DaVita

TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

August 31, 2017

Ms. Bernetta Thorne-Williams, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Project #J-11372-17/Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma/Develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis Center and four from FMC New Hope Dialysis/Johnston County

Dear Ms. Thorne-Williams:

The July 2017 Semiannual Dialysis Report indicates in Table D that there is a projected station deficit of 11 stations in Johnston County. Bio-Medical Applications of North Carolina, Inc. submitted a Certificate of Need application on July 17, 2017 to establish a fourth dialysis facility in Johnston County via transfer of stations from three facilities. The purpose of this letter is to bring to your attention several deficiencies in the CON application. The FKC Selma application should be found non-conforming with multiple statutory review criteria, including: Criteria 3, 3a, 6, 18a, and 20.

Mr. Mark Fawcett, Senior Vice President and Treasurer of Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma signed the Certification stating, "The undersigned applicant(s) hereby assures (assure) and certifies (certify) that the information included in this application and all attachments is correct to the best of my (their) knowledge and belief and that it is my (their) intent to develop and offer the proposed new institutional health service as described". Based on this statement the application presented must stand on its own and no other information should be requested or presented to add to or delete information to the application.

As an initial matter, there are multiple errors and misstatements in the FKC Selma application, which appear to be a result of BMA originally intending to submit an application for a new facility in Selma based only on relocating stations within Johnston County, from two of their existing facilities (FMC Four Oaks and Johnston Dialysis). It appears that the application was then changed to be both a relocation within Johnston County as well as a relocation from Wake County. However, many inconsistencies and errors remain. There are multiple references to only Johnston County, and instances where Wake County is not appropriately mentioned or taken into account (see pp. 11, 16, 17, 30, 37, 50, 74, 77, 80). There are incorrect statements that this application will not change the inventory of Johnston County (p. 16). BMA proposes to shift stations from Wake County, and thus the inventory of Johnston County is changing.

On page 30 of the application the applicant is asked to, "Describe in detail the necessity for relocation of stations, such as, physical inadequacy of existing facility or geographic accessibility of services". In response, the applicant states, "It is necessary to relocate the 10 stations to develop FKC Selma primarily for patient convenience. There are no physical plant deficiencies associated with either of the facilities contributing stations to this proposal. The patients who have signed letters of support for this project are indeed receiving dialysis care and treatment at an existing BMA dialysis facility."

In another part of the response to the request the applicant states, "The absence of a dialysis facility in this area of north, and eastern Selma forces patients to travel to other areas of Selma of Selma for dialysis. The closest facility is the FMC Four Oaks facility."

The applicant indicates in their response that there are no physical inadequacies. The applicant further states that the only reason for relocation of stations to develop the Selma facility is patient convenience. The statement that the Four Oaks facility is the closest facility to Selma is incorrect. Smithfield, where Fresenius operates Johnston Dialysis Center is 3.8 miles from Selma. Johnston Dialysis Center had 25 certified stations as of June 9, 2017 and a certificate of need for six additional stations that were not yet certified as of June 9th. Based on 31 in-center stations at Johnston Dialysis Center, the facility would have a utilization rate of 75.8% based on the 94 in-center patients as of 12/31/16. FMC Four Oaks had a utilization rate of 65.9% as of 12/31/16. Based on this information, there is significant room for new patients or for patients living in Selma who are receiving services at FMC Four Oaks to transfer their care to the closer Johnston County Dialysis.

The three dialysis centers in Johnston County, FMC Four Oaks, FMC Stallings Station and Johnston County Dialysis had a total of 71 certified stations with a certificate of need for an additional six stations for a total of 77 in-center stations as of 6/9/17. The three facilities had a total of 230 in-center patients as of 12/31/16. This equates to a utilization rate of 74.6% or 2.98 patients per station.

The applicant has provided 40 patient letters of support in the application. All of the patients live in Johnston County. However, only one of the patients is receiving their dialysis services outside of Johnston County. Table A of the July 2017 SDR indicates that as of December 31, 2016 there were 266 in-center ESRD patients living in Johnston County. As indicated above, the three dialysis facilities operated by Fresenius in Johnston County had a census of 230 in-center patients. Table A of the July 2017 SDR indicates that 222 of the 230 or 96.5% of the in-center patients live in Johnston County.

The other 44 Johnston County in-center patients (266 – 222 = 44) were receiving their dialysis services at six dialysis facilities operated by DaVita Inc. (15 in-center patients) and nine dialysis facilities operated by Fresenius (29 in-center patients). If all of the 29 Johnston County in-center patients receiving services outside of Johnston County were added to the December 31, 2016 census of 230 in-center patients, the overall utilization rate of the facilities in Johnston County would be 79.9%. Increasing the utilization rate by the Average Annual Change Rate for Past

Five Years of 6.3% for Johnston County, the combined facilities would have a utilization rate of 84.8% or 275 in-center patients (230 + 29 = 259 X 1.063 = 275).

The chart below contains a list of Fresenius facilities that are dialyzing in-center patients who live in Johnston County and the number of patients in each facility. There are a total of 29 in-center patients who are receiving their care at Fresenius facilities located in other counties. Based on the information above, there is no need for a new Fresenius facility in Johnston County. The proposed facility would only serve one of the twenty-nine Johnston County patients who receive services outside of the county. The applicant has failed to address any of the other twenty-eight Johnston County in-center patients.

Facility	County	# of Johnston County IC Patients
Wake Dialysis Clinic	Wake	3
BMA of Raleigh Dialysis	Wake	2
Dunn Kidney Center	Harnett	5
FMC New Hope Dialysis	Wake	5
Southwest Wake County Dialysis	Wake	5
BMA of Fuquay Varina Kidney Center	Wake	4
Zebulon Dialysis	Wake	3
New Bern Dialysis	Carteret	1
FMC Central Raleigh	Wake	1
Total # of In-Center Patients		**29**

The three existing in-center dialysis facilities located in Johnston County have had a combined average utilization rate of less than 75% in each of the past five years. See the chart below:

SDR	# of Johnston County Stations	# of IC Patients	Utilization %
July 2017 SDR	77	230	74.6%
July 2016 SDR	71	212	74.6%
July 2015 SDR	71	194	68.3%
July 2014 SDR	71	187	65.8%
July 2013 SDR	71	183	64.4%

The applicant indicates on page 15 and 16 of the application, "Development of the FKC Selma facility should be recognized in two ways. First, this is another effort by Fresenius Medical Care to promote community based delivery of dialysis care. And secondly, this facility will enhance access to care for patients residing in the north and east areas Selma within Johnston County, and nearby areas of Johnston County". The applicant is already providing community based care for the patients in and around Selma. The Smithfield community is located just 3.8 miles from Selma and has an underutilized facility with 31 in-center stations and a utilization rate of 75.8%.

The applicant indicates in the application that the Four Oaks facility is the closest dialysis facility to Selma, which is incorrect. Smithfield is located just 3.8 miles from Selma.

On page 50 the applicant states, "Approval of this application will not unnecessarily duplicate any existing health service. The July SDR reports an 11 station deficit in for Johnston County. With such a deficit it is not reasonable to suggest relocation of existing stations, to a location closer to the residence of the patients to be served, is duplicative. Approval of this application will not create additional stations in the county, but does enhance community based delivery of health care". The development of this facility will duplicate an existing healthcare service. There is already an underutilized facility available to serve the target patient population just 3.8 miles from the proposed location of the Selma facility. If the Selma facility was developed, there would be three Fresenius facilities within 12.5 miles of each other. Two of the facilities would continue to be underutilized. The applicant is incorrect in stating that the approval of the application will not create additional stations in the county. The applicant is proposing to transfer four stations from a facility in Wake County which would increase the station count to 81 stations. However, the applicant is proposing to serve only one additional Johnston County patient who receives their dialysis services outside of Johnston County. The application will not enhance community based delivery of health care. The services already exist and the facilities that provide the services are underutilized.

On page 74 of the application the applicant states, "The projected patient population for the FKC Selma facility begins with patients currently served by BMA at other nearby BMA locations…". The fact that the patients are being served at other nearly BMA locations is proof that the Selma facility is unnecessary. The identified patients are being served at nearby facilities that are already underutilized.

The applicant states on page 13 of the application, "In this application BMA has elected to relocate stations from FMC News Hope to the new facility in Johnston County. Of the seven BMA facilities serving Johnston County patients, FMC New Hope and Southwest Wake Dialysis were both serving five Johnston County residents….." "BMA has elected to relocate stations from one of its facilities serving the most number of Johnston County patients". The applicant proposes to transfer four stations from FMC New Hope, but only one Johnston County resident receiving their services outside of Johnston County. This is the only justification provided by the applicant for the movement of four stations across county lines.

Based on this information, the FKC Selma application should have been found non-conforming with Criterion 3 because the applicant did not demonstrate the need for its project. In addition, the project unnecessarily duplicates BMA's existing facilities in the area, which have sufficient capacity to treat patients, and thus the FKC Selma application should also be found non-conforming with Criterion 6.

Criterion 3a requires the applicant to demonstrate that patients served by existing services will not be harmed by the relocation of services. BMA fails to demonstrate that the patients currently served at FMC Four Oaks, Johnston Dialysis Center, and FMC New Hope will not be adversely impacted by this relocation. Specifically, the utilization at FMC Four Oaks is projected to be

95.31% after the shift. Utilization at FMC New Hope is proposed to be 96.09%. The application does not describe any future plans for adding new stations at these facilities, and it merely concludes (without any support) that there will not be any adverse impact on its patients.

Criterion 18a is intended to require applicants to address the impact that the application will have on competition. BMA is currently the sole provider of dialysis services in Johnston County, with a monopoly on dialysis stations there. Davita intends to submit an application on September 15, 2017 for a new dialysis facility to address the station deficit in Johnston County, which would provide patients with choice and would promote competition among providers. BMA did not provide any information about how the FKC Selma facility would have a positive impact on competition.

Finally, the application should be found nonconforming with Criterion 20. The FKC Selma application discloses information which demonstrates that the applicant has not provided quality of care in the past.

Criterion 20 states that: "An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past."

The FKC Selma application discloses in Section O of its application that in the 18 month look-back period, BMA had two "Immediate Jeopardy" citations at the following facilities:

- RAI West College – Warsaw, NC
- FMC Four Oaks – Four Oaks, NC

FMC Four Oaks is one of the facilities BMA proposes to transfer stations from to develop the FKC Selma facility.

BMA did not include the actual Immediate Jeopardy surveys to the Agency in the FKC Selma application. Based on the exhibits to the application, it appears that the Immediate Jeopardy citations occurred at RAI West College and BMA East Rocky Mount, instead of FMC Four Oaks. It is impossible to tell from the application whether FMC Four Oaks also had an Immediate Jeopardy citation, or whether BMA erroneously included the reference to FMC Four Oaks instead of BMA East Rocky Mount. In any event, the information provided to the Agency in the FKC Selma application regarding BMA's Immediate Jeopardy citations is not correct. The FMC Four Oaks facility did have a survey which identified standard level deficiencies, but the deficiencies did not result in an Immediate Jeopardy citation.

Davita has been able to obtain copies of the survey indicating the Immediate Jeopardy citation at BMA East Rocky Mount, attached as Exhibit A. The FMC Four Oaks survey is attached as Exhibit B.

<u>BMA East Rocky Mount</u>
One of the primary issues noted in the CMS survey for the BMA East Rocky Mount facility relates to Infection Control. The following information came directly from the CMS survey:

- "The facility failed to prevent staff members from providing care to (Hepatitis B Surface Antigen) **positive** patients and HBV (Hepatitis B) **susceptible** patients ***concurrently*** during hemodialysis treatment for 12 of 12 HBV susceptible patients receiving care in stations located across and/or diagonally from the facility's dedicated isolation room." (p. 1)

- Some of the general descriptions of the facility's deficiencies in infection control were that the staff:

    - **Failed to** perform hand hygiene and glove changes as necessary to prevent cross-contamination between clean and dirty processes. (p. 3)

    - **Failed to** ensure containers of clean cloth/wipes soaked with bleach solution were not stored in designated dirty areas. (p. 4)

    - **Failed to** ensure vascular access clamps and scissor clamps were fully submerged in bleach solution to ensure proper disinfection. (p. 4)

    - **Failed to** ensure all non-disposable equipment and contaminated surfaces were cleaned and disinfected in manner to prevent cross-contamination between patients. (p. 4)

    - **Failed to** ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B antigen patients was labeled as dedicated "isolation" equipment and supplies to prevent potential transmission of HBV to HBV susceptible patients

    - **Failed to** use aseptic techniques when preparing medications syringes., (p. 5)

    - **Failed to** ensure a patient's PPE mask fully covered the mouth and nose to prevent potential cross-contamination during initiation of treatment via a central venous catheter (CVC). (p. 5)

Some details regarding BMA's infractions are as follows:

- "The PCT failed to remove their gloves, perform hand hygiene, and don clean gloves after removing the old dressings and before cleansing the area around the CVC exist site with an antiseptic." (p. 7)
- "The soaked white cloths/wipes used for cleaning and disinfection were being stored in a designated dirty area." (p. 10)
- "Observation revealed the PCT failed to first empty the PWC prior to cleaning and disinfecting the surfaces of the machine and failed to remove her contaminated gloves, perform hand hygiene, and don clean gloves after emptying the PWC and before cleaning and disinfecting the machine's surfaces." (p. 14)

- "PCT failed to clean and disinfect the counters around (behind the dialysis station)." (p. 14)
- "The staff do not clean the countertops after each patient treatment." (p. 15)

One of the most concerning issues noted was the lack of care taken with the possible transmission of Hepatitis B.

- "The facility's staff failed to ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B Antigen (HBsAg+) patients was labeled as dedicated 'isolation' equipment and supplies; to prevent potential transmission to HBV susceptible patients and staff." (p. 15)
- A single RN was assigned to both the isolation room with a Hepatitis B patient and the right side bay, which included susceptible patients NOT immune to Hepatitis B. (p. 19)
- Multiple patients susceptible to Hepatitis B "were concurrently cared for by one or more of the same facility staff members who provided direct patient care" to a Hepatitis B positive patient, and BMA "failed to prevent potential Hepatitis B transmission." (p. 28)
- A nurse provided care to HBV susceptible patients after administering an IV medication to a Hepatitis B patient in the isolation room. (p. 30)

Aseptic techniques were also not followed, as evidenced by the following findings:

- "The PCT failed to clean and disinfect the injection port of the normal saline bag prior to each needle insertion." (p. 33)
- In using an open vial of Heparin, "the PCT failed to disinfect the rubber diaphragm of the medication vial prior to insertion of the needle." (p. 33)

In addition to Infection control the following other issues were noted as well:

- Staff failed to ensure patient vascular accesses and bloodline connections were visible during hemodialysis treatment. (p. 43)
- Facility's RN failed to perform a patient's pre-dialysis treatment assessment prior to starting treatment. In some cases, these assessments were documented after the patient had begun treatment. (p. 47)

Finally, BMA had violations related to managing the patient's volume status, evidencing a lack of attention to detail and a general lack of supervision and care provided to BMA's patients. The facility's patient care staff failed to monitor a patient at a minimum of every 30 minutes during hemodialysis treatments, as required.

Some patients endured dialysis for the following periods of time without being monitored by staff:

- 60 minutes
- 47 minutes
- 42 minutes
- 60 minutes
- 48 minutes

- 40 minutes
- 138 minutes
- 54 minutes

The result of all of these findings, as contained in the BMA East Rocky Mount survey, are that:

> **"The facility's staff failed to develop and implement an effective infection control program that demonstrated recognition of cross-contamination and potential transmission of bloodborne pathogens; as evidence by the facility's inability to ensure the provision of safe infection control practices for all 123 hemodialysis patients on census; resulting in an identification of immediate jeopardy (IJ) to the health and safety of the facility's patients."**

(p. 59) (emphasis added).

The FKC Selma CON application also misrepresents what is contained in the exhibits relating to this BMA East Rocky Mount survey.

Exhibit O-4b to the application is a letter dated January 30, 2017 from the state Agency recommending a 23 day termination from the Medicare Program. Instead of accurately describing this exhibit, the FKC Selma application states that exhibit O-4b is "Notice to BMA that the IJ has been recommended for abatement." This is not true.

In addition, Exhibit O-4a to the application is a letter dated March 2, 2017 from the state Agency recommending removal of the Immediate Jeopardy and recommending that the facility be back in compliance. Instead of accurately describing this exhibit, the BMA application states that exhibit O-4a is "notice that the facility is back in compliance." This is simply false, and there is no evidence in the FKC Selma application that BMA East Rocky Mount was back in compliance.

FMC Four Oaks

The survey for FMC Four Oaks, although not rising to the level of Immediate Jeopardy, also raised the issue of Infection Control, and some of the deficiencies are for 494.30, Infection Control. The issues noted in these surveys demonstrate that there is a pattern of substandard infection control that demonstrates that BMA has not provided adequate quality of care to its patients, and it should be found nonconforming with Criterion 20.

Specifically, the following violations in the FMC Four Oaks survey relate to infection control:

- "The facility's staff failed to wear cover gowns with long sleeves covering forearms and a face mask over the nose during a CVC initiation." (p. 1)
- "The PCT did not remove the prime waste bucket for cleaning and disinfecting that was attached to the dialysis machine. The observation revealed the CT wiped over the prime bucket with a disinfectant cloth but failed to clean and disinfect he prime waste bucket

according to facility policy and procedure by removing it from the machine to empty it before cleaning." (p. 4)

- A "machine's front casing covering above and below the blood flow pump was missing and the irregularity on the surface of the dialysis machine that may allow fluids or blood (and/or dirt or bacteria) to enter the machine, which would be difficult to remove during routine disinfection." (p. 7)

The building was also not maintained in a safe and clean manner, as evidenced by the following findings:

- The surveyor found a dead roach that was squashed and stained on the facility floor located directly beside a chair. (p. 5)
- Broken and cracked tiles were "potentially not able to be cleaned and disinfected as well as potential trip or fall hazards." (p. 6)

Finally, "the facility failed to develop, individualize and implement blood pressure alarm parameters for patient dialysis machines to alert staff for patient abnormal blood pressures for 8 of 8 observed patients." (p. 8). These machines had capabilities to provide this additional layer of safety, such that staff can be notified if a patient's blood pressure goes outside of certain parameters. There is no evidence in the survey that staff even knew about this capability, and staff "had never done anything with setting alarms for the dialysis machines blood pressure." Based on the interview, the machines were likely on their default, factory settings. (p. 9)

Although not rising to the level of an Immediate Jeopardy, this survey reveals serious issues relating to a pattern of infection control problems and provides further support that the FKC Selma application should be found nonconforming with Criterion 20.

RAI West College

The FKC Selma application also misrepresents what is contained in the exhibits relating to the RAI West College survey. It does accurately describe Exhibit O-3a as notice that the facility is back in compliance, but it provides a false and misleading description of Exhibit O-3b. Instead of accurately describing this exhibit, the FKC Selma application states that exhibit O-3b is "Notice to BMA that the IJ has been recommended for abatement." This is not true. In fact, the letter appearing at Exhibit O-3b is the letter from CMS, notifying BMA that "the facility no longer meets the requirements for participation in the Medicare program because of deficiencies that represent an immediate jeopardy to patient health and safety. . . . Accordingly, the Medicare provider/ supplier agreement between RAI Care Centers of North Carolina (West College Warsaw) and the Secretary of [DHHS] is being terminated **effective April 17, 2016**." (emphasis in original)

By reviewing p. 79 of the FKC Selma application alone, the reader is erroneously led to the believe the that supporting documents provided do nothing more than notify BMA that its facilities are back in compliance and that Immediate Jeopardy status has been recommended for

abatement. As described above, many of these statements are false and misleading, and the documents are not as described.

