Exhibit E

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr
Drexdall Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

February 16, 2011

Lori Todd, RN, Facility Administrator
Southeastern Dialysis-Wilmington
2215 Yaupin Drive
Wilmington, NC 28401

Re: Follow-up Survey
ESRD CMS Certification Number (CCN): 34-2511

Dear, Ms. Todd

Thank you for the cooperation and courtesy extended during my recent visit on February 14, 2011,for the purpose of conducting a follow up to the Immediate Jeopardy (IJ condition level deficiencies 494.90 Patient Plan of Care, 494.30 Infection Control and 494.110 Quality Assurance that was cited during your Medicare recertification survey and complaint investigation on January 19-21, 2011. It was determined that the IJ was removed and the condition level deficiencies have been corrected, as well as the standard level deficiencies, and you are back in compliance with Medicare's Conditions of Coverage for End Stage Renal Disease facilities.

Enclosed is your copy of form CMS-2567B reflecting the correction.

Should you have any questions or if this office can be of other assistance, please do not hesitate to call me at (919) 855-4620.

Sincerely,

Ralph Mills

Ralph Mills, RN,BSN
Facility Survey Consultant
Acute & Home Care Licensure & Certification

Enclosure: CMS-2567B

COPY

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

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Fax: 919-715-8476

February 15, 2011

Arlene Mullin-Lane
24801 Northeast 219th Street
Battle Ground, WA 98604

Re: Southeastern Dialysis Center -Wilmington - Complaint Investigation NC00070336

Dear Ms. Mullin-Lane:

This letter is in reference to your complaint against Southeastern Dialysis Center -Wilmington in Wilmington, NC. An unannounced visit was made to the facility on January 19, 2011 through January 21, 2011 in order to investigate your concerns.

The investigation included observations of care, interviews with staff, physicians, policy review and medical record reviews, including the record for the named patients. We were able to substantiate 2 of 2 allegation(s) in your complaint. Following is a summary of the allegations and overall findings:

The facility failed to provide adequate monitoring and assessment of vascular access sites and patient condition changes for hemodialysis patients during hemodialysis treatments.
The facility failed to prevent delays in hemodialysis treatments due to electricity and water problems.
Furthermore, any deficiences realized during the investigation were cited accordingly.

We appreciate you bringing these concerns to our attention. It is through such efforts as yours that we are better able to monitor the level of patient care being provided by health care facilities. Please contact me at (919) 855-4620 if I can be of further assistance.

Sincerely,

Ralph Mills , RN,BSN
Facility Survey Consultant
Acute Care Licensure and Certification Section

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
1301 Young Street, Room 833
Dallas, Texas 75202

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Division of Survey and Certification, Region VI

January 31, 2011

CMS Certification Number (CCN): 342511

Administrator
Southeastern Dialysis Center -Wilmington
2215 Yaupon Drive
Wilmington, NC 28407

Dear Administrator:

After a careful review of the facts on the report dated January 21, 2011, Centers for Medicare and Medicaid Services (CMS) has determined that Southeastern Dialysis Center-Wilmington no longer meets the requirements for participation in the Medicare program because of deficiencies that represent an immediate jeopardy to patient health and safety, placing the following Medicare Conditions for Coverage out of compliance:

42 CFR 494.30	Infection control;
42 CFR 494.90	Patient plan of care; and
42 CFR 494.110	Quality assessment and performance improvement.

To participate as suppliers of services in the Medicare program, renal dialysis facilities must meet all of the Medicare Conditions of Coverage for Renal Dialysis Facilities, and be free of hazard to patient health and safety.

Unless the immediate jeopardy to patient health and safety is removed, the date on which your end stage renal disease facility's Medicare agreement terminates is February 15, 2011. No payment for dialysis services provided on or after that date will be made by the Medicare program. **You must send us a letter of credible allegation and an acceptable plan of correction (PoC) within ten days of receipt of this notice in order to ensure a revisit by or before February 15, 2011.** Upon written notification of how and when you actually corrected all serious deficiencies, CMS will evaluate the information provided and, if it seems possible another survey may result in a finding of compliance, we will try to arrange it before the termination date. The decision will be based on all the facts surrounding the termination, and a new survey may be authorized before the impending termination date even though not required by law or our procedures.

You are required to submit your plan of correction under the appropriate column on the Form CMS-2567. **In order to allow time for a revisit, should a visit be allowed, choose the earliest reasonable correction date for each deficient practice, with no dates later than February 7, 2011.** You must address each deficiency and include the month, date, and year of the expected completion. You must sign, date, and indicate your title in the appropriate blocks on page 1 of the form. Send the CMS-2567 to: Attention, Glenda Payne or Rachel McCarty, CMS/DSC, 1301 Young Street, Room 827, Dallas, Texas 75202.

If you remain out of compliance at the time of your revisit, you will receive a notice from our office advising you of your termination and appeal rights, and notice to the public will also be issued. A **legal notice will be placed in the *Wilmington Star-News*, Wilmington, North Carolina advising the public of both the termination date and the reasons for your termination from the Medicare program.** Because the requirements for participation in the Medicaid program are substantially the same as those for Medicare, we have notified the appropriate State officials concerning termination of your Medicare approval under Title XVIII.

If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the Associate Regional Administrator, Division of Survey and Certification, Attention: Rachel McCarty, 1301 Young Street, Room 827, Dallas, Texas 75202. At your option, you may instead submit a hearing request directly (accompanied by a copy of this letter) to the Departmental Appeals Board, Civil Remedies Division, Attention: Oliver Potts, Room G-644, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201, and send a copy of your request to this office.

A request for a hearing should identify the specific issues, and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. You may be represented by counsel at a hearing at your own expense.

Under Medicare regulation 42 CFR 405.2180(c), when a supplier of services is terminated by CMS, a new agreement will not be accepted until it has been determined that the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur. The terminated facility will have to operate for a period of time determined by CMS, during which the reasonable assurance requirement must be satisfied. During this period the facility must fulfill, all of the statutory and regulatory responsibilities of the previous agreement.

If you have any questions, please contact Glenda Payne at (214) 767-4436 or Rachel McCarty at (214) 767-2082.

Sincerely,

Ginger Odle, Manager
Non-Long Term Care Certification & Enforcement Branch

Enclosure

cc: North Carolina State Department of Health

COPY

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

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http://www.ncdhhs.gov/dhsr
Drexdall Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

January 26, 2011

****Via Electronic Delivery****

Lori Todd, Facility Administrator
Southeastern Dialysis Center-Wilmington
2215 Yaupon Drive
Wilmington, NC 28407

RE: Recertification Survey, Immediate Jeopardy Complaint Investigation # NC00070336

Dear Ms. Todd,

Thank you and your staff for the assistance and cooperation extended during the survey conducted January 19, 2011 through January 21, 2011. The purpose of conducting the recertification survey and complaint investigation was to evaluate the Facility's compliance with the Federal Medicare Conditions for Coverage. The recertification survey and complaint investigation resulted in Immediate Jeopardy (IJ) identification as of **January 21, 2011** at **3:20 pm**.

Specifically, the IJ was identified when the facility failed to provide monitoring, assessment and quality of care to a hemodialysis patient that bled out from a vascular access site after a hemodialysis treatment on 01/17/2011.

As discussed during the survey, the information gathered was forwarded to the CMS Regional Office in Dallas. Our state agency is recommending 23 day termination due to noncompliance with the **Conditions for Coverage: 494.90 Patient's Plan of Care, 494.30 Infection Control and 494.110 Quality Assurance and Performance Improvement.** The Immediate Jeopardy is ongoing. CMS Regional Office in Dallas will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Glenda Payne
Division of Survey and Certification
CMS Dallas Regional Office
1301 Young Street, Room 827
Dallas, Texas 75202
214-767-6301

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Ralph Mills

Ralph Mills, RN, BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

EPARTMENT OF HEALTH AND HUMAN SE CES — CENTERS FOR DICARE & MEDICAID SERVICES

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTA.. — ID: TFT8

Facility ID: 956055

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

MEDICARE/MEDICAID PROVIDER NO.
(L1) 342511
STA.. VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) SOUTHEASTERN DIALYSIS CENTER -WILMINGTON
(L4) 2215 YAUPON DRIVE
(L5) WILMINGTON, NC (L6) 28407

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) 04/01/2000

DATE OF SURVEY 01/21/2011 (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 FTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	15 ASC
04 SNF	08 OPT/SP	12 RHC	16 HOSPICE

FISCAL YEAR ENDING DATE: (L35)
12/31

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

2. Total Facility Beds Statutory 49 (L18)

3. Total Certified Beds Statutory 49 (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: * Code: B* (L12)

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

4. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(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):
See Attached Remarks

17. SURVEYOR SIGNATURE Ralph Miller, RN Date: 02/15/2011 (L19)

18. STATE SURVEY AGENCY APPROVAL Ann Cay 2/17/11 Date: (L20)

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

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

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
03/26/1979
(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.
00040
(L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

&T REMARKS - CMS 1539 FORM

An 'te recertification survey and complaint investigation NC00070336 was conducted 01/19/2011 through 01/21/2011. The survey related to the complaint investigation est n an Immediate Jeopardy (IJ) identification on 01/21/2011 at 1520. The IJ was not removed onsite during the recertification survey. The Conditions for Coverage 494.90 'atient Plan of Care, 494.30 Infection Control and 494.110 Quality Assurance were not met. A 23 day termination process is recommended. A follow up survey was conducted on 12/14/2011 as directed from the CMS Dallas Regional Office. The SA recommends that the IJ was removed on 02/14/2011 and the Conditions for Coverage 494.90 Patient Plan of Care, 494.30 Infection Control and 494.110 Quality Assurance were back in compliance. No deficiencies were found during the follow up survey.

Control Number: TFT811 (NC00070336)

Department of Health and Human Services
Medicare/Medicaid/CLIA Complaint Form

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number
3 4 2 5 1 1

Facility Name and Address
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON
2215 YAUPON DRIVE
WILMINGTON, NC 28407

3. Date Complaint Received
0 1 1 8 1 1
M M D D Y Y

4. Receiving Component
1 State Survey Agy.
[1] 2 RO

5. Date Acknowledged
0 1 1 9 1 1
M M D D Y Y

6A. Source of Complaint
1 [5]
2 [ ]
3 [ ]
1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants
0 1

7. Allegations

	7.A. Category	7.B. Findings (To be completed following investigation)	7.C. Number of Complainants per Allegation
1	0 6	0 1	0 1
2			
3			
4			
5			

7.A. Category:
1 Resident Abuse
2 Resident Neglect
3 Resident Rights
4 Patient Dumping
5 Environment
6 Care or Services
7 Dietary
8 Misuse of Funds/ Property
9 Certification/Un-authorized Testing
10 Proficiency Test
11 Falsification of Records / Reports
12 Unqualified Personnel
13 Quality Control
14 Specimen Handling
15 Diagnostic Erroneous Test Results
16 Fraud/False Billing
17 Fatality/Transfusion Fatality
18 Other (Specify)
19 Life Safety Code
20 State Monitoring

7.B. Findings (To be completed following investigation):
01 Substantiated
02 Unsubstantiated/ Unable to Verify

8. Action (if multiple actions, indicate earliest action)
[1]
1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify)
6 Other Action (Specify)
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by
[1] 1 State Survey Agency
2 RO
3 Other (Specify) _____

10. Complaint Survey Date
0 1 2 1 1 1
M M D D Y Y

11. Findings (Under 7B Above)

12. Proposed Actions Taken by SA or RO

1:	0 4
2:	
3:	

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify) _____
23 Enforcement Action

13. Date of Proposed Action
0 1 2 1 1 1
M MD D Y Y

14. Parties Notified and Dates

	Party	Date
1 Facility	1. [1]	0 1 2 6 1 1
2 Complainant	2. [2]	0 1 3 1 1 1
3 Representative	3. [ ]	
4 Other (Specify) _____		M M D D Y Y

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)
M MD DY Y

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt
M M D D Y Y

17. CMS RO/MSA Action
[ ]
1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify) _____
14 Enforcement Action

18. Date of Final Action Sign-off
M M D D Y Y

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342511	SOUTHEASTERN DIALYSIS CENTER -WILMINGTON

Type of Survey (select all that apply) [I]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply) [A]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	01/19/2011	01/21/2011	2.00	0.00	20.00	0.00	5.50	8.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours..... 0.00

Total SA Clerical/Data Entry Hours..... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

as Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342511	SOUTHEASTERN DIALYSIS CENTER -WILMINGTON

Type of Survey (select all that apply)

[A] [ ] [ ] [ ] [ ]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[A] [ ] [ ] [ ] [ ]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID								
1. 15546	01/19/2011	01/21/2011	1.00	0.00	10.00	0.00	1.00	5.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 on-site recertification survey and complaint investigation NC00070336 was conducted 01/19/2011 through 01/21/2011. The survey related to the complaint investigation resulted in an Immediate Jeopardy (IJ) identification on 01/21/2011 at 1520. The IJ was not removed onsite during the recertification survey. The Conditions for Coverage 494.90 Patient Plan of Care, 494.30 Infection Control and 494.110 Quality Assurance were not met. A 23 day termination process is recommended.	V 000	V000 An emergency Governing Body meeting was held on 1/24/11 to review findings from the state audit, completed on 1/21/11. At that time, the Governing Body began formulating immediate plans of correction for deficiencies stated in exit interview, pending the SOD from CMS. Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC)	
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Based on observations, staff interview and review of the facility's policies and procedures, it was determined that the facility failed to implement and maintain an effective infection control program. The facility staff failed to wear gloves while touching patients hemodialysis machines during hemodialysis treatments; failed to wear personal protective equipment (PPE) that covered arms while performing patient care procedures to patients during hemodialysis treatments ; failed to dedicate wooded clipboards that cannot be disinfected to a single patient while used in the patient dialysis stations at the facility; failed to dispose of potentially-infectious waste in a designated biohazardous waste container; and failed to adhere to infection control standards to include providing a glove for holding pressure on vascular access sites in 1 of 3 patients observed holding their vascular access site after treatment of hemodialysis. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality infection	V 110	V110 A Governing Body (GB) meeting was held to review the deficiencies received. This Condition for Coverage (CFC) that is not met as supported by standards V113, V115, V116, and V121, V142, has detailed Plans of Correction (POC) referenced to in the specific V tags. Ongoing compliance to the POC includes promoting implementation of policies and procedures to ensure correct and effective practices in infection control techniques and precautions for handwashing, biohazardous waste disposal, cross contamination, proper PPE, disinfectant/disposal of individual patient care items, and patients wearing gloves when holding sites. Members of the GB including the FA, Regional Operations Director (ROD), and Medical Director, have agreed to meet weekly to monitor the facility's progress toward compliance. Then ongoing compliance to the POC will be monitored during GB meetings at least quarterly. This POC will also be reviewed at each monthly Quality Improvement Facility Management Meetings (QIFMM) meeting when the FA will report progress, as well as any barriers to maintaining compliance, to the committee. 2/7/11	2/7/11

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Lori Todd RN
TITLE: Facility Administrator
(X6) DATE: 2/4/11

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.

