 00	<p>494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT</p> <p>Based on record review and interview, the dialysis facility failed to ensure patients' plans of care [POC] were signed by the patient or if the patient chose not to sign the plan of care the decision would be documented on the plan of care along with the reason the signature was not provided in 4 of 6 in center hemodialysis [HD] (a process to filter the blood of a patient whose kidneys do not work properly) clinical records reviewed (Patient #2, Patient #3, Patient #4, Patient #5).</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. A revised policy dated October 2024, titled, "Interdisciplinary Team [IDT] Patient Assessment and Plan of Care," indicated an annual stable patient plan of care would have a completed patient plan of care meeting within 15 days of the completion of the reassessment and plan of care. The policy indicated a monthly unstable patient plan of care would have a completed patient plan of care meeting within 15 days of the completion of the reassessment and plan of care. 2. A Plan of Care, dated 11/17/2024, for Patient #3 indicated the patient was unstable and failed to evidence a patient signature or date for the reviewed with patient/responsible party section. The plan of care failed to include documentation of the reason Patient's signature was not provided. 	V 0556	<p>(FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction. 3/14/2025</p> <p>The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Surveyor observations were reviewed as examples. Education included a review of Policy: 1-14-01 INTERDISCIPLINARY TEAM (IDT) PATIENT ASSESSMENT AND PLAN OF CARE with emphasis on but not limited to the following: The patient's plan of care must- (i) Be completed by the interdisciplinary team, including the patient if the patient desires; and (ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided. Verification of attendance is evidenced by a signature sheet for each in-service. The Governing Body reviewed and discussed V-556 and developed the following plan of correction, outlined in Governing Body Titled: Obtaining Signature on Patient Plan of Care</p>	03/14/2025	

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	<p>A Plan of Care, dated 01/29/2025, for Patient #3 indicated the patient was unstable and failed to evidence a patient signature or date for the reviewed with patient/responsible party section. The plan of care failed to evidence documentation of the reason Patient's signature was not provided.</p> <p>3. A Plan of Care, dated 07/31/2024, for Patient #5 indicated the patient was unstable and failed to evidence a patient signature or date for the reviewed with patient/responsible party section. The plan of care failed to evidence documentation of the reason Patient's signature was not provided.</p> <p>A Patient Plan of Care, dated 08/24/2024, for Patient #5 indicated the patient was stable and failed to evidence a patient signature or date for the reviewed with patient/responsible party section. The plan of care failed to evidence documentation of the reason Patient's signature was not provided.</p> <p>4. During an interview on 02/11/2025, beginning at 10:50 AM, the Master Social Worker [MSW] indicated the plan of care meeting with the patient could be completed chairside or by a private conference and the Registered Dietician [RD] and the MSW would go over the plan of care 1 on 1 with the patient.</p> <p>5. During an interview on 02/11/2025, beginning at 11:10 AM, the RD indicated a plan of care meeting would be scheduled with a patient.</p> <p>6. During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator (Administration Staff 1) indicated the plan of care should be</p>		<p>Teammates to obtaining patient or patient representative signatures on Patient Plan of Care moving forward. 1) The role of Care Plan Manager has been 2) Facilities IDT consists patient or representative, RN, MD or NPP (if allowed), MSW and RD. 3) The Care Plan Manager, or designee, will provide the patient or personal representative with an invitation to attend their care plan meeting, giving at least 14-day notice. 4) The patient or personal representative may elect to attend or not attend their care plan meeting. 5) They may choose to attend their Care Plan Meeting in one of the following manners: i. Conducted at chair side during their dialysis treatment ii. Conducted at the facility in a private setting before or after their dialysis treatment iii. Conducted at the facility on a non-dialysis treatment day in a private setting 6) It is the responsibility of the Care Plan manager to obtain all required signatures. If the patient chooses not to sign the plan of care, this choice will be documented on the plan of care, along with the reason the signature was not provided. The Facility Administrator or designee will conduct observational audits of all Care Plans completed each month for adherence to obtaining all required signatures and review of copy of invitation given to</p>	

