STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	X2) MULTIPLE CONSTRUCTION	X3) DATE SURVEY COMPLETED
	152556	A. BUILDING 00 B. WING	08/27/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE NOBLESVILLE	165 SHERIDAN RD NOBLESVILLE, IN 46060

(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	An Emergency Preparedness survey was conducted by the Indiana Department of Health in accordance with 42 CFR 494.62, for a Medicare participating End Stage Renal Disease Supplier. Date of survey: 8-25, 8-26, and 8-27-2021 Facility #: 010516 CCN: 152556 Stations: 12 ICHD Patients: 49 Home Hemodialysis: 3 Home Peritoneal Dialysis patients: 27 Home Peritoneal Dialysis in a SNF: 2 Total Census: 81 At this Emergency Preparedness survey, Fresenius Medical Center Noblesville, was found to have been in compliance with the requirements of Emergency Preparedness Requirements for Medicare participating providers and suppliers, including staffing and implementation of staffing during a Pandemic, at 42 CFR 494.62. Quality Review Completed on 09/02/2021 by Area 3 Sent to provider with corrections and adding HHD modality on 9/9/21 by Area 3	E 0000		

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

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V 0000 Bldg. 00	This visit was for a CORE Federal recertification survey of an ESRD provider by the Indiana Department of Health. Date of survey: 8-25, 8-26, and 8-27-2021 Facility #: 010516 CCN: 152556 Stations: 12 ICHD Patients: 49 Home Hemodialysis: 3 Home Peritoneal Dialysis patients: 27 Home Peritoneal Dialysis in a SNF: 2 Total Census: 81 Quality Review Completed on 09/02/2021 by Area 3 Sent to provider with corrections and adding HHD modality on 9/9/21 by Area 3	V 0000		
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.	V 0113	V113	09/25/2021

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	Based on observation, record review, and interview, the facility failed to ensure their staff changed gloves between the central venous catheter (CVC) dressing changes and obtaining lab specimens in 1 of 2 observations and failed to ensure all staff performed hand hygiene between glove changes in 3 of 6 staff observations. Findings include: On 8-26-2021 at 2:26 PM, a November 2019 Fresenius Kidney Care policy titled, "Hand Hygiene" was provided by employee M. The policy indicated but was not limited to, "...Hands will be decontaminated using alcohol-based hand rub or by washing hands with antimicrobial soap and water before performing any invasive procedure such as vascular access...immediately after removing gloves..." During an observation on 8-25-2021 at 11:47 AM, Patient Care Tech (PCT), employee P, failed to remove their gloves following the removal of a needle site. Employee P moved from station #9 to station #8 to answer a request of the patient and place patients belongings in their bag. During an observation on 8-25-2021 at 12:10 PM, PCT, employee P, failed to remove their gloves following the location and palpation of the access site and the cleaning of the access site. Employee P moved from palpating the access site to the computer and back to the access site to clean it. During an observation on 8-25-2021 at 3:10 PM, PCT, employee P, removed their gloves and donned new gloves when moving from station #11 and station #12. Employee P, failed to wash their hands between the application of new gloves.		On September 17, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy & procedure: · Hand Hygiene Education emphasis was placed on: · Change gloves and practice hand hygiene between each patient and station to prevent cross-contamination. · Removal of soiled gloves and performing hand hygiene after direct contact with patient access and/or after contact with inanimate objects within the hemodialysis station. · Hand hygiene may be performed by hand washing or using an alcohol based hand rub. · Hand washing will include wetting hands, applying soap, rubbing hands vigorously, rinsing hands under running water and drying thoroughly with a disposable towel. Duration of the entire hand washing procedure will be 40-60 seconds. · Decontaminating hands with an alcohol based hand rub includes applying hand rub, rub hands together covering all surfaces of hands and fingers, allow to dry. Duration of the entire hand rub decontaminating procedure will be 20 seconds. Effective September 20, 2021, the Clinic Manager or designee will conduct infection control audits	

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	During an observation on 8-25-2021 at 1:30 PM, Registered Nurse, employee L, was observed completing Central Venous Catheter (CVC) exit site care. Employee L removed the dressing and proceeded to clean the exit site. Before applying a new dressing to the CVC, employee L proceeded with lab draws filling two vacutainers (blood specimen tubes) with blood and placing them between the chair and chair table. Employee L failed to remove gloves and wash hands. During an interview on 8-26-2021 at 3:05 PM, Clinical Manager, employee M, confirmed gloves should be removed when moving between patients and between the process of palpation and cleaning of the access site.		five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on changing gloves and practicing hand hygiene per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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.	