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

TEMENT OF DEFICIENCIES J PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 110	Continued From page 1 control practices for all the hemodialysis patients. Findings include: A. The facility staff failed to wear gloves while touching patients hemodialysis machines during hemodialysis treatments. ~Cross refer to 494.30(a)(1) Infection Control - Tag V0113 B. The facility staff failed to wear personal protective equipment (PPE) that covered arms while performing patient care procedures to patients during hemodialysis treatments ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0115 C. The facility failed to dedicate wooded clipboards that cannot be disinfected to a single patient while used in the patient dialysis stations at the facility. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0116 D. The facility staff failed to dispose of potentially-infectious waste in a designated biohazardous waste container. ~Cross refer to 494.30(a)(4)(i) Infection Control - Tag V0121 E. The facility staff failed to adhere to infection control standards by providing a glove for holding pressure on vascular access sites in 1 of 3 patients observed holding their vascular access site after treatment of hemodialysis	V 110		

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
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 110	Continued From page 2 ~Cross refer to 494.30(b)(1) Infection Control-Tag V0142	V 110	V113 Clinical Teammates (TMs) were in-serviced 1/27/11 in the following: *Policies #1-05-01, #1-05-0A and #1-05-01B: Infection Control for Dialysis Facilities, Use of Alcohol-Based Hand Rubs, and Handwashing.* Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) to remove gloves and wash hands between dirty and clean tasks, 2) to perform hand hygiene whenever gloves are removed, 3) to wear gloves for all machine contact, 4) wear proper PPE covering arms while performing patient care procedures, 5) no individual patient items on machines, 6) disposing infectious waste properly, 7) provide gloves to all patients holding access sites. Clipboards have been removed from facility, signs have been posted to designate PPE only areas and paper towel dispensers near sinks have been raised to accommodating level. The Charge Nurse (CN) is responsible for oversight of infection control practice daily. Instances of non-compliance will be addressed with the TM responsible immediately and corrective discipline action will be taken. The Facility Administrator (FA) or designee will conduct observational infection control audits on random shifts three times daily for one week, then 3x week for one month, then 2x week for one month, then monthly with regularly scheduled infection control audits. An Infection Control team was also formulated to perform "Clean Sweep" audits weekly for 4 weeks, then bimonthly for 8 weeks, then monthly. Results of all audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. Governing Body meeting on 1/25/11 stating that it is mandatory for all patients to use a gloved hand to hold access sites. cont. pg 4	2/7/11
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 observations, staff interview and review of the facility's policies and procedures, the facility staff failed to wear gloves while touching patients hemodialysis machines during hemodialysis treatments. Findings include: 1. Observation of the patient care dialysis technician #1 assigned to "POD #3" in the patient treatment area on 01/19/2011 at 1340 through 1343 revealed that the staff member touched the patient hemodialysis machines in stations #4, 5, 7 and 8 (total of 4 separate stations) without wearing gloves while patients were undergoing hemodialysis treatments at the stations. The observation revealed that the patient care dialysis technician also touched the dialysis blood lines in station #7 without wearing gloves. The observation also revealed that the patient care dialysis technician went from station's #4, 5, 7 and 8 touching the face panel of the machines with her bare hands and not hand sanitizing or hand washing noted between the patient stations. An interview on 01/19/2011 at 1345 with a facility	V 113		

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V 113	Continued From page 3 licensed practical nurse #1 revealed that all staff should wear gloves anytime they are touching a dialysis machine during patient hemodialysis treatments. "I will talk to her (patient care dialysis technician #1) about touching the machines without gloves." 2. Observation of the patient care dialysis technician #2 on 01/19/2011 at 1415 assigned to "POD #4" in the patient treatment area revealed that the staff member touched the patient hemodialysis machines in station #3 without wearing gloves while the patient was undergoing hemodialysis treatment. At 1418 the same staff member was again observed to touch a patient hemodialysis machine in "POD #5" at station #9 without wearing gloves while the patient was undergoing hemodialysis treatment. A review of the facility's policies and procedures for "Infection Control for Dialysis Facilities" (revision date 09/2010) revealed "Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station, and will remove gloves and wash hands or perform hand hygiene between each patient and/or station. Gloves should be worn when touching the blood lines, dialyzer or dialysis delivery system during or after dialysis treatment." An interview with the facility administrator on 01/19/2011 at 1450 revealed that the two patient care dialysis technicians did not follow facility policy and wear gloves as they touched the patient hemodialysis machines during their dialysis treatments. The interview revealed "They know and have been taught to wear gloves anytime they touch the patient's machine."	V 113	V113 cont. Additional supporting education provided to the team is as follows: Clinical Teammates educated on tool: *Recommended Infection Control for Dialysis Units At a Glance*, with verification of review evidenced by signature sheet. In-service provided by CSS on 2/2/11- Dirty to Clean and proper PPE attire, In-service provided by Infection Control Manager on 2/3/11-Proper Biohazard waste disposal. For additional education from an outside resource an in-service has also been scheduled to be completed 2/10/11 on Infection Control in the dialysis setting, provided by Southeastern Kidney Council network 6. Verification of attendance at in-services will be evidenced by signature sheets. The FA is responsible for compliance with this POC. ..	2/7/11 (an outside vendor presenting additional education 2/10/11)
V 115	494.30(a)(1)(i) IC-GOWNS,	V 115		

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V 115	Continued From page 4 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 observation, staff interview and review of the facility's policies and procedures, the facility staff failed to wear personal protective equipment (PPE) that covered arms while performing patient care procedures to patients during hemodialysis treatments (Patient #1). Findings include: 1. Observation on 01/19/2011 at 1320 in the patient treatment area of POD #1 revealed patient care dialysis technician #3 wearing sleeves on her PPE gown rolled up and not covering her arms while providing care to a patient. The observation revealed that the staff member was in a patient's (station #4) hemodialysis station touching the patient hemodialysis machine but had her PPE gown sleeves rolled up and exposing both of her arms during potential exposure while the patient was receiving hemodialysis treatment. An interview on 01/19/2011 at 1450 with the facility administrator revealed that all of the staff providing patient care during hemodialysis treatment should have their arms covered. "They should not have their gown sleeves rolled up."	V 115	V115 Clinical Teammates (TMs) were in-serviced 1/27/11 in the following: *Policies #I-05-01, #I-05-0A and #I-05-01B: Infection Control for Dialysis Facilities, Use of Alcohol-Based Hand Rubs, and Handwashing.* Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) to remove gloves and wash hands between dirty and clean tasks, 2) to perform hand hygiene whenever gloves are removed, 3) to wear gloves for all machine contact, 4) wear proper PPE covering arms while performing patient care procedures, 5) no individual patient items on machines, 6) disposing infectious waste properly, 7) provide gloves to all patients holding access sites. Clipboards have been removed from facility, signs have been posted to designate PPE only areas and paper towel dispensers near sinks have been raised to accommodating level. The Charge Nurse (CN) is responsible for oversight of infection control practice daily. Instances of non-compliance will be addressed with the TM responsible immediately and corrective discipline action will be taken. The Facility Administrator (FA) or designee will conduct observational infection control audits on random shifts three times daily for one week, then 3x week for one month, then 2x week for one month, then monthly with regularly scheduled infection control audits. An Infection Control team was also formulated to perform "Clean Sweep" audits weekly for 4 weeks, then bimonthly for 8 weeks, then monthly. Results of all audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. Governing Body meeting on 1/25/11 stating that it is mandatory for all patients to use a gloved hand to hold access sites. cont. pg 6	2/7/11

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V 115	Continued From page 5 2. Observation on 07/19/2011 at 1420 in the patient treatment area of POD #4 (stations #1, 2, 3, 4) revealed patient care dialysis technician #4 wearing his PPE gown opened at the front without any closure noted. The observation revealed that the staff member had the gown not closed by buttons on the gown and it was open exposing the staff member to potential exposure during patient hemodialysis treatments. An interview on 07/19/2011 at 1425 during the observation with the patient care dialysis technician #4 revealed that he should have the gown closed. "I should have it buttoned up. I didn't think about it. " A review of the facility's policy and procedure for "Infection Control for Dialysis Facilities" (revision date 09/2010) revealed "Appropriate PPE will be worn whenever there is the potential for contact with body fluids, hazardous chemicals, contaminated equipment and environmental surfaces, for example, reuse room, patient care areas. Appropriate lab coats or gowns will be worn at all times when on the treatment floor." The review of the policy revealed that no guidance was given for staff to fully cover their arms and aprons without sleeves are not sufficient PPE for procedures which may result in potential exposure.	V 115	V115 cont. Additional supporting education provided to the team is as follows: Clinical Teammates educated on tool: *Recommended Infection Control for Dialysis Units At a Glance*, with verification of review evidenced by signature sheet. In-service provided by CSS on 2/2/11- Dirty to Clean and proper PPE attire, In-service provided by Infection Control Manager on 2/3/11-Proper Biohazard waste disposal. For additional education from an outside resource an in-service has also been scheduled to be completed 2/10/11 on Infection Control in the dialysis setting, provided by Southeastern Kidney Council network 6. Verification of attendance at in-services will be evidenced by signature sheets. The FA is responsible for compliance with this POC.	2/7/11 (an outside vendor presenting additional education 2/10/11)
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	V 116		

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V 116	Continued From page 6 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 observation, staff interview and review of the facility's policies and procedures, the facility failed to dedicate wooded clipboards that cannot be disinfected to a single patient while used in the patient dialysis stations at the facility. Findings include: Observation in the patient treatment area on 01/19/2011 at 1230 revealed a total of 35 wooden clipboards that were placed on top of patient's hemodialysis machines while they were receiving hemodialysis treatments. The observation revealed that the wooden clipboards were holding the patient's paper chart information. The observation further revealed that the wooden clipboards were placed directly on top of the patient's hemodialysis machines. An interview on 01/19/2011 at 1450 with the facility administrator revealed that she knew that the wooden clipboards were a concern because they could not be disinfected and that they were used for different patients using the patient dialysis stations. The interview also revealed that the clipboards had been in the facility since she took the role of the facility administrator in 09/2010.	V 116	V116 Clinical Teammates (TMs) were in-serviced 1/27/11 in the following: *Policies #I-05-01, #I-05-0A and #I-05-01B: Infection Control for Dialysis Facilities, Use of Alcohol-Based Hand Rubs, and Handwashing.* Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) to remove gloves and wash hands between dirty and clean tasks, 2) to perform hand hygiene whenever gloves are removed, 3) to wear gloves for all machine contact, 4) wear proper PPE covering arms while performing patient care procedures, 5) no individual patient items on machines, 6) disposing infectious waste properly, 7) provide gloves to all patients holding access sites. Clipboards have been removed from facility, signs have been posted to designate PPE only areas and paper towel dispensers near sinks have been raised to accommodating level. The Charge Nurse (CN) is responsible for oversight of infection control practice daily. Instances of non-compliance will be addressed with the TM responsible immediately and corrective discipline action will be taken. The Facility Administrator (FA) or designee will conduct observational infection control audits on random shifts three times daily for one week, then 3x week for one month, then 2x week for one month, then monthly with regularly scheduled infection control audits. An Infection Control team was also formulated to perform "Clean Sweep" audits weekly for 4 weeks, then bimonthly for 8 weeks, then monthly. Results of all audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. Governing Body meeting on 1/25/11 stating that it is mandatory for all patients to use a gloved hand to hold access sites. cont. pg 7	2/7/11

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V 116	Continued From page 7 A review of the facility's policy and procedure "Infection Control for Dialysis Facilities" (revision date 09/2010) revealed that "Non disposable items that cannot be cleaned and disinfected will be dedicated for use only on a single patient. Items taken into the dialysis station will 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. The review of the policy did not address the use of wooden clipboards in the facility.	V 116	V116 cont. Additional supporting education provided to the team is as follows: Clinical Teammates educated on tool: *Recommended Infection Control for Dialysis Units At a Glance*, with verification of review evidenced by signature sheet. In-service provided by CSS on 2/2/11- Dirty to Clean and proper PPE attire, In-service provided by Infection Control Manager on 2/3/11-Proper Biohazard waste disposal. For additional education from an outside resource an in-service has also been scheduled to be completed 2/10/11 on Infection Control in the dialysis setting, provided by Southeastern Kidney Council network 6. Verification of attendance at in-services will be evidenced by signature sheets. The FA is responsible for compliance with this POC.	2/7/11 (an outside vendor presenting additional education 2/10/11)
V 121	494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;	V 121	V121 Clinical Teammates (TMs) were in-serviced 1/27/11 in the following: *Policies #1-05-01, #1-05-0A and #1-05-01B: Infection Control for Dialysis Facilities, Use of Alcohol-Based Hand Rubs, and Handwashing.* Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) to remove gloves and wash hands between dirty and clean tasks, 2) to perform hand hygiene whenever gloves are removed, 3) to wear gloves for all machine contact, 4) wear proper PPE covering arms while performing patient care procedures, 5) no individual patient items on machines, 6) disposing infectious waste properly, 7) provide gloves to all patients holding access sites. Clipboards have been removed from facility, signs have been posted to designate PPE only areas and paper towel dispensers near sinks have been raised to accommodating level. The Charge Nurse (CN) is responsible for oversight of infection control practice daily. Instances of non-compliance will be addressed with the TM responsible immediately and corrective discipline action will be taken. cont. pg 9	2/7/11
	This STANDARD is not met as evidenced by: Based on observation, staff interview and review of the facility's policies and procedures, the facility staff failed to dispose of potentially-infectious waste in a designated biohazardous waste container. Findings include: Observation on 01/19/2011 at 1330 in the patient treatment area at station # 4 in POD #1 revealed that a bag of saline solution that had noted blood			

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V 121	Continued From page 8 in the bag and on the septum area of the bag was placed in a waste container not designated as a biohazardous waste container. The observation revealed that the blood tinged bag of saline was inside of the waste container with other regular waste items. An interview on 01/19/2011 at 1450 with the facility administrator revealed that the bloody bag of saline should not ever be placed in a regular none biohazardous waste container. The interview revealed that the facility has dedicated biohazardous waste containers that should be used by the staff. A review of the facility's policy and procedure "Infection Control for Dialysis Facilities" (revision date 09/2010) revealed "All potentially infectious waste will be placed in sealable, leak proof biohazard waste bags that are clearly marked or colored."	V 121	V121 cont. The Facility Administrator (FA) or designee will conduct observational infection control audits on random shifts three times daily for one week, then 3x week for one month, then 2x week for one month, then monthly with regularly scheduled infection control audits. An Infection Control team was also formulated to perform "Clean Sweep" audits weekly for 4 weeks, then bimonthly for 8 weeks, then monthly. Results of all audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. Governing Body meeting on 1/25/11 stating that it is mandatory for all patients to use a gloved hand to hold access sites. Additional supporting education provided to the team is as follows: Clinical Teammates educated on tool: *Recommended Infection Control for Dialysis Units At a Glance*, with verification of review evidenced by signature sheet. In-service provided by CSS on 2/2/11- Dirty to Clean and proper PPE attire, In-service provided by Infection Control Manager on 2/3/11-Proper Biohazard waste disposal. For additional education from an outside resource an in-service has also been scheduled to be completed 2/10/11 on Infection Control in the dialysis setting, provided by Southeastern Kidney Council network 6. Verification of attendance at in-services will be evidenced by signature sheets. The FA is responsible for compliance with this POC.	2/7/11 (an outside vendor presenting additional education 2/10/11)
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit; This STANDARD is not met as evidenced by: Based on observation, staff interview and review of the facility's policies and procedures, the facility staff failed to adhere to infection control standards by providing a glove for the patient to hold pressure on vascular access sites in 1 of 3 patients observed holding their vascular access site after treatment of hemodialysis(Patient #16).	V 142	V142 Clinical Teammates (TMs) were in-serviced 1/27/11 in the following: *Policies #1-05-01, #1-05-0A and #1-05-01B: Infection Control for Dialysis Facilities, Use of Alcohol-Based Hand Rubs, and Handwashing.* Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed using surveyor observations as examples with emphasis on, but not limited to, the following: 1) to remove gloves and wash hands between dirty and clean tasks, (cont. pg 10)	2/7/11

