STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152562	A. BUILDING 00 B. WING	03/02/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE MUNSTER	314 RIDGE RD MUNSTER, IN 46321

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (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
E 0000 Bldg. 00	A Recertification (CORE) Survey was conducted by Healthcare Management Solutions, LLC on behalf of Centers for Medicare & Medicaid Services (CMS). An unannounced on-site Recertification (CORE) survey (ASPEN #JKYN11) conducted at the above-named End Stage Renal Disease (ESRD) facility from 02/28/22 to 03/02/22 resulted in a finding of no deficiency respective to the Emergency Preparedness Program Condition for Coverage under 42 CFR 494.62. Survey Dates: 02/28/22 to 03/02/22 Total Facility Census: 43 In-Center Hemodialysis: 43 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): Nocturnal: 0 Pediatrics: 0 Sample Size: 5 Supplemental Sample: 8 Total Sample Size: 13 Network 9 was contacted after entrance.	E 0000		
V 0000 Bldg. 00	A Recertification (CORE) survey was conducted	V 0000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any defiencystatement ending with an asterisk (*) denotes a deficency which the institution may be excused from correcting providing it is determin other safegaurds 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 disclo 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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	by Healthcare Management Solutions, LLC on behalf of Centers for Medicare & Medicaid Services (CMS). An unannounced on-site Recertification (CORE) survey (ASPEN #JKYN11) conducted at the above-named End Stage Renal Disease (ESRD) facility from 02/28/22 to 03/02/22 resulted in a finding of substantial compliance respective to applicable Conditions for Coverage (CfC) under 42 CFR 494, Subpart A through D with the following standard-level deficiencies listed below. Total Facility Census: 43 In-Center Hemodialysis: 43 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): Nocturnal: 0 Pediatrics: 0 Sample Size: 5 Supplemental Sample: 8 Total Sample Size: 13 Network 9 was contacted after entrance.			
V 0111 Bldg. 00	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. Based on observation, interview, review of facility's policies, the facility failed to 1) ensure all	V 0111	By March 15, 2022, the Clinic Manager or designee held a staff	04/15/2022

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	patients (P) and staff wore a facial mask appropriately while in the treatment area, to minimize the transmission of COVID within the dialysis facility, 2) ensure all staff followed policy regarding artificial nails, 3) ensure garbage was disposed of when containers were full. This had the potential to affect all patients receiving hemodialysis and staff at this facility, potentially exposing them to COVID-19, and the potential to spread infectious disease. Findings include: 1. Observations on 02/28/22 between 8:30 AM and 11:10 PM on the dialysis treatment floor revealed, P7 and P8 were observed not wearing a facial mask appropriately. P7 had the mask under his/her chin, and P8 wore the mask under his/her nose. During an interview on 02/28/22 at 8:55 AM Registered Nurse (RN) 1 stated P7 never wear his/her mask correctly. Observation on 03/01/22 between 7:10 AM and 1:10 AM, RN3 was observed wearing his/her mask on the tip of the nose while performing treatment and under the nose when sitting at the nursing desk on the dialysis treatment floor. During an interview on 03/01/22 at 2:00 PM RN Clinical Manager (RNCM)1 confirmed masks should be worn all the time and they do have some difficult patients, and then asked, "was it RN3"? Review of facility's policy titled "Use of Surgical and N95 Respirator Face Masks during A Pandemic," dated 07/30/21, revealed, "All FKC staff, physicians. physician extenders. visitors and patients are required by policy to adhere to		meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Use of Surgical and N95 Respirator Face Masks during a Pandemic · Human Resources Policy Employee Dress Code Patients will be reeducated on wearing mask per policy by 3/18/22, documentation will be placed in the medical record. Emphasis will be placed on: ensuring that the facility 1) all patients (P) and staff wear a facial mask appropriately while in the treatment area, to minimize the transmission of COVID within the dialysis facility; All FKC staff, physicians, physician extenders, visitors and patients are required by policy to adhere to personal protective equipment (PPE) guidelines laid out in FKC pandemic policies. The required face masks for use in FKC in-center hemodialysis locations are company provided surgical face masks and N95 respirator masks. Adhere to all PPE guidelines per FKC policy, including face mask guidance. Regardless of the type of approved face mask that is used, the FKC staff member should be careful not to touch their eyes, nose, and mouth when removing their face covering and follow hand hygiene practices immediately after	