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V 0634	<p>reviewed with the patient by the physician and RN.</p> <p>7. The clinical record for Patient 2 included the following,</p> <p>A. A POC dated 11/27/2024, identified to be an annual POC, was signed by the IDT team members and dated 11/27/2024; the POC failed to evidence was reviewed with Patient, nor their designee, nor was the document signed by Patient nor their designee. The documentation failed to evidence why the POC was not signed.</p> <p>B. A POC, dated 01/29/2025, identified Patient; status was changed to unstable by MD, beginning 01/20/2025 due to Peritonitis (an infection of the peritoneum). Patient #2 's updated POC was signed by the IDT team members and dated 01/29/2025 and failed to evidence the POC was reviewed with Patient #2, nor their designee, nor was the document signed by Patient #2 nor their designee. The documentation failed to evidence why the POC was not signed.</p> <p>8. A clinical record review for Patient #4 evidenced a POC dated 02/01/2025 failed to evidence Patient's signature and indicated the POC was not reviewed with Patient. The clinical record failed to evidence documentation the agency reviewed the POC in its entirety with Patient.</p> <p>On 02/23/2025, at 1:15 PM, the FA indicated there was not any documentation in the clinical record that the facility reviewed the POC with Patient and would look for additional documentation. No additional documentation or information was provided prior to survey exit on 02/13/2025.</p> <p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL</p>		<p>patient or patient representative indicating their decision to attend or not attend, along with how they wanted their meeting conducted when choosing to attend.</p> <p>Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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Bldg. 00	<p>INJURIES/ERRORS</p> <p>Based on record review and interview, the dialysis facility failed to ensure the Quality Assessment and Performance Improvement [QAPI] included central venous catheter [CVC] (catheter into a large vein) dislodgement (catheter securement method fails, and the catheter may become displaced) in 1 of 1 CVC dislodgements (Patient #3).</p> <p>Findings include:</p> <p>1. A revised policy dated, April 2021, titled, "Continuous Quality Improvement Program," indicated the facility administrators conduct period facility health meetings [FHM] also know as QAPI to review issues and indicators regarding facility's management and performance. The policy indicated the program would include written documentation and plans of actions within the FHM. The policy indicated the facility would measure, analyze, and track quality indicators of performance to include but not limited to patient safety including review of sentinel events, trends of adverse patient occurrences including falls and blood loss.</p> <p>2. An RN Patient Note dated 01/03/2025, indicated Patient #3 had Hemodialysis [HD] (a process to filter the blood of a patient whose kidneys do not work normally) treatment and ran most of the treatment besides 15 minutes. The note indicated the CVC looked ok at the beginning of treatment and near the end the CVC was found to be 5 inches out after the HD machine alarmed. The note indicated the treatment was stopped and 911 was called. The note indicated Patient was taken to the emergency room.</p> <p>3.A Review of the Adverse Events, dated</p>	V 0634	<p>The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples. Education included a review of Policy: 1-14-06 CONTINUOUS QUALITY IMPROVEMENT PROGRAM with emphasis on but not limited to the following: the Facility Administrators conduct periodic facility health meetings [FHM] also known as QAPI to review issues and indicators regarding facility's management and performance. FHMs are conducted monthly. Written documentation and plans of actions will be documented within the FHM. The facility will measure, analyze, and track quality indicators of performance to include but not limited to patient safety including review of sentinel events, trends of adverse patient occurrences including falls and blood loss. Education also included a review of Policy: 13-01-02 RISK EVENT REPORTING POLICY (NON-TEAMMATE RELATED) and the REM Event Category List with emphasis on but not limited to: The teammate involved in the risk event or who witnessed the risk event firsthand will complete a Risk Event Management (REM) Report. The teammate will</p>	03/14/2025	