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V 142	Continued From page 9 Findings include: Observation on 01/21/2011 at 1335 in the patient treatment area revealed that patient #16 was holding his left arm vascular access site after his hemodialysis treatment. The patient was noted to be holding his left arm access site with his right bare hand. No glove was noted to be used or given to the patient while holding his vascular access site. The observation at 1345 further noted that the patient had blood on his right hand and was walked out of the facility's patient treatment area by a staff member. The patient was observed not to wash or sanitize his hands before leaving the patient treatment area. An interview on 01/21/2011 at 1350 with the facility's clinical coordinator revealed that all patients should be given a glove to hold pressure on their vascular access site. The interview revealed no reason why the patient was not given a glove to use while holding pressure on the bleeding access site. The interview further revealed that the patient should also have been encouraged to wash his hands before leaving the facility. A review of the facility's policy and procedure "Infection Control for Dialysis Facilities" (revision date 09/2010) revealed "Gloves should be provided to patients and gloves and gown to visitors if these individuals assist with procedures such as self-cannulation or holding access sites.	V 142	V142 cont. 2) to perform hand hygiene whenever gloves are removed, 3) to wear gloves for all machine contact, 4) wear proper PPE covering arms while performing patient care procedures, 5) no individual patient items on machines, 6) disposing infectious waste properly, 7) provide gloves to all patients holding access sites. Clipboards have been removed from facility, signs have been posted to designate PPE only areas and paper towel dispensers near sinks have been raised to accommodating level. The Charge Nurse (CN) is responsible for oversight of infection control practice daily. Instances of non-compliance will be addressed with the TM responsible immediately and corrective discipline action will be taken. The Facility Administrator (FA) or designee will conduct observational infection control audits on random shifts three times daily for one week, then 3x week for one month, then 2x week for one month, then monthly with regularly scheduled infection control audits. An Infection Control team was also formulated to perform "Clean Sweep" audits weekly for 4 weeks, then bimonthly for 8 weeks, then monthly. Results of all audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. Governing Body meeting on 1/25/11 stating that it is mandatory for all patients to use a gloved hand to hold access sites. Additional supporting education provided to the team is as follows: Clinical Teammates educated on tool: *Recommended Infection Control for Dialysis Units at a Glance*, with verification of review evidenced by signature sheet. In-service provided by CSS on 2/2/11- Dirty to Clean and proper PPE attire, In-service provided by Infection Control Manager on 2/3/11-Proper Biohazard waste disposal. cont pg 11	2/7/11
V 540	494.90 CFC-PATIENT PLAN OF CARE This CONDITION is not met as evidenced by: Based on the facility's policies and procedures	V 540		

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V 540	Continued From page 10 review, physician interview, patient interview, clinical record review and staff interview, it was determined that the facility failed to adjust and individualize the plan of care for patients to ensure safe and quality care for hemodialysis patients. The facility staff failed to provide monitoring and assessment for an vascular access with impending failure in 1 of 1 sampled patients (Patient #1) that expired after uncontrolled bleeding occurred from the vascular access site; and failed to complete treatment checks in accordance with the facility's policy for 2 of 12 sampled in-center patients (Patients #1,12). The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of assessment, monitoring and quality of care as a result of the plan of care for all the hemodialysis patients on census. Findings include: A. The facility staff failed to provide monitoring and assessment for an vascular access with impending failure in 1 of 1 sampled patients that expired after uncontrolled bleeding occurred from the vascular access site. (Patient #1). ~Cross refer to 494.90(a)(5) Patient Plan of Care - Tag V0551 B. The facility staff failed to complete treatment checks in accordance with the facility's policy for 2 of 12 sampled in-center patients. (Patients #1,12). ~Cross refer to 494.90(a)(1) Patient Plan of Care - Tag V0543	V 540	V142 cont.For additional education from an outside resource an in-service has also been scheduled to be completed 2/10/11 on Infection Control in the dialysis setting, provided by Southeastern Kidney Council network 6. Verification of attendance at in-services will be evidenced by signature sheets. The FA is resporisible for compliance with this POC. 2/7/11..2/10/11 **V540** A Governing Body (GB) meeting was held to review the deficiencies received. This Condition for Coverage (CFC) that is not met as supported by standardsV543 and V551, has detailed Plans of Correction (POC) referenced to in the specific V tags. Ongoing compliance to the POC will include promoting implementation of policies and procedures to ensure correct and effective practices in vascular access assessment and monitoring, patient monitoring and treatment checks Q 30 minutes, patient plan of care, and quality assurance. In addition, the GB has implemented the following processes to address these issues cited: Physician/extender will be notified of all access concerns. No verbal orders will be accepted by extenders, and all verbal orders given by physician are to be read back for verification. Extender will meet with the Vascular Access manager and FA monthly to review the One Stop Tool which addresses CVCs and new vascular accesses in the facility. Rounding physicians/extenders will meet with charge nurse before and after rounding on patients to ensure all patient concerns have been addressed. If any patient refuses to remain in the facility for an assessment by the nurse of the physician/ extender, the patient will be required to sign AMA form. All AMA forms will be reviewed in QA monthly. cont pg 12	2/7/11 (an outside vendor presenting additional education 2/10/11) 2/7/11
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS	V 543		

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V 543	Continued From page 11 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 the facility's policies and procedures review, patient interview, clinical record review and staff interview, the facility staff failed to complete treatment checks in accordance with the facility's policy for 2 of 12 sampled in-center patients (Patient #1,12). Findings include: A review of the facility's policy and procedure "Intradialytic Treatment Monitoring" (revision date 09/2008) revealed "To provide an effective, safe and comfortable dialysis treatment to every patient in accordance with his/her individual plan of care. Treatment checks should be completed at least every thirty (30) minutes." 1. A closed clinical record on 01/20/2011 for patient #12 revealed that the patient was admitted to the facility on 12/11/2009 for in-center hemodialysis treatments. A review of the patient treatment sheet for 06/24/2010 revealed that the patient received hemodialysis treatment from 0731 through 1142. The review further revealed that the patient care staff failed to complete a treatment check from 1031 until 1142 (total 1 hour and 11 minutes). The patient was documented as having his/er blood rinsed back and being taken off of hemodialysis at 1142. Documentation review of the patient's clinical record revealed that the patient expired away from the clinic on 06/25/2010 after bleeding from	V 543	V540 cont. All substantiated chest pain will be sent to the ER via 911. If any patient refuses, they will be required to sign AMA by the facility and the 911 transport. This will be tracked throughout the month and reviewed in QA monthly. The admitting physicians, extenders and clinical teammates have been informed of these practices. Members of the GB including the FA, Regional Operations Director (ROD), and Medical Director, have agreed to meet weekly x 4 then monthly x2 to monitor the facility's progress toward compliance. Then ongoing compliance to the POC will be monitored during GB meetings at least quarterly. This POC will also be reviewed at each monthly Quality Improvement Facility Management Meetings (QIFMM) meeting when the FA will report progress, as well as any barriers to maintaining compliance, to the committee.	2/7/11

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V 543	Continued From page 12 his unused vascular access site. An interview on 01/20/2011 at 1330 with the facility's clinical coordinator revealed that the patient did expire away from the facility by bleeding from his old graft vascular access site. The interview revealed that the facility's staff did not do the treatment checks throughout his hemodialysis treatment on 06/24/2010 as required in the facility's policy for 30 minute checks. 2. An open clinical record review on 01/20/2011 for patient #1 admitted to the facility for hemodialysis treatments on 02/01/2010 revealed that the facility's staff failed to complete treatment checks for the patient at least every 30 minutes on 12/22/2010, 12/31/2010 and 01/03/2011. The review of the record revealed on 12/22/2010 that the patient received hemodialysis from 1033 through 1404. The review for 12/22/2010 revealed that the facility staff failed to complete a treatment check from 1200 until 1339 (total 1 hour and 39 minutes). On 12/31/2010, the patient had hemodialysis from 1145 through 1628. The review for 12/31/2010 revealed that the facility staff failed to complete a treatment check from 1225 until 1359 (total 1 hour and 39 minutes). On 01/03/2011, the patient had hemodialysis from 1058 through 1400. The review for 01/03/2011 revealed that the facility staff failed to complete a treatment check from 1145 until 1230 (total 45 minutes). A patient interview on 01/19/2011 at 1320 with patient #1 in the patient treatment area revealed that the patient feels that staff at the facility does not provide treatment and checks consistently. The interview revealed, "The staff I think is	V 543	V543 All licensed teammates in-serviced on 1/25/11 and all clinical teammates in-serviced on 1/27/11 on Intradialytic monitoring of all patients. TMs were in-serviced on the following: *Policy #1-03-09: Intradialytic Treatment Monitoring*: Verification of attendance at in-service is evidenced by a signature sheet. TMs were instructed to: monitor and document vital signs at least every 30 minutes. The Charge Nurse (CN) is responsible for oversight of patient monitoring per policy. The CN will monitor Q 30 minute monitoring of all patients daily to ensure documentation is in place. Instances of non-compliance will be addressed with the TM responsible immediately. The FA or designee will audit treatment flow sheets of 100% daily for 4 weeks, then 10% weekly. All non-compliance will be reviewed by FA, and continued non-compliance will have corrective disciplinary actions delivered. Results of audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. The FA is responsible for compliance with this POC.	2/7/11

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V 543	Continued From page 13 overworked and sometimes they do not check on me during the treatments as I think that they should." The interview revealed that the patient felt that the staff has too much work for the type of patients at the facility. An interview on 01/19/2011 at 1450 with the facility administrator revealed that the administator believed the facility does have enough staff and she feels that they are trained appropriately. Another interview on 01/20/2011 at 1430 revealed that the patient should have been monitored no longer than every 30 minutes in the treatment checks.	V 543	V551 All teammates were in-serviced on the Patient Plan of Care process and the importance of providing vascular access monitoring and assessment on 1/27/11. Verification of attendance at in-service is evidenced by a signature sheet. Clinical TMs also reviewed the following policies and protocols: *Vascular Access : Monitoring and Diagnostics Protocol, Policy #1-03-07 New Patient Pre-Treatment Evaluation, #1-03-10 Pre/Post Dialysis Treatment Data Collection, #1-03-12 Post Treatment Patient Assessment, #1-03-12A Termination of Dialysis, #1-04-03 Infected Vascular Access Care, #1-04-07 Prolonged Bleeding of Cannulation Sites, #1-04-11 Vascular Access Monitoring and Surveillance.* All licensed	2/7/11
V 551	494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. This STANDARD is not met as evidenced by: ~~Based on clinical record review, physician~~ interview, staff interview, and review of the facility's policies and procedures, it was determined that the facility staff failed to provide monitoring and assessment for an vascular access with impending failure in 1 of 1 sampled patients that expired after uncontrolled bleeding occurred from the vascular access site (patient #14). Findings include: A closed clinical record review on 01/20/2011 for patient #14 revealed that the patient began	V 551	teammates (LPN, RN, SW and RD) reviewed *policy #1-01-07 Patient Assessment and Plan of Care when utilizing Duck* as of 2/4/11. Verification of review is evidenced by a signature sheet. An in-service provided on 1/25/11 with licensed teammates and on 1/27/11 with all teammates that discussed all the plans of correction, put in place during Governing Body meetings on 1/24/11, 1/25/11 and 1/27/11. The Vascular Access Monitoring and Diagnostics protocol was reviewed with all clinical teammates as of 2/5/11 and evidenced by signature sheet. A ~~Mandatory In-service will be provided to the~~ teammates by Medical Director on 2/7/11. Topic: Vascular Access Complications. In-Services will also be provided to all local area nursing homes on 2/7/11 by the FA. Topic: Emergency complication related to dialysis patients, including data on bleeding from vascular access site after treatment. An updated plan of care is to be done on all patients that have access related occurrences during the month and reviewed during QIFMM to address occurrences and review for needed plans of correction. Clinical Coordinator will track all access related occurrences. FA and Gov Body to ensure compliance cont pg 15	

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V 551	Continued From page 14 hemodialysis treatments at the facility on 09/23/2002. The review revealed that the patient received a hemodialysis treatment on 01/17/2011 from 0555 through 0952. The patient was documented as having a primary vascular access of an "AV Graft" in her left arm used for the hemodialysis treatment. Documentation at 0552 from the facility's nursing staff (nurse #1) revealed that the patient's vascular access site had "Large scab on access, patient states going to surgeon." The documentation revealed that the patient had the access site on her left arm cannulated with the hemodialysis treatment given through the access site. A review of the post assessment again from nurse #1 revealed that the vascular access site as "LLA Graft, positive bruits/thrills." The patient was documented as leaving the facility ambulatory with no other complaints. A review of the clinical record's narrative nursing notes revealed that nurse #1 on 01/19/2011 at 1055 documented a late entry from 01/17/2011 as "I assessed patient's LLA access, found to have raised scab area approximately 1/2 tall, as though patient had been picking at scab. When I asked patient had she been picking it, she yelled and said no she had not. I explained we need to have a surgeon assess her access. She is turn said she would take care of it herself. A surgical referral was sent. __The Physician Assistant (PA) wrote for antibiotics, vancomycin the last hour of treatment." A review of the clinical record's narrative nursing notes also revealed documentation from the facility's clinical coordinator on 01/19/2011 at 1047 as late entry for 01/17/2011 as "Patient received treatment without problem. __(Physician Assistant) saw patient, ordered vancomycin for	V 551	V551 cont. 100% daily flow sheet audit X 4 weeks, then 10% weekly, to be completed by FA or designee, observing compliance in vascular access assessment documentation. All non-compliance will result in corrective disciplinary action. Results of audits will be reviewed with the Medical Director during the monthly QIFMM and continued frequency of audits determined by the team with supporting documentation included in the meeting minutes. The FA is responsible for compliance with this POC. All patients that have a fistula or graft have been educated on post treatment bleeding occurrences with post demonstration provided by the patient or caregiver. Verification of completion is evidenced by a signed demonstration sheet. This will be done upon admission, annually, and in the event of fistula or graft placement. Clinical coordinator will ensure tracking of process and FA will ensure compliance. All patients that have a fistula or graft are given an emergency kit for post treatment bleeding occurrence and educated on the use of the kit. The emergency kit contains two packs of gauze and a roll of tape. This kit will be given on admission and in the event of fistula or graft placement. . Patient education has been provided to all current patients with fistula or graft, "How to keep your fistula/Graft healthy". ~~All new admissions or fistula/graft~~ placement will be provided same education. Verification of review will be evidenced by patient/ teammate signature on education sheet. A large education poster has been placed on treatment floor in area where patients are entering. This poster contains education on emergency bleeding after treatment. This poster will remain in the centralized location. cont pg. 16	2/7/11