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	personal protective equipment (PPE) guidelines laid out in FKC pandemic policies:. . .The required face masks for use in FKC in-center hemodialysis locations are company provided surgical face masks and N95 respirator masks." 2. Observations on 02/28/22 between 8:30 AM and 12:10 PM on the dialysis and 03/01/22 between 7:10 AM and 1:10 PM, Patient care Technician (PCT)1 and PCT 2 were observed to have artificial nails. PCT1 had jewels attached to the artificial nails near the cuticle. Interview on 03/01/22 at 2:05 PM, RNM1 confirmed PCT 1 and PCT2 do have artificial nails, and that staff have been reminded about the facilities dress code that prohibits artificial nails. Review of facility's policy titled, "Employee Dress Code," dated 06/18/21, revealed, "Fingernails must be clean and no more than l/4 of an inch beyond the rip of the finger. Chipped nail polish and artificial nails are not allowed." 3. Observations on 02/28/22 between 8:30 AM and 11:10 PM revealed dialysis station garbage bins in "POD" 1, 2, and 4 overflowing, with paper, discarded packaging, and used gloves on the floor. During an interview on 02/28/22 at 9:00 AM the overflowing garbage was pointed out to PCT1 who stated, "the (station) garbage's get emptied with they are full, it is up to each person." During an interview on 02/28/22 at 12:05 PM, RN1 confirmed garbages get emptied when they are full and put in a larger covered garbage bin. RN1 picked gloves and packaging off the floor and placed them in the larger garbage bin between		removing face masks. 2) To ensure employees maintain a work environment that adheres to safety and infection control protocols, the following applies, fingernails must be clean and no more than 1/4 of an inch beyond the tip of the finger. Chipped nail polish and artificial nails are not allowed. 3)General cleaning of the dialysis treatment area: ensure garbage is disposed of when containers are full and pick up loose trash. Effective 3/16/22, Clinic Manager or designee will conduct weekly audits utilizing clinic audit tool for 4 weeks with a focus on staff and patients wearing masks per policy; ensuring staff are not wearing false fingernails, have chipped nail polish and nails are clean and no more than ¼ inch beyond the tip of the finger; ensure loose trash is picked up in the dialysis treatment area and garbage cans are not overflowing. Once compliance is sustained at 90 %, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and	

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	PODs 2 & 3, the covered garbage was observed filled to the top. During an interview on 03/02/22 at 8:00 AM, RNCM1 stated the garbage bins should not be overflowing and should be emptied when full. Review of the facility's policy titled, "Cleaning the Dialysis Treatment Area and Isolation Area Procedures," dated 11/01/21, revealed, " Procedure: General Cleaning. . .Empty all waste containers at the workstations."		trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	
V 0113 Bldg. 00	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. Based on observations, interview, and policy review, the facility failed to ensure 1) staff performed hand hygiene (sanitizing with an alcohol-based hand rub or washing with soap and water) when changing gloves and between tasks, and 2) patient performed hand hygiene after	V 0113	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on:	04/15/2022

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	holding dialysis site to assist with obtaining hemostasis (stop bleeding) for two of two observation days. Failure to perform hand hygiene provided a mode of cross contamination with the potential spread of infection which could negatively impact the 43 patients receiving hemodialysis treatments at this facility. Findings include: During an observation on 02/28/22 at 8:30 AM, upon entering the dialysis treatment entrance, was a hand washing sink with a large sign to remind patient to perform hand hygiene before dialysis treatment. Observations on 02/28/22 as follows: At 11:20 AM, Patient Care Technician (PCT)2 at Station 14, after washing the fistula access site with antibacterial scrub and evaluating the fistula site for Patient (P)10, PCT2 failed to change gloves and perform hand hygiene before applying antiseptic to the skin before cannulation (needle insertion). At 11:55 AM, after dialysis treatment stopped and needles were removed for P12 at Station 15, P12 with gloved hand assisted PCT2 by holding pressure of the fistula site to obtain hemostasis (stop the bleeding). After hemostasis was obtained and P12 removed gloves, PCT2 failed to remind P12 to perform hand hygiene. P12 was observed to go out to the scale perform a weight come back into the dialysis treatment area to hand PCT2 the slip of paper, and left the treatment area and walked out of the building without performing hand hygiene. At 12:15 PM, Registered Nurse (RN)1 during the initiation of dialysis on a Central Venous Catheter		· Hand Hygiene · Initiation of Treatment Using a Central Venous Catheter and Optiflux Single Use Ebeam Dialyzer · Changing the Catheter Dressing Emphasis will be placed on: Ensuring the facility 1) staff perform hand hygiene (sanitizing with an alcohol-based hand rub or washing with soap and water) change gloves between tasks, 2) patient performs hand hygiene. Gloves should be worn at all times while touching the machine or any documenting components of the machine. After removing of catheter dressing, it should be discarded, gloves removed and hand hygiene should be performed before moving onto the next task. **Hands Will Be …** **When …** Washed with antimicrobial soap and water · Hands are visibly dirty or contaminated with proteinaceous material, blood, or other body fluids. · Before eating · After using a restroom · Anthrax or C-difficile exposure Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water · Before and after direct contact with patients	