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			Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0116 Bldg. 00	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. Based on observation, record review, and interview, the facility failed to ensure the employees disinfected non-disposable equipment (blood pressure cuffs) in 4 of 4 observations of cleaning the dialysis station after a treatment. Findings include: On 8-25-2021 at 10:15 AM, employee P, Patient Care Technician (PCT) failed to disinfect the blood pressure cuff. The blood pressure cuff Velcro pad is covered with thin material that is adhered to the Velcro.	V 0116	On September 17, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · Dialysis Precautions · Cleaning and Disinfection of the Dialysis Station Education emphasis was placed on: · All reusable instruments and equipment will be thoroughly cleaned and disinfected prior to use on a patient. · Cleaning and disinfected all	09/25/2021

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	On 8-25-2021 at 11:57 AM, Certified Clinical Hemodialysis Technician (CCHT), employee K, failed to disinfect the blood pressure cuff. The blood pressure cuff Velcro pad is covered with thin material that is adhered to the Velcro. On 8-26-2021 at 9:17 AM, employee U, PCT, failed to disinfect the blood pressure cuff. The blood pressure cuff Velcro pad is covered with thin material that is adhered to the Velcro. On 8-26-2021 at 1:30 PM, Certified Clinical Hemodialysis Technician (CCHT), employee H, failed to disinfect the blood pressure cuff. The blood pressure cuff Velcro pad is covered with thin material that is adhered to the Velcro. On 8-26-2021 at 2:27 PM, employee M, Clinical Manager, provided a November 2020 Fresenius Kidney Care policy. Titled, "Cleaning and Disinfection of the Dialysis Station", the policy indicated but was not limited to, "...After use, all non-disposable equipment and supplies must be disinfected with 1:100 bleach or...". On 8-26-2021 at 3:05 PM, the Facility Administrator and employee M were queried about the cleaning of the blood pressure cuffs. The Facility Administrator indicated the blood pressure cuffs would be difficult to clean.		work surfaces within the hemodialysis station with 1:100 bleach solution after completion of procedures, including Blood Pressure (BP) cuffs. · Replacing BP cuffs when unable to clean per policy. Effective September 20, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on cleaning BP cuffs per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

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			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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0122 Bldg. 00	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. Based on observation, record review and interview the facility failed to ensure infection control practices were maintained when cleaning and disinfecting the treatment center areas for 3 of 4 patients observed. Findings include: A November 2020 Fresenius Kidney Care policy titled, "Cleaning and Disinfection of the Dialysis Station" was provided by the Clinical Manager,	V 0122	On September 17, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Cleaning and Disinfection of the Dialysis Station Education emphasis was placed on: · Cleaning and disinfected all work surfaces within the hemodialysis station with 1:100	09/25/2021

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	employee M. The policy stated but was not limited to, "...The chair and dialysis equipment are used by multiple patients during a treatment day and it is critical that these items be thoroughly cleaned and disinfected between uses." During an observation at station #6 on 8-25-2021 at 11:57 AM, Patient Care Tech (PCT), employee K, failed to allow time for wet services to dry or fully open the entire chair to thoroughly clean interior surfaces prior to setting up for the next patient. During an observation at station #5 on 8-26-2021 at 11:30 AM, Certified Clinical Hemodialysis Technician (CCHT), employee H, did not fully open the entire chair to thoroughly clean interior surfaces prior to setting up for the next patient. During an observation at station #9 on 8-27-2021 at 9:17 AM, (PCT), employee U, did not fully open the entire chair to thoroughly clean interior surfaces prior to setting up for the next patient. During an interview on 8-26-2021 at 3:05 PM, Clinical Manager, employee M confirmed the chairs should be fully reclined and the sides fully opened when cleaning and disinfecting the chairs.		bleach solution after completion of procedures. · Patient chairs within the hemodialysis station will be fully reclined in Trendelenburg position and sides opened to clean all surfaces thoroughly. · Ensure the surfaces are glistening wet and allow to air dry before placing the next patient into the hemodialysis station. Effective September 20, 2021, the Clinic Manager or designee will conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on fully opening chairs and cleaning with 1:100 bleach solution per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