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V 551	Continued From page 15 sore on leg and access arm, which nurse had assessed access and explained to patient she should not be picking at scab on the access, and they cannulated away from the area, patient referred to surgeon for evaluation of access, information about scabbed area and vancomycin given. Patient had bleeding post treatment, but was controlled and patient was kept 15 minutes after bleeding had stopped without problem. Was informed on 01/18/2011 patient had expired at home with the access bleeding out. Talked to __(PA) and he was aware." An interview on 01/20/2011 at 1230 with the facility's physician director for the in-center hemodialysis patients revealed that patient #14 had expired on 01/18/2011 away from the facility after bleeding out from her "AV Graft" vascular access site. "I have not had a chance to review the death, but I understand that the patient did have an unfortunate death. She was an older in years dialysis patient and I think she was trained to recognize if grafts were about to blow." "I really did not know much about her death as of yet." An interview on 01/21/2011 at 1120 with nurse #1 in reference to patient #14's 01/17/2011 treatment revealed the following: "The staff LPN (licensed practical nurse) wanted me to look at her arm. She had a raised scab at her graft access. It looked like she had been picking at the site. I offered the patient to help set up a surgical consult and she yelled out to me "no". I told her she needs to be seeing a surgeon, __(Clinical Coordinator) took care of surgery consult and scheduled it. __,PA(physician assistant) looked at the site. also on 01/17/2011. He ordered Vancomycin and a wound culture but no drainage was there at the access site. She (the patient)	V 551	V551 cont. Physician/extender will be notified of all access concerns. No verbal orders will be accepted by extenders, and all verbal orders given by physician are to be read back for verification. Extender will meet with the Vascular Access manager and FA monthly to review the One Stop Tool which addresses CVCs and new vascular accesses in the facility. Results and minutes of meeting will be reviewed in QIFMM minutes monthly. Rounding physicians/extenders will meet with charge nurse before and after rounding on patients to ensure all patient concerns have been addressed. (Ongoing) FA to ensure compliance If any patient refuses to remain in the facility for an assessment by the nurse of the physician/ extender, the patient will be required to sign AMA form. All AMA forms will be reviewed in QA monthly. All substantiated chest pain will be sent to the ER via 911. If any patient refuses, they will be required to sign AMA by the facility and the 911 transport. This will be tracked throughout the month and reviewed in QA monthly. FA and Gov Body are responsible for ongoing compliance.	2/7/11

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V 551	Continued From page 16 seemed alert and oriented. He (PA) did not say anything about using the site or not using the site. Graft failures are usually shiny if ready to blow and hers did not look like that. We made decision to go above the scab for cannulation and it (the needles) were placed an inch above the scab. The patient was assessed and sent home. I did not know anything about the patient's death on 01/19/2011 when I documented the late entry in the clinical record. We do and are allowed to do late entries. No one in the administration asked me to go back on 01/19/2011 and do a late entry." An interview on 01/21/2011 at 1240 with the facility's Physician Assistant (PA) that saw the patient on 01/17/2011 revealed that " I was rounding that day on 01/17/2011, the nursing staff got me and told me she (Patient #14) was on dialysis, When I saw her, she had on tape on her arm when I was called and I was unable to see her access site. I went ahead and ordered the vancomycin based on the nurse's description and I told staff that I wanted to make sure she was seen after she finished her treatment. I know I instructed staff at the facility to make sure and page me so I could come back if not here and see the access. I told the nurses to make sure that I saw the access after the patient finished dialysis but she left before. I never saw the access site. I am not sure what would have been done different, but I did ask to see the patient before she left and I was never contacted to see the patient before she left on 01/17/2011. She did die of bleed out from her access site on 01/18/2011." An interview on 01/21/2011 at 1455 with the facility administrator revealed that the patient did die at home on 01/18/2011 from bleeding from	V 551		

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V 551	Continued From page 17 her access site. The interview revealed that the administrator was not aware that the PA never saw the patient's access site and that she assumed that he had assessed the site and gave permission for the access site to be used despite the patient having a scab on the access site. The interview revealed that the administrator was not aware of the events that occurred on 01/17/2011 and that the PA had instructed the facility staff that he needed to see the patient before she left the facility. Consequently, An Immediate Jeopardy (IJ) was identified when the facility failed to provide monitoring, assessment and quality of care to a hemodialysis patient that bled out from a vascular access site after a hemodialysis treatment on 01/17/2011. The facility's staff had cannulated the patient's vascular access site after observing scabbing over the access site. The facility's physician assistant was called during rounding at the facility to see the patient's vascular access site. The patient was already receiving hemodialysis treatment with the vascular access site cannulated. The physician assistant instructed the facility staff that the patient needed to be seen by him before leaving the facility. The facility staff failed to follow the physician assistant's instructions and the patient left the facility on 01/17/2011 without the physician assistant assessing the patient. The patient died on 01/18/2011 away from the facility as a result of bleeding out from her vascular access site. The facility's administration and physician director was not aware of the patient leaving the facility without being assessed by the physician assistant as was instructed to the facility staff.	V 551		
V 625	494.110 CFC-QAPI	V 625		

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V 625	Continued From page 18 This CONDITION is not met as evidenced by: Based on "ESRD (End Stage Renal Disease) Death Notification" report review, clinical record review, physician interview, the facility's "Quality Improvement and Facility Management Meeting Minutes" review, and staff interview, it was determined that the facility failed to recognize problems that may threaten the health and safety of patients and address those problems in its Quality Assurance program. The facility failed to review data related to a patient death to identify and prevent potential problems related to bleeding vascular access sites. The cumulative effect of these systemic problems resulted in the facility's inability to ensure a facility-based assessment and improvement of care to prevent major problems in the health and safety of all hemodialysis patients on its census. Findings include: A. The facility failed to review data related to a patient death to identify and prevent potential problems related to bleeding from vascular access sites. ~Cross refer to 494.110(a)(2) Quality Assurance Performance Improvement - Tag V0628	V 625	V625 A Governing Body (GB) meeting was held to review the deficiencies received. This Condition for Coverage (CFC) that is not met as supported by standard V628, has detailed Plans of Correction (POC) referenced to in the specific V tags. Ongoing compliance to the POC will include promoting implementation of policies and procedures to ensure correct and effective practices in vascular access assessment and monitoring, patient monitoring and treatment checks Q 30 minutes, patient plan of care, and quality assurance. The Governing body meeting of 1/25/11 included adoption of the form: *Mortality Review* which is to be completed on all patient deaths in all modalities. Mortality of each death will be reviewed by the quality improvement committee for trends and needed action plans during each QA meeting monthly. A copy of the mortality review will be kept on all deaths reviewed in QA meetings and attached to the minutes. Action plans that are put in place will be documented in detail in QIFMM minutes and tracked monthly in QA meetings monthly. Action is immediate, beginning 1/27/11. FA and Gov Body will be responsible for ensuring compliance.	1/31/11
V 628	494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components	V 628	Beginning 1/27/11, all patient events will be reviewed by the quality improvement committee in monthly QA meetings, recognizing trends or concerns that may threaten the health and safety of all patients and prevent potential problems. Action plans that are put in place will be documented in detail in QIFFM minutes and tracked monthly in QA meetings monthly. Action is immediate and ongoing. FA and Gov Body will be responsible for ensuring compliance.	

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SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

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V 628	Continued From page 19 must influence or relate to the desired outcomes or be the outcomes themselves. This STANDARD is not met as evidenced by: Based on "ESRD (End Stage Renal Disease) Death Notification" report review, clinical record review, physician interview, the facility's "Quality Improvement and Facility Management Meeting Minutes" review, and staff interview, it was determined that the facility failed to review data related to a patient death to identify and prevent potential problems related to bleeding from vascular access sites (Patient #12). Findings include: A review on 01/20/2011 of the "ESRD Death Notification" report dated 06/28/2010 revealed that the patient was an incenter hemodialysis patient at the facility that died on an off dialysis day of 06/25/2010. The documentation revealed "This 61 year old male has been on hemodialysis at this facility for several years. This patient always remained compliant with his treatment and medications. Patient exsanguinated (Bled out) on an off dialysis day. Central venous catheter was main access. Status post graft infection." A closed clinical record review on 01/20/2011 for patient #12 revealed that the patient a 61 year old male that was a hemodialysis patient at facility from 12/11/2009 through 06/25/2010. The review revealed that the patient's last hemodialysis treatment was at the facility on 06/24/2010 from 0731 through 1142. The documentation revealed that the patient had an access of CVC (central venous catheter) right jugular area. No other documentation was found on the patient treatment sheet that indicated that the patient had	V 628	V628 The Governing body meeting of 1/25/11 included adoption of the form: *Mortality Review* which is to be completed on all patient deaths in all modalities. Mortality of each death will be reviewed by the quality improvement committee for trends and needed action plans during each QA meeting monthly. A copy of the mortality review will be kept on all deaths reviewed in QA meetings and attached to the minutes. Action plans that are put in place will be documented in detail in QIFMM minutes and tracked monthly in QA meetings monthly. Action is immediate, beginning 1/27/11. FA and Gov Body will be responsible for ensuring compliance. Beginning 1/27/11, all patient events will be reviewed by the quality improvement committee in monthly QA meetings, recognizing trends or concerns that may threaten the health and safety of all patients and prevent potential problems. Action plans that are put in place will be documented in detail in QIFFM minutes and tracked monthly in QA meetings monthly. Action is immediate and ongoing. FA and Gov Body will be responsible for ensuring compliance.	2/7/11

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
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 628	Continued From page 20 any other access site or as a secondary access site. The review revealed no documented issues on the patient treatment sheet for 06/24/2010. An interview on 01/20/2011 at 1310 with the facility's physician director revealed that patient #12 was a patient that expired on 06/25/2010 (day after dialysis treatment) by "bleeding out from his graft site in a public place." The interview further revealed that the physician director had reviewed the death and felt that the patient was trained to look for problems of his graft. The interview revealed that he as physician director did remember looking over the case. A review of the facility's "Quality Improvement and Facility Management Meeting Minutes" on 01/21/2011 revealed that facility's Quality Improvement committee had monthly meetings held in the months of 06/2010, 07/2010, 08/2010, 09/2010, 10/2010, 11/2010 and 12/2010. The review of the meeting minutes revealed that no documentation the demonstrate that the facility discussed or analyzed the patient's death from bleeding from his vascular access site on 06/25/2010. No documentation was found anywhere in the facility's quality assurance and performance improvement materials to indicate that the patient's death on 06/25/2010 was ever addressed or reviewed by the facility for potential problems or areas for improvement to prevent future vascular access site problems to prevent similar events int he future. An interview on 01/21/2011 at 1340 with the facility administrator revealed that the facility's quality improvement committee did not address the patient death for 06/25/2010. The interview revealed that no evidence could be produced to	V 628		

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

STEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 628	Continued From page 21 demonstrate that the facility examined the death as a result of the vascular access site bleed out to identify potential ways to improve the monitoring of vascular access sites by the facility staff. The interview further revealed that the patient had a surgical dressing covering the site where the graft had been removed and the bandage on 06/24/2010. This site was the source of the fatal bleedout.	V 628		
V 711	494.150 MD RESP-MED DIR QUAL/ACCOUNTABLE TO GOV BODY The dialysis facility must have a medical director who meets the qualifications of §494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients. This STANDARD is not met as evidenced by: Based on the facility's governing body document review and staff interview, the facility failed to have a single medical director to be responsible for both the facility's in-center hemodialysis, home hemodialysis program and home peritoneal program. Findings include: A review on 01/21/2011 of the facility's governing body internal documentation revealed that the facility had two physician's listed as the facility's physician directors. The review revealed that the facility listed one physician director Dr.__(physician A) that was listed as the medical director for the in-center hemodialysis program and listed another physician Dr.__ (physician B)	V 711	V711 Governing Body meeting on 1/24/11 established a single medical director to be responsible for the facility's in-center hemodialysis, home hemodialysis program and home peritoneal program. The designated medical director will oversee activities/ processes, and sign off on all pertinent documents in the stated programs.. FA and Governing Body will ensure compliance. Letter of communication with above notification sent to all physician partners of medical group by Governing Body.	1/31/11

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

TEMENT OF DEFICIENCIES PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342511	A. BUILDING _____ B. WING _____	C 01/21/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

(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 711	Continued From page 22 as the facility's medical director for the facility's home hemodialysis and home peritoneal program. No evidence was found anywhere in the documentation review for the governing body that Dr.__(physician B) reported to Dr.__(physician A). No documentation was found where Dr.__(Physician A) ever reviewed any of the home hemodialysis and home peritoneal program. An interview on 01/20/2011 at 1335 with the facility's peritoneal nurse revealed that the she reported to Dr.__(physician B) as the medical director for the home program. The interview revealed that the physician (physician B) was the one recognized as the home programs medical director and was the one responsible for the entire home program with him reporting to no other physician. An interview on /01/20/2011 at 1420 with the facility administrator revealed that the facility did currently have two medical directors with Dr.__ (physician A) responsible for the hemodialysis program in the center and Dr. __(physician B) handling the home programs. "I did not think that sounded right, but that is the way we have the directors at the facility. I think that their contract is written that way and the home program is Dr. __(physician B)'s specialty." The administrator also revealed in interview no evidence that Dr.__(physician A) ever reviews the home hemodialysis and home peritoneal programs. Reference NC00070336	V 711		

epartment of Health and Human Services
enters for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

olic reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and in[illegible] data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information lud[illegible] suggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork duction Project (0938-0390), Washington, D.C. 20503.