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	(CVC-a thin, flexible tube (catheter) that is placed into a large vein above the heart) for P5, after cleaning the hubs and flushing, RN1 needed recheck machine that had not passed testing, and without changing gloves or performing hand hygiene, entered data on dialysis machine. RN1 saw the prime waste bucket still had fluid in it and dumped it out before performing hand hygiene and changing gloves. Observations on 03/01/22 as follows: At 7:15 AM, after completing needle insertion for P11 at Station 9, PCT1 failed to remove gloves or perform hand hygiene before entering data on the computer. PCT1 then returned to P11 to hook up the dialysis tubing to start the dialysis treatment, returned to the computer to enter data, before removing gloves and performing hand hygiene. At 7:30 AM, PCT2 performed a CVC exit site care (dressing change) for P9 at Station 14, after removing and discarding the old dressing without changing gloves or performing hand hygiene, PCT2 continued to cleanse area around CVC exit site with antiseptic cleanser, removed gloves and without the benefit of hand hygiene donned new gloves and applied the sterile dressing, but failed to removed gloves and perform hand hygiene before moving on to a new task. At 7:40 AM, PCT 2 without changing gloves after application of the sterile dressing continued to initiate dialysis for the CVC catheter. At 11:51 AM, after dialysis treatment stopped and needles were removed for P13 at station 6, P13 with gloved hand assisted RN3 by holding pressure of the fistula site to obtain hemostasis. After hemostasis was obtained with the same gloves P13 put on his/her own pressure dressing, stood up pushed the dialysis machine button to		· Entering **and** leaving the treatment area · Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications · Immediately after removing gloves · After contact with body fluids or excretion, mucous membranes, non-intact skin, and wound dressings if hands are not visibly soiled. · After contact with inanimate objects near the patient. · When moving from a contaminated body site to a clean body site of the same patient · After contact with the dialysis wall box, concentrate, drain, or water lines. **Hand** **Hygiene: Patients** Patients should perform hand hygiene if able, prior to and after each dialysis treatment. As needed, direct patient care staff will demonstrate how to operate the sinks, demonstrate hand washing to patients who are able to perform hand washing, and explain risk of contamination with regard to their vascular access and hands to all patients. Gloves must be provided to	

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	take his/her own blood pressure before removing glove RN3 failed to remind P13 to perform hand hygiene. P13 was observed to go out to the scale take a weight and left the facility without performing hand hygiene. On 02/28/22 from 8:30 AM to 11:30 AM and 03/02/22 from 7:00AM-1:10 PM patient's entering the dialysis treatment floor did not wash their hands. On 03/02/22 at 8:05 AM during an interview with RN Case Manager (RNCM) 1, RNCM1 stated we could do better at reminding them (patients). RNCM1 stated he/she does not always perform the staff audits for hand hygiene, he/she would need to look into that. Review of the facility's policy titled, "Hand Hygiene," dated 11/04/19 revealed, "All staff patients, patient care givers, including physicians and non-physician practitioners, social workers, dietitians and any other indirect patient care staff must follow the same requirements for hand hygiene. Decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water. Before and after direct contact with patients. Entering and leaving the treatment area. Before performing any invasive procedures such as vascular access cannulation or administration of parenteral medications. Immediately after removing gloves. After contact with body fluids or excretion, mucous membranes, non-intact skin- and wound dressings if hands are not visibly soiled. After contact with inanimate objects near the patient. When moving from a contaminated body site to a clean body site of the same patient. After contact with the dialysis wall box, concentrate, drain, or water lines.		patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis To help ensure the prevention of cross contamination to their family members or other patients, hand hygiene must be performed. 100% of patients on census will be reeducated on the importance of hand hygiene pre, post and after holding needle sites post treatment by 4/18/22. Documentation will be placed in patient medical record and will be available for review. Effective 3/16/22, Clinic Manager or designee will conduct weekly audits utilizing clinic audit tool for 4 weeks with a focus on appropriate hand hygiene for each task performed. Once compliance is sustained at 90%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit	