Even if these BMA facilities have been deemed to have returned to compliance with the Medicare Conditions of Participation by the date the application is submitted and a Plan of Correction has been accepted, the serious incidents giving rise to the Immediate Jeopardy status at BMA East Rocky Mount and RAI West College should be considered and taken into account by the Agency in evaluating Criterion 20. Additionally, the FMC Four Oaks survey indicates quality issues and a pattern of infection control problems at a facility which is proposing to transfer stations to develop the FKC Selma facility.

Criterion 20 does not ask whether a facility has been brought back into compliance as of the date a CON application is submitted or is back in compliance by the date the CON Section makes a decision. Instead, this statutory provision requires the Agency to evaluate whether an applicant already involved in the provision of health services has provided evidence that quality care has been provided in the past. Discussed herein and attached to these comments are surveys that demonstrate that BMA has not provided quality care in the past, and BMA should be found nonconforming with Criterion 20.

Conclusion

The applicant has presented a CON applications based on the July 2017 Semiannual Dialysis Report with the intent to keep a monopoly of dialysis services for the End Stage Renal Disease patients living in Johnston County.

DaVita Inc. reserves the right to provide additional documentation in opposition to the development of the Fresenius Kidney Care Selma. DaVita Inc. is requesting a Public Hearing on the above referenced certificate of need application. We respectfully request that the public hearing be held on or before September 19th.

Davita intends to submit an application on September 15, 2017 for a new dialysis facility to address the station deficit in Johnston County. Were the FKC Selma application to be approved, despite the numerous and significant non-conformities identified in these comments, Davita would be substantially harmed, prejudiced, and disadvantaged in its efforts to develop a Johnston County facility. This would also be a great disservice Johnston County's citizens.

Davita requests that the CON Section deny the FKC Selma application.

Sincerely,

William L. Hyland
Director or Healthcare Planning

c: Martha Frisone, Chief
Lisa Pittman, Team Leader

Exhibits

Signed 3/14/17

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

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

ID: NJ94
Facility ID: 970528

MEDICARE/MEDICAID PROVIDER NO. (L1) 342603 STATE VENDOR OR MEDICAID NO. (L2)	3. NAME AND ADDRESS OF FACILITY (L3) BMA EAST ROCKY MOUNT (L4) 230 SOUTH FAIRVIEW ROAD (L5) ROCKY MOUNT, NC (L6) 27801	4. TYPE OF ACTION: 2 (L8) 1. Initial 2. Recertification 3. Termination 4. CHOW 5. Validation 6. Complaint 7. On-Site Visit 9. Other 8. Full Survey After Complaint
EFFECTIVE DATE CHANGE OF OWNERSHIP (L9) DATE OF SURVEY 01/26/2017 (L34) ACCREDITATION STATUS: __ (L10) 0 Unaccredited 1 TJC 2 AOA 3 Other	7. PROVIDER/SUPPLIER CATEGORY 09 (L7) 01 Hospital 05 HHA 09 ESRD 13 PTIP 22 CLIA 02 SNF/NF/Dual 06 PRTF 10 NF 14 CORF 03 SNF/NF/Distinct 07 X-Ray 11 ICF/IID 15 ASC 04 SNF 08 OPT/SP 12 RHC 16 HOSPICE	FISCAL YEAR ENDING DATE: (L35) 12/31
11. LTC PERIOD OF CERTIFICATION From (a): To (b): 12. Total Facility Beds (L18) 13. Total Certified Beds (L17)	10. THE FACILITY IS CERTIFIED AS: A. In Compliance With Program Requirements Compliance Based On: 1. Acceptable POC X B. Not in Compliance with Program Requirements and/or Applied Waivers: And/Or Approved Waivers Of The Following Requirements: __ 2. Technical Personnel __ 6. Scope of Services Limit __ 3. 24 Hour RN __ 7. Medical Director __ 4. 7-Day RN (Rural SNF) __ 8. Patient Room Size __ 5. Life Safety Code __ 9. Beds/Room * Code: B* (L12)	

14. LTC CERTIFIED BED BREAKDOWN					15. FACILITY MEETS
18 SNF	18/19 SNF	19 SNF	ICF	IID	1861 (e) (1) or 1861 (j) (1): (L15)
(L37)	(L38)	(L39)	(L42)	(L43)	

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):

An onsite ESRD [CORE] Recertification Survey was conducted January 25-26, 2017. The survey resulted in an IJ identification on January 25, 2017 at 1700. The IJ was not removed onsite during the survey. Condition level deficiencies were cited in 494.30 Infection Control and 494.180 Governance. Standard level deficiencies were cited in 494.40 Water and Dialysate Quality, 494.60 Physical Environment, 494.80 Patient Assessment, 494.90 Patient Plan of Care, and 494.140 Personnel Qualifications. SA recommends 23 day termination. Findings sent to RO for final determination of compliance.

17. SURVEYOR SIGNATURE	Date:	18. STATE SURVEY AGENCY APPROVAL	Date:
	02/02/2017 (L19)		3/7/2017 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY	20. COMPLIANCE WITH CIVIL RIGHTS ACT:	21.
1. Facility is Eligible to Participate __ 2. Facility is not Eligible (L21)		1. Statement of Financial Solvency (HCFA-2572) 2. Ownership/Control Interest Disclosure Stmt (HCFA-1513) 3. Both of the Above :

22. ORIGINAL DATE OF PARTICIPATION	23. LTC AGREEMENT BEGINNING DATE	24. LTC AGREEMENT ENDING DATE	26. TERMINATION ACTION: (L30)
03/29/2000 (L24)	(L41)	(L25)	VOLUNTARY 00 01-Merger, Closure 02-Dissatisfaction W/ Reimbursement 03-Risk of Involuntary Termination 04-Other Reason for Withdrawal INVOLUNTARY 05-Fail to Meet Health/Safety 06-Fail to Meet Agreement OTHER 07-Provider Status Change 00-Active

25. LTC EXTENSION DATE:	27. ALTERNATIVE SANCTIONS	
(L27)	A. Suspension of Admissions:	(L44)
	B. Rescind Suspension Date:	(L45)

28. TERMINATION DATE:	29. INTERMEDIARY/CARRIER NO.	30. REMARKS
(L28)	00310 (L31)	

31. RO RECEIPT OF CMS-1539	32. DETERMINATION OF APPROVAL DATE	
(L32)	(L33)	DETERMINATION APPROVAL

REC'D MAR 06 2017

EXHIBIT A

ALL-STATE LEGAL®

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

FORM APPROVED
OMB NO. 0938-0360

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0360. The time required to complete this information collection is estimated to average of 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART I – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply; if "Other," specify in "Remarks" section [Item 33]): (V1)
☐ 1. Initial ☒ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services ☐ 5. Change of ownership
☐ 6. Other, specify

2. Name of Dialysis Facility: BMA EAST ROCKY MOUNT
3. CCN: 342603
4. Street Address: 230 SOUTH FAIRVIEW ROAD
5. NPI: 1982716791
6. City: ROCKY MOUNT
7. County: NASH
8. Fiscal Year End Date: 2017
9. State: NORTH CAROLINA
10. Zip Code: 27801
11. Administrator's Email Address: anita.harris@fmc-na.com
12. Telephone No: 252-442-6311
13. Facsimile No: 252-442-0585
14. Medicare Enrollment (CMS 855A) completed? ☐ Yes ☐ No ☐ NA

15. Dialysis Facility Administrator Name: Anita Harris
Business Address: 230 SOUTH FAIRVIEW ROAD
City: ROCKY MOUNT State: NC Zip Code: 27801 Telephone No: 252-442-6311

16. Ownership (V2) ☒ 1. For Profit ☐ 2. Not for Profit ☐ 3. Public

17. Is this dialysis facility independent (i.e., not owned or managed by a hospital)? (V3) ☒ 1. Yes ☐ 2. No
Is this dialysis facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (V4) ☐ 1. Yes ☒ 2. No
Is this dialysis facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (V5) ☐ 1. Yes ☒ 2. No

18. Is this dialysis facility located in a SNF/NF (LTC) (check one): (V6) ☐ 1. Yes ☒ 2. No
If SNF/NF owned and managed by a hospital: hospital name: (V7)_____ CCN: (V8)_____
If Yes, SNF/NF name: (V9)_____ CCN: (V10)_____

19. Is this dialysis facility owned &/or managed by a multi-facility organization? (V11) ☐ 1. No ☒ 2. Yes, Owned ☐ 3. Yes, Managed
If Yes, name of multi-facility organization: (V12) Frensenius Kidney Care
Multi-facility organization's address: 230 SOUTH FAIRVIEW ROAD, ROCKY MOUNT, NC 27801

20. Current modalities/services for dialysis facilities requesting recertification only (check all that apply): (V13)
☒ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse

21. New modalities/services being requested (check all that apply; must have 1 permanent patient for any modality requested): (V14)
☐ 1. In-center HD ☐ 2. In-center PD ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse ☒ 9. N/A

NOTE: For dialysis in more than 1 LTC facility, record this same information in the "Remarks" (item 33) section or attach list

22. Does the dialysis facility have any dialysis (PD/HD) patients physically receiving dialysis within long-term care (LTC) facilities? (V15)
☐ 1. Yes ☒ 2. No LTC (SNF/NF) facility name: (V16)_____ CCN: (V17)_____
Staffing for home dialysis in LTC provided by: (V18) ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify:_____
Number of dialysis residents by modality receiving dialysis within this LTC facility: (V19) ☐ 1. HD_____ ☐ 2. PD_____

23. Number of dialysis patients currently on census: 123

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

In-Center HD: (V20) \ In-Center Nocturnal HD: (V21) ____ In-Center PD: (V22) ____

Home PD: (V23) ____ Home HD <= 3x/week: (V24) ____ Home HD >3x/week: (V25) ____

24. Number of **currently** approved in-center dialysis stations: (V26) 30 Are onsite home training room(s) provided? (V27) ☐ 1. Yes ☒ 2. N/A

25. Additional in-center stations requested: (V28) ____ or ☒ None

26. How is isolation provided? (V29) ☒ 1. Room ☐ 2. Area (existing 2/9/2009 only) ☐ 3. CMS Waiver/Agreement (Attach copy)

27. If applicable, number of hemodialysis stations designated for isolation: (V30) 1

28. Days/times for in-center shifts or operating hours if home only (check all days that apply and complete time field in military time): (V31)

1st in-center shift starts or home only facility opens: M 0645 T 0645 W 0645 Th 0645 F 0645 Sat 0645 Sun N/A

Last in-center shift ends or home only facility closes: M 1930 T 1730 W 1930 Th 1730 F 1930 Sat 1730 Sun N/A

29. Dialyzer reprocessing: (V32) ☐ 1. Onsite ☐ 2. Centralized/Offsite ☒ 3. N/A

30. Staff (List full-time equivalents): Registered Nurse: (V33) 4 Certified Patient Care Technician: (V34) 13

LPN/LVN: (V35) 0 Technical Staff (water, machine): (V36) 1

Registered Dietitian: (V37) 1 Masters Social Worker: (V38) 1

Others: (V39) 1 secretary

31. State license number (if applicable): (V40)_____	32. Certificate of Need required? (V41) ☐ 1. Yes ☒ 2. No ☐ 3. NA

33. Remarks (copy if more and attach additional pages if needed):

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488.604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date
Anita R Harris	Director of Operations	1/25/2017

PART II TO BE COMPLETED BY STATE AGENCY

35. Medicare Enrollment (CMS 855A recommended for approval by the Medicare Administrative Contractor)? (V42) ☒ 1. Yes ☐ 2. No

(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V43) ☐ 1. Initial ☒ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services

☐ 5. Change of ownership ☐ 6. Complaint ☐ 7. Revisit ☐ 8. Other, specify_____

37. State Region: (V44) NCE	38. State County Code: (V45) 630

39. Network Number: (V46) 06

My signature below indicates that I have reviewed this form and it is complete.

40. Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline *(Print)*	43. Survey Exit Date
[signature]	Duane Jones 25936	RN	01/26/2017

INSTRUCTIONS FOR FORM CMS-3427

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

FORM APPROVED
OMB NO. 0938-0360

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0360. The time required to complete this information collection is estimated to average of 20 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

PART I – APPLICATION – TO BE COMPLETED BY FACILITY

1. Type of Application/Notification (check all that apply; if "Other," specify in "Remarks" section [Item 33]): (V1)
☐ 1. Initial ☒ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services ☐ 5. Change of ownership
☐ 6. Other, specify

2. Name of Dialysis Facility: BMA EAST ROCKY MOUNT		3. CCN: 342603
4. Street Address: 230 SOUTH FAIRVIEW ROAD		5. NPI: 1982716791
6. City: ROCKY MOUNT	7. County: NASH	8. Fiscal Year End Date: 2017
9. State: NORTH CAROLINA	10. Zip Code: 27801	11. Administrator's Email Address: anita.harris@fmc-na.com
12. Telephone No.: 252-442-6311	13. Facsimile No: 252-442-0585	14. Medicare Enrollment (CMS 855A) completed? ☐ Yes ☐ No ☐ NA

15. Dialysis Facility Administrator Name: Anita Harris
Business Address: 230 SOUTH FAIRVIEW ROAD
City: ROCKY MOUNT State: NC Zip Code: 27801 Telephone No: 252-442-6311

16. Ownership (V2) ☒ 1. For Profit ☐ 2. Not for Profit ☐ 3. Public

17. Is this dialysis facility independent (i.e., not owned or managed by a hospital)? (V3) ☒ 1. Yes ☐ 2. No
Is this dialysis facility owned and managed by a hospital and on the hospital campus (i.e., hospital-based)? (V4) ☐ 1. Yes ☒ 2. No
Is this dialysis facility owned and managed by a hospital and located off the hospital campus (i.e., satellite)? (V5) ☐ 1. Yes ☒ 2. No

18. Is this dialysis facility located in a SNF/NF (LTC) (check one): (V6) ☐ 1. Yes ☒ 2. No
If SNF/NF owned and managed by a hospital: hospital name: (V7)_____ CCN: (V8)_____
If Yes, SNF/NF name: (V9)_____ CCN: (V10)_____

19. Is this dialysis facility owned &/or managed by a multi-facility organization? (V11) ☐ 1. No ☒ 2. Yes, Owned ☐ 3. Yes, Managed
If Yes, name of multi-facility organization: (V12) Fresenius Kidney Care
Multi-facility organization's address: 230 SOUTH FAIRVIEW ROAD, ROCKY MOUNT, NC 27801

20. Current modalities/services for dialysis facilities requesting recertification only (check all that apply): (V13)
☒ 1. In-center Hemodialysis (HD) ☐ 2. In-center Peritoneal Dialysis (PD) ☐ 3. In-center Nocturnal HD
☐ 4. Home HD Training & Support ☐ 5. HD in LTC
☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse

21. New modalities/services being requested (check all that apply; must have 1 permanent patient for any modality requested): (V14)
☐ 1. In-center HD ☐ 2. In-center PD ☐ 3. In-center Nocturnal HD
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☐ 6. Home PD Training & Support ☐ 7. PD in LTC ☐ 8. Dialyzer Reuse ☒ 9. N/A

NOTE: For dialysis in more than 1 LTC facility, record this same information in the "Remarks" (item 33) section or attach list

22. Does the dialysis facility have any dialysis (PD/HD) patients physically receiving dialysis within long-term care (LTC) facilities? (V15)
☐ 1. Yes ☒ 2. No LTC (SNF/NF) facility name: (V16)_____ CCN: (V17)_____
Staffing for home dialysis in LTC provided by: (V18) ☐ 1. This dialysis facility ☐ 2. LTC staff ☐ 3. Other, specify:_____
Number of dialysis residents by modality receiving dialysis within this LTC facility: (V19) ☐ 1. HD_____ ☐ 2. PD_____

23. Number of dialysis patients currently on census: 123

END STAGE RENAL DISEASE APPLICATION AND SURVEY AND CERTIFICATION REPORT

In-Center HD: (V20) ↘ In-Center Nocturnal HD: (V21) ____ In-Center PD: (V22) ____

Home PD: (V23) ____ Home HD <= 3x/week: (V24) ____ Home HD >3x/week: (V25) ____

24. Number of currently approved in-center dialysis stations: (V26) 30 Are onsite home training room(s) provided? (V27) ☐ 1. Yes ☒ 2. N/A

25. Additional in-center stations requested: (V28) ____ or ☒ None

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29. Dialyzer reprocessing: (V32) ☐ 1. Onsite ☐ 2. Centralized/Offsite ☒ 3. N/A

30. Staff (List full-time equivalents): Registered Nurse: (V33) 4 Certified Patient Care Technician: (V34) 13

LPN/LVN: (V35) 0 Technical Staff (water, machine): (V36) 1

Registered Dietitian: (V37) 1 Masters Social Worker: (V38) 1

Others: (V39) 1 secretary

31. State license number (if applicable): (V40)____	32. Certificate of Need required? (V41) ☐ 1. Yes ☒ 2. No ☐ 3. NA

33. Remarks (copy if more and attach additional pages if needed):

34. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my knowledge. I understand that incorrect or erroneous statements may cause the request for approval to be denied, or facility approval to be rescinded, under 42 C.F.R. 494.1 and 488.604 respectively.

I have reviewed this form and it is accurate:

Signature of Administrator/Medical Director	Title	Date
Anita R Harris	Director of Operations	4/25/2017

PART II TO BE COMPLETED BY STATE AGENCY

35. Medicare Enrollment (CMS 855A recommended for approval by the Medicare Administrative Contractor)? (V42) ☒ 1. Yes ☐ 2. No

(Note: approved CMS 855A required prior to certification)

36. Type of Survey: (V43) ☐ 1. Initial ☒ 2. Recertification ☐ 3. Relocation ☐ 4. Expansion/change of services ☐ 5. Change of ownership ☐ 6. Complaint ☐ 7. Revisit ☐ 8. Other, specify____

37. State Region: (V44) NCG	38. State County Code: (V45) 630

39. Network Number: (V46) 06

My signature below indicates that I have reviewed this form and it is complete.