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
342511	A. Building B. Wing	2/14/2011

Name of Facility	Street Address, City, State, Zip Code
SOUTHEASTERN DIALYSIS CENTER -WILMINGTON	2215 YAUPON DRIVE WILMINGTON, NC 28407

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously eported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should e fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix V0110 Reg. # 494.30 LSC	Correction Completed 02/14/2011	ID Prefix V0113 Reg. # 494.30(a)(1) LSC	Correction Completed 02/14/2011	ID Prefix V0115 Reg. # 494.30(a)(1)(i) LSC	Correction Completed 02/14/2011
ID Prefix V0116 Reg. # 494.30(a)(1)(i) LSC	Correction Completed 02/14/2011	ID Prefix V0121 Reg. # 494.30(a)(4)(i) LSC	Correction Completed 02/14/2011	ID Prefix V0142 Reg. # 494.30(b)(1) LSC	Correction Completed 02/14/2011
ID Prefix V0540 Reg. # 494.90 LSC	Correction Completed 02/14/2011	ID Prefix V0543 Reg. # 494.90(a)(1) LSC	Correction Completed 02/14/2011	ID Prefix V0551 Reg. # 494.90(a)(5) LSC	Correction Completed 02/14/2011
ID Prefix V0625 Reg. # 494.110 LSC	Correction Completed 02/14/2011	ID Prefix V0628 Reg. # 494.110(a)(2) LSC	Correction Completed 02/14/2011	ID Prefix V0711 Reg. # 494.150 LSC	Correction Completed 02/14/2011
ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed	ID Prefix Reg. # LSC	Correction Completed

Reviewed By State Agency	Reviewed By	Date:	Signature of Surveyor: Ralph Miller RN	Date: 2/14/11
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on: 1/21/2011

Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES (NO)

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE & MEDICAID SERV

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342511	SOUTHEASTERN DIALYSIS CENTER -WILMINGTON

Type of Survey (select all that apply)

I	D				

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
M Other
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW

Extent of Survey (select all that apply)

A				

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	02/14/2011	02/14/2011	1.00	0.00	2.00	0.00	4.00	1.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE & MEDICAID SERV

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342511	SOUTHEASTERN DIALYSIS CENTER -WILMINGTON

Type of Survey (select all that apply)

[A][D][ ][ ][ ]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[A][ ][ ][ ][ ]

A Routine/Standard Survey (all providers/suppliers)
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Team Leader ID 1. 15546	02/14/2011	02/14/2011	1.00	0.00	1.00	0.00	1.00	1.00
2.								
3.								
4.								
5.								
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9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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

MEDICAL MEDICAID CERTIFICATION AND TRANSM. AL — ID: W2CORK

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY — Facility ID: 956055

1. MEDICARE/MEDICAID PROVIDER NO.
342511
2. STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) SOUTHEASTERN DIALYSIS OF WILMI
(L4) 2215 YAUPON DRIVE
(L5) WILMINGTON, NC (L6) 28407

4. TYPE OF ACTION: 4 (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) 04/01/2000

6. DATE OF SURVEY (L34)

8. ACCREDITATION STATUS: ___ (L10)
0 Unaccredited 1 JCAHO
2 AOA 3 Other

7. PROVIDER/SUPPLIER CATEGORY 09 (L7)

01 Hospital	05 HHA	09 ESRD	13 PTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	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:
___1. Acceptable POC

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

B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: A* (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(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):
CHOW effective April 1, 2000.
(New owner: Total Renal Care of North Carolina, LLC) Received CMS 3427 2/6/09

SURVEYOR SIGNATURE Date: (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 2/16/09 (L20)

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

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

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
03/26/1979
(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.
00454
(L31)

30. REMARKS
Send to DRO

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

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

020

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

FORM APPROVED
OMB 0938-0360

END STAGE RENAL DISEASE APPLICATION/NOTIFICATION AND SURVEY AND CERTIFICATION REPORT

PART I - APPLICATION - TO BE COMPLETED BY FACILITY

Name of Facility: Southeastern Dialysis Wilmington

2. Provider Number: 3 4 2 5 1 1

3. Street Address: 2215 Yaupon Drive

4. City: Wilmington

5. County: New Hanover

6. State: NC

7. ZIP Code: 28401

8. Telephone No.: 910 343-0664

9. Facsimile No.: 910 343-0674

10. Fiscal Year Ending Date: 12/31/11

11. Name/Address/Telephone Number of Authorized Official
Name: Lori Todd RN
Address: PO Box 98 Clarendon, NC 28432
Telephone No.: 910 840-2581

12. Type of Application/Notification: (V1) *(check all that apply and specify in Remarks section [see item 27])*
☐ 1. Initial ☐ 2. Expansion to new location ☐ 3. Change of ownership
☐ 4. Change of location ☐ 5. Expansion in current location ☐ 6. Change of services/operations
☑ 7. Other *(specify)* Complaint/recertification

13. Ownership (V2) ☑ For Profit ☐ Not for Profit ☐ Public

14. Is this Facility Hospital-Based *(check one)* (V3) ☐ Yes ☑ No *If Yes, hospital provider number* (V4) ☐☐☐☐☐☐

15. Is this Facility SNF-Based *(check one)* (V5) ☐ Yes ☑ No *If Yes, SNF provider number* (V6) ☐☐☐☐☐☐

16. Is this facility owned and/or managed by a multi-facility organization? (V7) ☐ Yes ☐ No *If Yes, name and address of parent organization*
Name: Davita Inc.
Address: Davita Inc. 1551 Wewatta St. Denver Co. 80202
(V8)

17. Services Provided: (V9) *(check all that apply and specify in Remarks section [see item 27])*
☑ 1. Hemodialysis ☑ 2. Peritoneal Dialysis ☐ 3. Transplantation
☑ 4. Home Training: ☑ Hemodialysis ☑ Peritoneal Dialysis
☑ 5. Home Support: ☑ Hemodialysis ☑ Peritoneal Dialysis

18. Is Reuse Practiced? (V10) ☑ Yes ☐ No

19. Reuse System (V11) *(check all that apply)* ☐ 1. Manual ☒ 2. Semi-Automated ☑ 3. Automated

20. Germicide (V12) *(check all that apply)* ☐ 1. Formalin ☐ 2. Heat ☐ 3. Gluteraldehyde ☑ 4. Peracetic Acid Mixture
☐ 5. Other *(specify)*

21. Number of Dialysis Patients
(V13) 261 Total Patients = 197 (V14) ☑ Hemodialysis + 51 (V15) ☑ Peritoneal Dialysis 13 HomeHemo pts

22. Number of Stations *(check all that apply and include isolation stations under Total Stations)*
(V16) 49 Total Stations = 47 (V17) ☑ Hemodialysis + 2 (V18) ☑ Hemodialysis Training

23. Does the facility have isolation stations? (V19) ☑ Yes ☐ No

24. Total Number of Patients *(enter number of dialysis facility patients treated on each shift for full week prior to submission of this form)*

A. SUNDAY				B. MONDAY				C. TUESDAY				D. WEDNESDAY			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				46	45	14		45	37			46	45	12	

E. THURSDAY				F. FRIDAY				G. SATURDAY			
1	2	3	4	1	2	3	4	1	2	3	4
46	37			46	45	15		43	37		

25. Total Number of patients followed at home (V20) 64

. Staffing	(V21) ☑ Registered rse	12.0	(V22) ☑ Licen' Practical Nurse	5.0
ist full-time equivalents)	(V23) ☐ Social Worker	2.0	(V24) ☐ Dietitian	3.2
	(V25) ☑ Technicians	24.0	(V26) ☐ Others	

', arks: *(Use this space for explanatory statements for items 1–26)*

3. The information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my belief. I derstand that incorrect or erroneous statements may cause the Request for Approval to be denied, or facility approval to be escinded, under 42 C.F.R. 405.2100 and 405.2180, respectively.

gnature of Authorized Official	Title	Date
Lori Todd	Facility Administrator	1/21/11

PART II TO BE COMPLETED BY STATE AGENCY

9. ESRD Provider Number *(if the facility has a provider number)* 3 4 2 5 1 1

0. Network Number (V27) 0 6

1. State Region (V28) NCE | 32. State County Code (V29) 640

3. Type of Survey (V30) *(check all that apply)* ☐ Initial ☒ Complaint ☒ Recertification ☐ Other

4. Survey Protocol (V31) *(check all that apply)* ☒ Basic ☐ Initial ☐ Supplemental ☐ Combination

5. Surveyor Name/Number *(print)*	Professional Discipline *(print)*
Ralph Mills, RN / 15546	Registered Nurse

3. Date of Survey

January 19-21, 2011

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

RECEIVED JUN 1 9 2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
1301 Young Street, Room 833
Dallas, Texas 75202

CENTERS for MEDICARE & MEDICAID SERVICES

Division of Survey and Certification, Region VI

June 8, 2009

CC: CON
MFP

CMS Certification Number CCN#: 342511

Administrator
Southeastern Dialysis Center -Wilmington
2215 Yaupon Drive
Wilmington, NC 28407

Dear Administrator:

We have been notified that effective April 1, 2000, your organization became the new owner of the facility listed above. You should use the certification number, shown above, on all Medicare claims and correspondence. Payments will continue to be made for covered services unless evidence is received which indicates your facility is not in compliance with the requirements for participation. Your Medicare Administrative Contractor (MAC), Palmetto GBA, will be notified via email by form CMS-2007.

Southeastern Dialysis Center -Wilmington has been approved for the following stations and services: forty-nine (49) performing hemodialysis, peritoneal dialysis (CAPD, CCPD), home training (hemodialysis and peritoneal dialysis (CAPD, CCPD)), and home support (hemodialysis and peritoneal dialysis (CAPD, CCPD)).

If you have any questions, please call Rachel McCarty at (214) 767-2082.

Sincerely,

Gregory Loccio for
Ginger Odle, Manager
Non-Long Term Care Certification & Enforcement Branch

cc:
Palmetto (email)/NCarolina 18/NCarolina Medicaid/ESRD CMS CO/
Network 6-Fac #(910)555-5555

Exhibit F

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary
Jeff Horton, Acting Division Director

http://www.ncdhhs.gov/dhsr

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

March 30, 2009

Chelsey Byrum, RN, GFA
Dialysis Care of Richmond County
South NC HWY 177
Hamlet, NC 28345

RE: Medicare Complaint Survey
CMS Certification Number (CCN): 342539

Dear Ms. Bryum:

Thank you and your staff for the assistance and cooperation extended to me during the survey conducted March 23-24, 2009. The purpose of the visit was to conduct a Medicare complaint survey. The allegations reported were substantiated and deficiencies were cited. On March 24, 2009, at 2:43 p.m. an immediate jeopardy to the health and safety of patients was identified related to patient care. The Immediate Jeopardy was related to licensed staff's failure to assess and notify medical staff of patients sustaining hypertensive episodes post hemodialysis treatment. This was discussed with appropriate staff and immediate measures were taken to correct the deficient practice. The immediate jeopardy was abated on March 24, 2009 at 6:10 p.m.

As a result of this survey, it was determined that this facility was not in compliance with one (2) of Medicare's Conditions of Coverage:

494.150-Responsibilities of the Medical Director
494.180-Governance

Federal Regulations prohibit us from recertifying a provider when the provider has been determined to be out of compliance with one or more Conditions of Participation. We are unable to recertify your facility in the Medicare program. For this reason, deficiencies affecting the Condition of Participation must be corrected within **30 days** of the survey date; and a follow-up visit will be conducted within **45 days** of the survey, if a "Credible Allegation of Compliance" is received by the State Agency within 10 days of receipt by the provider. If not in compliance, a recommendation for termination from the Medicare/Medicaid program will be made effective within **45days** from the last date surveyed.

Please find enclosed both "standard" and "condition" level deficiencies cited as a result of the survey. These are recorded on the enclosed Statement of Deficiencies (Form CMS-2567). A written plan of correction should be submitted to this office and should include the following:

(a) A description of the correction action(s) and the systems that have been or will be implemented to correct the deficiency.

(b) A description of the monitoring system that has been or will be implemented including the person(s) responsible for the monitoring to assure compliance; and

(c) The date by which all correction actions will be completed and in place. This date must be included on the CMS Form 2567.

The enclosed CMS form 2567 must contain an **original signature, with the date signed, and returned to me at the above mailing address** **WITHIN 10 WORKING DAYS OF RECEIPT.** Do not fax this form. We must have the original form returned. The plan of correction will be reviewed, and if additional information is needed, we will contact you.

Should you have any questions please do not hesitate to contact me at (919) 550-0870, or (919) 855-4623.

Sincerely,

Kay D. Cuaton, RN

Kay D. Cuaton, RN
Acute and Home Care Licensure & Certification

Enclosures: CMS-2567 (w/patient/staff list)

Exhibit G

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center • Raleigh, North Carolina 27699-2701
http://www.ncdhhs.gov/dhsr/

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

January 10, 2011

Charles Sheppard, Facility Administrator
Charlotte East Dialysis
3204 Sharon Amity Road
Charlotte, NC 28205

Re: Follow-up Survey
ESRD CMS Certification Number (CCN):34-2627

Dear Mr. Sheppard

Thank you for the cooperation and courtesy extended during my recent visit on December 21, 2010, for the purpose of conducting a follow up to the condition level deficiencies 494.180 Governance, 494.30 Infection Control and 494.60 Physical Environment that was cited during your Medicare recertification survey on October 1, 2010. It was determined that the condition level deficiency has been corrected, as well as the standard level deficiencies, and you are back in compliance with Medicare's Conditions of Coverage for End Stage Renal Disease facilities.

Should you have any questions or if this office can be of other assistance, please do not hesitate to call me at (919) 218-2638.

Sincerely,

Ralph Mills

Ralph Mills,RN,BSN
Facility Survey Consultant
Acute & Home Care Licensure & Certification

RECEIVED NOV 2 9 2010

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
1301 Young Street, Room 833
Dallas, Texas 75202

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Division of Survey and Certification, Region VI

November 15, 2010

CMS Certification Number (CCN): 342627

Charlotte East Dialysis
3204 Sharon Amity
Charlotte, NC 28205

Dear Administrator:

The Centers for Medicare & Medicaid Services (CMS) has been notified your facility had a survey on October 26, 2010, and that while the immediate and serious threat to patient health and safety has been removed Charlotte East Dialysis remains out of compliance with the following Medicare Conditions for Coverage:

42 CFR 494.30	Infection Control
42 CFR 494.60	Physical Environment; and
42 CFR 494.180	Governance.

The date on which your hospital's Medicare agreement terminates is **December 30, 2010.** A listing of deficiencies for the October 26, 2010, survey is enclosed for your response. Note that the on-site visit of October 26, 2010 was conducted to determine whether or not the immediate jeopardy situation had been abated. Correction of the deficiencies not related to the immediate jeopardy was not assessed; these deficiencies are included in the attached report as cited on the resurvey and complaint investigation of October 1, 2010. You must submit a plan of correction to include corrective action dates no later than December 23, 2010, to ensure time for another revisit by the North Carolina Department of Health and Human Services prior to the termination date. Please submit these your plans of correction within 10 days of receipt of this letter to:

Azzie Conley
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center
Raleigh, North Carolina 27699-2712

An acceptable plan of correction must contain the following elements:

1. The plan of correcting the specific deficiency. The plan should address the processes that lead to the deficiency cited.

2. The procedure for implementing the acceptable plan of correction for the specific deficiency cited.
3. The monitoring procedure to ensure that the plan of correction is effective and that specific deficiency cited remains corrected and/or in compliance with the regulatory requirements.
4. The title of the person responsible for correcting the deficiency and/or for implementing the acceptable plan of correction.

Compliance with all Conditions for Coverage must be achieved at the time of this second revisit if termination is to be avoided. If the deficiencies have not been satisfactorily corrected at the time of this revisit, you can expect to receive a letter advising you of your termination and appeal rights. No further revisits will be authorized at that time. In addition, a legal notice will be placed in The Charlotte Observer in Charlotte, North Carolina advising the public of your termination from the Medicare program. Please be advised that, under Medicare, a provider is not entitled to a formal hearing before termination, but only after adverse action actually takes place.