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			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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0147 Bldg. 00	494.30(a)(2) IC-STAFF EDUCATION-CATHETERS/CATHETER CARE Recommendations for Placement of Intravascular Catheters in Adults and Children I. Health care worker education and training A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections. B. Assess knowledge of and adherence to guidelines periodically for all persons who manage intravascular catheters. II. Surveillance A. Monitor the catheter sites visually of individual patients. If patients have			

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	tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site. Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients. VI. Catheter and catheter-site care B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. Based on observation, record review and interview the facility failed to follow facility policy related to central venous catheter (CVC) care for 1 of 2 CVC care observations. Findings include: On 8-26-2021 at 2:26 PM, a November 2019 Fresenius Kidney Care policy titled, "Changing the Catheter Dressing" was provided by employee M. The policy indicated but was not limited to "...Complete catheter exit-site care and dressing replacement before initiation of treatment." During an observation on 8-25-2021 at 1:30 PM, Registered Nurse, employee L, was observed completing Central Venous Catheter (CVC) exit site care. Employee L removed the dressing and proceeded to clean the exit site. Before applying a new dressing to the CVC, employee L proceeded with lab draws filling two vacutainers (blood specimen tubes) with blood and placing them between the chair and chair table. Employee L did not remove gloves and wash hands. Employee L	V 0147	On September 17, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Changing the Catheter Dressing Education emphasis was placed on: · Completion of catheter exit-site care and dressing replacement before initiation of treatment and prior to performing next task, such as lab draws. · Appropriate infection control measures to prevent intravascular catheter-related infections. · Removal of soiled gloves and performing hand hygiene after direct contact with patient access and/or after contact with inanimate objects within the hemodialysis station. Effective September 20, 2021, the Clinic Manager or designee will	09/25/2021

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	then proceeded with the application of the dressing over the exit site of the CVC. The disposable backside of the dressing came into contact with the CVC exit site. Employee L lifted the backside and removed the disposable shield of the dressing and proceeded to apply it to the CVC exit site. During an interview on 8-26-2021 at 3:05 PM, Clinical Manager, employee M, confirmed the dressing change should be complete prior to moving ahead with the next task, the employee would also remove their gloves and complete hand hygiene before applying the dressing as they touched the vacutainers.		conduct infection control audits five times weekly for one month, then two times weekly for one month, then weekly for one month utilizing the Infection Control Monitoring Tool. The focus will be on catheter exit-site care and dressing replacement per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

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			effective and is providing resolution of the issues. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0715 Bldg. 00	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; Based on observation, record review and interview the facility failed to ensure that the staff maintained standards of nursing practice while administering Venofer (iron supplement) into the medication hub of the intravenous (IV) line in 1 of 2 dialysis medication observations. Findings include: An April 2021 Fresenius Kidney Care policy titled, "Medication Preparation and Administration" was provided by the Clinical Manager (employee M). The policy indicated but was not limited to "... When administering medication, do not instill air into any component of the extracorporeal line, including the saline administration line." A review of the June 2019 Centers for Disease Control (CDC) guidelines for injection safety, "CDC.gov/injection safety/providers", indicates but is not limited to, "...expelling the air as part of	V 0715	On September 17, 2021, the Clinic Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policy: · Medication Preparation and Administration Education emphasis was placed on: · Ensuring all policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and non-physician providers. · Ensure staff maintain standards of nursing practice while administering Venofer (iron supplement) into the medication	09/25/2021