40. Surveyor Team Leader (sign)	41. Name/Number (print)	42. Professional Discipline *(Print)*	43. Survey Exit Date
[signature]	Duane Jones 25936	RN	04/26/2017

INSTRUCTIONS FOR FORM CMS-3427

02/15/2017 - Reviewed RO to have [illegible] approval and acceptance. DEJ

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

PRINTED: 02/02/2017
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342603	A. BUILDING _____ B. WING _____	01/26/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BMA EAST ROCKY MOUNT	230 SOUTH FAIRVIEW ROAD ROCKY MOUNT, NC 27801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	INITIAL COMMENTS An onsite ESRD [CORE] Recertification Survey was conducted at the facility on January 25-26, 2017. The survey resulted In an Immediate Jeopardy (IJ) identification on January 25, 2017 at 1700. The IJ was not removed onsite during the Recertification survey. The Conditions for Coverage in 494.30 Infection Control and 494.180 Governance were not met. Standard level deficiencies were also cited in 494.40 Water and Dialysate Quality, 494.60 Physical Environment, 494.80 Patient Assessment, 494.90 Patient Plan of Care, and 494.140 Personnel Qualifications. The survey findings revealed during observation of the facility's patient hemodialysis treatments, the facility failed to prevent staff members from providing care to HBsAg (Hepatitis B Surface Antigen) positive patients and HBV (Hepatitis B) susceptible patients concurrently during hemodialysis treatment for 12 of 12 HBV susceptible patients receiving care in stations located across and/or diagonally across from the facility's dedicated isolation room. Observations and documentation reviews revealed the facility's nursing staff and patient dialysis care technicians concurrently provided hemodialysis patient care to both HBsAg (Hepatitis B Surface Antigen) positive patients and HBV (Hepatitis B) susceptible patients that resulted in the identification of the IJ to the health and safety of the facility's patients. The facility's Clinical Manager and Director of Operations were notified of the IJ on January 25, 2017 at 1700. On January 26, 2017 the facility submitted an immediate action plan to ensure	V 000	The Governing Body (GB) of which the Medical Director is a member takes seriously the management of the day to day operations of the facility and its responsibility for ensuring the health and safety for all patients receiving hemodialysis at this facility. A meeting of the GB was held on 1/25/2017 to discuss the needed immediate actions to be taken following the issuance of the Immediate Jeopardy (IJ) at 5:00 pm. The GB put into place a plan of correction on 1/26/2017 for this IJ see V Tag 110 494.30 CFC - Infection Control and V Tag 750 494.180 CFC – Governance. The GB met on 1/27/2017 and began a plan to cover all deficiencies that were cited during the closing conference on 1/26/2017. The GB continues to meet every day (Monday through Friday) to monitor and provide oversight to this plan. The Governing Body met again on 2/9/2017 after receipt of the Statement of Deficiency to review and to discuss a plan of correction (POC) for these findings. The Medical Director has committed to continued daily Governing Body meetings to provide oversight and monitoring of the POC ensure that full implementation of the corrective actions are being followed through. Meetings of the GB are documented and available for review. As the result of this Re-certification survey findings from January 25-26, 2017 the following Plan of Correction has been implemented:	02.24.17

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
[signature]	Regional Vice President	02.15.17

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients (See Instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342603	A. BUILDING _____ B. WING _____	01/26/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BMA EAST ROCKY MOUNT	230 SOUTH FAIRVIEW ROAD ROCKY MOUNT, NC 27801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	Continued From page 1 safe blood borne pathogen infection control procedures during the facility's hemodialysis treatments. The IJ was not recommended to be removed onsite and a 23-day termination process was recommended. Glossary of Terms: AVF/G=Arteriovenous Fistula/Graft CN=Charge Nurse CVC=Central Venous Catheter EDW=Estimated Dry Weight ESA=Erythropoiesis-Stimulating Agent ESRD=End Stage Renal Disease EST=Eastern Standard Time FDA=Federal Food and Drug Administration HBsAg+=Hepatitis B Surface Antigen Positive HBV=Hepatitis B Virus ICHD=In-center hemodialysis IJ=Immediate Jeopardy IV=Intravenous IVP=Intravenous Push LPN=Licensed Practical Nurse MWF=Monday, Wednesday, and Friday PCT=Patient Dialysis Care Technician QAI=Quality Assurance & Improvement PPE=Personal Protective Equipment PWC=Prime Waste Container RN=Registered Nurse TTS=Tuesday, Thursday, and Saturday UAP=Dialysis Technician VS=Vital Signs Note: Dialysis machine numbers (i.e. M6) were used as station identifiers during observations of hemodialysis patient care. The facility had removed all station identification numbers prior to survey entrance.	V 000		02.24.17
V 110	494.30 CFC-INFECTION CONTROL	V 110	Cross reference 494.30 Infection Control - V 131, 113, 116, 122, 130, 143, 550	02.24.17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342603	A. BUILDING _____ B. WING _____	01/26/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 110	Continued From page 2 This CONDITION is not met as evidenced by: Based on policy and procedure reviews, observations, "Hepatitis B Summary Report" review, daily assignment sheet reviews, staffing reviews, medical record reviews, physician interview, staff and patient interviews; the facility's staff failed to develop and implement an effective infection control program that demonstrated recognition of cross-contamination and potential transmission of bloodborne pathogens; as evidenced by the facility's inability to ensure the provision of safe infection control practices for all 123 hemodialysis patients on census; resulting in an identification of immediate jeopardy (IJ) to the health and safety of the facility's patients. Findings include: A. The facility failed to prevent staff members from providing care to HBsAg (Hepatitis B Surface Antigen) positive patients and HBV (Hepatitis B) susceptible patients concurrently during hemodialysis treatment for 12 of 12 HBV susceptible patients receiving care across and/or diagonally across from the facility's dedicated isolation room (Patients #27, #24, #22, #28, #30, #12, #9, #14, #17, #18, and #25; RN #1, RN #2 and PCT #4). ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0131. B. The facility's staff failed to perform hand hygiene and glove changes as necessary to prevent cross-contamination between clean and dirty processes for 1 of 2 central venous	V 110	On 1/25/2017, to ensure susceptible patients are assigned to stations located outside the buffer zone, the Clinical Manager revised the patient seating assignment using the current Hepatitis Summary report for current Hepatitis labs for January. The system uses the color coded seating plan (red = HbsAg positive and must be isolated, yellow= anti Hbs susceptible titer is < 10 miu/ml, green =anti Hbs protected, titer is >/= 10 miu /ml). The Clinical Manager reviewed the staff/ patient assignments to ensure scheduling of adequate coverage by the Registered Nurse and Patient Care Techs to provide safe care to susceptible patients during monitoring, medication delivery, and assessments to include coverage during breaks throughout the time a Hepatitis B positive patient is dialyzing. This will be monitored by the Clinical Manager and/or assigned nurse on a daily basis via the Isolation Practices Monitoring Tool. The Hepatitis B Summary report will be ran every day to monitor and ensure seating assignment maintains antibody positive patients only in the buffer zone. No changes to the seating assignment will be made without approval by the Clinical Manager. Additionally, and to ensure that seroconversion of the susceptible patients has not occurred; the Medical Director completed the following actions: On 1/25/2017 the Medical Director requested that Hepatitis labs be drawn on all susceptible patients in the clinic on 1/26/2017 and 1/27/2017 to cover all days and shifts of patients looking for HBsAG as well as the most recent Alanine Aminotransferase (ALT).	02.24.17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 110	Continued From page 3 catheters (CVC) observed having exit site care performed by staff (PCT #2, Patient #1, Station M24). ~Cross refer to 494.30(a)(1) Infection Control - Tag V0113. C. The facility's staff failed to label containers of prepared bleach solution for 4 of 4 containers observed (#1, #2, #3, and #4); failed to ensure containers of clean cloth/wipes soaked with bleach solution were not stored in designated dirty areas for 2 of 2 containers observed (#2 and #4); and failed to ensure vascular access clamps and scissor clamps were fully submerged in bleach solution to ensure proper disinfection for 1 of 2 containers observed (#3). ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0116. D. The facility's staff failed to ensure all non-disposable equipment and contaminated surfaces were cleaned and disinfected in manner to prevent cross-contamination between patients for 1 of 2 hemodialysis stations observed being cleaned and disinfected by staff (Station M15, PCT #1). ~Cross refer to 494.30(a)(4)(ii) Infection Control - Tag V0122 E. The facility's staff failed to ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B Antigen (HBsAg+) patients; was labeled as dedicated "isolation" equipment and supplies to prevent potential transmission of HBV to HBV susceptible patients and staff for 1 of 1 isolation rooms observed	V 110	• The Medical Director reviewed the lab results to ensure seroconversion had not occurred to susceptible patients. • According to the hepatitis status found with this review the seating assignment was immediately adjusted to maintain a buffer zone which is defined as **Bay A 1-8, 11-17** by the Clinical Manager. • HBsAG and ALT will be followed on these patients monthly for 6 months and reviewed by the Medical Director. • On 1/27/2017 and 1/28/2016 the Medical Director discussed the potential for cross contamination of Hepatitis B with susceptible patients identified with education being provided. • Any patients that are found to be susceptible are to be offered Hepatitis B vaccine or a booster if antibody titer < 10 miu/ml and consents for Hepatitis Vaccines were signed. Declinations will be signed by the patients if refused after education is provided. These acknowledgements will be placed in each of the patients' medical record. • Reeducation of all staff on the following policies and processes with attention to maintenance of the buffer zone (**Bay A 1-8, 11-17**) was completed on 1/26/2017 by the Education Coordinator and Clinical Manager: • FMS-CS-IC-II-155-140A Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) Policy • FMS-CS-IC-II-155-142A Patient Testing and Vaccination for Hepatitis • Coloring Coding System for Hepatitis Schedule - The system will use a color	02.24.17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 110	Continued From page 4 (Station M6). ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0130. F. The facility's staff failed to use aseptic techniques when preparing medication syringes for 1 of 2 staff observed preparing medication syringes (PCT #2); failed to label pre-filled medication syringes with the name of the medication, route, dose, name of patient, date, time, and initials of the person who prepared the medication for 5 of 5 observed pre-filled medication syringes (Syringes #1, #2, #3, #4, and #5); and failed to label a multidose medication vial with the date, time, and initials of the person who opened the medication vial for 1 of 1 observed opened multidose medication vials (Vial #1). ~Cross refer to 494.30(b)(2) Infection Control - Tag V0143. G. The facility's staff failed to ensure a patient's PPE mask fully covered the mouth and nose to prevent potential cross-contamination during initiation of treatment via a central venous catheter (CVC) for 1 of 2 CVCs observed being accessed (Patient #2, Station M4, PCT #3); and failed to place a clean field underneath the CVC ports to prevent potential cross-contamination prior to termination of treatment via a CVC for 1 of 2 CVCs observed being terminated (Patient #4, Station M10, PCT #3). ~Cross refer to 494.30(a)(2) Infection Control - Tag V0147. H. The facility's staff failed to verbally confirm	V 110	coded seating plan (red = HbsAg positive and must be isolated, yellow= anti Hbs susceptible titer is < 10 miu/ml, green =anti Hbs protected, titer is >/= 10 miu /ml). • Seating plan can only be changed by Clinical Manager • RN and PCT Staff assignments to maintain the buffer zone • The RN and PCT assigned to care for Hepatitis B Positive Antigen patient can only care patients assigned to Buffer Zone with Hepatitis antibody titer of >/= 10 miu /ml. This is to include coverage during breaks. • The RN's and PCT's assigned to care for susceptible patients with titer < 10 miu/ml cannot care for Hepatitis B Antigen positive patient. Documentation of this education will be available at the facility for review. Monitoring of the treatment floor to ensure compliance with maintaining a buffer zone will be completed daily for 3 months on the days the facility has an isolation patient utilizing the Isolation Practices monitoring tool starting on 1/27/2017. If 100% compliance is maintained after the 3 months, the auditing will decrease to weekly for 3 months more. If 100% compliance rate is maintained then the audits will resume per the QAI schedule for monitoring. Monitoring tools will be available for review. Monitoring Tool audit findings will be discussed daily during huddles with the direct patient care staff and education and appropriate corrective action taken during this time. Audit findings will be discussed during daily GB meetings to monitor and provide oversight.	02.24.17

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	342603	A. BUILDING _____ B. WING _____	01/26/2017

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V 110	Continued From page 5 with the patient if the patient washed their AVF/G access site with soap and water or an antibacterial scrub upon entering the facility; and failed to wash the patient's AVF/G access site with soap and water or an antibacterial scrub before performing skin antisepsis and cannulation for 1 of 2 staff observed accessing a patient's AVF/G (PCT #1, Patient #3, Station M32). ~Cross refer to 494.90(a)(5) Patient Plan of Care - Tag V0550.	V 110	A summary of audit findings will be reviewed / discussed monthly with the QAI team until resolved. The Clinical Manager will address noncompliance through coaching increasing to progressive disciplinary action as needed. The GB will exercise oversight	02.24.17
V 113	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. This STANDARD is not met as evidenced by: Based on policy reviews, observation, and staff interview, the facility's staff failed to perform hand hygiene and glove changes as necessary to prevent cross-contamination between clean and dirty processes for 1 of 2 central venous catheters (CVC) observed having exit site care performed by staff (PCT #2, Patient #1, Station M24). Findings included: Review on 01/26/2017 of current policy "Personal Protective Equipment", FMS-CS-IC-II-155-080A, effective 03/20/2013, revealed "Policy ...Employees shall use personal protective equipment....gloves, in accordance with the type	V 113	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the following facility polices occurred: "Personal Protective Equipment" (FMS-CS-IC-II-155-080A) and "Hand Hygiene" (FMS-CS-IC-II-155-090A), specifically focusing on relation to care of the perm cath exit site. The facility Education Coordinator reviewed the aforementioned policies, specifically focusing on the care of the perm cath exit site, with all available Direct Patient Care (DPC) staff during an Inservice held at the facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator.	02.24.17

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V 113	Continued From page 6 of patient contact expected and anticipated exposure. ...Change gloves and practice had hygiene between each patient and/or station to prevent cross-contamination. Remove gloves and wash hands after each patient contact, and after exposure to blood or body fluids. If hands are not visibly soiled, use of a waterless antiseptic hand rub is acceptable. (See hand hygiene policy)..." Review on 01/26/2017 of current policy "Hand Hygiene", FMS-CS-IC-II-155-090A, effective: 03/20/2013, revealed "Purpose The purpose of this policy is to prevent transmission of pathogenic microorganisms to patients and staff through cross contamination. ...Policy: ...Hands Will Be,.. Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water When,.. Before and after direct contact with patients ...Before performing any invasive procedure such as vascular access cannulation... Immediately after removing gloves... After contact with inanimate objects near the patient. ...When moving from a contaminated body site to a clean body site of the same patient. ..." Observation on 01/25/2017 at 1205 in the patient treatment area at station M24 revealed PCT #2 preparing to perform CVC exit site care on Patient #1. The PCT donned clean gloves and removed and discarded the old dressing from over the patient's CVC exit site and CVC ports. The PCT then cleansed around the CVC exit site with an antiseptic and applied a sterile dressing. The PCT failed to remove their gloves, perform hand hygiene, and don clean gloves after removing the old dressings and before cleansing the area around the CVC exit site with an antiseptic. Observation revealed	V 113	An additional Inservice, focusing on the "Changing the Catheter Dressing Procedure", (FMS-CS-IC-I-105-032C), will be done with all DPC staff completed by 2/17/2017 by the Facility Education Coordinator or Clinical Manager. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit perm cath exit site care, as specifically related to glove changes and hand hygiene after old dressing removal using the POC Floor Monitoring Tool daily x 30 days, then weekly x 4 weeks, and then monthly, as per the clinical audit checklist. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 113	Continued From page 7 cross-contamination. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed, after the old CVC dressings have been removed, staff should remove their dirty gloves, perform hand hygiene, and put on new gloves before cleaning the CVC exit site with antiseptic. Interview confirmed the observation findings.	V 113		02.24.17
V 116	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. This STANDARD is not met as evidenced by: Based on policy reviews, observations, and staff interviews, the facility's staff failed to label containers of prepared bleach solution for 4 of 4 containers observed (Containers #1, #2, #3, and #4); failed to ensure containers of clean cloth/wipes soaked with bleach solution were not stored in designated dirty areas for 2 of 2 containers observed (Containers #2 and #4); and	V 116	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the following facility polices occurred: "Mixing Bleach" (FMS-CS-IC-II-155-110C5), "Cleaning and Disinfection" (FMS-CS-IC-II-155-110A), specifically related to the labeling and storage of bleach water and submersion of vascular and scissor clamps. The facility Education Coordinator reviewed the aforementioned policies, specifically focusing on relation to labeling and storage of bleach water, with all available staff during an Inservice held at the facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator.	02.24.17

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V 116	Continued From page 8 failed to ensure vascular access clamps and scissor clamps were fully submerged in bleach solution to ensure proper disinfection for 1 of 2 containers observed (Container #3). Findings included: Review on 01/26/2017 of current policy "Mixing Bleach", FMS-CS-IC-II-155-110C5, effective: 03/20/2013, revealed "Procedure Follow the steps below for mixing bleach: ...4. Label opaque container with "Bleach Solution", strength of solution, date and time prepared and your initials. 5. Cover opaque container with lid. ..." Review on 01/26/2017 of current policy, "Cleaning and Disinfection", FMS-CS-IC-II-155-110A", effective: 01/28/2015, revealed "General Cleaning ...Sodium Hypochlorite (Bleach Water) Solutions ...Bleach solution will be stored in labeled covered opaque containers to prevent disintegration of the chemical (sodium hypochlorite) when exposed to sunlight and air. ..." Review on 01/26/2017 of current policy "Dialysis Precautions", FMS-CS-IC-II-155-070A, effective: 01/04/2012, revealed "...Clean Versus Dirty Areas Clean area: An area designated for clean and unused equipment, supplies and medications. Dirty area: An area where there is a potential for contamination with blood or body fluids and areas where contaminated or used supplies, equipment, blood supplies, or biohazard containers are stored or handled. Clean areas should be clearly designated for the preparation and handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from dirty areas where used supplies, equipment or blood samples are handled or	V 116	Since the audit, the facility has purchased new opaque bleach containers and has designated clean and dirty areas, utilizing the use of a clean cart to separate clean items from the dirty sink. All sinks have been designated as "Dirty" or "Clean". This has been reviewed with all pertinent facility staff. To ensure compliance, the CM or designee will audit for bleach containers labeled, bleach rags kept in clean area, and clamps submerged in bleach water using the POC Floor Monitoring Tool, daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 116	Continued From page 9 stored. ..." 1. Observation on 01/25/2017 at 1052 in the patient treatment area at the lab countertop/sink area, revealed "dirty area" signage posted on the wall above the countertop. An uncovered plastic container (#1) was stored down inside the sink; and contained blue scissor clamps and white vascular clamps submerged in a clear liquid (bleach solution). A second uncovered plastic container (#2) was stored on the countertop next to the dirty sink; and contained a stack of soaked white cloth/wipes (clean) submerged in a clear liquid (bleach solution). Each of the two containers were uncovered and not labeled with the name of the clear liquid solution, strength of solution, date and time prepared, and preparer's initials. Further observation revealed the soaked white cloth/wipes used for cleaning and disinfection were being stored in a designated dirty area. Observation revealed potential for cross-contamination. Interview on 01/25/2017 at 1133 with RN #2 revealed the lab countertop/sink area and the dirty countertop/sink (in front of nursing station) were considered "dirty areas" and the clear liquid in the plastic containers was bleach solution. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the lab countertop/sink area and countertop/sink in front of the nurses' station were considered dirty areas. Staff should have labeled the bleach containers with the date, time, and their initials after being prepared. The soaked white cloth/wipes were considered clean and were used for cleaning and disinfection and should not be stored in dirty areas. Interview confirmed the observation findings.	V 116		02.24.17

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V 116	Continued From page 10 2. Observation on 01/25/2017 at 1113 in the patient treatment area at the dirty countertop/sink (located across from the nurses' station) revealed "dirty sink" signage posted on the wall above the sink. A uncovered plastic container (#3) was stored on the dirty sink's left side countertop; and contained blue scissor clamps and white vascular clamps submerged in a clear liquid (bleach solution). Three (3) blue scissor clamps were not fully submerged by the clear liquid. A second uncovered plastic container (#4) was stored on the dirty sink's right side countertop; and contained a clear liquid (bleach solution) with a stack of soaked white cloth/wipes (clean) submerged in the liquid. Each of the two containers were uncovered and not labeled with the name of the clear liquid solution, strength of solution, date and time prepared, and preparer's initials. Further observation revealed the soaked cloth/wipes used for cleaning and disinfection were being stored in a designated dirty area. Follow-up observation at 1610 revealed three (3) blue scissor clamps and three (3) white vascular clamps not fully submerged in container #3's bleach solution. Observation revealed potential for cross-contamination. Interview on 01/25/2017 at 1133 with RN #2 revealed the lab countertop/sink area and the dirty countertop/sink (in front of nursing station) were considered "dirty areas" and the clear liquid in the plastic containers was bleach solution. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the lab area countertop/sink area and countertop/sink in front of the nurses' station were considered dirty areas. Staff should have labeled the bleach containers with the date,	V 116		02.24.17