If you have any questions concerning this action, please contact Glenda Payne at (214) 767-3350 or Rachel McCarty at (214) 767-2082.

Sincerely,

Ginger Odle, Manager
Non-Long Term Care Certification & Enforcement Branch

cc:
North Carolina Department of Health and Human Services

COPY

PDFed 10/4/10

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

http://www.ncdhhs.gov/dhsr
Drexdall Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

**** VIA FASCIMILE ****

October 4, 2010

Charles Sheppard, Facility Administrator
Charlotte East Dialysis
3204 Sharon Amity
Charlotte, NC 28205

RE: Recertifiction Survey Immediate Jeopardy]

Dear Mr. Sheppard,

Thank you and your staff for the assistance and cooperation extended to the Acute Care team during the survey conducted September 22, 2010 through October 1, 2010. The purpose of conducting the complaint survey was to evaluate the Facility's compliance with the Federal Medicare Conditions for Coverage. The complaint investigation resulted in an Immediate Jeopardy (IJ) identification as of **October 1, 2010 at 1130am** as a result of survey findings from a Life Safety Code survey occuring on 09/30/2010.

Specifically, pursuant to **494.60 Physical Environment-Life Safety Code.** the facility failed to have a fire alarm system or battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire..

As discussed during the survey, the information gathered was forwarded to the CMS Regional Office in Atlanta (Region IV). Our state agency is recommending 23 day termination due to noncompliance with the **Conditions for Coverage: 494.60 Physical Environment, 494.30 Infection Control and 494.180 Governance.**. The Immediate Jeopardy is ongoing. CMS Regional Office in Dallas will make the determination of compliance or noncompliance and will notify you of their findings and of any action to be taken.

If you have questions regarding the status of the investigation, please contact the CMS representative for North Carolina:

Ms. Glenda Payne
Division of Survey and Certification
CMS Dallas Regional Office
1301 Young Street, Room 827
Dallas, Texas 75202
214-767-6301

COPY

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Ralph Mills, R,BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Acute and Home Care Licensure and Certification Section
2712 Mail Service Center ▪ Raleigh, North Carolina 27699-2712

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Drexdall Pratt, Division Director

Azzie Y. Conley, Chief
Phone: 919-855-4620
Fax: 919-715-8476

October 4, 2010

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Ms. Glenda Payne
Division of Survey and Certification
CMS Dallas Regional Office
1301 Young Street, Room 827
Dallas, Texas 75202
214-767-6301

If you have any questions, please do not hesitate to contact this office at (919) 855-4620.

Sincerely,

Ralph Mills, RN, BSN
Facility Survey Consultant
Acute and Home Care Licensure and Certification

CC: Azzie Conley, Section Chief

** VIA FASCIMILE **

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

ID: WB31

Facility ID: 001554

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

1. MEDICARE/MEDICAID PROVIDER NO.
342627
STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CHARLOTTE EAST DIALYSIS
(L4) 3204 SHARON AMITY
(L5) CHARLOTTE, NC (L6) 28205

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 10/01/2010 (L34)

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

7. PROVIDER/SUPPLIER CATEGORY 09 (L7)

01 Hospital	05 HHA	09 ESRD	13 FTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	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

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

X B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: B* (L12)

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(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):
See Attached Remarks

17. SURVEYOR SIGNATURE Date: 01/11/2011 (L19)

18. STATE SURVEY AGENCY APPROVAL Date: 1/16/11 (L20)

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

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

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
01/30/2003
(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.
00101
(L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

C&T REMARKS - CMS 1539 FORM

A ification survey was conducted onsite September 22-October 1, 2010. As a result of the survey in conjunction with a Life Safety Code survey, an immediate jeopardy (IJ) w. entified on October 1, 2010 at 1130. The IJ was no removed during the recertification survey. Condition level deficiencies were identified in 494.180 Governance, 494.30 Infection Control and 494.60 Physician Environment. Standard level deficiencies were also identified in 494.40 Water and Dialysate Quality, 494.50 Reuse, 494.80 Patient Rights and 494.140 Personnel Qualifications. A plan of correction was requested.

An onsite follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the IJ at 1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation. THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey. (RM)

Another follow up survey was conducted December 21, 2010. The State Agency recommends that the condition level deficiencies in 494.30 Infection Control, 4894.60 Physical Environment and 494.180 Governance are back in compliance. No other deficiencies were found during the follow up survey.

epartment of Health and Human Services
enters for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

lic reporting for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and int data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information ud. uggestions for reducing the burden, to CMS, Office of Financial Management, P.O. Box 26684, Baltimore, MD 21207; and to the Office of Management and Budget, Paperwork duction Project (0938-0390), Washington, D.C. 20503.

(1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
342627	A. Building B. Wing	12/21/2010

lame of Facility	Street Address, City, State, Zip Code
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

his report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously eported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should e fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each equirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix V0110 Reg. # 494.30 LSC	Correction Completed 12/21/2010	ID Prefix V0114 Reg. # 494.30(a)(1)(i) LSC	Correction Completed 12/21/2010	ID Prefix V0117 Reg. # 494.30(a)(1)(i) LSC	Correction Completed 12/21/2010
ID Prefix V0120 eg. # 494.30(a)(1)(i) LSC	Correction Completed 12/21/2010	ID Prefix V0122 Reg. # 494.30(a)(4)(ii) LSC	Correction Completed 12/21/2010	ID Prefix V0196 Reg. # 494.40(a) LSC	Correction Completed 12/21/2010
ID Prefix V0331 Reg. # 494.50(b)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0340 Reg. # 494.50(b)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0400 Reg. # 494.60 LSC	Correction Completed 12/21/2010
ID Prefix V0403 Reg. # 494.60(b) LSC	Correction Completed 12/21/2010	ID Prefix V0408 Reg. # 494.60(d) LSC	Correction Completed 12/21/2010	ID Prefix V0417 Reg. # 494.60(e)(1) LSC	Correction Completed 12/21/2010
ID Prefix V0463 Reg. # 494.70(a)(12) LSC	Correction Completed 12/21/2010	ID Prefix V0502 Reg. # 494.80(a)(1) LSC	Correction Completed 12/21/2010	ID Prefix V0686 Reg. # 494.140(b)(3)(i)-(ii) LSC	Correction Completed 12/21/2010

viewed By tate Agency	Reviewed By	Date:	Signature of Surveyor:	Date: 12/21/2010
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB NO. 0938-0390

Post-Certification Revisit Report

(Y1) Provider / Supplier / CLIA / Identification Number	(Y2) Multiple Construction	(Y3) Date of Revisit
342627	A. Building B. Wing	12/21/2010

Name of Facility	Street Address, City, State, Zip Code
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

This report is completed by a qualified State surveyor for the Medicare, Medicaid and/or Clinical Laboratory Improvement Amendments program, to show those deficiencies previously reported on the CMS-2567, Statement of Deficiencies and Plan of Correction that have been corrected and the date such corrective action was accomplished. Each deficiency should be fully identified using either the regulation or LSC provision number and the identification prefix code previously shown on the CMS-2567 (prefix codes shown to the left of each requirement on the survey report form).

(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date	(Y4) Item	(Y5) Date
ID Prefix V0750 Reg. # 494.180 LSC	Correction Completed 12/21/2010				

Reviewed By State Agency	Reviewed By	Date:	Signature of Surveyor: Robin Miller RN	Date: 12/22/2010
Reviewed By CMS RO	Reviewed By	Date:	Signature of Surveyor:	Date:

Followup to Survey Completed on: 10/1/2010

Check for any Uncorrected Deficiencies. Was a Summary of Uncorrected Deficiencies (CMS-2567) Sent to the Facility? YES NO

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342627	CHARLOTTE EAST DIALYSIS

Type of Survey (select all that apply)

I	D			

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

A				

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	12/21/2010	12/21/2010	1.00	0.00	3.00	0.00	5.00	2.00
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342627	CHARLOTTE EAST DIALYSIS

Type of Survey (select all that apply)

I	D				

A Complaint Investigation
B Dumping Investigation
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E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW

Extent of Survey (select all that apply)

A				

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
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Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	12/21/2010	12/21/2010	1.00	0.00	3.00	0.00	5.00	2.00
2.								
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14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

RECEIVED NOV 2 9 2010

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

PRINTED: 11/16/2010
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
	342527	A. BUILDING _____ B. WING _____	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMTY CHARLOTTE, NC 28205

(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 follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the IJ at 1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation. The conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey.	(V 000)	V000- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm was installed as required. The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. The Governing Body will meet monthly x 3 or more often as required to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi- annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	
(V 110)	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Not reviewed onsite on 10/28/2010. Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to implement and maintain an effective infection control program. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit	(V 110)		

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

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.

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

PRINTED: 11/15/2010
FORM APPROVED
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342627	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3404 SHARON AMITY CHARLOTTE, NC 28205

(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 110)	Continued From page 1 bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality infection control practices for dialysis patients. The findings include: A. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0117 B. The facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0120 C. The facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments. ~Cross refer to 494.30(a)(4)(ii) Infection Control - Tag V0122	(V 110)	V110- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is place to install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. Plexiglas barriers will be placed to prevent potential cross contamination. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers . Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need for appropriate cleaning and disinfecting of vascular clamps. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. cont pg 3	10-15-10

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	342527	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	6204 SHARON AMITY CHARLOTTE, NC 28205

(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 110)	Continued From page 2 D. The facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing. -Cross refer to 494.60(b)(1) Reuse of Hemodialyzers and Bloodlines - Tag V0331 E. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. -Cross refer to 494.60(b) Physical Environment- Tag V0403 F. The facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. -Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0114.	(V 110)	V110 cont. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as pf 09/29/10.The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10.	10-18-10
(V 114)	494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by: No reviewed onsite on 10/26/2010. Based on facility policy review, observations and staff interview, the facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The findings include: A review of the facility's policy "Infection Control	(V 114)	Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	

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	342627	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3226 SHARON AMITY CHARLOTTE, NC 28205

(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 114)	Continued From page 3 for Dialysis Facilities" (revision date 03/2010) revealed "The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink." Observation on 09/23/2010 at 1300 in the patient treatment area revealed that a paper towel dispenser located for the patients to wash their access sites at the exit area had no available paper towels for use after handwashing. The observation revealed that the paper towels were located in a machine with a sensor to dispense the towels. After washing hands was observed by a patient and surveyor, it was noted that the sensor was not working and no paper towels were available. An interview with the facility's registered nurse during the observation on 09/23/2010 at 1300 revealed that the paper towel dispenser was not working. The interview revealed that paper towels would have to be obtained in a different fashion until the sensor was fixed.	(V 114)	V114 Paper towels in the dispenser were replaced and threaded properly. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings(QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10/18/10.
(V 117)	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used	(V 117)		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3824 SHARON AMITY CHARLOTTE, NC 28208

(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 117	Continued From page 4 (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, observations and staff interview, the facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients. The findings include: 1. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled." Observation on 09/22/2010 at 1025 in the patient treatment area revealed that a medication cart filled with medications and other unused supplies along with syringes was located directly beside the handwashing sink used by patients to wash their access sites. The sink was designated for patient hand washing and had a sign that was	V 117	V117 Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. FA is responsible for ongoing compliance with POC.	10-18-10

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CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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(V 117)	Continued From page 5 written as "Patients must wash access sites" and located at the base of the sink. The observation further revealed that no splash guard or barrier was noted to prevent water splashes on the medications and supplies. An interview on 09/22/2010 at 1000 with the facility's nursing staff revealed that the patient medications and unused supplies are stored on the cart was kept beside the handwashing sink. The interview revealed that the staff has always kept the medications and supplies in this location due to lack of space. The interview also confirmed that the supplies and medications can get wet from patients and staff washing hands. The interview revealed that the staff had not considered the potential contamination of the medications or supplies. An interview with the facility administrator on 09/22/2010 at 1240 revealed that the supplies and medications should be prevented from being wet or contaminated from people washing their hands at the nearby sink. 2. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled." Observation on 09/22/2010 at 1550 revealed the medication preparation area used by the facility. The observation revealed that the preparation area is located on a wheeled cart (Craftsman Brand) with the medication vials located on top of	(V 117)		

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	342827	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3924 SHARON AMITY CHARLOTTE, NC 28205

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(V 117)	Continued From page 6 the cart with a cleared area noted. Observation revealed the medication preparation area (cart) was stationary and located directly beside of the facility's designated handwashing sink for patients to wash their access sites. Observation revealed that the facility had a sign on the sink that was written as "Patients must wash access sites" located at the base of the sink. The observation further revealed that no barrier and splash guard was present to prevent potential cross contamination during medication preparation. No separate clean area was observed for patient medication preparation. An interview on 09/22/2010 at 1555 during the observation) with the facility's registered nurse revealed that the cart was the area where the facility's nursing staff prepares patients medications. The interview revealed that she never thought of the potential splashing of water from handwashing sink on the clean medication preparation area. An interview on 09/22/2010 at 1650 with the facility's administrative staff revealed that the potential cross contamination has to be corrected and that lack of space is a problem at the facility.	(V 117)		
(V 120)	494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors. If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified	(V 120)		

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CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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{V 120}	Continued From page 7 personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, observations and staff interview, the facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients whose dialysis machines were observed to have wet or blood tinged external transducer protectors (Patient stations #1,11). The findings include: A review of the facility's policy "Changing Transducer Protectors" (revision date of 12/2008) revealed "External transducer protectors will be inspected for the presence of blood or saline every 30 minutes during patient treatment and included in the monitoring process. The external transducer protector will be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector."	{V 120}	V120 The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect the external transducers for the presence of blood or saline every 30 minutes during patient treatment. The external transducer protector is to be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-7-10

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CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 120)	Continued From page 8 1. Observation on 09/22/2010 at 1605 for the patient in station #1 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector. 2. Observation on 09/22/2010 at 1610 for the patient in station #11 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1510 through 1645 revealed that no staff member inspected or changed the transducer protector. 3. An interview on 09/22/2010 at 1650 with the facility's registered nurse in the patient treatment area revealed that the staff should change the bloody transducers and check the back of the transducer to make sure that the machine is not contaminated. 4. An interview with the facility's administrative staff on 09/22/2010 at 1655 revealed that the transducer protectors should be immediately changed and checked by staff when they become bloody.	(V 120)		
(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)		

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(V 122)	Continued From page 9 This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, observations and staff interview, the facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments. The findings include: A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 05/2010) revealed "Equipment if accessible to patients and teammates including outside of sharps containers and all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedures, after spills of blood, throughout the day, and after each treatment. Any areas contaminated with visible blood or body fluids are cleaned promptly with a well wrung out wipe using 1:10 bleach solution." 1. a. Observation on 09/22/2010 at 1013 in the patient treatment area revealed that a rolling wheeled cart with a total of six (6) acid bath jugs on the cart had noted dialysate powder (white in color and chalky)and dust noted on the cart. 1. b. Observation on 09/22/2010 at 1605 revealed trash (paper wrappers) scattered on the patient treatment area floor near patient stations #4 and #11. Observation further revealed three trash cans in the patient treatment area that were full	(V 122)	V122- The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor and blood stains and blood stains are cleaned when they occur. Carts will be replaced by 10/15/2010; removed the existing soap dispensers and mounting brackets and replaced with disposable bottle-type dispensers. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need for appropriate cleaning and disinfecting of vascular clamps. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward Results of audits will be reviewed in Quality Improvement Management Meetings(QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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CHARLOTTE EAST DIALYSIS	2201 SHARON AMITY CHARLOTTE, NC 28205