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	Hand Hygiene for Patients: Patients should perform hand hygiene if able, prior to and after each dialysis treatment. Gloves must be provided to patients when performing procedures which risk exposure to blood or body fluids, such as when self-cannulating or holding access sites post treatment to achieve hemostasis. To help ensure the prevention of cross contamination to their family members or other patients, hand hygiene must be performed.		results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	
V 0126 Bldg. 00	494.30(a)(1)(i) IC-HBV-VACCINATE PTS/STAFF Hepatitis B Vaccination Vaccinate all susceptible patients and staff members against hepatitis B. Based on interview record review, and policy review, the facility failed to ensure all patients and staff were offered the Hepatitis B virus (HBV) vaccination after identifying on laboratory antibody titer for HBV antibodies, two of five patients (Patient (P3 and 5) and one of six staff (Patient care Technician (PCT) 1) were not immune. This has the potential to cause anyone	V 0126	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Employee Requirements for Testing and Vaccination for	04/15/2022

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	not vaccinated to become infected if they come in contact with the blood of a Hepatitis B positive patients' blood. Findings include: 1. Review of P3s medical record revealed P3 was admitted to service on 01/24/22. Admission laboratory tests revealed P3 did not have antibodies for HBV immunity. Review nursing notes revealed P3 had not been offered the HBV vaccination. Review of the vaccination records revealed P3 did not have a HBV declination signed. During an interview on 03/01/22 at 1:45 PM at the time of the record review, Registered Nurse Clinical Manager (RNCM)1 confirmed that P3s lab test showed P3 did not have immunity to HBV. RNCM1 confirmed the medical record did not have documentation that P3 was offered the HBV vaccination series or that P3 declined the HBV vaccine series. 2. Review of P5s medical record revealed P5 was admitted to service on 10/08/21. Admission laboratory tests revealed P5 did not have antibodies for HBV immunity. Review nursing notes revealed P5 had not been offered the HBV vaccination. Review of the vaccination records revealed P5 did not have a HBV declination signed. During an interview on 03/02/22 at 10:15 AM at the time of the record review, RNCM1 confirmed that P5s lab test showed P5 did not have immunity to HBV. RNCM1 confirmed the medical record did not have documentation that P5 was offered the HBV vaccination series or that P5 declined the HBV vaccine series.		Hepatitis B · Patient Vaccination for Hepatitis B Emphasis will be placed on: ensure all patients and staff are offered the Hepatitis B virus (HBV) vaccination after identifying on laboratory antibody titer for HBV antibodies, are not immune. The Hepatitis B vaccine shall be offered to all employees upon hire or rehire within 10 working days of initial assignment to all employees that have occupational exposure to blood or other potentially infectious materials, A protective antibody response is 10 or more milli-international units (mIU) per milliliter (anti-HBs ³ 10mIU/mL). If susceptible, offer vaccine. If the employee declines, a signed declination must be maintained in the employee file. The Hepatitis B vaccine shall be offered to all susceptible patients including peritoneal and home hemodialysis patients. Document locally administered vaccines, non-locally administered vaccines, and vaccine declinations in the patients' electronic medical record. Reasons for vaccine declination include: Refusals, Medical Contraindication (e.g., allergies, other) · Vaccinated elsewhere, (e.g., local pharmacy, health clinic or primary care physician) · Vaccinated in another FKC Clinic. Effective 3/16/22, Clinic Manager	