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V 116	Continued From page 11 time, and their initials after being prepared. The blue scissor clamps and white vascular clamps should have been completely submerged in the bleach solution. The soaked white cloth/wipes were considered clean and were used for cleaning and disinfection and should not be stored in dirty areas. Interview confirmed the observation findings.	V 116		02.24.17
V 122	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. This STANDARD is not met as evidenced by: Based on policy and procedure reviews, observations, and staff interview, the facility's staff failed to ensure all non-disposable equipment and contaminated surfaces were cleaned and disinfected in manner to prevent cross-contamination between patients for 1 of 2 hemodialysis stations observed being cleaned and disinfected by staff (Station M15, PCT #1). Findings included: Review on 01/26/2017 of current policy "Cleaning and Disinfection", FMS-CS-IC-II-155-110A", effective: 01/28/2015, revealed "General Cleaning ...After use, all equipment and supplies must be considered as potentially blood contaminated,	V 122	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policies "Cleaning and Disinfection" (FMS-CS-IC-II-155-110A), "Priming Bucket Disinfection" (FMS-CS-IC-I-105-007C), "Use of Priming Buckets for the Fresenius 2008H and K Machine" (FMS-CS-IC-I-105-006C),"Personal Protective Equipment" (FMS-CS-IC-II-155-080A) and "Hand Hygiene" (FMS-CS-IC-II-155-090A) as specifically related to prime bucket disinfection and cleaning of the patient area between treatments, particularly the counter behind the patient station. The facility Education Coordinator reviewed the aforementioned policies, specifically focusing on relation to cleaning and disinfection of the prime bucket and also cleaning the counter behind the dialysis station after each patient treatment during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the the inservice is responsible to review	02.24.17

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V 122	Continued From page 12 and should be separated, handled with caution and either disinfected or discarded. ...Work Surface Cleaning and Disinfection without Visible Blood using Bleach Solutions All work surfaces shall be cleaned and disinfected with 1:100 bleach solution after completion of procedures. ...Cleaning the Dialysis Machine Externally disinfect the dialysis machine with 1:100 bleach solutions after each dialysis treatment. Give special attention to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated. ...Discard all fluid and clean and disinfect all containers associated with the prime waste (including buckets attached to the machine). ..." Review on 01/26/2017 of current procedure "Use of Priming Buckets for the Fresenius 2008 H and K Machine", FMS-CS-IC-I-105-006C, revised 06/19/2013, revealed "...4. At the completion of the patient treatment, remove the priming bucket....and dispose of the Normal Saline in the utility room hopper or down a sink that has been designated as dirty or hand washing sink. 5. After routine surface disinfection with 1:100 bleach solution, replace on machine. ..." Review on 01/26/2017 of current policy "Personal Protective Equipment", FMS-CS-IC-II-155-080A, effective 03/20/2013, revealed "Policy ...Employees shall use personal protective equipment....gloves, in accordance with the type of patient contact expected and anticipated exposure. ...Change gloves and practice had hygiene between each patient and/or station to prevent cross-contamination. Remove gloves and wash hands after each patient contact, and after exposure to blood or body fluids. If hands are not visibly soiled, use of a waterless antiseptic hand	V 122	the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit for prime buckets being dumped prior to cleaning of the dialysis machine, as well as counter tops cleaned after each patient treatment using the POC Floor Monitoring Tool, daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 122	Continued From page 13 rub is acceptable. (See hand hygiene policy)..." Review on 01/26/2017 of current policy "Hand Hygiene", FMS-CS-IC-II-155-090A, effective: 03/20/2013, revealed "...Hands Will Be,.. Decontaminated using alcohol based hand rub or by washing hands with antimicrobial soap and water When... Immediately after removing gloves... After contact with inanimate objects near the patient. ..." Observation on 01/25/2017 at 1220 in the patient treatment area at station M15 revealed PCT #1 preparing to clean and disinfect the dialysis machine. The machine's prime waste container (PWC) attached to the upper left side of the machine contained approximately one (1) inch of clear liquid inside. The PCT used a disinfectant-soaked cloth/wipe and began to clean and disinfect the top and front surfaces of the machine. The PCT removed the PWC from the machine, emptied it into a dirty sink, cleaned and disinfected it and re-attached the PWC to the machine. The PCT then proceeded to clean and disinfect the remaining surfaces of the machine. Observation revealed the PCT failed to first empty the PWC prior to cleaning and disinfecting the surfaces of the machine and failed to remove her contaminated gloves, perform hand hygiene, and don clean gloves after emptying the PWC and before cleaning and disinfecting the machine's surfaces. Further observation revealed after cleaning and disinfecting the dialysis machine and treatment chair, the PCT failed to clean and disinfect the counters around (behind) the dialysis station. Observation revealed cross-contamination. Interview on 01/26/2017 at 1645 with Clinical	V 122		02.24.17

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V 122	Continued From page 14 Manager #2 revealed the facility's policy did not specifically list the order in which staff should clean the dialysis machines and PWCs. The countertops behind the stations area considered dirty areas. Staff clean the countertops as needed and at the end of the day. The staff do not clean the countertops after each patient treatment. Interview confirmed the observation finding.	V 122		02.24.17
V 130	494.30(a)(1)(i) IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES Isolation of HBV+ Patients To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients. This STANDARD is not met as evidenced by: Based on policy review, observations, and staff interviews, the facility's staff failed to ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B Antigen (HBsAg+) patients was labeled as dedicated "isolation" equipment and supplies; to prevent potential transmission to HBV susceptible patients and staff for 1 of 1 isolation rooms observed (Station M6). Findings included: Review on 01/26/2017 of current policy "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)", FMS-CS-IC-II-155-140A, effective: 03/20/2013, revealed "...Isolation of Hepatitis B virus positive patients (HBsAg+) ...If there are current HBsAg positive patients on census, the	V 130	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Dialyzing Patients with Positive Hepatitis B Antigen" (FMS-CS-IC-II-155-140A) as related to the labeling of equipment and supplies dedicated to the isolation room. The facility Education Coordinator reviewed the aforementioned policy, specifically focusing on relation to the labeling of equipment and supplies dedicated to the isolation room at an Inservice on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. On 1/26/17, the Education Coordinator labeled all equipment and supplies dedicated to the Isolation Room as "Isolation". To ensure compliance, the CM or designee will audit for the labeling of	02.24.17

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V 130	Continued From page 15 isolation area/room and equipment cannot be used for HBV negative patients on other shifts or days due to the risk of cross-contamination. ...Equipment and Supplies Separated dedicated supplies and equipment....must be used to provide care to the HBsAg positive patient. ...All supplies used in the isolation room/area such as clamps, blood pressure cuffs, testing reagents, etc., should be labeled 'isolation' and not routinely removed. ..." Observation on 01/25/2017 at 1038 in the patient treatment area revealed one treatment isolation room (station M6) with Patient #5 (HBsAg+ patient) receiving hemodialysis treatment with 1 hour and 10 minutes left on his treatment. Follow-up observation at 1300 inside the isolation room revealed the following dedicated equipment and patient supplies not clearly marked "isolation": 1.) 1 - Crit line III monitor; 2.) 1 - Dialysis Machine #M6; 3.) 1 - Patient treatment chair; 4.) 5 - Boxes of disposable gloves (various sizes); 5.) 10 - PPE faceshields; 6.) 9 - Bicarbonate concentrate jugs; 7.) 7 - Dialysate jugs; 8.) 3 - Mesa Labs pH Control Solution containers; 9.) 1 - Blood Centrifuge; 10.) 1 - Tympanic Thermometer; 11.) 1 - pHoenix Meter; 12.) 1 - Bleach jug; 13.) 1 - Fox Mountain White Vinegar jug; 14.) 2 - Mop handles; 15.) 2 - Acetic Acid 5% jugs; and 16.) 2 - Yellow Cap Disinfectant jugs.	V 130	"Isolation" for all equipment and supplies dedicated to isolation room use using the POC Floor Monitoring Tool, daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 130	Continued From page 16 Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the facility had one isolation room and one patient currently on census with Hepatitis B. The equipment and supplies inside the isolation room were dedicated to the isolation room and patient. The equipment was cleaned after each patient treatment. She was not aware all dialysis machines, equipment and supplies dedicated for use in the isolation room had to be clearly marked "isolation." Interview confirmed the observation findings.	V 130		02.24.17
V 131	494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING Isolation of HBV+ Patients Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another. This STANDARD Is not met as evidenced by: Based on policy reviews, observations, "Hepatitis Summary Report" review, medical record reviews, physician and staff interviews, the facility failed to prevent staff members from providing care to HBsAg (Hepatitis B Surface Antigen) positive patients and HBV (Hepatitis B) susceptible patients concurrently during hemodialysis treatment for 12 of 12 HBV susceptible patients receiving care across and/or diagonally across from the facility's dedicated Isolation room (#27, #24, #22, #28, #30, #12, #9, #14, #17, #18, #25 and #26; RN #1, RN #2 and PCT #4). Findings included:	V 131	To prevent the care given by staff concurrently for patients with Hepatitis B Antigen positive and susceptible patients, the below plan was been put into place: On 1/26/2017 the Governing Body (Clinical Manager, Regional Vice President, Director of Operations, and Medical Director) with clinic's Education Coordinator held a meeting to educate all staff on the below: Policy and Procedures: FMS-CS-IC-II-155-140A Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+) with emphasis on how staff will not to concurrently care for the Hepatitis B Antigen positive patient and Hepatitis B susceptible at the same time. FMS-CS-IC-II-155-142A Patient Testing and Vaccination for Hepatitis with emphasis on the need to maintain current Vaccine status of every patient with their Hepatitis titers. The facility Education Coordinator reviewed the aforementioned policies, specifically focusing on not providing care to Hepatitis B antigen positive patients concurrently with Hepatitis B susceptible patients again during inservices on 1/31/17 and 2/7/2017. Any DPC staff missing the inservice is	02.24.17

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V 131	Continued From page 17 Review on 01/25/2017 of current policy "Dialyzing Patients with Positive Hepatitis B Antigen (HBsAg+)", FMS-CS-IC-II-155-140A, effective date: 03/20/2013, revealed "Purpose: To prevent transmission of Hepatitis B. ...Patient/Staff Assignments: Make patient/staff assignments to reflect patient and staff hepatitis antibody and antigen status. ...Ensure that staff caring for HBsAg positive patients care only for HBV antibody positive (immune) patients at the same time. This includes nurses and PCTs. Examples include, but are not limited to: a) The nurse who administers any medications (oral or IV) to the hepatitis B antigen positive patient cannot administer any medications to susceptible patients while the hepatitis B antigen positive patient is being treated. The nurse can only care for immune patients while caring for the antigen positive patient. b) PCTs and/or nurses who perform machine set-up/tear down, treatment initiation/discontinuation with CVC or other access, 30 minute checks or any other care of the antigen positive patient can only care for immune patients at the same time. c) Only when the HBsAg positive patient has left the treatment area and the isolation room/area has been completely disinfected and there are no further tasks to be done in the isolation room/area can these staff members care for susceptible patients. ...A buffer zone around the hepatitis B isolation treatment room/area must be maintained at all times. This is done by ensuring that patients closest to the hepatitis B isolation treatment room/area are HBV immune. ...Staff having any contact with the HBsAg positive patient must at the same time have NO contact with susceptible patients. ..." Interview on 01/25/2017 (Wednesday) at 1034	V 131	responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. The Governing Body provided oversight to create new processes to maintain the health and safety for all patients cared for at this facility: • The Hepatitis Summary report is to be ran daily and reviewed for any Hepatitis status changes. • The patients schedule will be based on this Hepatitis summary report. • The schedule will be updated daily using a system that uses the color coded seating plan (red = HbsAg positive and must be isolated, yellow= anti Hbs susceptible titer is < 10 miu/ml, green =anti Hbs protected, titer is >/= 10 miu /ml). • Only the Clinical Manager can approve any changes in this daily seating plan • The RN and PCT staff assignments will be maintained to ensure that no staff member caring for a Hepatitis B Antigen positive patient will care for Hepatitis B susceptible patient concurrently or that no Registered Nurse or PCT that is caring for Hepatitis B susceptible patients will care for a Hepatitis B Antigen Positive patient concurrently. A buffer zone will be maintained at all times. This includes breaks which will be assigned to maintain care for these patients according to their Hepatitis status. Monitoring of the treatment floor to ensure staffing compliance with maintaining a buffer zone will be completed daily for 3 months on the days that the facility has an isolation patient utilizing the Isolation Practices monitoring tool starting on 1/27/2017. If 100% compliance is maintained after the 3 months, the auditing will decrease to weekly	02.24.17

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V 131	Continued From page 18 with RN #1 in the patient treatment area revealed she was the "charge nurse" for today. The facility currently had two (2) registered nurses (RN #1 and RN #2) and 7 patient care technicians (PCTs) including one "floater" PCT on-duty. First shift patients were currently dialyzing. One RN was assigned to either the left (Bay B) or right (Bay A) side of the treatment area. RN #1 was the RN assigned to the right side (Bay A) today and was also assigned the isolation room. The facility had one isolation room (station M6) located across from Bay A. The patient (patient #5) in the isolation room was Hepatitis B positive and was the only patient on census requiring isolation for Hepatitis B. PCT #4 was the patient care technician assigned to the isolation room. PCT #4 was also assigned four (4) additional stations (M21, M17, M26, and M7 in Bay A). RN #1 stated she was responsible for all patients on the right side of the treatment area (Bay A) and RN #2 was responsible for the left side of the treatment area (Bay B). RN #1 stated both susceptible and immune patients were assigned stations on the right side of the treatment area (Bay A). She stated she provided care to all patients assigned in her area including those susceptible patients NOT immune to Hepatitis B. Observation on 01/25/2017 at 1038 in the patient treatment area revealed two (2) RNs (RN #1 and RN #2) and seven (7) PCTs on-duty (including PCT #4) providing care to patients in the patient treatment area (Bay A and Bay B) and treatment isolation room. Observation revealed the following patients: #9, #12, #14, #17, #18, #22, #27, and #28 (ALL susceptible to HBV) were receiving hemodialysis treatments at patient stations in Bay A and Bay B located across and diagonally across, respectively, from the facility's	V 131	weekly for 3 months more. If 100% compliance rate is maintained then the audits will resume per the QAI schedule for monitoring. Monitoring tools will be available for review. Monitoring Tool audit findings will be discussed daily during huddles with the direct patient care staff and education and appropriate corrective actions taken during that time. Audit findings will be discussed during daily GB meetings to monitor and provide oversight. If an employee has continued compliance issues the corrective action process with the application of progressive disciplinary action up to and including termination will take place. A summary of the audit findings will be reviewed and discussed monthly with the QAI team until full resolution.	02.24.17

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V 131	Continued From page 19 dedicated treatment isolation room (station M6). Observation revealed the treatment isolation room had Patient #5 (HBsAg+ patient) receiving hemodialysis treatment concurrently with the observations of patients #9, #12, #14, #17, #18, #22, #27, and #28 hemodialysis treatments. Patient #5 had 1 hour and 10 minutes left on his treatment. Observation on 01/25/2017 at 1043 in the patient treatment area revealed RN #1 in-side of the isolation room wearing PPE and providing care to Patient #5. At 1105, observation revealed PCT #4 was in-side the isolation room wearing PPE and providing care to Patient #5. Review on 01/25/2017 of the "(Facility Name) Daily Assignment Sheet Monday - Wednesday - Friday - Team Two", dated 01/25/2017, revealed RN #1 was assigned as team leader for "Team Two" (Bay A). Review revealed the RN was assigned the following patients on 1st Shift: 1. Patient #5 (HBsAg+ patient)(Isolation Room); 2. Patient #6 (Immune)(Buffer Zone); 3. Patient #7 (Immune)(Buffer Zone); 4. Patient #8 (Immune)(Buffer Zone); 5. Patient #9 (Susceptible)(Buffer Zone); 6. Patient #10 (Immune)(Buffer Zone); 7. Patient #11 (Immune); 8. Patient #12 (Susceptible); 9. Patient #13 (Immune); 10. Patient #14 (Susceptible); 11. Patient #15 (Immune); 12. Patient #16 (Immune); 13. Patient #17 (Susceptible); 14. Patient #18 (Susceptible); 15. Patient #19 (Immune); and 16. Patient #20 (Immune). Review revealed RN #1 was assigned to provide	V 131		02.24.17

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V 131	Continued From page 20 direct patient care to Patient #5 (HBsAg+ patient) concurrently with five (5) HBV susceptible patients (#9, #12, #14, #17, and #18) during the first shift on 01/25/2017. Review on 01/25/2017 of the "(Facility Name) Daily Assignment Sheet Monday - Wednesday - Friday - Team One", dated 01/25/2017, revealed RN #2 was assigned as team leader for "Team One" (Bay B). Review revealed the RN was assigned the following patients on 1st Shift: 1. Patient #21 (Immune); 2. Patient #22 (Susceptible); 3. Patient #23 (Immune); 4. Patient #24 (Susceptible); 5. Patient #25 (Susceptible); 6. Patient #26 (Susceptible); 7. Patient #27 (Susceptible); 8. Patient #28 (Susceptible); 9. Patient #29 (Immune); 10. Patient #30 (Susceptible); 11. Patient #31 (Immune); 12. Patient #32 (Immune); and 13. Patient #33 (Immune). Review revealed RN #2 was assigned to provide direct patient care concurrently to seven (7) HBV susceptible patients (#22, #24, #25, #26, #27, #28, and #30) when Patient #5 (HBsAg+ patient) was receiving hemodialysis during the first shift on 01/25/2017. Review on 01/25/2017 of the "(Facility Name) Daily Assignment Sheet Monday - Wednesday - Friday - Team Two", dated 01/25/2017, revealed PCT #4 was assigned the following patients on 1st Shift (Bay A): 1. Patient #5 (HBsAg+ patient); 2. Patient #6 (Immune); 3. Patient #7 (Immune);	V 131		02.24.17

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V 131	Continued From page 21 4. Patient #8 (Immune); Review revealed PCT #4 was assigned to provide direct patient care to Patient #5 (HBsAg+ patient) concurrently with three (3) immune patients (#6, #7, and #8) during the first shift on 01/25/2017. Review on 01/25/2017 of the facility's "Hepatitis Summary Report", dated 01/24/2017, revealed the most recent hepatitis status for Patient #5 was "antigen positive" and Patients #27, #24, #22, #28, #30, #12, #9, #14, #17, #18, #25 and #26 were "susceptible" to Hepatitis B. Further review of the summary revealed a total of one (1) patient on census at the facility as "antigen positive" and requiring the use of the facility's treatment isolation room. 1. Open medical record review on 01/25/2017 for Patient #5 (HBsAg+ patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 05/06/2016. Review of the patient's "Hepatitis B" status revealed he was documented as "antigen positive" and received hemodialysis treatment inside of the facility's isolation treatment room (station M6) located directly across from Bay A and diagonally across from Bay B. Review of the patient's treatment sheet for his treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #6 (isolation room) from 0739 to 1136. Review revealed the patient received care from the following facility staff members: RN #1 (assigned patient), RN #2 (NOT assigned patient), and PCT #4 (assigned patient), during his dialysis treatment. Review of the patient's treatment sheet further revealed RN #2 (NOT assigned patient) administered an intravenous medication of "Hectorol" (vitamin medication) to the patient on 01/25/2017 at 0848.	V 131		02.24.17