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	general medication guidelines for drawing medication into a syringe." On 8-25-2021 at 11:20 AM, Registered Nurse, employee L, was observed administering the medication Venofer (iron supplement) via the medication hub of the extracorporeal line. Employee L did not remove the excess air in the barrel of the syringe prior to administration for patient # 11. During an interview on 8-26-2021 at 3:30 PM, Clinical Manager, employee M, confirmed there should never be air infused in the line and it should be expelled prior to administration.		hub of the intravenous (IV) line. · When administering medication, do not instill air into any component of the extracorporeal line, including the saline administration line. Effective September 20, 2021, the Clinical Manager or designee will conduct medication preparation and administration audits daily for two weeks, then weekly for four weeks, then every two weeks for one month utilizing the Medication Administration Monitoring Tool. The focus will be on IV Venofer administration per policy. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. 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	

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	152556	A. BUILDING 00 B. WING	08/27/2021

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			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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	
V 0751 Bldg. 00	494.180 GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients ' personal and property rights, and to the general operation of the facility. Based on record review and interview, the agency failed to ensure CMS form 3427 was submitted to the state agency indicating FMC Noblesville would provide dialysis services within a contracted nursing home for 1 of 1 home dialysis being performed in a long term care facility. Findings include: According to SOM (State Operations Manual)	V 0751	On September 17, 2021, the Clinic and Home Therapy (HT) Program Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: · State Operations Manual, Chapter 2, 2271A-Dialysis in Nursing Homes · Administration of Home Therapy Services for Skilled	09/25/2021

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	Chapter 2, 2271A-Dialysis in Nursing Homes (Rev. 1, 18) indicates " ... ESRD Notififcation to the State Survey Agency of a New or Additional Contract with a Nursing Home to Provide Dialysis Services On-Site: ... the ESRD facility must notify its State Survey Agency of any such agreement(s). This notification is accomplished through submitting a completed Form CMS-3427 End Stage Renal Disease Application and Survey and Certification Report .... " Review of a Fresenius Kidney Care policy dated 8/2/2021 and titled, "Administration of Home Therapy Services for Skilled Nursing Facility ESRD Resident" was provided by the Clinical Manager (employee M). The policy indicated but was not limited to "...The Home Therapy program must file CMS form 3427 to indicate that it will be providing home dialysis services at a LTC Facility..." On 8-25-2021 at 10:30 AM, during the entrance conference, it was noted that Fresenius Medical Care of Noblesville was contracted to provide dialysis services to Long Term Care (LTC) residents from their Home Therapy program. On 8-26-2021 at 11:30 AM, a document titled, "Long Term Care Facility Coordination Agreement for Certain Home Dialysis Related Services" was provided by Home Dialysis Manager, employee C. The document indicates but is not limited to, "...Home dialysis means dialysis performed at home (which includes a Long Term Care Facility)...". The document was dated 4-20-2021. During an interview on 8-27-2021 at 12:50 PM, employee C confirmed they were unaware of the process and a Form 3427 was required.		Nursing Facility ESRD Resident Education emphasis was placed on: · The HT program must file CMS form 3427 to indicate that it will be providing home dialysis services at a Long Term Care (LTC) Facility. · ESRD Notification to the State Survey Agency of a new or additional contract with a nursing home to provide dialysis services on-site. Immediate actions taken on August 27, 2021, the Director of Operations completed and submitted a complete 3427, including the requested LTC information, to the surveyor. Effective September 20, 2021, the HT Program Manager or designee will conduct administrative audits weekly for four weeks, then every two weeks for one month utilizing the HT Documentation Monitoring Tool. The focus will be 3427 completion for all patients receiving HT services in an LTC. Once 100% compliance is sustained, monitoring will be completed per the Quality Assessment and Performance Improvement (QAI) calendar with oversight from the Governing Body. The Medical Director will review the results of audits each month at the QAI Committee meeting monthly. The Clinical Manager is	

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			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. Documentation of education, monitoring, QAI, and Governing Body is available for review. The Clinic Manager is responsible for overall compliance.	