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	<p>08/01/2024 through 02/11/2025, failed to evidence the CVC dislodgement for Patient #3.</p> <p>4. During an interview on 02/13/2025, beginning at 12:45 PM, the Administrator (Administrative Staff 1) indicated adverse occurrence reports would include infiltration, blood loss and dislodgement and Patient #3's CVC dislodgement should have been included in the adverse events report. The Administrator indicated the RN would be responsible for completing the adverse events report.</p>		<p>complete the Risk Event Management (REM) Report as soon after the occurrence as is reasonably possible, but no later than the completion of the teammates' shift during which the risk event happened. Verification of attendance is evidenced by a signature sheet for each in-service. The Licensed nurse will ensure the teammate involved in the risk event has completed the REM. The Facility Administrator will review REMs as they are reported to follow up on any additional information needed. The Facility Administrator or licensed nurse will ensure REMs are evidenced in the FHM/QAPI process as outlined in the policy. The ROD or MCS will review FHR meeting minutes monthly x 4 months to ensure compliance with the policy. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of correction.</p> <p>3/14/2025</p>	

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V 0638 Bldg. 00	<p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE</p> <p>Based on record review and interview, the dialysis facility failed to evidence the facility took actions of Phosphorus level monitoring that resulted in performance improvements and ensured that improvements were sustained over time in 2 of 2 in center hemodialysis [HD](a process to filter the blood of a patient whose kidneys do not work normally) clinical records reviewed with Phosphorus levels greater than 7 [normal phosphorus blood level 2.8 to 4.5 milligrams per deciliter] (Patient #3, Patient #4).</p> <p>Findings include:</p> <p>1. A revised policy dated April 2021, titled, "Continuous Quality Improvement Program," indicated the facility would measure, analyze, and track quality indicators of performance. The program would include monitoring mineral metabolism and renal bone disease. The policy indicated an area identified as underperforming would be reviewed to identify the root cause, have an action plan identified that would result in performance improvement and would track the change in performance over time to verify improvement were sustained. The policy indicated the action plan would be evaluated as priority for the Patient Safety and Clinical Outcomes indicator considered to be the highest level of priority.</p> <p>2. A Registered Dietician [RD] FHR [facility health meeting][also known as quality assessment performance improvement] indicated 19% of HD</p>	V 0638	<p>The Facility Administrator (FA) held mandatory in-service(s) for all clinical teammates starting on 2/13/2025. Teammates were instructed using surveyor observations as examples Education included a review of Policy: 1-14-06 CONTINUOUS QUALITY IMPROVEMENT PROGRAM with emphasis on but not limited to the following: 1) The facility will measure, analyze, and track quality indicators or other aspects of performance. The program must include, but not be limited to, the following... Mineral Metabolism and Renal Bone Disease. Any area identified as underperforming will be reviewed to identify root causes for underperformance, will have an action plan identified that will result in performance improvement, Each action plan will be evaluated as to priority with Patient Safety and Clinical Outcomes indicators considered for the highest level of priority and track this change in performance over time to verify improvements are sustained. Education also included a review of Policy: 1-14-04 PROVISION OF NUTRITION SERVICES with</p>	03/14/2025