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V 131	Continued From page 22 2. Open medical record review on 01/25/2017 for Patient #27 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 06/24/2016. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #9 from 0740-1208. Review revealed the patient received care from the following facility staff members: RN #2, PCT #3 and PCT #9 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #2 administered an intravenous medication of "Hectoral" on 01/25/2017 at 0904 to the patient (total of 16 minutes after 0848 IV medication administration to Patient #5 in isolation). 3. Open medical record review on 01/25/2017 for Patient #24 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 01/14/2011. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #28 from 0725-0945. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), RN #2, PCT #1, PCT #3 and PCT #8 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectoral" on 01/25/2017 at 0940 to the patient. 4. Open medical record review on 01/25/2017 for	V 131		02.24.17

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V 131	Continued From page 23 Patient #22 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 11/16/2015. Review of the patient's "Hepatitis B" status revealed he was documented as "susceptible" to HBV. Review of the patient's treatment sheet for his treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #29 from 0735-1143. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), RN #2, PCT #1, PCT #3 and PCT #8 during his dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectoral" on 01/25/2017 at 0918 to the patient. 5. Open medical record review on 01/25/2017 for Patient #28 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 09/18/2012. Review of the patient's "Hepatitis B" status revealed he was documented as "susceptible" to HBV. Review of the patient's treatment sheet for his treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #10 from 0744-1130. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), RN #2, PCT #1, PCT #3 and PCT #9 during his dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectoral" on 01/25/2017 at 0944 to the patient. 6. Open medical record review on 01/25/2017 for Patient #30 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 04/22/2009. Review of	V 131		02.24.17

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V 131	Continued From page 24 the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #8 from 0700-1007. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), RN #2, PCT #1, PCT #3 and PCT #9 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectoral" on 01/25/2017 at 0940 to the patient. 7. Open medical record review on 01/25/2017 for Patient #12 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 07/13/2015. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #23 from 0729-1145. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), PCT #4 (assigned to HBsAg+ patient) and PCT #6 during her dialysis treatment. 8. Open medical record review on 01/25/2017 for Patient #9 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 02/06/2009. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #2 from 0738-1122. Review revealed the patient	V 131		02.24.17

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V 131	Continued From page 25 received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient) and PCT #5 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an oral medication of "Loperamide" (antidiarrheal agent) on 01/25/2017 at 0713 and an intravenous medication of "Hectorol" on 01/25/2017 at 0917 to the patient. 9. Open medical record review on 01/25/2017 for Patient #14 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 11/04/2015. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #19 from 0734-1131. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient) and PCT #7 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectorol" on 01/25/2017 at 0943 to the patient. 10. Open medical record review on 01/25/2017 for Patient #17 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 03/17/2013. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #20 from 0657-1103. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient) and PCT #7 during her dialysis treatment. Review	V 131		02.24.17

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V 131	Continued From page 26 of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Hectorol" on 01/25/2017 at 0943 to the patient. 11. Open medical record review on 01/25/2017 for Patient #18 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 10/30/2013. Review of the patient's "Hepatitis B" status revealed she was documented as "susceptible" to HBV. Review of the patient's treatment sheet for her treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #3 from 0704-1145. Review revealed the patient received care from the following facility staff members: RN #1 (assigned to HBsAg+ patient), PCT #2, PCT #6 and PCT #7 during her dialysis treatment. Review of the patient's treatment sheet further revealed RN #1 administered an intravenous medication of "Venofer" (iron sucrose medication) on 01/25/2017 at 0950 to the patient. 12. Open medical record review on 01/25/2017 for Patient #25 (susceptible patient) revealed the patient was admitted to the facility for in-center hemodialysis treatment on 02/08/2001. Review of the patient's "Hepatitis B" status revealed he was documented as "susceptible" to HBV. Review of the patient's treatment sheet for his treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #20 from 0710-1025. Review revealed the patient received care from the following facility staff members: RN #2, PCT #1, PCT #3 and PCT #8 during her dialysis treatment. 13. Open medical record review on 01/25/2017 for Patient #26 (susceptible patient) revealed the patient was admitted to the facility for in-center	V 131		02.24.17

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V 131	Continued From page 27 hemodialysis treatment on 11/19/2007. Review of the patient's "Hepatitis B" status revealed he was documented as "susceptible" to HBV. Review of the patient's treatment sheet for his treatment on 01/25/2017 revealed the patient received hemodialysis treatment at station #2 from 0726- (stop time not documented). Review revealed the patient received care from the following facility staff members: RN #2 and PCT #3 during her dialysis treatment. The review of Patient #5's (HBsAg+ patient) and Patients #27, #24, #22, #28, #30, #12, #9, #14, #17, #18, #25 and #26's (ALL susceptible to HBV) medical records revealed that ALL patients were concurrently cared for by one or more of the same facility staff members who provided direct patient care to Patient #5 (RN #1, RN #2, and PCT #4) between 0739-1136 on 01/25/2017 and failed to prevent potential Hepatitis B transmission. Interview on 01/25/2017 at 1500 with Clinical Manager #1, revealed RN #3 was responsible for coordinating staffing schedules, daily staffing assignments, patient treatment times and station assignments. The hepatitis status of every patient should be reviewed before making changes to patient treatment times and station assignments. Only immune patients should be placed into the "buffer zone." The "buffer zone" consisted of six (6) stations directly across from the isolation room, the four (4) stations on the right side of the right bay (Bay A) next to the windows and two (2) stations on the left side of the right bay (Bay A). The RN assigned to Bay A, "should not be taking care of any patients that are not immune." It was the responsibility of the vaccination/immunization nurse (RN #1) and	V 131		02.24.17

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V 131	Continued From page 28 scheduling nurse (RN #3) to follow-up with each other to coordinate treatment time and station assignment changes. "There was a lack of communication between the nurses." Typically, there were two (2) RNs scheduled on Tuesday, Thursday, and Saturday and three (3) RNs scheduled on Monday, Wednesday, and Friday. On Monday, Wednesday, and Friday, one (1) RN takes care of the isolation and buffer zone patients. "Today, we just happened to have only 2 RNs." There was supposed to be a third shift today but because of transferring patients out and a census drop; there were vacant chairs on the first shift that could be filled up with other patients. Third shift was canceled and the patients were rescheduled from the third and second shifts to the first shift. Interview on 01/25/2017 at 1555 with RN #1 revealed she was the RN assigned Patient #5 in the isolation room on 01/25/2017. She performed and documented the patient's dialysis assessment. She entered the isolation room, performed safety checks, and documented the monitoring of the patient at 1008 and 1044. She did not administer any medications to the patient. The PCT accessed and discontinued the patient's vascular access. RN #1 stated she had read the facility's policy (Dialyzing Patients with Positive Hepatitis B Antigen) and "We feel horrible. Nobody working with that patient (#5) should have been working with other susceptible patients." Interview confirmed RN #1 provided care concurrently to HBV susceptible patients and to Patient #5 (HBsAg+ patient) during his treatment on 01/25/2017. Concurrent interview on 01/25/2017 at 1555 with RN #2 revealed she was not the RN assigned the	V 131		02.24.17

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V 131	Continued From page 29 isolation room on 01/25/2017 when Patient #5 received hemodialysis treatment on first shift. She documented vital signs and monitoring of the patient at 0825 and 0834 because the PCT was on break and she did not want the monitoring to get behind. She monitored the patient from outside the isolation room through the window, then documented in the computer at the nurses' station. At 0848 she did enter the isolation room during treatment and administered Hectorol IV to the patient. She donned a PPE gown and gloves, but did not physically touch the patient. The facility normally had three (3) RNs on-duty on Monday, Wednesday, and Friday, but had only two RNs on-duty today; due to one RN out sick since January and a decrease in census. The third RN would have been assigned the isolation room and "buffer zone" patients. RN #2 stated she provided patient care to HBV susceptible patients after administering patient #5 his IV medication and exiting the isolation room. She stated "I realized I should not have done that." Interview confirmed RN #2 provided care concurrently to HBV susceptible patients and to patient #5 (HBsAg+ patient) during his treatment on 01/25/2017. Telephone interview on 01/26/2017 at 1044 with Physician A revealed he was the facility's Medical Director. He had been made aware of staff concurrently taking care of Hepatitis B positive patients and susceptible patients on 01/25/2017. Staff assigned to isolation patients should not be concurrently taking care of susceptible patients. As the Medical Director, he was responsible for all care provided within the clinic. Interview on 01/26/2017 at 1205 with RN #3 revealed she was responsible for completing the	V 131		02.24.17

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V 131	Continued From page 30 daily assignment schedules. The daily assignment schedules were usually completed the day before. The schedule for Wednesday (01/25/2017) was completed on Tuesday (01/24/2017). Patient treatment times/stations were changed to eliminate the third shift on 01/25/2017; and because there were "new" PCTs who could not access CVCs; and so PCTs would have two patients instead of only one. She stated the facility "usually, does not pull this many patients forward to different shifts." Names in type print on the schedule have not been changed. Names handwritten on the schedule have been changed. The clinical manager checks the schedule to assure the schedule is alright. If any schedule/station changes are made during the treatment shift, no one is responsible for checking hepatitis status. Interview on 01/26/2017 at 1645 with Clinical Manager #2, revealed when staff are assigned to take care of patients in the isolation room; they are not to concurrently take care of HBV susceptible patients. Staff who are not assigned the isolation room should not enter or provide care to the patient in the isolation room except for emergency situations. The facility currently had one isolation room and one Hepatitis B positive patient on census. Interview confirmed the findings.	V 131		02.24.17
V 143	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	V 143	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body.	02.24.17

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V 143	Continued From page 31 This STANDARD is not met as evidenced by: Based on policy review, observations, and staff interview, the facility's staff failed to use aseptic techniques when preparing medication syringes for 1 of 2 staff observed preparing medication syringes (PCT #2); failed to label pre-filled medication syringes with the name of the medication, route, dose, name of patient, date, time, and initials of the person who prepared the medication for 5 of 5 observed pre-filled medication syringes (Syringes #1, #2, #3, #4, and #5); and failed to label a multidose medication vial with the date, time, and initials of the person who opened the medication vial for 1 of 1 observed opened multidose medication vials (Vial #1). Findings included: Review on 01/26/2017 of current policy "Medication Preparation and Administration", FMS-CS-IC-I-120-040A, effective: 01/28/2015, revealed "...Labeling Reconstituted Medication Solutions and Syringes ...All medications in syringes not being administered immediately shall be labeled appropriately with the name of the medication, route, dose, name of patient, date, time, and initials of the person who prepared the medication. ...Label any open multi-dose vial that is not used immediately and store vial accordingly. ...Medications may be pre-drawn up to 4 hours prior to administration.... These pre-drawn medications shall be labeled and must be kept under the preparer's control or in a locked designated medication storage area...until delivery to the appropriate patient for	V 143	As a result, the following actions have occurred: A review of the facility policy "Medication Preparation and Administration" (FMS-CS-IC-I-120-040A) as specifically related to using aseptic technique when preparing medication syringes from a multidose vial or normal saline bag, properly labeling medication syringes, properly labeling multidose vials when opened, and the need to secure all medications either under preparers control or in locked area until delivery to appropriate patient. The facility Education Coordinator reviewed the aforementioned policy at an Inservice on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. All pertinent facility staff have been inserviced specifically of the need to clean the septum of the medication vial or normal saline bag with a separate clean alcohol pad prior to inserting a needle into multidose vial or normal saline bag, of the need to label medications appropriately (with name of the medication, route, dose, name of patient, date, time and initials of person who prepared the medication), of the requirement to secure all predrawn medications in a locked area, of the need to label an open multidose vial with the date, time and initials of the person who opened it, and of the requirement to secure pre drawn medication until immediately needed for use. In addition, after receiving further clarification from FKC Quality Department, all PCTs will be instructed to draw NS for catheter flushes out of the patients' normal saline bag	02.24.17

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V 143	Continued From page 32 administration. ...Infection Control The following steps must be taken to ensure infection control. ...Aseptic technique will be used to prepare and administer IV medications. ...Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor or chlorhexidine/alcohol agent. Allow to dry prior to accessing. ...Cleanse the diaphragm of a vial prior to accessing the vial. If the vial is a multi-dose vial, cleanse the diaphragm with alcohol each time the vial is accessed with a needle using friction and 70% alcohol. Allow to dry before inserting a device into the vial. ..." 1. Observation on 01/25/2017 at 1210 in the patient treatment area at station M24 revealed PCT #2 preparing to initiate dialysis via patient #1's CVC. The PCT used two (2) ten (10) milliliter medication syringe with needles to obtain Normal Saline (a medication) from the 1000 milliliter bag of Normal Saline hanging on dialysis machine's IV pole. The PCT inserted the needle of syringe #1 into the injection port of the Normal Saline bag and removed 10 milliliters of Normal Saline (for flush). The PCT then inserted the needle of syringe #2 into the injection port of the Normal Saline bag and removed 10 milliliters of Normal Saline. The PCT failed to clean and disinfect the injection port of the Normal Saline bag prior to each needle insertion. The PCT exited the station and at 1212 was observed at a clean countertop (adjacent to entry door into storage/water treatment area) preparing a medication syringe with needle for patient #1. The PCT used an opened 30,000 unit/30 milliliter multi-dose vial of Heparin (anticoagulant); and inserted the needle into the vial and withdrew heparin solution. The PCT failed to disinfect the rubber diaphragm of the medication vial prior to insertion of the needle. The PCT discarded the prepared Heparin syringe	V 143	by the Facility Education Coordinator or Clinical Manager. Any DPC staff missing the inservice will be responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit for multidose vial labeled appropriately, septum of medication vial cleaned with clean alcohol pad prior to the insertion of each needle, septum of the normal saline bag cleaned with clean alcohol pad prior to the insertion of each needle, medication syringes labeled appropriately and medication stored in secure area using the POC Floor Monitoring Tool, daily x 30 days, then weekly x 4, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 143	Continued From page 33 after being prompted by an RN during the observation. Observation revealed the PCT failed to use aseptic technique when preparing medication syringes. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are allowed to use the patient's Normal Saline bag hanging on the dialysis machine's IV pole at the station for flush syringes. Staff are supposed to clean and disinfect the injection port of the Normal Saline bag with an alcohol wipe before each needle insertion and staff are also supposed to clean and disinfect the medication vial's rubber diaphragm with an alcohol pad before each needle insertion. Interview confirmed the observation findings. 2. Observation on 01/25/2017 at 1046 in the patient treatment area at a clean countertop (adjacent to entry door into storage/water treatment area) revealed an opened 30,000 units/30 milliliter medication vial of Heparin (vial #1), Lot #6012599, expired: 08/18, stored on top of the counter with other clean supplies. Review of the Heparin vial's label revealed no date, time, or staff initials as to when the medication vial had been opened. The medication was left unattended and unsecured by staff. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed medications should be kept secured in a locked cabinet or drawer in the medication preparation area. Staff are supposed to write their initials, date, and time on the medication vial's label when it is opened. Interview confirmed the observation finding. 3. Observation on 01/25/2017 at 1150 in the patient treatment area at station M12 revealed	V 143		02.24.17

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V 143	Continued From page 34 the station had been cleaned, disinfected, and prepared for the next patient. A blue chux pad was placed on the treatment chair's left chairside table. On top of the blue chux pad were two (2) pre-filled ten (10) milliliter medication syringes (syringes #1 and #2) containing a clear liquid (Normal Saline). The two syringes were not labeled. No staff were present at the station. Observation revealed the two prepared medication syringes were unlabeled, unsecured, and not in the preparer's control at the station. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed prepared medication syringes should be labeled with the patient's name, medication, date, time, and preparer's initials when not immediately administered. Prepared medication syringes should not be left in the stations unsecured and unattended. Interview confirmed the observation findings. 4. Observation on 01/25/2017 at 1310 in the patient treatment area at the nurses' medication preparation/storage area revealed an unlocked cabinet containing medications. Observation revealed two (2) pre-filled three (3) milliliter medication syringes (syringe #3 and #4) of "Heparin" (anticoagulant medication) for Patient #2 and one (1) pre-filled ten (10) milliliter medication syringes (syringe #5) of Heparin for Patient #4, stored on a shelf inside the cabinet. Observation revealed all three (3) medication syringes had a label with the patient's name and date, but failed to have the preparer's name and/or initials and time the medication was prepared documented on the labels. Further observation revealed the medication storage cabinet was unlocked and no staff were present in the medication area.	V 143		02.24.17

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V 143	Continued From page 35 Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed prepared medication syringes should be labeled with the patient's name, medication, date, time, and preparer's initials when not immediately administered. Medications should be kept secured in a locked cabinet or drawer in the medication preparation area. Interview confirmed the observation findings.	V 143		02.24.17
V 147	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 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	V 147	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy FMS-CS-IC-I-105-002A Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use E-beam Dialyzer Policy, FMS-CS-IC-I-105-002C Initiation of Treatment Using a Central Venous Catheter and Optiflux® Single Use Ebeam Dialyzer Procedure , focusing on the patient's need to wear a mask that covers their nose and mouth entirely during initiation of treatment and FMS-CS-IC-105-028A Termination of Treatment Using a Central Venous Catheter focusing on the need for staff to change the blue chux pad prior to termination of treatment for a CVC patient. The facility Education Coordinator reviewed the aforementioned policies, specifically focusing on the	02.24.17

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V 147	Continued From page 36 B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI [catheter related blood stream infections]. This STANDARD is not met as evidenced by: Based on policy and procedure reviews, observations, and staff interview, the facility's staff failed to ensure a patient's PPE mask fully covered the mouth and nose to prevent potential cross-contamination during initiation of treatment via a central venous catheter (CVC) for 1 of 2 CVCs observed being accessed (Patient #2, Station M4, PCT #3); and failed to place a clean field underneath the CVC ports to prevent potential cross-contamination prior to termination of treatment via a CVC for 1 of 2 CVCs observed being terminated (Patient #4, Station M10, PCT #3). Findings included: Review on 01/26/2017 of current policy, "Termination of Treatment Using a Central Venous Catheter...", FMS-CS-IC-105-028A, IS-I-520-031A, effective 01/06/2014, revealed "...Infection Control ...The patient and the staff must wear a mask that covers their nose and mouth for all procedures that require accessing the catheter. ..." Review on 01/26/2017 of current procedure, "Termination of Treatment Using a Central Venous Catheter...", FMS-CS-IC-I-105-028C, effective 01/06/2014, revealed "...Prior to Termination: Preparation ...5. Ensure that a clean under pad is below the catheter limbs to	V 147	patient's need to wear a mask that covers their nose and mouth entirely during initiation of treatment and also the need for staff to change the blue chux pad prior to disconnecting the patient post treatment during an Inservice at the Facility on 1/31/2017 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit for patient wearing a mask that covers their mouth and nose completely prior to opening the patient's perm cath during initiation of the patients dialysis treatment and that staff changes the blue chux pad prior to opening the system at termination of the patient's treatment using the POC Floor Monitoring Tool, daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342603	A. BUILDING _____ B. WING _____	01/26/2017

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V 147	Continued From page 37 protect the work area and the clothing. ..." 1. Observation on 01/25/2017 at 1148 in the patient treatment area at station M4 revealed PCT #3 preparing to initiate dialysis via patient #2's CVC. The PCT placed a yellow PPE face mask on the patient's face. The PPE face mask did not fully cover the patient's nose and mouth. The patient's nares were uncovered. The PCT failed to ensure the patient's PPE face mask fully covered the patient's mouth and nose during the procedure. Observation revealed potential for cross-contamination. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff and patients are supposed to wear a PPE face mask during initiation and termination of dialysis via a CVC. If the patient refuses to wear a face mask they are requested to turn their head away from the CVC. The PPE face mask should fully cover the mouth and nose. The nares should not be exposed. 2. Observation on 01/25/2017 at 1620 in the patient treatment area at station M10 revealed PCT #3 preparing to discontinue dialysis via patient #4's CVC. The patient had a blue chux pad taped to his clothing underneath the CVC ports and bloodline connections. The blue chux pad had three (3) blood stains on it. The PCT discontinued dialysis. The PCT failed to place a new clean field under the CVC ports prior to cleaning and disinfecting the CVC ports. Observation revealed potential for cross-contamination. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed a clean field is placed under the patient's CVC ports by staff before the	V 147		02.24.17