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(V 122)	Continued From page 10 and overflowing with trash. 1. c. Observation on 09/22/2010 at 1515 revealed that two automated (GOJO Brand) soap dispensers in the facility's service area at handwashing sinks designated as clean had caked rusted buildup observed directly under the dispensers. No observed evidence of cleaning the dispensers was observed. An interview with the facility administrator on 09/22/2010 revealed that the area should remain free from clutter and dirty buildup around supplies. The interview also revealed that the trash should be cleaned up by the staff. No reason was given us to why the areas were not cleaned by the staff. 2. Observation on 09/22/2010 at 1020 in the patient treatment area revealed that vascular clamps used for patient vascular access sites were located in a container of 1:100 bleach disinfectant and had visible clotted blood on the clamp heads. The observation further revealed that the clamps were not fully submerged in the disinfectant bleach. An interview with the facility administrator on 09/22/2010 at 1215 revealed that the clamps should be below the level of bleach solution according to the facility policy. 3. Observation on 09/22/2010 at 1015 in the patient treatment area revealed blood stains on top of the needle sharps container located directly beside the patient dialyzing in station #16. The blood stains were located on top of the sharps container from 1015 through 1155 without staff observed to clean the stains.	(V 122)		

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(V 122)	Continued From page 11 An interview with the facility administrator on 09/22/2010 at 1210 revealed that the blood stains should be cleaned when they occur or soon as possible.	(V 122)		
(V 195)	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 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: Not reviewed onsite on 10/25/2010.	(V 195)		

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	342827	A. BUILDING _____ B. WING _____	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3804 SHARON AMITY CHARLOTTE, NC 28205

(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 196)	Continued From page 12 Based on facility policy review, the facility's total chlorine testing log review and staff interview, the facility failed to ensure regularly performed testing to monitor the total chlorine in its water system used in patient hemodialysis and failed to provide color blindness testing in 2 of 4 sampled staff members that test the facility's water system for the presence of chlorine (Staff #1,3). The findings include: A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed "Total Chlorine testing is done on a daily basis prior to the first patient treatment and every four (4) hours until all activities that require use of dialysis quality water are completed." A review on 09/23/2010 of the facility's "Routine Total Chlorine Testing Log" for 02/15/2010 revealed that the facility staff failed to document Chlorine testing every 4 hours. The review revealed that for 02/15/2010, the facility staff documented Chlorine testing at 0900, 0540, 1345 and 1740. The review further revealed that the facility staff wrote a time of 0945 on the log but failed to document any results, initials or signatures for the Chlorine testing. The review revealed that the 0945 testing for Chlorine was not documented as completed. An interview with the facility's Biomed technician on 09/23/2010 at 1400 revealed that the total chlorine checks should be done every 4 hours with a 15 minute extra window of time given. The interview revealed that some times the nursing staff does not fully document on the water log	(V 196)	V196- The CSS in-serviced the teammates on the importance of completing the water system total chlorine monitoring every 4 hours per policy 2-07-04 "Daily Water Total Chlorine Monitoring" and documenting on the appropriate log. FA/designee will be checked daily for 7 days then weekly on going. Color blindness testing was completed on the 2 RN's cited and it was found that they did have testing and results are in teammates files. Color blindness testing will be done on all new hires and annually there after. Facility Administrator will spot check 25% of teammates file monthly for 3 months and annually there after. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-18-10

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	342827	A. BUILDING _____ B. WING _____	R 10/20/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 195)	Continued From page 13 record. A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed that the facility uses the "Lamotte SL-MW Test Kit Colorimeter" for the chlorine testing in its water system. The policy also revealed that the staff instructions include "Holding the Octa-Slide Viewer so that non-direct light enters the back of the comparator. Match the test tube color standard on the Octa-Slide and read the ppm value on the Octa-Slide standard that matches color of the test tube sample." 1. A review of the facility's personnel file for staff nurse #1 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed. 2. A review of the facility's personnel file for staff nurse #3 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed. 3. An interview on 09/23/2010 at 1400 with the facility administrator revealed that these staff nurses did not have any documented color blindness testing in her personnel file. The interview revealed no reason as to why these staff nurses did not have any testing done. The interview also revealed that these nurses do check the water system for chlorine and should have color blind testing to ensure that each nurse	(V 195)		

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	342527	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3234 SHARON AMITY CHARLOTTE, NC 28205

(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 195)	Continued From page 14 can read the color matches.	(V 195)		
(V 331)	494.60(b)(1) REPROCESSING-TRANSPORTATION & HANDLING 11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, observation, refrigerator temperature log review and staff interview, the facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing. The findings include: A review of the facility policy "Reuse of Dialyzers" (revision date 09/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reuse is begun. Refrigerated dialyzers may be stored for up to 36 hours prior to being reprocessed. The refrigerator used for contaminated dialyzer storage is maintained between 36-50 degrees	(V 331)	V331 Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	9-30-10

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	342537	A. BUILDING ______ B. WING ______	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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{V 331}	Continued From page 15 Fahrenheit." Observation on 09/22/2010 at 1100 in the patient treatment area revealed a total of seven (7) patient used dialyzers inside of the storage refrigerator used for reuse storage. Inspection of the thermometer revealed that the temperature was 56 degrees Fahrenheit at 1105. The observation of the outside of the refrigerator revealed that a handwritten notation was placed on the front of the refrigerator that was written as "Temperature should be 35 degrees F (Fahrenheit) - 50 degrees F. " An interview during the observation at 1105 with a patient dialysis care staff member confirmed that the temperature was 56 degrees F and it should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times. A review on 09/22/2010 of the refrigerator log for 09/2010 revealed that the facility's refrigerator temperature limits should be "36 degrees F to 46 degrees F." The review of the 09/2010 log revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review for 09/01/2010 revealed documentation by staff of the refrigerator temperature to be a range of 32-38 degrees F. On 09/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 09/22/2010 (date of observation) revealed that the temperature reading was documented as 30-48 degrees F. An interview with the registered nurse in the patient treatment area on 09/22/2010 at 1155 revealed that the refrigerator has constantly been	{V 331}		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3104 SHARON AMITY CHARLOTTE, NC 28205

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(V 331)	Continued From page 16 a concern with the temperature readings. The interview revealed "Everytime we put hot dialyzers in that refrigerator, the temperature goes in the 50s." An interview with the facility administrator on 09/22/2010 at 1210 revealed that he was not aware of the elevated temperature readings of the reprocessing storage refrigerator. The interview revealed that the staff had not informed him of the elevated temperature changes.	(V 331)		
(V 340)	494.50(b)(1) DIALYZER GERM=90% CONC/CAPS DISINFECT 11.4.1.4 Chemical germicidal procedure: = 90% conc/port caps disinfected If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration. The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010. Based on facility policy review, observations and staff interview, the facility's reuse staff failed to ensure that reuse dialyzer caps were cleaned and disinfected by appropriate immersion in a germicide before reassembling of the reprocessed dialyzers.	(V 340)	V340- The CSS in-serviced reuse teammates on policy 6-04-03 Cleaning and Disinfection of Reuse Supplies with emphasis on the need to fully immerse the caps below the germicide surface level. Facility Administrator will monitor submersion of caps per policy for 7 days then once a week for 2 weeks, then monthly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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CHARLOTTE EAST DIALYSIS	3304 SHANNON ANEY CHARLOTTE, NC 28205

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{V 340}	Continued From page 17 The findings include: A review of the facility's policy "Cleaning and Disinfection of Reuse Supplies Policy" (origination date 08/2008) revealed "Reuse supplies will be cleaned and disinfected with a 1% peracetic acid solution for a minimum of 30 minutes. Blood and dialysate port caps, barrier adapters, extension tubing must be disinfected for a period of 30 minutes but no greater than 24 hours prior to use." Observation on 09/22/2010 at 1606 in the facility's reprocessing room revealed that reprocessing caps and port caps used for patient reprocessed dialyzers were placed in two 1% peracetic acid (germicide) solution plastic containers located in the designated dirty section for disinfection. The observation revealed that the caps in both containers of the disinfectant were not fully immersed below the disinfectant germicide surface level. The observation was during a time when no staff was present in the reprocessing area. An interview on 09/22/2010 at 1620 with the facility's reuse technician revealed that the containers with the caps should have the caps fully below the level of the disinfection surface. The interview revealed no reason as to why the caps in both containers were not below the disinfectant surface level.	{V 340}	V400-Physical Environment Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. *In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. cont pg 19	10-22-10 for Fire system 12-31-10 for additional physical plant work
{V 400}	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Not reviewed onsite on 10/28/2010.	{V 400}		

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CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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(V 400)	Continued From page 18 Based on observations as referenced in the Life Safety Report of a complaint investigation completed 09/30/2010, facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to maintain a physical environment that decreased the potential risks to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only interviewing staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the health and safety of patients, staff and visitors at the dialysis facility. The findings include: A. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying	(V 400)	V400 cont. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. * Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device* This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. cont . pg 20	9-30-10 *12-31-10 for additional physical plant work 10/07/10

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3804 SHARON AMITY CHARLOTTE, NC 28205

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{V 400}	Continued From page 19 conditions each quarter in place of only inservicing staff on the fire drills; and failed to remove storage in the front corridor of the facility next to the lobby at the side exit door. -Cross refer to 494.60(e)(1) Physical Environment Fire Safety and Life Safety Code-Tag V0417 B. The facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or unpassable. -Cross refer to 494.60(d) Physical Environment - Tag V0408 C. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. -Cross refer to 494.60(b) Physical Environment - Tag V0403.	{V 400}	V400 cont. *The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0" ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work 10-1-10 09/30/10.
{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: Not reviewed onsite on 10/26/2010.	{V 403}		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2704 SHERON AVE CHARLOTTE, NC 28205

(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 20 Based on facility policy review, observations, refrigerator temperature log review and staff interview, the facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. This deficient practice placed all patients participating in the reprocessing program at risk for exposure to contamination from bacterial growth in the dialyzers. The findings include: A review of the facility policy "Reuse of Dialyzers" (revision date 08/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reprocessing is begun. Refrigerated dialyzers may be stored for up to 36 hours prior to being reprocessed. The refrigerator used for contaminated dialyzer storage is maintained between 36-50 degrees Fahrenheit." Observation on 09/22/2010 at 1100 in the patient treatment area revealed that the facility had a refrigerator in the patient treatment area that was used to store reused dialyzers at a temperature to inhibit potential bacterial growth. The observation revealed a total of seven (7) patient used dialyzers inside of the refrigerator used for the reuse storage. The observation at 1105 of the thermometer revealed that the temperature was 58 degrees Fahrenheit. The observation of the outside of the refrigerator revealed that a handwritten note was placed on the front of the refrigerator indicating "Temperature should be 36 degrees F."	{V 403}	V403 Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	9-30-10

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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{V 403}	Continued From page 21 An interview during the observation at 1105 with patient dialysis care staff member revealed that the temperature was 50 degrees F and that the temperature should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times. A review on 09/22/2010 of the refrigerator log for 09/2010 revealed that the facility's refrigerator temperature limits should be "36 degrees F to 46 degrees F." The review of the log for 09/2010 revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review of 09/01/2010 revealed documentation by the staff that the refrigerator temperature to be a range of 32-38 degrees F. On 09/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 09/22/2010 (date of observation) revealed that the temperature reading was documented as 30-48 degrees F. An interview on 09/22/2010 at 1330 with the facility administrator revealed that the temperatures of the refrigerators should be monitored every day and that the exact temperature should be documented. The interview also revealed that the reuse storage refrigerator should not be greater than 50 degrees F. The interview further revealed that the log used by the staff was meant for use for refrigerators containing medications, and that the limits on the log were set for medication storage, instead of showing the highest degree of 50 F.	{V 403}		
{V 408}	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes	{V 408}		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3324 SHARON AMITY CHARLOTTE, NC 28205

(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 408)	Continued From page 22 and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on observations, fire safety reports review and staff interview, the facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or unpassable. The findings include: Observation on 09/22/2010 at 1015 during tour of the facility's patient treatment area revealed that the facility had a total of sixteen (16) total stations for hemodialysis treatments. The facility hemodialysis station locations were against the four (4) walls of the patient treatment area. The observation of the facility's fire safety emergency evacuation route revealed that the facility had one emergency exit leading directly into a hallway from the patient treatment area. The exit route led to a door with a fire exit sign leading out to the facility's lobby area and main exit doors. The observation further revealed that there was no other exit location or emergency evacuation route in the patient treatment area. Observation revealed that only one (1) exit route/egress	(V 408)	V408- *The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0"ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. * A copy of Certificate of Occupancy has been requested from the city of Charlotte, original architect and general contractor. Going forward any fire inspections will be kept on file in the facility. FA is responsible for ongoing compliance with POC. *The facility has been diligently working on correcting all the issues cited since the survey. The fire system has been installed as required. The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.*	10-13-10 *12-31-10 for additional physical plant work

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342527	A. BUILDING ______ B. WING ______	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 408}	Continued From page 23 existed in the patient treatment area for patients, visitors and staff. No other doors or exits were observed in the patient treatment area. An interview on 09/22/2010 at 1110 with the facility's registered nurse in the patient treatment area revealed that that the there was only one way out of the patient treatment area at the facility. The interview revealed, "I have never thought about it, but if there was a fire, the only way out would be through the that area (staff indicating by pointing to the one exit) there." The interview revealed that the staff were trained in fire drills to use the one exit in the treatment area to evacuate the patients. The interview also revealed that the facility administration did not instruct the staff what to do if that one fire exit route was blocked with fire or other objects. A review of the local fire marshall reports on 09/23/2010 revealed that no report could be found at the facility where any fire marshall or local fire inspection was done at the facility to determine fire safety compliance. No documentation could be produced by the facility that revealed any fire safety inspections were conducted at the facility. An interview on 09/23/2010 at 1000 with the facility administrator and regulatory staff revealed that the facility could not find or produce a fire marshall or local county/city report for any past inspection of the the facility's fire safety. The interview revealed that the facility should have one on file, but the administrative staff were unable to produce this document during the survey.	{V 408}	V417- 1.The fire system has been installed as required. 2. The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. 3. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. 4. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer devise. cont pg 25	*10-22-10 for Fire system
{V 417}	494.60(e)(1) PE-FIRE SAFETY-LIFE SAFETY CODE 2000	{V 417}		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 342527	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED R 10/28/2010

