STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	152543	A. BUILDING 00 B. WING	07/24/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP COD
FRESENIUS MEDICAL CARE - NORTH HAMMOND	5454 HOHMAN AVE HAMMOND, IN 46320

(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 the Centers for Medicare & Medicaid (CMS). The facility was found to be in compliance with the requirements of 42 CFR, Subsection 494.62- Condition for Coverage for Emergency Preparedness for End-Stage Renal Disease (ESRD) Facilities. Survey Dates: 07/22/19-07/24/19 Total facility census: 96 In-Center Hemodialysis: 96 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): 0 Nocturnal: 0 Pediatrics: 0 Sample Size: 9 Network 9 was contacted after entrance.	E 0000		
V 0000 Bldg. 00	A Recertification was conducted by Healthcare Management Solutions, LLC on behalf of the Centers for Medicare & Medicaid Services (CMS). The facility was found not to be in compliance with the requirements of 42 CFR, Part 494, Subparts A, B, C and D, Conditions for Coverage for End-Stage Renal Disease Facilities.	V 0000		

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

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	Survey Dates: 07/22/19-07/24/19 Total facility census: 96 In-Center Hemodialysis: 96 Home Hemodialysis (HHD): 0 Peritoneal Dialysis (PD): 0 Nocturnal: 0 Pediatrics: 0 Sample Size: 9 Network 9 was contacted prior to entrance.			
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 observation, interview, and policy review, the facility failed to ensure staff changed gloves and sanitized hands when going from station to station for one of three survey days. In addition, the facility failed to ensure patients washed or sanitized their hands, after holding vascular access site (a way to reach the blood during hemodialysis) for one of three survey day. The failure of patients to wash or sanitize their hands and staff not changing gloves and sanitizing hands between patient stations had the potential to cause patients to be at an increased risk for infection from cross contamination and could affect all 96 in-center patients.	V 0113	On July 26, 29 & 30, 2019, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·FMS-CS-IC-II-155-090A Hand Hygiene Policy ·FMS-CS-IC-II-155-090C Hand Hygiene Procedure Emphasis was placed on: ·Ensuring all staff, patients, patient care givers, including physicians and non-physician practitioners, social workers,	10/07/2019

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	Findings include: Observation on 07/22/19 at 9:55 AM revealed the patient at Station 19 held his/her access site. After the patient stopped bleeding Patient Care Technician (PCT) 11 walked the patient to the scale to obtain the patient's weight. The patient did not wash or sanitize hands and PCT 11 did not instructed or encourage the patient to disinfect hands. Observation on 07/22/19 at 11:05 AM revealed the patient at Station 6 held left upper arm access. After bleeding had stopped PCT12 walked the patient to the scale and did not instruct him/her to wash or sanitize his/her hands. The patient left the facility without washing or sanitizing hands. Observation on 07/23/19 at 10:00 AM revealed Physician 7 was on the treatment floor without any Personal Protective Equipment (PPE). He/she went to Station 10, retrieved a glove, checked the patient's ankle, then touched the dialysis machine screen. He/she left the glove on and proceed to Station 6, checked the patient ankle, and touched the machine screen. Physician 7 proceeded to Station 21 with the same glove, checked the patient ankle, and touched the dialysis machine screen. Physician 7 did not wash or sanitize hands when going from all three stations. During an interview on 07/23/19 at 10:10 AM, Physician 7 denied that he/she had touched the patients with the same glove and that he/she only touched the machine. When informed of observations Physician 7 only stated, "OK." During an interview on 07/24/19 at 9:58 AM. Charge Nurse 3 stated he/she "Chased Physician		dietitians and any other indirect patient care staff follow the 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 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 ·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 Effective September 3, 2019, Clinical Manager or designee will conduct visual handwashing audits twice weekly utilizing Clinical Practice Checklist for 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring	

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	7 around the treatment floor all the time about his/her infection control practices in the facility." Charge Nurse 3 acknowledged patients should be washing or sanitizing hands after holding access sites to prevent cross contamination. Review of the facility's policy titled, "Hand Hygiene," revised March 20, 2013, indicated, "Patients should perform hand hygiene if able prior to and after each dialysis treatment. All staff, patient's 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."		will be done through the Clinic Audit Checklist per QAI calendar. Any ongoing non-compliance by staff, per the Conditions for Coverage and the FMC policy, will be addressed with corrective action as appropriate. 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 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. Completion Date: October 7, 2019	
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 one of three multi-dose bottles of medication were labeled when opened. The failure to label opened medications had the potential for staff to use expired medications and could affect all 96	V 0143	On July 26, 29 & 30, 2019, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies:	10/07/2019