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	3. Review of personnel files for PCT1 revealed the PCT was hired 02/25/18. A laboratory test was completed on 02/27/19 to test for HBV antibodies, the results revealed, PCT1 did not have immunity and that information was reported on 03/01/19. PCT1 did not have evidence the HBV vaccine had been offered or declined. During an interview on 03/02/22 at 8:30 AM RNCM1 confirmed the facility did not have the information of HBV vaccine series acceptance or decline documented for PCT1. Review of the facility's policy titled, "Patient Vaccination for Hepatitis B," dated 02/07/22, revealed, "The Hepatitis B vaccine shall be offered to all susceptible patients including peritoneal and home hemodialysis patients." Review of the facility's policy titled, "Employee Requirements for Testing and Vaccination for Hepatitis B," dated 04/05/21 revealed, "The Hepatitis B vaccine shall be offered to all employees upon hire or rehire. Employees will be provided with the vaccine and vaccination at no charge. The hepatitis B vaccine shall be provided within l0 working days of initial assignment to all employees that have occupational exposure to blood or other potentially infectious materials. Unless: -The employee has previously received the complete series and antibody testing has revealed that the employee is immune. Or -The vaccine is contraindicated for medical reasons. Or -The employee has declined vaccination and signed declination form."		or designee will conduct 1.)100% medical record audit of census using the Hepatitis B summary report with a focus on ensuring every patient on census has been offered the Hepatitis B vaccine or a signed declination is on file in the patient medical record. 2.) 100% audit of staff personnel files to ensure that all staff have been offered the hepatitis B vaccine or a signed declination is on file. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as	

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			appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	
V 0143 Bldg. 00	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and Based on observation, interview, and policy review, the facility failed to ensure aseptic technique was used per policy for drawing up medication for one of two when drawing up from a multi-dose vial. This has the potential to negatively affect all 43 patients being treated in the facility. Findings include: During an observation 02/28/22 at 11:30 AM, PCT2 without cleaning the septum of an opened vial of Heparin, attempted to draw up 4000 units of Heparin in a bottle labeled for multi-dose use (30,000 unit/30 ml (milliliters)) and stated "oh, I have the wrong size syringe," pushed the medication drawn up back into the Heparin vial and discarded the syringe. PCT2 pulled out two syringes from the drawer, and without cleaning the septum drew up a syringe with 4000 units, without cleaning the septum drew up another	V 0143	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Medication Preparation and Administration Emphasis will be placed on: Ensuring the facility staff use aseptic technique when drawing up medication from a multi-dose vial. Always use a sterile syringe and needle when entering a vial. If both vials are single use and are discarded after the single entry into each, the same syringe may be used. If either vial is multi-use a different syringe must be used for entry into each vial. Cleanse the diaphragm of a vial with alcohol	04/15/2022

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	syringe with 2000 units of Heparin. During an interview on 02/28/22 at 11:30 AM the time of the observation, PCT2 confirmed the Heparin was in a multi-dose vial and the two bolus doses were for P6, showing the medication order and the label for P6, then PCT2 opened an alcohol wipe and cleaned the septum and continued to draw up Heparin. During an interview on 03/01/22 at 2:15 PM, Registered Nurse Clinical Manager (RNCM)1 confirmed cleaning the septum is a part of the skills check off, and staff should always be cleaning the septum each time they enter a multi-dose vial. Review of the facility's policy titled, "Medication Preparation and Administration," dated 11/01/21, revealed, "Cleanse the diaphragm of a vial with alcohol prior to accessing the vial. If the vial is a multidose vial, cleanse the diaphragm with a new alcohol pad each time the vial is accessed with a needle using friction and 70% alcohol. Allow to dry before inserting a device into the vial."		prior to accessing the vial. If the vial is a multidose vial, cleanse the diaphragm with a new alcohol pad each time the vial is accessed with a needle using friction and 70% alcohol. Allow to dry before inserting a device into the vial. Effective 3/16/22, Clinic Manager or designee will conduct weekly audits utilizing clinic audit tool for 4 weeks with a focus on aseptic technique while drawing medication from a vial per policy and procedure. Once compliance is sustained at 90 %, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible	

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			to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	
V 0196 Bldg. 00	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1			