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V 147	Continued From page 38 CVC is accessed. The clean field remains in place during treatment and is only changed by staff when it becomes visibly soiled. The chux pad should have been changed before discontinuing the CVC. Interview confirmed the observation findings.	V 147		02.24.17
V 184	494.40(a) ENVIRONMENT-SECURE & RESTRICTED 8 Environment: secure & restricted The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system. This STANDARD is not met as evidenced by: Based on observations and staff interviews the facility's staff failed to ensure the water purification and storage system was secure and restricted to authorized persons only. Findings included: Observation on 01/25/2017 at 1245 revealed the water treatment room was located within the facility's supply storage area. The supply storage area had three (3) access doors. Door #1 entered from the outside of the building and was secured with a locking mechanism. Door #2 entered from the administrative hallway and had a locking mechanism that was unlocked and unsecured. Door #3 entered from the patient treatment area and did not have any locking mechanism and was unsecured. Observation revealed no facility staff	V 184	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy FMS-CS-IC-II-140-120A Reverse Osmosis Machine Policy focusing on the need to maintain a secure facility water room from unauthorized personnel. To secure the water room from unauthorized personnel, the facility purchased digital code locks for the doors entering the water room, except for the delivery door at the back of the facility which remains locked. These were installed in the clinic on 1/31/17. The facility Education Coordinator discussed the need for the water treatment room doors to remained locked/secure at all times with facility staff during an Inservice at the Facility on 1/31/2017 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator.	02.24.17

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V 184	Continued From page 39 present in the supply storage area. Observation revealed the facility's water treatment area was unsecured and not restricted to potential unauthorized persons. Interview on 01/26/2017 at 1520 with the facility's Area Technical Operations Manager (ATOM) revealed the facility's water treatment room is located within the facility's supply storage area. The water treatment room does not have a secured door or barrier restricting access into it from the supply storage area. Facility staff (MD, RN, PCT, Dietician, Social Worker, etc.) and janitors (contracted staff) can travel unrestricted through the main supply storage area. Staff travel through the area to go to the lounge or smoking area out back. Authorized facility staff were not always present in the supply storage area. The door (#3) from the patient treatment area never had a locking mechanism on it and the door (#2) from the administrative hallway was normally left unlocked. Interview confirmed the observation findings.	V 184	An additional Inservice, focusing on FMS-CS-IC-II-140-120A Reverse Osmosis Machine Policy, will be done with all DPC staff focusing on restricted access to the water treatment area will be completed by 2/17/2017 by the Facility Education Coordinator or Clinical Manager. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit for compliance with the policy that the water treatment room door remains secure using the POC Floor Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17
V 196	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.	V 196	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Carbon Filtration System Monitoring for Central Water Systems" (FMS-CS-IC-II-140-115A3, IS-II-600-045A4) focusing on the facility's need to perform total chlorine/chloramine testing not more than <4 hours apart.	02.24.17

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	342503	A. BUILDING _____ B. WING _____	01/26/2017

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V 196	Continued From page 40 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 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. This STANDARD is not met as evidenced by: Based on policy review, total chlorine log reviews, and staff interviews, the facility's staff failed to ensure total chlorine testing was performed every four (4) hours. Findings included: Review on 01/26/2017 of current policy "Carbon Filtration Monitoring for Central Water Systems", FMS-CS-IC-II-140-115A3, IS-II-600-045A4, effective: 01/19/2013, revealed "...Testing Locations and Frequency ...Worker Carbon Filter Prior to the initiation of the first patient treatment of the day and At a minimum of every four hours. ..." Review on 01/26/2017 of the facility's Total Chlorine Logs from December 01, 2016 through January 25, 2017 revealed the facility staff failed to perform Total Chlorine Testing every four hours on the following dates:	V 196	The facility Education Coordinator reviewed the aforementioned policy, specifically focusing on the need for facility staff to perform total chlorine/chloramine testing at a frequency of not more than <4 hours apart during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. Since the survey, the facility is targeting to perform Total Chlorine/Chloramine testing at a frequency of every 3 hours, instead of every 4 hours, to ensure that no tests are late. In addition, the facility is now keeping written Chlorine/Chloramine testing logs as a visual reminder of when the test is due and to rule out any Total Maintenance System (TMS) documentation issues that may reflect late testing. Also, the timer for Chlorine/Chloramine testing has been moved to the Nurses Station, to improve the ability of the RNs to hear the timer when it goes off. The staff responsible for Water Testing are being designated on the daily floor schedule. To ensure compliance, the CM or designee will audit for compliance with Chlorine/ Chloramine testing performed at intervals not more than <4 hours using the POC Floor Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 196	Continued From page 41 1. 12/08/2016: Test Due: 1038; Time Reading(s) Were Taken: 1245 (127 minutes late); Test done by: PCT #2; Test confirmed by: RN #4; 2. 12/26/2016: Test Due: 0700; Time Reading(s) Were Taken: 0940 (160 minutes late); Test done by: PCT #10; Test confirmed by: RN #1; 3. 01/02/2017: Test Due: 1657; Time Reading(s) Were Taken: 1705 (8 minutes late); Test done by: RN #1; Test confirmed by: RN #4; and 4. 01/24/2017: Test Due: 1347; Time Reading(s) Were Taken: 1355 (8 minutes late); Test done by: PCT #2; Test confirmed by: RN #3. Interview on 01/26/2017 at 1611 with the facility's Area Technical Operations Manager (ATOM) during Total Chlorine Log reviews, revealed the facility's total chlorine logs were documented electronically by staff in the Total Maintenance System (TMS). The electronic system flags when total chlorine testing is performed late. Corporate policy requires staff to perform total chlorine testing at a minimum of every four (4) hours or sooner. The facility staff should not go over 4 hours. Paper logs were maintained and reviewed weekly by the Clinical Manager prior to the electronic logs. Currently there is no policy for reviewing the electronic logs by the Clinical Manager. Interview confirmed the total chlorine tests identified above were not performed within 4 hours per policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the facility's practice is to perform water testing (total chlorine test) every three (3) hours. Policy requires at a minimum every four (4) hours. Staff should not be going over four (4) hours. Tests should not be late. Interview confirmed the observation findings.	V 196		02.24.17

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V 407	Continued From page 42	V 407		
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on policy review, observations, and staff interview, the facility's staff failed to ensure patient vascular accesses and bloodline connections were visible during hemodialysis treatment for 2 of 2 stations observed with covered access sites/blood lines (Stations M10 and M5). Findings Included: Review on 01/26/2017 of current policy "Patient Monitoring During Patient Treatment", policy: FMS-CS-IC-I-110-133A, effective: 08/20/2014, revealed "...Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary. Observation All patients must be under visual observation by FMS Clinical staff during treatment. ...Access Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible. ...Ensure access remains uncovered throughout the treatment..." 1. Observation on 01/26/2017 at 0934 in the patient treatment area at station M10 revealed the patient's vascular access sites and bloodline connections were covered with a green blanket during hemodialysis treatment. The patient was resting with eyes closed and appeared to be asleep. Follow-up observation at 0955 revealed	V 407	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Patient Monitoring During Patient Treatment" (FMS-CS-IC-I-110-133A) focusing of the portion that pertains to monitoring/documenting the visualization of the patient's vascular access during treatment. The facility Education Coordinator reviewed the aforementioned policy, specifically focusing on the portion that pertains to monitoring/documenting the visualization of the patient's vascular access during treatment during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit for compliance with monitoring and documenting the patient's access remains uncovered during treatment using the Flow Sheet Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff	02.24.17

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V 407	Continued From page 43 the patient's vascular access and bloodline connections remained covered. Observation revealed staff traveling the treatment floor in front of the patient's station. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the patient's vascular access and bloodline connections should be uncovered at all times during treatment. This is ensure there is no bleeding or infiltration at the site. If covered, staff are supposed to ask the patient to uncover their access site; or if they are asleep staff should uncover the access site. Interview confirmed the observation findings. 2. Observation on 01/26/2017 at 0936 in the patient treatment area at station M5 revealed the patient's vascular access sites and bloodline connections were covered with a black coat during hemodialysis treatment. The patient was resting with eyes closed and appeared to be asleep. Follow-up observation at 0957 revealed the patient's vascular access sites and bloodline connections remained covered. Observation revealed staff traveling the treatment floor in front of the patient's station. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the patient's vascular access and bloodline connections should be uncovered at all times during treatment. This is ensure there is no bleeding or infiltration at the site. If covered, staff are supposed to ask the patient to uncover their access site; or if they are asleep staff should uncover the access site. Interview confirmed the observation findings.	V 407	members failing to ensure compliance will be counseled and corrective action may ensue. In addition, the Clinical Manager will prepare a written information sheet that will provide each patient with education on the need to keep their access uncovered during treatment. This information sheet will be discussed and given to all patients by Clinical Manager or designee and a clinical note stating that the education had been completed put into the medical record by 2/17/2017.	02.24.17
V 504	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS	V 504	On January 27, 2017, the Director of Operations convened a meeting of the	02.24.17

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V 504	Continued From page 44 The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on policy review, North Carolina Board of Nursing's "DIALYSIS in the Acute Care, Community Centers, and Home Settings Position Statement for RN, LPN and UAP Practice" review, medical record reviews, and staff interview, the facility's Registered Nurse (RN) failed to perform a patient's pre-dialysis treatment assessment prior to start of treatment for 3 of 5 sampled in-center hemodialysis patient medical records (Patients #35, #14, and #34). Findings included: Review on 01/26/2017 of current policy "Patient Evaluation Pre Dialysis Treatment", FMS-CS-IC-I-110-131A, revised 07/04/2012, revealed "Purpose The purpose of this policy is to provide guidance on evaluating the patient prior to initiating the dialysis treatment. Responsibility All patient care staff (as defined by scope of care in the job description, license, certification, State and Federal Regulations). Policy FMS patient care staff will complete a pre dialysis evaluation prior to initiation of patient treatment. ...Guidelines for Nursing Assessment Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff. Nurses assess the patient pre treatment as warranted by the patient's condition. The assessment must be documented in the patent's medical record.	V 504	when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Patient Evaluation Pre Dialysis Treatment" (FMS-CS-IC-I-110-131A) specifically pertaining to RN Assessment being performed and documented prior to initiation of the Dialysis Treatment. The facility Education Coordinator reviewed the aforementioned policy, specifically focusing of the portion that pertains to the need for the RN to perform and document a pre dialysis assessment prior to the initiation of the patient's dialysis treatment during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. The Clinical Manager interviewed all of the RNs at the facility to determine the root cause of why the assessments were not consistently being done prior to the patient initiation of treatment. The plan to address these issues are as follows: • All Chairside's (electronic health record) at the facility have been repaired by the Biomedical Department to interface with the hemodialysis machine. • The patients' schedule has been revised to allow more time for the RNs to complete pre assessments timely. • The patients' schedule has been arranged to have PCT's that have completed catheter training assigned to CVC patients.	02.24.17

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V 504	Continued From page 45 ...Facilities in states that require nursing assessments for all patients should continue to perform and document the assessments as required. ..." Review on 01/26/2017 of the North Carolina Board of Nursing's "DIALYSIS in the Acute Care, Community Centers, and Home Settings Position Statement for RN, LP and UAP Practice", revised: 05/2014, revealed "...Note: To support the provision of safe, effective nursing care throughout the dialysis process, activities including hemodialysis, peritoneal dialysis, accessing vascular routes, administering pharmaceutical agents, and monitoring the client throughout the dialysis process must be performed by the appropriate level of licensee and consistent with scope of practice, including assignment and supervision. ...Issue #2: Hemodialysis and Peritoneal Dialysis in Community Dialysis Centers/Chronic Endstage Renal Disease Clinics ...RN Role in Community Dialysis Centers/Chronic Endstage Renal Disease Clinics: ...3. Client assessment prior to initiation of dialysis and prior to client's discharge from facility. ..." 1. Medical record review on 01/26/2017 for Patient #35 revealed the patient was admitted to the facility on 04/14/2009 for ICHD treatments. Review of a "Treatment Sheet" dated 01/24/2017 revealed the patient received hemodialysis treatment on 01/24/2017 from 0910-1327 for 4 hours and 17 minutes. A pre-dialysis assessment was performed by RN #3 at 0956 (46 minutes after treatment was started by a PCT). Review failed to reveal any available documentation the pre-dialysis assessment was performed by the RN prior to treatment start by the PCT. Review of	V 504		02.24.17

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V 504	Continued From page 46 a "Treatment Sheet" dated 01/12/2017 revealed the patient received hemodialysis treatment on 01/12/2017 from 1125-1512 for 3 hours and 47 minutes. A pre-dialysis assessment was performed by RN #2 at 1151 (26 minutes after treatment was started by a PCT). Review failed to reveal any available documentation the pre-dialysis assessment was performed by the RN prior to treatment start by the PCT. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed each patient is to have a pre-dialysis assessment conducted by a RN prior to starting dialysis treatment. The assessment is performed to identify any problems the patient may have that would affect the dialysis treatment. The assessment is a general assessment focused on fluids, EDW, and VS. CM #2 reviewed the treatment records for Patient #35 and verified the pre-dialysis assessments were documented after the patient had started dialysis treatments. Interview confirmed the medical record review findings. 2. Medical record review on 01/26/2017 for Patient #14 revealed the patient was admitted to the facility on 11/04/2015 for ICHD treatments. Review of a "Treatment Sheet" dated 01/18/2017 revealed the patient received hemodialysis treatment on 01/18/2017 from 0802-1152 for 3 hours and 50 minutes. A pre-dialysis assessment was performed by RN #5 at 0808 (6 minutes after treatment was started by a PCT). Review failed to reveal any available documentation the pre-dialysis assessment was performed by the RN prior to treatment start by the PCT. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed each patient is to have a	V 504		02.24.17

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V 504	Continued From page 47 pre-dialysis assessment conducted by a RN prior to starting dialysis treatment. The assessment is performed to identify any problems the patient may have that would affect the dialysis treatment. The assessment is a general assessment focused on fluids, EDW, and VS. CM #2 reviewed the treatment record of Patient #14 and verified the pre-dialysis assessment was documented after the patient had started dialysis treatment. Interview confirmed the medical record review findings. 3. Medical record review on 01/26/2017 for Patient #34 revealed the patient was admitted to the facility on 12/12/2016 for ICHD treatments. Review of a "Treatment Sheet" dated 01/12/2017 revealed the patient received hemodialysis treatment on 01/12/2017 from 1247-1613 for 3 hours and 26 minutes. A pre-dialysis assessment was performed by RN #5 at 1258 (11 minutes after treatment was started by a PCT). Review failed to reveal any available documentation the pre-dialysis assessment was performed by the RN prior to treatment start by the PCT. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed each patient is to have a pre-dialysis assessment conducted by a RN prior to starting dialysis treatment. The assessment is performed to identify any problems the patient may have that would affect the dialysis treatment. The assessment is a general assessment focused on fluids, EDW, and VS. CM #2 reviewed the treatment record of Patient #34 and verified the pre-dialysis assessment was documented after the patient had started dialysis treatment. Interview confirmed the medical record review findings.	V 504		02.24.17

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V 507	Continued From page 48	V 507		
V 507	494.80(a)(4) PA-ASSESS ANEMIA The patient's comprehensive assessment must include, but is not limited to, the following: (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s). This STANDARD is not met as evidenced by: Based on medical record review and staff interview, the facility's staff failed to provide a hemodialysis patient risk and benefit information of Erythropoesis Stimulating Agent (ESA) use related to the FDA (Food and Drug Administration) Black Box Warnings in 1 of 1 medical records sampled of a newly admitted (less than 90 days) in-center hemodialysis patient receiving ESA therapy (Patient #34). Findings included: Open medical record review on 01/25/2017 for Patient #34 revealed the patient was admitted to the facility for in-center hemodialysis on 12/12/2016. Review revealed the patient receives an Erythropoiesis Stimulating Agent (ESA) "Micera 150,000 mcg/IVP" as part of his medication treatment at the facility. Review revealed the patient's last dose of Micera was administered on 01/17/2017 at 1334. Review of the record revealed no documentation that the patient ever received any information about the risks and benefits of ESA use.	V 507	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy FMS-CS-IC-I-120-028A with special Considerations: Mircera Policy focusing on the need to educate patients on the risks and benefits of ESA as related to the FDA Black Box Warnings. A separate inservice will be completed with all DPC staff by 2/17/2017 done by the Facility Education Coordinator or Clinical Manager to review the aforementioned policy focusing on the need to educate patients on the risks and benefits of ESA's. Any DPC staff missing the inservice will be responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. The physicians are providing their patients with the education on the risks and benefits of use of ESA's and are documenting this education on the ESA Risks and Benefits Acknowledgment Form from January 30th through February 17th. This has been completed for all patients at this time. Physicians are continuing to educate and document on patients who were unavailable (missed treatments, hospitalizations) at the time the education was completed. This education will be completed on all new	02.24.17

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V 507	Continued From page 49 Interview on 01/26/2017 at 1438 with Clinical Manager #2 revealed the physicians are responsible for informing the patients about the risk and benefits of ESA use. She reviewed the medical record for Patient #34. The record contained no documentation the patient had ever received any information about the risks and benefits of ESA use. Interview confirmed the finding.	V 507	admission by their physician with documentation on acknowledgement form. To ensure 100% compliance, the CM or designee are tracking the patients who have been educated and those who require the education. This documentation will be available at the clinic for review.	02.24.17
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on policy review, medical record reviews, and staff interview, the facility's patient care staff failed to monitor a patient at a minimum of every 30 minutes during hemodialysis treatments for 5 of 5 sampled in-center hemodialysis patient medical records (Patients #34, #14, #36, #35, and #37). Findings included: Review on 01/26/2017 of current policy "Patient Monitoring During Patient Treatment", FMS-CS-IC-I-110-133A, revised 08/20/2014, revealed "...Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary. ...Documentation Documentation of vital signs and machine parameters must be recorded in the patient's clinical record within 15 minutes of being performed. ..."	V 543	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Patient Monitoring During Patient Treatment" (FMS-CS-IC-I-110-133A) specifically pertaining to the monitoring/documentation of the patient at least every 30 minutes during the dialysis treatment. At a minimum, this monitoring should include vital signs, safety checks, access monitoring, and the condition of the patient. The facility Education Coordinator reviewed the aforementioned policy, specifically focusing on the portion that pertains to the monitoring/documentation of the patient at least every 30 minutes during the dialysis treatment during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification	02.24.17