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	in-center patients. Findings include: Observation on 07/23/19 at 9:35 AM revealed a multi-dose vial of Heparin 30,000 units per milliliter open and unlabeled, sitting in the medication preparation area across from Station 1. During an interview on 07/24/19 at 9:58 AM, Charge Nurse 3 acknowledged all medications opened, and not discarded immediately should be labeled with the date and time the medication was opened to ensure it was not expired. Review of the facility's policy titled, "Medication Preparation and Administration," revised 01/28/15, indicated, "Label any open multi-dose vial that is not used immediately and store vial accordingly."		·FMS-CS-IC-II-120-040A Medicatio n Preparation and Administration Policy ·FMS-CS-IC-II-120-040C Medicatio n Preparation and Administration Procedure Emphasis was placed on: ·Ensuring staff label any open multi-dose vial that is not used immediately and store vial accordingly. ·When preparing medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials. Effective September 3, 2019, Clinical Manager or designee will conduct visual audits weekly on all opened multi-dose medication vials for labeling of date/time/initials utilizing Clinical Practice Checklist for 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit Checklist per QAI calendar. Any ongoing non-compliance by staff, per the Conditions for Coverage and the FMC policy, will be addressed with corrective action as appropriate. The Clinical Manager is responsible to review, analyze and trend all data and Monitor/Audit results as related to this Plan of	

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			Correction prior to presenting to the QAI Committee monthly. 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. Completion Date: October 7, 2019	
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, interview, facility document review, and policy review, the facility failed to ensure staff answered machine alarms in a timely manner during two of three survey days. The failure to answer machine alarms in a timely manner had the potential for a change in the patient's condition to not be captured in a timely manner and could affect 96 in-center patients. Findings include: Observation on 07/22/19 at 10:35 AM revealed Machine 4 alarming "systolic low, (low blood pressure)" with a reading of 99/51 and treatment complete. No one attended to the alarm for greater than 5 minutes.	V 0401	On July 26, 29 & 30, 2019, the Clinical Manager held a staff meeting and reinforced the expectations and responsibilities of the facility staff on policies: ·Fresenius Kidney Care Clinical Services Patient Safety Reminder: Dialysis Machine Alarms Memo April 3, 2019 Emphasis was placed on: ·Ensuring that all staff recognize and understand the importance of responding promptly and appropriately to machine alarms. Effective September 3, 2019, Clinical Manager or designee will conduct visual audits twice weekly	10/07/2019

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	Observation on 07/23/19 at 10:55 AM revealed the machine at Station 24 alarming, treatment complete and systole low with a reading of 73/46. The machine alarmed for greater than 10 minutes before Patient Care Technician (PCT) 8 answered the alarm. During an interview on 07/23/19 at 10:57 AM, PCT 8 stated there were only two PCT's covering 12 stations. During an interview on 07/23/19 at 11:10 AM, with a patient who wished to remain anonymous, revealed that sometimes it took to long for staff to answer machine alarms with the blood pressure was reading low. The patient stated that sometimes it took to long to get on the dialysis machine, making treatment15-20 minutes late. Review of the seating chart for 07/23/19 revealed Charge Nurse 3 was assigned to Stations 13-16. Observation on 07/23/19 from 10:45 AM until 11:10 AM revealed no nurses covering Stations 13-16 and only the two PCT's were covering Stations 13-24, (12 stations). Observation on 07/23/19 from 11:10 AM until 11:18 AM, the machine at Station 14 alarmed systole high (blood pressure high) with a reading of 192/88. The station was not checked for eight minutes. During an interview on 07/23/19 at 11:20 AM, Registered Nurse (RN) 10 stated he/she should have been covering the floor during changeover, however he/she had to take a call to check on a patient and had been put on hold. During an interview on 07/24/19 9:58 AM, Charge		to assess all machine alarms are answered and resolved immediately utilizing Clinical Practice Checklist for 4 weeks. The Governing Body will determine on-going frequency of the audits based on compliance. Once compliance sustained monitoring will be done through the Clinic Audit checklist per QAI calendar. Any ongoing non-compliance by staff, per the Conditions for Coverage and the FMC policy, will be addressed with corrective action as appropriate. 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 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. Completion Date: October 7, 2019	

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	Nurse 3 stated it was inexcusable the machine alarms were not answered in a timely manner. Review of the facility's policy titled, "Patient Safety Reminders. Dialysis Machine Alarms," implemented April 3, 2019, indicated, "Machine alarms may be common occurrences that staff encounter when providing dialysis treatments. lt is imperative that all staff recognize and understand the importance of responding promptly and appropriately to machine alarms."			