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	mg/L]. Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly. Based on personnel file review, interview and policy review, the facility failed to ensure two of five personnel files (Registered Nurse (RN)1 and Patient Care Technician (PCT) 2) who performed water testing with color strips had completed color blind test documentation to validate what test components were completed and who verified the test was completed and passed the test. This has the potential to affect all 43 patients being treated at this facility. Findings include: During a review of personnel files on 03/01/22 revealed five of the six personnel files were trained and qualified to conduct water testing at this facility, continued reviewed identified RN1 (date of hire 07/13/15) and PCT2 (date of hire 09/14/15) did not have a color blind test documented on a facility form that include each test component, and the signature of the approved test giver, and date the test was performed. During an interview on 03/02/22 at 9:30 AM, the Facility Administrator confirmed that the papers in the personnel files for RN1 and PCT2 were computer generated and not acceptable to testing. Facility Administrator then provided the facility's color blind test form titled "Color and Quality Test Screen Results Form" dated 01/23/19 and the policy titled " Color Blindness Testing" dated 01/23/19. During an interview on 03/02/22 at 9:35 AM RN	V 0196	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Color Blindness Testing Emphasis will be placed on ensuring the staff who perform water testing with color strips have completed color blind test, documentation to validate what test components were completed and who verified the test was completed and passed the test. The manager or designee is responsible for administering and recording the results of the Ishihara Test for Color Blindness on the business specific scoring sheet. The manager is responsible for confirming the test results are documented and placed in the employee's medical file. Results of any required tests will be kept confidential and maintained in the employee's medical file. Effective 3/16/22, Clinic Manager or designee will conduct 100% personnel file audit to ensure that all staff functioning in a job role that requires a color blindness test have a completed one on file that	04/15/2022

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	Case Manager (RNCM)1 confirmed there was not a valid color blind test for RN1 and PCT2 who are currently conducting water testing at this facility. Review of the facility's' policy titled, "Color Blindness Testing," dated 01/23/19, revealed, "Patient care and biomedical staff are in positions that require the ability to interpret or distinguish color when performing water and/or other quality tests or maintenance on dialysis or other equipment. People who suffer from color blindness, may not be able to distinguish between certain colors used in water and other testing methodologies. New hire, rehire, or transfer staff working in a direct patient care or biomedical position are required to take the Ishihara for Color Blindness to ensure the ability to perform the essential functions of their job."		confirms test results utilizing the clinic audit checklist. Once compliance is sustained at 100%, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	

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V 0401 Bldg. 00	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. Based on observation, staff interview, and review of the facility's policy, the facility failed to maintain a safe environment by not removing expired supplies from the facility inventory. Failure to remove expired items provided the potential for staff to use supplies that were no longer viable or were deemed unusable by the manufacturer and had the potential to negatively affect the care of all 43 in-center patients at this facility. Findings include: On 03/01/22 at 11:15 AM on the dialysis treatment floor a cart of laboratory supplies was observed. A partially used package of red/black top laboratory tubes for blood collect was identified with eight tubes remaining for lot #1020641 that had the expiration as 01/31/22. During an interview on 03/01/22 at 11:15 AM at the time of the observation, Registered Nurse (RN) 2 confirmed the tubes had expired in January. RN2 stated they should not have been on the cart. In an interview with RN Clinical Manager 03/01/22 at 11:30 AM confirmed the facility did not have a policy addressing discarding expired supplies and provided a sheet from the laboratory company "Spectra Laboratories" not dated, revealed, "Prior to specimen collection, check the expiration date on all supplies." RNCM1 confirmed there was no	V 0401	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Storage of Supplies Emphasis will be placed on: removing expired supplies from the facility inventory to maintain a safe environment. Proper storage conditions are necessary to provide a safe environment and to ensure supplies are not expired, contaminated, or damaged. Supplies must be rotated First in-First Out (FIFO) to ensure products maintain quality and do not expire. Appropriately dispose of items that have reached the expiration date. Effective 3/16/22, Clinic Manager or designee will conduct weekly audits utilizing clinic audit checklist for 4 weeks with a focus on ensuring clinic staff are maintaining a safe environment and discarding any expired supplies. Clinic will implement a monthly schedule to check supply expiration dates. Once compliance is sustained at 90%,	04/15/2022

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	policy.		the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	