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V 543	Continued From page 50 1. Open medical record review on 01/26/2017 for Patient #34 revealed the patient was admitted to the facility on 12/12/2016 for ICHD treatments. Review of the "Treatment Sheet For Facility" dated 01/14/2017, revealed the patient received ICHD on 01/14/2017 from 1208-1609 for 4 hours and 01 minutes. Monitoring documentation revealed the patient was monitored by staff at 1338 and next at 1438 (60 minutes later); and at 1450 and next at 1537 (47 minutes later). Review revealed the facility staff failed to monitor the patient at least every 30 minutes during the hemodialysis treatment on 01/14/2017. Review revealed the staff failed to follow facility policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are supposed to monitor patients at least every 30 minutes. Staff are monitoring for safety. Staff check the patient's vital signs, blood and dialysate flow rates, arterial pressures, TMP (trans membrane pressures), access is visible, and transducer protectors are dry. CM #2 reviewed the treatment record of Patient #34. She stated "it is too long in-between monitoring." Interview confirmed the medical record review findings. 2. Open medical record review on 01/26/2017 for Patient #14 revealed the patient was admitted to the facility on 11/04/2015 for ICHD treatments. Review of the "Treatment Sheet For Facility" dated 01/23/2017, revealed the patient received ICHD on 01/23/2017 from 0751-1110 for 3 hours and 19 minutes. Monitoring documentation revealed the patient was monitored by staff at 0823 and next at 0905 (42 minutes later); and at 1010 and next at 1110 (60 minutes later). Review revealed the facility staff failed to monitor the	V 543	from Clinical Manager or Education Coordinator. During this education a discussion was held with DPC staff to determine issues that may be affecting their ability to perform/record vital signs/safety checks at a frequency of at least every 30 minutes. Facility staff reported they were not always able to perform/ document vital signs/safety checks at least every 30 minutes for several reasons, including chronic extensive chairside outages and the facility patient schedule was "tight" and did not always allow them to do so. The plan to address these issues are as follows: • All Chairside's (electronic health record) at the facility have been repaired by the Biomedical Department to interface with the hemodialysis machine. • The patients' schedule has been revised to allow more time for the DPC staff to complete monitoring/documentation timely at least every 30 minutes. • The Facility will be starting a new schedule, designed by the FKC ScheduleWise Team, during the week of February 12, 2017 to further facilitate more time for the staff to care for patients. • PCTs have been instructed by the Clinical Manager to now record vital signs every 20 minutes, routinely on the hour, 20 minutes after the hour and 20 minutes to the hour, example 8:00, 8:20, and 8:40. • Staff break times are now scheduled to ensure better coverage of monitoring of patients.	02.24.17

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V 543	Continued From page 51 patient at least every 30 minutes during the hemodialysis treatment on 01/16/2017. Review revealed the staff failed to follow facility policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are supposed to monitor patients at least every 30 minutes. Staff are monitoring for safety. Staff check the patient's vital signs, blood and dialysate flow rates, arterial pressures, TMP (trans membrane pressures), access is visible, and transducer protectors are dry. CM #2 reviewed the treatment record of Patient #14. She stated "it is too long in-between monitoring." Interview confirmed the medical record review findings. 3. Open medical record review on 01/26/2017 for Patient #36 revealed the patient was admitted to the facility on 12/07/2016 for ICHD treatments. Review of the "Treatment Sheet For Facility" dated 01/16/2017, revealed the patient received ICHD on 01/16/2017 from 1434-1836 for 4 hours and 02 minutes. Monitoring documentation revealed the patient was monitored by staff at 1601 and next at 1649 (48 minutes later); and at 1700 and next at 1740 (40 minutes later). Review revealed the facility staff failed to monitor the patient at least every 30 minutes during the hemodialysis treatment on 01/16/2017. Review revealed the staff failed to follow facility policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are supposed to monitor patients at least every 30 minutes. Staff are monitoring for safety. Staff check the patient's vital signs, blood and dialysate flow rates, arterial pressures, TMP (trans membrane pressures), access is visible, and transducer protectors are dry. CM #2 reviewed the treatment record of	V 543	To ensure compliance, the CM or designee will audit treatment sheets, at least 6 per shift, for compliance with monitoring at least every 30 minutes using the Flow Sheet Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 543	Continued From page 52 Patient #36. She stated "it is too long in-between monitoring." Interview confirmed the medical record review findings. 4. Open medical record review on 01/26/2017 for Patient #35 revealed the patient was admitted to the facility on 04/14/2009 for ICHD treatments. Review of the "Treatment Sheet For Facility" dated 01/24/2017, revealed the patient received ICHD on 01/24/2017 from 0910-1327 for 4 hours and 17 minutes. Monitoring documentation revealed the patient was monitored by staff at 1109 and next at 1327 (138 minutes later). Review revealed the facility staff failed to monitor the patient at least every 30 minutes during the hemodialysis treatment on 01/24/2017. Review revealed the staff failed to follow facility policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are supposed to monitor patients at least every 30 minutes. Staff are monitoring for safety. Staff check the patient's vital signs, blood and dialysate flow rates, arterial pressures, TMP (trans membrane pressures), access is visible, and transducer protectors are dry. CM #2 reviewed the treatment record of Patient #35. She stated "it is too long in-between monitoring." Interview confirmed the medical record review findings. 5. Open medical record review on 01/26/2017 for Patient #37 revealed the patient was admitted to the facility on 01/29/2016 for ICHD treatments. Review of the "Treatment Sheet For Facility" dated 01/18/2017, revealed the patient received ICHD on 01/18/2017 from 1505-1705 for 2 hours and 00 minutes. Monitoring documentation revealed the patient was monitored by staff at 1545 and next at 1639 (54 minutes later). Review	V 543		02.24.17

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V 543	Continued From page 53 revealed the facility staff failed to monitor the patient at least every 30 minutes during the hemodialysis treatment on 01/18/2017. Review revealed the staff failed to follow facility policy. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed staff are supposed to monitor patients at least every 30 minutes. Staff are monitoring for safety. Staff check the patient's vital signs, blood and dialysate flow rates, arterial pressures, TMP (trans membrane pressures), access is visible, and transducer protectors are dry. CM #2 reviewed the treatment record of Patient #37. She stated "it is too long in-between monitoring." Interview confirmed the medical record review findings.	V 543		02.24.17
V 550	494.90(a)(5) POC-VASCULAR ACCESS-MONITOR/REFERRALS The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. This STANDARD is not met as evidenced by: Based on policy and procedure reviews, observations, and staff interviews, the facility's staff failed to verbally confirm with the patient if the patient washed their AVF/G access site with soap and water or an antibacterial scrub upon entering the facility; and failed to wash the patient's AVF/G access site with soap and water or an antibacterial scrub before performing skin antisepsis and cannulation for 1 of 2 staff	V 550	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: A review of the facility policy "Assessment and Preparation of the Internal Access for Needle Placement" (FMS-CS-IC-I-115-006A) focusing on the area specifically related to asking the patient to wash their access area with soap and water for one minute, prior to the start of treatment. The facility Education Coordinator reviewed the aforementioned policy, focusing on the area specifically related to asking the patient to wash their access area with soap and water for one minute, prior to the start	02.24.17

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V 550	Continued From page 54 observed accessing a patient's AVF/G (PCT #1, Patient #3, Station M32). Findings included: Review on 01/26/2017 of current policy "Assessment and Preparation of Internal Access for Needle Placement", FMS-CS-IC-I-115-006A, effective: 09/25/2013, revealed "...Before each treatment....The access must be prepared properly to prevent bacteria from entering the bloodstream through the skin. ..." Review on 01/26/2017 of current procedure "Assessment and Preparation of Internal Access for Needle Placement", FMS-CS-IC-I-115-006C, effective: 09/25/2013, revealed "...Assessment of Internal Access Follow the steps below to assess the internal vascular access: Step 1 Ask your patient to wash access area with liquid soap for one minute, rinsing well. Dry with clean paper towel. ..." Observation on 01/25/2017 at 1240 in the patient treatment area, revealed Patient #3 entered the patient treatment area, was weighed, and walked to station M32. The patient did not stop at a clean sink and wash his access site before sitting down in the station's treatment chair. At 1255 PCT #1 entered the station to access the patient's AVF/G for initiation of dialysis. The PCT donned clean gloves, evaluated the access site and applied antiseptic to the skin over the cannulation sites; inserted the cannulation needles and secured them in place (one at a time). The PCT failed to wash the skin over the patient's access site with soap and water or antibacterial scrub and failed to verbally confirm with the patient that he had washed the skin over his access site after entry	V 550	of treatment during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Staff were instructed that they should wash the patients' access with soap and water, prior to preparation for cannulation, if the patient does not do so. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. In addition, the Clinical Manager will prepare a written information sheet that will provide each patient with education on the need to wash their access with soap and water pretreatment to lessen the risk of infections. This information sheet will be discussed and given to all patients by Clinical Manager or designee and a clinical note stating that the education had been completed put into the medical record by 2/17/2017. New signage, requesting the patient to wash their access upon entering the treatment area, has been placed in several visible areas for patients to see to act as reminder. To ensure compliance, the CM or designee will audit for patient's washing their access (or staff doing so) pre preparation for cannulation using the POC Floor Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

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V 550	Continued From page 55 into the treatment area. Observation revealed potential for cross-contamination. Interview on 01/25/2017 at 1315 with Patient #3 revealed he did not stop at a sink inside the treatment area to wash his access site. He stated he washed his access site in the bathroom before entering the treatment area. He stated the PCT did not ask him if he had washed his access site before coming to the dialysis station. Interview confirmed the observation finding. Interview on 01/26/2017 at 1645 with Clinical Manager #2 revealed the patients are instructed to wash their vascular access sites at the clean sink after entering the treatment area. Patients should not wash their access sites in the lobby's bathroom. If the PCT does not see the patient wash their access site, the PCT should ask the patient if they had washed it. If the patient has not, then staff should wash the patient's access site before antiseptic application and needle cannulation. Interview confirmed the observation findings.	V 550		02.24.17
V 686	494.140(b)(3)(i)-(ii) PQ-CHARGE NURSE-12 MO NURSING+3 MO DIALYSIS The charge nurse responsible for each shift must- (i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed; (ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis;	V 686	On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As a result, the following actions have occurred: The Governing Body discussed that during the recent CMS Survey, that when more than one Registered Nurse is working each shift, that no one was designated as "Charge Nurse", leaving questions as to who	02.24.17

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V 686	Continued From page 56 This STANDARD is not met as evidenced by: Based on observations, staff schedule review, daily assignment sheet reviews, and staff interviews, the facility's leadership failed to designate a qualified Charge Nurse (CN) responsible for each hemodialysis patient shift when two (2) or more RNs were on duty. Findings included: Observation on 01/25/2017 at 1038 during facility tour revealed two (2) RNs and seven (7) PCTs on-duty in the patient treatment area. Observation on 01/26/2017 at 0930 during facility tour revealed three (3) RNs and seven (7) PCTs on-duty in the patient treatment area. Review on 01/25/2017 of the facility's current staffing schedule for January 16, 2017 to February 11, 2017 revealed three (3) RNs scheduled to work on MWF and two (2) RNs scheduled to work TTS. Review failed to reveal any available documentation identifying the one RN designated as the facility's qualified Charge Nurse on days when two or more RNs were scheduled to be on-duty. Review on 01/25/2017 of the "(Facility Name) Daily Assignment Sheet Monday - Wednesday - Friday - Team One", dated 01/25/2017, revealed RN #2 was assigned as "Team Leader" for "Team One" (Bay B)." Further review of the "(Facility Name) Daily Assignment Sheet Monday - Wednesday - Friday - Team Two", dated 01/25/2017, revealed RN #1 was assigned as "Team Leader" for "Team Two" (Bay A). Review of the two daily assignment sheets failed to reveal any available documentation identifying the one RN designated as the facility's qualified Charge	V 686	was in Charge for the day. Furthermore, the Surveyor noted that staff was unsure who was in Charge. To eliminate this confusion, the Governing Body directed the Charge Nurse should be designated on the Facility's daily schedule to ensure that staff knew who was in Charge for the day. The facility Education Coordinator reviewed the aforementioned with the staff during an Inservice at the Facility on 1/31/17 and then again on 2/7/2017. Any DPC staff missing the inservice is responsible to review the policies and if there are any questions to seek further clarification from Clinical Manager or Education Coordinator. To ensure compliance, the CM or designee will audit the facility's floor schedule for Charge Nurse Assignment using the POC Floor Monitoring Tool daily x 30 days, then weekly x 4 weeks, then monthly until 100% compliance is noted and the Governing Body agrees further monitoring is unnecessary. Findings will be reported to the Governing Body during scheduled meetings. Staff members failing to ensure compliance will be counseled and corrective action may ensue.	02.24.17

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342603	A. BUILDING _____ B. WING _____	01/26/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BMA EAST ROCKY MOUNT	230 SOUTH FAIRVIEW ROAD ROCKY MOUNT, NC 27801

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 686	Continued From page 57 Nurse on days when two or more RNs were scheduled to be on-duty. Interview on 01/25/2017 at 1500 with Clinical Manager #1 revealed, "Both RNs are in charge." The RNs are considered "team leaders." There is a 1:15 RM to patient ratio with the clinical manager being a backup. Each RN is responsible for the bay (Bay A or B) assigned. "We do not have a dedicated charge nurse for each patient shift." The daily assignment sheets and weekly schedules do not identify a dedicated charge nurse for each shift. Interview confirmed the findings. Interview on 01/25/2017 at 1555 with RN #1, revealed she was the "charge nurse" today. "Usually, whoever has the isolation room is in charge." She stated "I don't think the techs (PCTs) know who is in charge. The techs go to the nurse assigned to their bay." Interview on 01/26/2017 at 0940 with PCT #2 revealed, "this facility, I do not believe has a charge nurse." The PCTs assignment today was split between the two bays. The PCT stated "I would go to the nurse responsible for the assigned bay." Interview on 01/26/2017 at 0950 with PCT #4 revealed "I think they have a charge nurse." The PCT stated, "I usually will go to the nurse assigned to my bay." Interview on 01/26/2017 at 1645 with Clinical Manager #2, revealed the facility did not have an assigned charge nurse. The PCTs report to the RN assigned to their bay. The nurses work as a team. Interview confirmed the findings.	V 686		02.24.17

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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V 686	Continued From page 58 Interviews revealed an inconsistency among direct patient care staff as to who was the facility's dedicated charge nurse for each patient shift.	V 686		02.24.17
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on policy and procedure reviews, observations, "Hepatitis B Summary Report" review, daily assignment sheet reviews, staffing review, medical record review, physician interview and staff interview; the facility's Governing Body failed to demonstrate responsibility for monitoring and oversight of the facility's infection control program resulting in the facility's inability to ensure the provision of safe infection control practices. Findings included: The facility's staff failed to develop and implement an effective infection control program that demonstrated recognition of cross-contamination and potential transmission of bloodborne pathogens; as evidenced by the facility's inability to ensure the provision of safe infection control practices for all 123 hemodialysis patients on census; resulting in an identification of immediate jeopardy (IJ) to the health and safety of the facility's patients. ~Cross refer to 494.30 Infection Control (Condition) - Tag 0110.	V 750	Please cross reference V110 494.30 Infection Control The Governing Body of this facility takes seriously its responsibility to provide direct oversight to ensure an effective infection control program is maintained to provide a safe environment to all facility patients. On January 27, 2017, the Director of Operations convened a meeting of the Governing Body to review the citations from the January 25th and 26th survey and to develop an initial plan of corrections. Then on February the 9, 2017, when the Statement of Deficiency was received the plan of corrections was reviewed and updated via the Governing Body. As such, the Governing Body has committed to meet daily providing oversight to the following implemented corrective actions until full resolution is achieved maintaining safe infection control practices: • A new Clinical Manager was appointed by the Governing Body on January 25, 2017 to provide direct oversight of day to day operations of the facility. • On Feb 15, 2017, the Regional Vice President provided education on the responsibility of each of the roles relevant to governance of the clinic to include training and education of staff, ensuring adequate staff coverage, and carrying out the day to day management, operations, and administrative oversight of the facility.	02.24.17

Additional page added by facility to complete documentation of the Plan of Correction.

		V750	• All staff have been educated on the Policies and Procedures necessary to ensure safe infection control practices are being followed. Please cross reference V Tags 113, 116, 122, 130, 131, 143, 147, and 550 for specific education. Documentation on each inservice completed will be available for review. • To ensure compliance with infection control practices the below monitoring processes have been put into place: o The Isolation Practice Monitoring Tool will be completed every day a patient that is Hepatitis B antigen positive is dialyzing o The POC Floor Monitoring Tool will be completed every day to ensure policy and procedures are being followed for infection control • That all staff are educated and monitored in maintaining a buffer zone for susceptible patients when a Hepatitis B positive patient is dialyzing • To ensure the buffer zone is maintained at all times when a Hepatitis B positive antigen patient is dialyzing a Color Coding System for the Hepatitis Schedule has been completed. The system will use a color coded seating plan (red = HbsAg positive and must be isolated, yellow= anti Hbs susceptible titer is < 10 miu/ml, green =anti Hbs protected, titer is >/= 10 miu /ml) to provide a visual support to maintain the buffer zone. Minutes of the Governing Body, completed monitoring tools and educational documentation will provide evidence of these actions. This documentation will be available for review. The Governing Body may recommend procedural, process or operational changes necessary to prevent reoccurrence.	02.24.17

dupl 9/19/16

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

9/19/16

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

ID: UTH3

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

Facility ID: 956062

1. MEDICARE/MEDICAID PROVIDER NO. (L1) 342545
2. STATE VENDOR OR MEDICAID NO. (L2)

3. NAME AND ADDRESS OF FACILITY
(L3) FMC FOUR OAKS
(L4) 5815 US HWY 301 S
(L5) FOUR OAKS, NC (L6) 27524

4. TYPE OF ACTION: 2 (L8)
1. Initial 2. Recertification
3. Termination 4. CHOW
5. Validation 6. Complaint
7. On-Site Visit 9. Other
8. Full Survey After Complaint

5. EFFECTIVE DATE CHANGE OF OWNERSHIP (L9)

6. DATE OF SURVEY 08/31/2016 (L34)

8. ACCREDITATION STATUS: __ (L10)
0 Unaccredited 1 TJC
2 AOA 3 Other

7. PROVIDER/SUPPLIER CATEGORY 09 (L7)

~~01 Hospital~~	~~05 HHA~~	~~09 ESRD~~	~~13 PHP~~	~~22 CLIA~~
02 SNF/NF/Dual	06 PRTF	10 NF	14 CORF	
03 SNF/NF/Distinct	07 X-Ray	11 ICF/IID	15 ASC	
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE	

FISCAL YEAR ENDING DATE: (L35) 12/31

11. LTC PERIOD OF CERTIFICATION
From (a):
To (b):

12. Total Facility Beds (L18)
13. Total Certified Beds (L17)

10. THE FACILITY IS CERTIFIED AS:
X A. In Compliance With Program Requirements
Compliance Based On:
X 1. Acceptable POC
B. Not in Compliance with Program Requirements and/or Applied Waivers:

And/Or Approved Waivers Of The Following Requirements:
__ 2. Technical Personnel
__ 3. 24 Hour RN
__ 4. 7-Day RN (Rural SNF)
__ 5. Life Safety Code
__ 6. Scope of Services Limit
__ 7. Medical Director
__ 8. Patient Room Size
__ 9. Beds/Room

* Code: A1* (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IID
(L37)	(L38)	(L39)	(L42)	(L43)

15. FACILITY MEETS 1861 (e) (1) or 1861 (j) (1): (L15)

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):
An onsite ESRD [CORE] Recertification survey was conducted August 29-31, 2016. Standard level deficiencies were cited under 494.30 Infection Control, 494.60 Physical Environment, 494.90 Patient Plan of Care, and 494.180 Governance. A plan of correction was requested from the facility.