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	<p>patients had a Phosphorus level greater than 7 in October 2024, 23.2% of HD patients had a Phosphorus level greater than 7 in November and December of 2024. The report indicated the CMS [center for Medicare services] goal was 12.6%. The report indicated the RD would provide ongoing education aimed at reducing phosphorus levels to include diet education and binders (medication to help lower the phosphorus level in the body) therapy and taking the binders as prescribed. The report indicated the RD followed up with extended care facilities to ensure patients were receiving appropriate binder therapy for daily intake of food, and physician orders included binder options to strive for better mineral bone disorder management.</p> <p>During an entrance conference on 02/10/2025, the current incenter HD patients were 64.</p> <p>The current census indicated 15 patients of 64 had a Phosphorus level greater than 7 in November and December of 2024 and 12 patients of 64 had a Phosphorus level greater than 7 in October 2024. The FHR report failed to evidence sustained improvement for Phosphorus levels greater than 7.</p> <p>3. A nephrologist (kidney doctor) note, titled, "Comprehensive Encounter," dated 10/16/2024, indicated Patient #3's phosphorus level was elevated at 7.7 and needed binders (medication to help lower the phosphorus level in the body).</p> <p>A nephrologist note, titled, "Comprehensive Encounter," dated 11/11/2024, indicated Patient #3's phosphorus level was elevated at 7.8 and needed binders.</p> <p>A nephrologist note, titled, "Limited Encounter," dated 12/16/2024, indicated Patient #3's</p>		<p>emphasis on the RD to participate in the Facility Health Meetings and role responsibilities. Verification of attendance is evidenced by a signature sheet for each in-service. In addition, the Governing Body met and completed a Governing Body, named Mineral & Bone Disease Management Team (MBDMT) to closely monitor and review timely patient MBD related lab results and any medications adjustments per physician order or protocol are entered timely in CWOW and followed up on for patient adherence and effectiveness. All individual patient notes and orders will be documented in CWOW. FHM/QAPI will evidence a facility overview as outlined above to reflect root cause of underperformance and action plans. The ROD or MCS will review FHR meeting minutes monthly x 4 months to ensure compliance with the QAPI policy. Instances of non-compliance will be addressed immediately. The Facility Administrator will review results of all audits with TMs during homeroom meetings and with the Medical Director during monthly Quality Assurance Performance Improvement (QAPI) meetings, known as Facility Health Meeting (FHM). The Facility Administrator is responsible for ongoing compliance with this plan of</p>	

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	<p>phosphorus level was elevated at 10.8 and needed binders (medication to help lower the phosphorus level in the body).</p> <p>A nephrologist note, titled, "Comprehensive Encounter," dated 01/20/2025, indicated Patient #3's phosphorus level was elevated at 6.7 and needed binders.</p> <p>The patient's clinical record failed to evidence documentation binders were prescribed, the patient received the binders, the patient was aware of added binders, or the RD discussed binders with the patient.</p> <p>A Mineral Bone Disorder Report indicated Patient's phosphorus level 09/04/2024 was 5.8, 10/11/2024 was 7.7, 11/06/2024 was 7.8, 12/06/2024 was 10.8, and 01/15/2025 was 6.7.</p> <p>A Medication List, last updated 01/20/2025, failed to evidence a phosphorus binder medication.</p> <p>4. During an interview on 02/11/2025, beginning at 11:10 AM, the RD indicated she provided education to patients about blood test results chairside once a month and protocols would be used for adjustments to medications.</p> <p>5. During a follow up interview on 02/13/2025, beginning at 3:52 PM, the RD indicated she reached out to entity 2 and Patient #3 and Patient #4 were not enrolled in entity 2's prescription program and did not receive binders. The RD indicated there was a gap in patients' receiving phosphorus binders as ordered by the physician due to physicians only had access to the prescribing system. The RD indicated there were no phosphorus binder medications prescribed for Patient #3 or Patient #4. The RD indicated she did</p>		correction. 3/14/2025	

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	<p>reach out to the medical director and Patient #3 and Patient #4 were prescribed to start Renvela (a phosphorus binder).</p> <p>6. A clinical record review for Patient #4 evidenced a Comprhensive Encounter electronically signed by the physician dated 12/11/2024 which indicated their phosphorous (mineral) level in the blood was 7.8 was indicated to be abnormally high. The comprehensive encounter indicated the physician sent an order for phosphorous binders (medication to lower the phosphorous in the blood) to the pharmacy.</p> <p>The Comprehensive Encounter electronically was signed by the physician, dated 2/10/2025, indicated the phosphorous level was abnormally high at 6.6 and indicated the physician sent phosphorous binders to the pharmacy. The review failed to evidence the phosphorous binder was included in the patient's medication list and failed to evidence the patient had been instructed to begin taking phosphorous binders.</p> <p>On 02/23/2025, at 2:22 PM, the RD indicated the phosphorous binders were not included in the patient's medication list and indicated the physician must have ordered the binders in one ordering system that did not electronically upload the order into the facility's electronic medical record.</p>			