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V 0504 Bldg. 00	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. Based on interview and record and policy review the facility failed to follow policy for blood pressure (BP) management for two of five patients (Patients (P) 4 and P5). The failure to monitor blood pressure during dialysis treatment has the potential to negatively affect health outcomes for all 43 patients being treated at this facility. Findings include: 1. Review of treatment sheets for P4 for dialysis treatment received on 02/26/22 revealed dialysis treatment started at 7:38 AM, BP was 196/92, at 8:00 AM BP was 194/96, at 8:00 AM BP was 195/96 and immediately retaken BP was 209/100no nurse note was document and BP was not retaken until 8:36 AM BP was 191/95. No post treatment assessment was completed. During an interview of 03/02/22 at 10:05 AM Registered Nurse Clinical Manager (RNCM) 1 confirmed that P4s blood pressure was elevated above the perimeters set in the facilities policy, and that RN3 did not document at the time of the elevated BP and that no post treatment nursing assessment was documented 2. Review of treatment sheets for P5 started dialysis treatment on 02/16/22: At 11:25 AM dialysis treatment was started with BP at 103/53, at 11:30 AM the BP was 102/56, at	V 0504	By March 15, 2022, the Clinic Manager or designee held a staff meeting, elicited input, and reinforced the expectations and responsibilities of the facility staff on: · Patient Assessment and Monitoring · Determination of Blood Pressure · Nursing Supervision and Delegation Emphasis will be placed on: Follow policy for blood pressure management. Prior to discharge, the RN must review the treatment record to: Confirm patent is stable for discharge; The record must be reviewed for: Slow/fast/irregular heart rate, Low or high blood pressures, whether patient is achieving dry weight and identifying reason for patient not achieving dry weight. Document findings in the medical record. Monitoring during treatment: Obtain blood pressure and pulse rate every 30 minutes or more as needed but not to exceed 45 minutes or per state regulations. Document machine parameters	04/15/2022

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	12:00 PM the BP was 95/52, at 12:40 PM the BP was 98/52, at 1:02 PM at BP was 98/52, at 1:33 PM the BP was 95/54, at 2:00 PM the BP was 97/53. No blood pressure was taken between 2:00 PM and 3:02 PM (the end of treatment) BP was 104/52. Review of treatment sheets for P5 started dialysis treatment on 02/23/22: At 11:23 AM dialysis treatment was started with BP at 100/57, at 11:30 AM the BP was 104/56, at 12:00 PM the BP was 91/51, at 12:36 PM the BP was 93/55. No BP was taken between 12:36 PM and 1:40 PM. At 1:40 PM the BP was 108/58, at 2:02 PM BP was 115/61, 3:01PM BP was 108/57 and 3:25 (the end of treatment) BP was 122/56. During an interview of 03/02/22 at 10:30 AM RNCM1 confirmed that P5s blood pressures were habitually low, for P5 and should have a physician's order for special perimeters to address the low BPs. RNCM confirmed staff did not follow policy that required every 30-minute blood pressure to evaluate P5s blood pressure during treatment. Review of the facility's policy titled, "Determination of Blood Pressure," dated 02/07/22, revealed, "Blood pressure measurements in patients with kidney failure are most often indicators of changes in fluid status. As fluid weight increases, the blood pressure increases; when fluid is removed. the blood pressure decreases. Hypertension may indicate volume overload: hypotension may indicate dehydration. The following conditions can lead to serious outcomes and even death: Untreated/unattended severe hypertension (>200 s) systolic (greater than 200) Untreated/unattended severe hypotension (<80 s)		and safety checks every 30 or more often as needed but not to exceed 45 minutes or per state regulations. Recheck blood pressures after a drop in blood pressure that requires a patient to receive normal saline. A recheck is needed to determine if the intervention improved the patient's blood pressure. Verify by repositioning electronic cuff or use a manual cuff for blood pressures that show an aberrant reading as compared to other blood pressures or when a large drop or elevation in blood pressure is noted. The parameters can also be modified by the nephrologist for individual patients that may require modifications based on their comorbid conditions. Effective 3/16/22, Clinic Manager or designee will conduct weekly audits utilizing treatment sheet audit tool for 4 weeks with a focus on ensuring clinic staff are obtaining patient blood pressure checks every 30 minutes or more as needed and that they are not exceeding 45 minutes. Documentation must be present if patient's blood pressure reading is out of ordered parameters. Once compliance is sustained at 90 %, the Governing Body will decrease frequency to monthly then resume regularly scheduled audits based on the QAI calendar. Monitoring will be done through the clinic	

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	systolic (less than 80) Blood pressures not rechecked to verify, correctness of the result when a significant drop or increase occurs. Obtain blood pressure readings pre- and post-dialysis sitting and standing (if applicable) and every 30 minutes or more during hemodialysis treatments as indicated."		audit checklist. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is responsible to review, analyze and trend all data and monitor/audit results as related to this Plan of Correction prior to presenting to the QAI Committee monthly. The Director of Operations is responsible to present the status of the Plan of Correction and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the sustained resolution of all identified issues. The QAI Committee is responsible to provide oversight, review findings, and take actions as appropriate. The Governing Body is responsible to provide oversight to ensure the Plan of Correction, as written to address the issues identified by the Statement of Deficiency, is effective and is providing resolution of the issues. The in-service sheets are available in the clinic for review.	