17. SURVEYOR SIGNATURE Date: 9/16/2016 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 9/16/2016 (L20)

PART II - TO BE COMPLETED BY HCFA REGIONAL OFFICE OR SINGLE STATE AGENCY

19. DETERMINATION OF ELIGIBILITY (L21)
X 1. Facility is Eligible to Participate
____ 2. Facility is not Eligible

20. COMPLIANCE WITH CIVIL RIGHTS ACT:

21. 1. Statement of Financial Solvency (HCFA-2572)
2. Ownership/Control Interest Disclosure Stmt (HCFA-1513)
3. Both of the Above :

22. ORIGINAL DATE OF PARTICIPATION 06/26/1989 (L24)

23. LTC AGREEMENT BEGINNING DATE (L41)

24. LTC AGREEMENT ENDING DATE (L25)

25. LTC EXTENSION DATE: (L27)

27. ALTERNATIVE SANCTIONS
A. Suspension of Admissions: (L44)
B. Rescind Suspension Date: (L45)

26. TERMINATION ACTION: (L30)
VOLUNTARY 00
01-Merger, Closure
02-Dissatisfaction W/ Reimbursement
03-Risk of Involuntary Termination
04-Other Reason for Withdrawal
INVOLUNTARY
05-Fail to Meet Health/Safety
06-Fail to Meet Agreement
OTHER
07-Provider Status Change
00-Active

28. TERMINATION DATE: (L28)

29. INTERMEDIARY/CARRIER NO. 00310 (L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

EXHIBIT B

ALL-STATE LEGAL®

FORM CMS-1539 (7-84) (Destroy Prior Editions)

020499

PRINTED: 09/06/2016
FORM APPROVED
OMB NO. 0938-0391

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342545	A. BUILDING _____ B. WING _____	08/31/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FMC FOUR OAKS	5815 US HWY 301 S FOUR OAKS, NC 27524 VRM 9/16/2016

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	INITIAL COMMENTS An onsite ESRD [CORE] Recertification survey was conducted August 29-31, 2016. Standard level deficiencies were cited under 494.30 Infection Control, 494.60 Physical Environment, 494.90 Patient Plan of Care, and 494.180 Governance. Glossary of Abbreviations: ESRD=End Stage Renal Disease PCT=Patient Dialysis Care Technician CVC=Central Venous Catheter OPIM=other potentially infectious material	V 000		
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Based on facility policy review, observation and staff interview, the facility's staff failed to wear cover gowns with long sleeves covering forearms and a face mask over the nose during a CVC initiation for 1 of 2 observed staff members initiating hemodialysis treatment through a patient's CVC access site (PCT #1, Patient #7, Patient Station #22). Findings included:	V 115	See attached	10/11/16

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Sylvia Baker — TITLE: Director of Operations — (X6) DATE: 9/12/2016

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 115	Continued From page 1 Review of the facility's policy and procedure "Personal Protective Equipment" (effective 03/20/2013) revealed "Policy..Employees who may have potential occupational exposure shall be provided, without cost, appropriate equipment including gloves, fluid resistant gowns, face shields masks, eye protection with full sideshields as appropriate. Personal protective equipment such as full face shield or mask and protective eyewear with full sideshield, fluid resistant gowns and gloves will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through to or reach the employee's skin, eyes, mouth, other mucous membranes, or work clothes when performing procedures during which spurting or spattering of blood might occur. Background..OSHA Directive Number CPL 2-2.69 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens 1910.1030, 11/27/2001: Requirements for the use of protective body clothing, such as fluid-resistant gowns, aprons, laboratory coats, clinic jackets, surgical caps, or shoe covers, and the degree to which PPE must resist penetration, are performance-based. The employer must evaluate the task and the type of exposure expected and, based on the determination, select the "appropriate" personal protective clothing. Fluid-resistant laboratory coats or fluid-resistant gowns with long sleeves must be used for procedures in which exposure of the forearm to blood or other potentially infectious material (OPIM) is reasonably anticipated to occur." Observation on 08/30/2016 at 1116 in the patient treatment area at dialysis station #22 revealed PCT #1 initiating patient #7's CVC access pre-dialysis in the patient's right thigh area. The	V 115		

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V 115	Continued From page 2 observation revealed that during the initiation of the CVC the PCT was not wearing her mask over her nose and had her cover gown sleeves not covering her forearms. The observation revealed the staff member failed to protect herself from potential spurting or spattering of blood, body fluids, and/or potentially-contaminated substances. Interview during the observation period on 08/30/2016 at 1119 with PCT #1 revealed that she failed to cover her nose with her mask as well as not wearing her cover gown sleeves fully covering her forearms. The interview revealed, "My mask slides down sometimes and they have trained us to wear our gowns to cover our arms when we initiate treatment." The interview confirmed the observation finding. Interview on 08/30/2016 at 1121 with the facility's Clinical Manager revealed that staff members should always wear their masks covering their noses during CVC initiations and discontinuing as well as wearing their gown sleeves over the forearms to prevent potential contamination and blood exposures. The interview confirmed the observation finding.	V 115		
V 122	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.	V 122	See attached	10/1/16

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V 122	Continued From page 3 This STANDARD is not met as evidenced by: Based on facility policy review, observation and staff interview, the facility failed to maintain infection control standard precautions by ensuring that staff cleaned and disinfected priming buckets according to facility policy and procedure for 1 of 2 observed dialysis machine cleanings (PCT #1, Patient Dialysis Station #14) between patient shifts and failing to maintain a patient waiting room free of insects. Findings included: 1. Review of the facility's policy "Use of Priming Buckets" (Effective date: 06/19/2013) revealed "4. At the completion of the patient treatment, remove the priming bucket or approved removable container, and dispose of the Normal Saline in the utility room hopper or down a sink that has been designated as dirty or hand washing sink. 5. After routine disinfection with 1:100 bleach solution, replace on machine." Observation on 08/30/2016 at 1042 in the patient treatment area revealed PCT #1 cleaning and disinfecting dialysis station #14 during the facility's changeover from the 1st shift to the 2nd shift of patients. The observation further revealed the PCT did not remove the prime waste bucket for cleaning and disinfecting that was attached to the dialysis machine. The observation revealed the CT wiped over the prime bucket with a disinfectant cloth but failed to clean and disinfect the prime waste bucket according to facility policy and procedure by removing it from the machine to empty it before cleaning.	V 122		

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V 122	Continued From page 4 Interview on 08/30/2016 at 1138 with the facility's Clinical Manager revealed that prime waste buckets should be removed, emptied along with cleaning and disinfecting between patient shifts. The interview confirmed the observation finding. 2. Observation on 08/29/2016 at 1405 in the facility's patient and family waiting area revealed one (1) dead roach that was squashed and stained on the facility floor located directly beside of a chair. Interview on 08/29/2016 at 1510 with the facility's Clinical Manager revealed the facility does have monthly and as needed pest control services at the facility. The interview confirmed the observation finding of a dead roach located in the patient waiting area of the facility.	V 122		
V 402	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. This STANDARD is not met as evidenced by: Based on facility policy review, observation and staff interview, the facility failed to ensure that a fire exit alarm pull station and fire extinguisher was free of obstacles and not blocked in 1 of 1 designated treatment floor fire exits and failed to ensure the environment was equipped to provide a safe and functional environment based on broken and cracked floor tiles in the patient treatment area (Patient Stations #3, #16).	V 402	See attached	10/1/16

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V 402	Continued From page 5 Findings included: 1. Review of the facility's policy "Guidelines for Emergency Preparedness" (Effective date: 10/03/2012) revealed "Key steps in preparing for emergency and disaster events include: Evaluate the readiness of your facility. Secure the facility to prevent injuries during emergency/disaster. Emergency exits are well marked and pathways are clear." Observation on 08/29/2016 at 1447 in the patient treatment area near the back bay Fire exit passageway with dedicated fire alarm pull station revealed a chair and computer on wheels blocking the egress area. The observation revealed passageway and fire exit was not free of obstacles and not blocked. Interview on 08/29/2016 at 1510 with the facility's Clinical Manager revealed that the fire exit and egress should not be blocked with items. The interview confirmed the observation finding. 2. Observation on 08/29/2016 at 1440 in the patient treatment area revealed broken and cracked tiles in the center area of the treatment floor as well as between patient dialysis stations #3 and #16. The observation revealed the broken and cracked tiles were potentially not able to be cleaned and disinfected as well as potential trip or fall hazards. The observation further revealed the facility failed to have intact surface integrity on the treatment floor to allow for effective cleaning and to limit the potential for microbial growth on a porous surface. Interview on 08/29/2016 at 1510 with the facility's	V 402		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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V 402	Continued From page 6 Clinical Manager revealed the broken tile and cracks are being looked at to be fixed but there are no definitive plans for repair at the present time. The interview confirmed the observation finding.	V 402		
V 403	494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations. This STANDARD is not met as evidenced by: Based observation and staff interview, the facility failed to ensure that hemodialysis machines exterior front panels were maintained to prevent potential cross-contamination in 1 of 20 observed hemodialysis machines (Machine #14). Findings included: Observation on 08/30/2016 at 1050 in the patient treatment area revealed a patient dialysis machine (#14) was located inside of patient dialysis station #12 and was being used for hemodialysis patient treatments. The observation revealed that the machine's front casing covering above and below the blood flow pump was missing and the irregularity on the surface of the dialysis machine that may allow fluids or blood (and/or dirt or bacteria) to enter the machine, which would be difficult to remove during routine disinfection.	V 403	See attached	10/11/16

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 403	Continued From page 7 Interview on 08/30/2016 at 1218 with the facility's Clinical Manager revealed the dialysis machine outer casing should be intact in order to clean and disinfect the machine appropriately. The interview further revealed the machine was an older machine and it needed to be replaced. The interview confirmed the observation finding.	V 403		
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on manufacturer's operators manual for the "2008K Hemodialysis Machines" review, observation, staff interview and physician interview, the facility failed to develop, individualize and implement blood pressure alarm parameters for patient dialysis machines to alert staff for patient abnormal blood pressures for 8 of 8 observed patients (Patient Dialysis Stations #3, #5, #7, #8, #10, #11, #17, #19). Findings included: Review on 08/31/2016 of the manufacturer's operators manual for the "2008K Hemodialysis Machines" (used at facility) revealed "Blood Pressure Screen...The blood pressure alarm limits are set in the upper, right side of the screen. The upper and lower alarm limits for pulse rate and systolic and diastolic blood pressures are set here. If a pressure valve is outside the set alarm limits, the machine sounds a series of short, intermittent beeps."	V 543	See attached	10/19/16

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V 543	Continued From page 8 1. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #3 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 100, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1112 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized.	V 543		

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V 543	Continued From page 9 2. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #5 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 110, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1113 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized.	V 543		

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V 543	Continued From page 10 3. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #7 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 110, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1114 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized.	V 543		

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V 543	Continued From page 11 4. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #8 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 100, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1115 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized.	V 543		

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V 543	Continued From page 12 5. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #10 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 100, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1116 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be	V 543		

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V 543	Continued From page 13 individualized. 6. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #11 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 100, and Lower Diastolic Blood Pressure 40". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1117 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood pressure alarms." The interview confirmed that	V 543		

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V 543	Continued From page 14 patient's blood pressures needed to be individualized. 7. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #17 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 100, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1118 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be nice to have different range sets for blood	V 543		

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V 543	Continued From page 15 pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized. 8. Observation on 08/31/2016 at 1110 in the patient treatment area for patient dialysis station #19 revealed a patient was receiving hemodialysis treatment with a setting of parameters for the blood pressure alarms as "Upper Systolic Blood Pressure 200, Upper Diastolic Blood Pressure 100, Lower Systolic Blood Pressure 110, and Lower Diastolic Blood Pressure 50". Interview during the observation and dialysis prescription verification check with the facility's Clinical Manager at 1119 revealed that clinical staff have not done anything with the alarms for blood pressures and that biomedical staff sets. The interview revealed no parameters that biomedical staff used to set the alarms. The interview also revealed that clinical staff has not had any specific individualized blood pressure parameters for patients and has never set parameters on the dialysis machines blood pressure alarms. Interview during the observation period on 08/31/2016 at 1120 with the facility's Area Operations Technical Manager revealed that biomedical has never done anything with setting alarms for the dialysis machines blood pressure. The interview revealed it was probably default and the alarms could be adjusted by clinical staff as needed. Interview on 08/31/2016 at 1219 with the facility's Medical Director revealed some of the patient's blood pressures may be more sensitive than other patients. The interview further revealed "Some patients need monitoring so it might be	V 543		

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V 543	Continued From page 16 nice to have different range sets for blood pressure alarms." The interview confirmed that patient's blood pressures needed to be individualized.	V 543		
V 771	494.180(h) GOV-ELECTRONIC DATA SUBMISSION REQUIRED (8) Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must- (1) Be submitted at the intervals specified by the Secretary; (2) Be submitted electronically in the format specified by the Secretary; (3) Include, but not be limited to- (i) Cost reports; (ii) ESRD administrative forms; (iii) Patient survival information; and (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary. This STANDARD is not met as evidenced by: Based on "ESRD Network 6 CROWNweb Data Management Reporting" information and staff interview, the facility failed to submit electronic required information as required for the CROWNweb Data Management Guidelines.	V 771	See attached	10/11/16

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V 771	Continued From page 17 Findings included: Review on 08/29/2016 of a correspondence letter from the ESRD Network 6 related to an ESRD CORE survey revealed the facility was out of compliance with CROWNweb Data Management Guidelines for the area of "missing forms." The correspondence letter revealed the missing forms for UPI numbers for affected patients as the following; "Missing Forms. Below are the UPI numbers of the affected patients. 600764457 2728 Re-entitlement Missing 02/23/2016 Past Due 08/30/2016" Interview on 08/29/2016 at 1410 with the facility's Social Worker revealed patient #13 began dialysis at facility on 01/09/2016. The facility's social worker thought the patient was a transfer in rather than a "restart" and did not realize the patient was discharged from a sister facility as well as was listed as "regain function" and therefore did not know that a form 2728 was needed for CROWNweb data submission. The facility revealed they did not receive any information from the ESRD Network 6 indicating there were missing forms.	V 771		

CMS Recertification Survey For 342545

V 000 Initial Comments

The Governing Body (GB) of this facility of which the Medical Director is a member takes seriously the management of the day to day operations of the facility and its responsibility for ensuring safety and adequate dialysis treatments for all patients receiving hemodialysis at this facility. A meeting of the Governing Body was held on 9/15/16 to discuss and review the Statement of Deficiency as written and discuss the Plan of Correction (POC) that is needed. Governing Body will meet again following the completion of the POC to review and approve for submission to CMS.

Plan of Correction

Completion Date for all Deficiencies October 1, 2016

V115 494.30(a)(1)(i) A mandatory staff meeting will be held on 9/21/2016 to review audit findings and educate all staff on the policy V115 FMS-CS-IC-II-155-080A Personal Protective Equipment. Personal Protective Equipment such as a full face shield or mask and protective fluid-resistant gown will be worn to protect and prevent employees from blood or other potentially infectious materials to pass through or reach the employee's skin, eyes, mouth, or other mucous membranes, or work clothes when performing procedures during which spurting or spattering of blood might occur. Staff members should wear their gown cover with long sleeves pulled down and not pushed up at any time. CM or designee will audit, review and monitor patient care staff adherence to Protective Personal Equipment policy with specific audits 2 times a week X 3 months.

The meeting and in-service attendance records will be available for review at the facility.

In the event that a staff member is found to continually not follow the facility procedure the Clinical Manager will be responsible to ensure progressive disciplinary action is applied.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V122 494.30(a)(4)(ii)IC - A mandatory staff meeting will be held 9/21/2016 to review audit findings and to educate all staff on policy FMS-CS-IC-II-155-110A Cleaning and Disinfection Policy. Discard all fluid and clean and disinfect all containers associated with the prime waste (including buckets attached to the machines). CM or designee will audit, review and monitor patient care staff adherence to policy Cleaning and Disinfection with specific audits 2 times a week x 3 months.

The meeting and in-service attendance records will be available for review at the facility.

In the event that a staff member is found to continually not follow the facility procedure the Clinical Manager will be responsible to ensure progressive disciplinary action is applied.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V 122 494.30(a)(4)(ii)(2) -IC- - A mandatory staff meeting will be held 9/21/2016 to review audit findings and to discuss that the facility has a contract with Clegg's Pest Control Company. CM or designee will inspect clinic 3 times a week to ensure no pests. If found in noncompliance the PEST company will be called for a follow-up visit.

The meeting and in-service attendance records will be available for review at the facility.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure facility compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V 402 494.60(a)- - A mandatory staff meeting will be held 9/21/2016 to review audit findings and to educate all staff on policy FMS-CS-IC-II-130-014C Guidelines for Emergency Preparedness Policy Secure the facility to prevent injuries during emergency/disaster. All Emergency exits and pull stations are to be well marked and pathways are to remain clear. CM or designee will audit, review and monitor patient care staff adherence to policy Guidelines for Emergency Preparedness with specific audits 2 times a week X 3 months.

The meeting and in-service attendance records will be available for review at the facility.

In the event that a staff member is found to continually not follow the facility procedure the Clinical Manager or Director of Operations will be responsible to ensure progressive disciplinary action is applied.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V402 494.60(a)(2) A mandatory staff meeting will be held 9/21/2016 to discuss Building Maintenance Manual. Broken Tiles-Inadequate subfloor. If bouncy, need to replace subfloor and /or use more flexible tiling. If unleveled, need to re-level subfloor or use underlayment. If extensive, replace tiles and revise maintenance program. CM met with AB Denning Commercial Interiors on 9/6/16 and the floor is to be repaired within 60 days. CM or designee will audit, review and monitor to make sure this gets done in a timely manner.

The Clinical Manager will review and monitor findings and report to monthly QAI committee. The Governing Body will review status of compliance and will determine further needs. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V 403 494.60(b) - A mandatory staff meeting will be held 9/21/2016 to review audit findings and to discuss that an audit of 100% of all machines were performed on 9/1/16 going forward any machines with missing parts or front panels are to be removed from service until repaired by technical. CM or designee will audit, review and monitor with specific audits 2 times a week X 3 months.

The meeting and in-service attendance records will be available for review at the facility.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V 543 494.90(a)(1) A mandatory staff meeting will be held 9/21/2016 to educate all staff on policy and procedure FMS-CS-IC-II-110-134AC Determination of Blood Pressure Blood Pressure alarm parameters for patient dialysis machines will be reviewed 9/15/2016 with Medical Director and a determination will be made to alert staff of patient abnormal blood pressures. Once parameters are established CM or designee will audit October 1, 2016, review and monitor patient care staff adherence to policy and procedure with specific audits 3 times a week x 3 months.

The meeting and in-service attendance records will be available for review at the facility.

In the event that a staff member is found to continually not follow the facility procedure the Clinical Manager will be responsible to ensure progressive disciplinary action is applied.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance.

V 771 494.180(h) A mandatory staff meeting will be held 9/21/2016 to educate appropriate staff on Government-Electronic Data Submission that is required on admissions. All patients' must have ESRD Network 6 Crownweb Data Management reporting entered into the system per Crownweb Data Management Guidelines. CM or designee will audit, review and monitor patient records for adequate paperwork within 45 days of admission. Monitoring with specific audits to be completed every month and appropriate submissions made into Crownweb data base.

The meeting and in-service attendance records will be available for review at the facility.

In the event that a staff member responsible is found to continually not follow the facility procedure the Clinical Manager will be responsible to ensure progressive disciplinary action is applied.

The Clinical Manager will summarize the audit, review and monitor findings and report to monthly QAI committee. The Governing Body will review status of staff compliance and will determine further need of audit frequency. The action plan will be revised as needed to meet compliance.

The Clinical Manager is responsible to ensure staff compliance to all policies and procedures and the QAI committee and the Governing Body monitor for ongoing compliance

All action plans will be in place by October 1, 2016