NAME OF PROVIDER OR SUPPLIER: CHARLOTTE EAST DIALYSIS

STREET ADDRESS, CITY, STATE, ZIP CODE: 3304 SHARON AMITY, CHARLOTTE, NC 28205

(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 417}	Continued From page 24 (1) Except as provided in paragraph (e)(2) of this section, by February 9, 2009. The dialysis facility must comply with applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744 (a)(1)(i) of this chapter). This STANDARD is not met as evidenced by: Not reviewed onsite on 10/28/2010. Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted: 1) The Server Room is lined with a plywood interior finish on the walls which does not comply with the required fire resistance rating for the area. 2) Facility is approximately 7800 sq. ft. in size and does not have a smoke barrier separating the building into two separate smoke compartments. 3) The facility has Bio Hazard Storage room is not self closing nor fire-rated. 4) The emergency battery operated light located next to the re-use room was not operational when tested. 5) The facility inservices the staff on Fire Drills each quarter in place of holding Fire drills being held at unexpected times under varying conditions. 6) There is storage in the front corridor next to the lobby to the side exit door, partially blocking the exit.	{V 417}	V417 cont. 5. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. 6. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. 7. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. *The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.*	*12-31-10 for additional physical plant work
{V 463}	494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC	{V 463}		

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	342627	A. BUILDING ______ B. WING ______	R 10/20/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 463}	Continued From page 28 The patient has the right to- (12) Receive the necessary services outlined in the patient plan of care described in §494.90; This STANDARD is not met as evidenced by: Not reviewed onsite on 10/20/2010. Based on facility policy review, clinical record review, patient interview and staff interview, the facility failed to include the patient in the facility's interdisciplinary team annual meeting involving the patient's plan of care for 2 of 7 sampled patient records (Patient #1,B). The findings include: A review of the facility policy "Patient Assessments and Plan of Care" (revision date 03/2010) revealed "The patient plan of care will be completed by the facility's interdisciplinary team, including patient or personal representative and be signed by team members including the patient or the patient's personal representative." A review on 09/22/2010 of the open clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2005. The review of the clinical record revealed that an "Annual Care Plan" meeting was scheduled for Wednesday 03/03/2010 for the patient. A review of the form inviting the patient was found in the clinical record of the patient. The review of the form revealed that the facility's dietician signed the staff signature portion and dated it 03/03/2010 but failed to obtain a patient signature that she would either attend or not attend the meeting. The	{V 463}	V463- Policy #1-01-07 Patient Assessment and Plan of Care" was reviewed with the interdisciplinary team (IT) with emphasis on the need to include the patient/patient designee in the development of the plan of care unless the patient declines. Each patient will be given a written and verbal invitation to the care plan meeting as care plans become due. Patients will be asked to sign invitation and note if they will attend. If patient declines the invitation the plan of care a member of the IDT will review with them and ask for their signature on the plan. If the patient refuses to sign, this will be noted in the record as well. FA/designee will audit all plans of care completed x 3months and then 10% of those completed quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-18-10

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	342627	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3205 SHARON AMITY CHARLOTTE, NC 28205

(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 483)	Continued From page 26 space was not completed and left blank but the staff member (dietician) had signed the staff signature witness section. No documentation was found where the patient received individualized care and a chance to participate in her plan of care meeting. An interview with patient #8 on 09/22/2010 at 1040 during the facility tour and observation revealed that the patient had not been invited by the facility staff to her plan of care meetings. The interview revealed "I am usually told they happened, but the staff does not really invite me to attend. I would try to make it if possible. I usually sign the paper after the meeting happens." An interview with the facility administrator on 09/22/2010 at 1629 revealed that that this form should have indicated whether the patient was going to attend or not, that the staff should not sign the form before the patient signed, and that patients are invited to the meetings and usually sign the form.	(V 483)		
(V 502)	494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBDS The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions. This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, clinical record	(V 502)	V502- The Required documentation for the administration of PRN medication to include the reason given and effectiveness of the medication was reviewed with RN's. Facility Administrator will monitor documentation of PRN meds once a week for 3 weeks then complete random audits quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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	342027	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2304 SHARON AMITY CHARLOTTE, NC 28205

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(V 502)	Continued From page 27 review and staff interview, the facility failed to ensure that registered nurses met the clinical needs of patients by failing to document and reassess as needed (PRN)medication administration in 5 of 5 sampled patients receiving PRN medication (Patients #1,2,3,4,5). The findings include: 1. A review on 09/22/2010 of the clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2006 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 and 08/27/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1705 and on 08/27/2010 at 1430 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/29/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 2. A review on 09/23/2010 of the clinical record for patient #2 revealed that the patient was admitted to the facility on 10/20/2008 for chronic hemodialysis. A review of the patient treatment sheets for 09/24/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment	(V 502)		

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	343627	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3224 SHARON AMITY CHARLOTTE, NC 28205

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(V 502)	Continued From page 28 of the medication effectiveness. This review revealed that on 08/24/2010 at 1149 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 3. A review on 09/23/2010 of the clinical record for patient #3 revealed that the patient was admitted to the facility on 12/29/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/18/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/18/2010 at 1422 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 4. A review on 09/23/2010 of the clinical record for patient #4 revealed that the patient was admitted to the facility on 03/11/2010 for chronic hemodialysis. A review of the patient treatment sheets for 09/20/2010 revealed that the facility	(V 502)	V686 The facility will ensure qualified charge nurse is designated for each shift during hemodialysis treatments. The opening nurse is designated as the charge nurse for the day and this will be identified on the daily schedule on an ongoing basis. FA is responsible for ongoing compliance with POC.	10-15-10

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	9204 SHARON AMITY CHARLOTTE, NC 28205

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(V 502)	Continued From page 29 nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 09/20/2010 at 1807 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 6. A review on 09/23/2010 of the clinical record for patient 60 revealed that the patient was admitted to the facility on 07/21/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/19/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/19/2010 at 1443 the patient was administered the medication "Loperamide (anti diarrhea medication) 2 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.	(V 502)	V750 Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height will also be installed around the medication prep area to further designate this space as a clean area. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers . Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need appropriate cleaning and disinfecting of vascular clamps. cont. pg 31	10-18-10
(V 686)	494.140(h)(3)(i)-(ii) PQ-CHARGE NURSE-12 MO NURSING+3 MO DIALYSIS	(V 686)		

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

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(V 686)	Continued From page 30 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; This STANDARD is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review and staff interview, the facility failed to designate a charge nurse for each shift during hemodialysis treatments. The findings include: A review of the facility policy "Teammate Qualifications, Licensure and Adequate Teammate Staffing" (revision date of 12/2006) revealed "Charge Nurse Standards: The charge nurse responsible for each shift will be a registered nurse, licensed practical nurse/vocational nurse who meets the practice requirements in each State in which he or she is employed." An interview on 09/22/2010 at 0900 with the facility administrator revealed that the facility does not currently have a designated charge nurse during the hemodialysis treatments. The interview revealed "We do not have enough patients to have an established charge nurse. All of the staff knows we have a nurse that can handle things and who to report problems to."	(V 686)	V750 cont.Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward. *The facility has been diligently working on correcting all the issues cited since the survey. The fire alarm has been installed as required. cont pg 32	10-18-10 *10-22-10 for Fire system

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	342527	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	1234 SHARON ABBY CHARLOTTE, NC 28205

(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 31 An interview on 09/22/2010 at 1300 with the facility administrator revealed that the facility does not have a official charge nurse but everyone knows the nurse role. The interview revealed that each shift does not have any formal or assigned charge nurse.	(V 686)	V750 cont. *The physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	
(V 750)	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Not reviewed onsite on 10/26/2010. Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility's governing body failed to provide oversight and have systems in place to ensure the facility implemented and maintained an effective infection control program; and failed to ensure that the facility maintained a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7800 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to conduct fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit	(V 750)	*The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer devise. cont pg 33	*12-31-10 for additional physical plant work

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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
	342627	A. BUILDING _____ B. WING _____	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE FAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 750)	Continued From page 32 blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure safe and effective care for all dialysis patients, and the safety of staff and visitors. The findings include: A. For findings causing the Condition for Infection Control to be not met, see V110 and its associated tags, reprocessing; and failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. ~Cross refer to 494.30 Infection Control Condition- Tag V0110 B. The facility failed to maintain a physical	(V 750)	V750 cont.This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. Please review the attached MSDS Sheet for Renalin, Section 16 for Other Information. The NFPA Flammability Classification for this chemical is 0, thereby qualifying as a low hazard in accordance with NFPA 101 Section 6.2.2.2. NFPA 101 Section A6.2.2.4 for High Hazardous contents are described as the following "contents include occupancies where flammable liquids are handled or used or are stored under conditions involving possible release of flammable vapors; where grain dust, wood flour, or plastic dust, aluminum or magnesium dust, or other explosives are produced; where hazardous chemicals or explosives are manufactured, stored, or handled under conditions producing flammable flyings; and other situations of similar hazards." cont pg 34	10/07/10 09/30/10 12-31-10 for additional physical plant work

PRINTED: 11/16/2010
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
	342527	A. BUILDING _____ B. WING _____	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 750)	Continued From page 33 environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7800 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to remove storage in the front corridor of the facility next to the lobby at the side exit door; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. ~Cross refer to 494.60 Physical Environment Condition~ Tag V0400	(V 750)	V750 cont. *The Storage Room is classified as a Low Hazard area in accordance with Section 6.2.2.2. Due to this, NFPA 101 Section 8.4.1 will require this area as well as the Janitor's Closet to be upgraded to the Minimum 1 Hour Fire Resistant Rating. This will be accomplished by upgrading the existing Non-Rated Partition and Doors according to the attached Sketches. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work

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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
	342527	A. BUILDING 01 - CHARLOTTE EAST DIALYSIS B. WING ______	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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
{K 014}	416.44(b)(1) LIFE SAFETY CODE STANDARD Interior finish on walls and ceilings of exits, enclosed corridors, and exit access furnishing are Class A or B (offices Class A, B, or C). 38.3.3.2, 39.3.3.2 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) In the server room the walls were covered with plywood. Facility is to insure that the walls are in compliance with NFPA 101 Chapter "10.2.3.1 "Interior wall or ceiling finish that is required elsewhere in this Code to be Class A, Class B, or Class C, shall be classified based on test results from NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials."	{K 014}		
{K 029}	416.44(b)(1) LIFE SAFETY CODE STANDARD Hazardous areas separated from other parts of the building by fire barriers have at least one hour fire resistance rating or such areas are enclosed with partitions and doors and the area is provided with an automatic sprinkler system. High hazard areas are provided with both fire barriers and sprinkler systems 38.3.2, 39.3.2 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted, 1) The facility has a Bio Hazard Storage Room and the doors are not self closing or fire rated.	{K 029}		
{K 032}	416.44(b)(1) LIFE SAFETY CODE STANDARD	{K 032}		

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

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.

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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
	342827	A. BUILDING 01 - CHARLOTTE EAST DIALYSIS B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3264 SHARON AMITY CHARLOTTE, NC 28205

(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
(K 032)	Continued From page 1 At least two exits, located remote from each other, are provided for each floor or fire section of the building. 20.2.4.1, 21.2.4.1, 7.5.1.4 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) There is storage in the front corridor next to the lobby that exits to the side exit door.	(K 032)		
(K 045)	416.44(b)(1) LIFE SAFETY CODE STANDARD Emergency illumination is provided in accordance with section 7.9. 20.2.9.1, 21.2.9.1 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The battery operated emergency lights located by the re-use room did not operate when tested.	(K 045)		
(K 050)	416.44(b)(1) LIFE SAFETY CODE STANDARD Fire drills are held at unexpected times under varying conditions, at least quarterly on each shift. The staff is familiar with procedures and is aware that drills are part of established routine. 20.7.1.2, 21.7.1.2 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The facility in-services the staff on fire drills	(K 050)		

PRINTED: 11/15/2010
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
	342827	A. BUILDING 01 - CHARLOTTE EAST DIALYSIS B. WING	R 10/28/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	1200 SHARON AMITY CHARLOTTE, NC 28205

(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
(K 050)	Continued From page 2 each quarter in place of holding fire drills at unexpected times under varying conditions.	(K 050)		
(K 115)	418.44(b)(1) LIFE SAFETY CODE STANDARD Ambulatory health care facilities are divided into at least two smoke compartments with smoke barriers having at least 1 hour fire resistance rating. Doors in smoke barriers are equipped with positive latcher. Doors are constructed of not less than 1¾ inch thick solid bonded core wood or equivalent. Vision panels are provided and are of fixed wire glass limited to 1,296 sq. inch per panel. 20.3.7.1, 20.3.7.2, 20.3.7.3, 21.3.7.1, 21.3.7.2, 21.3.7.3 This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted. 1) The facility is approximately 7500 sq. ft. in size and the facility does not have a smoke barrier separating the building into two smoke compartments.	(K 115)		

DEPARTMENT OF HEALTH AND HUMAN . .VICES — CENTERS F. MEDICARE & MEDICAID SERVICES

ID: W831

Facility ID: 001554

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

1.)ICARE/MEDICAID PROVIDER NO
(L1) 342627
2.STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CHARLOTTE EAST DIALYSIS
(L4) 3204 SHARON AMITY
(L5) CHARLOTTE, NC (L6) 28205

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 10/01/2010 (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 PTIP
02 SNF/NF/Dual	06 LAB	10 NF	14 CORF
03 SNF/NF/Distinct	07 X-Ray	11 IMR	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~~ Stations 16 (L18)

13. Total Certified ~~Beds~~ Stations 16 (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: * Code: B* (L12)

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

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(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)
See Attached Remarks

17. SURVEYOR SIGNATURE
Date: 10/26/2010 (L19)

18. STATE SURVEY AGENCY APPROVAL
Date: 11/2/2010 (L

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

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

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
01/30/2003
(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.
00101
(L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539
(L32)

32. DETERMINATION OF APPROVAL DATE
(L33)

DETERMINATION APPROVAL

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

C&T REMARKS - CMS 1539 FORM

certification survey was conducted onsite September22-October 1, 2010. As a result of the survey in conjunction with a Life Safety Code survey an immediate jeopardy was indentified on October 1, 2010 at 1130. The IJ was no removed during the recertification survey Condition level deficiencies were identified in494.180 Governance, 494.30 Infection Control and 494.60 Physician Environment. Standard level deficiencies were also identified in494.40 Water and Dialysate Quality. 494.50 Reuse, 494.80 Patient Rights and 494.140 Personnel Qualifications. A plan of correction was requested

An onsite follow up was conducted at the facility October26, 2010. The State Agency recommended removal of the IJ at1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey(RM)

DEPARTMENT OF HEALTH AND HUM. 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
	342627	A. BUILDING _____ B. WING _____	R 10/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 follow up was conducted at the facility October 26, 2010. The State Agency recommended removal of the IJ at 1250 based on compliance with a fire alarm system in place. The CMS Dallas regional office was notified of the recommendation. THe conditions in 494.30 Infection Control, 494.60 Physical Environment and 494.180 Governance were not recommended to be in compliance based on the plan of correction not completed during follow up survey.	{V 000}		
{V 110}	494.30 CFC-INFECTION CONTROL	{V 110}		
{V 114}	This CONDITION is not met as evidenced by: 494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.	{V 114}		
{V 117}	This STANDARD is not met as evidenced by: 494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare	{V 117}		

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

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

ID: WB31

Facility ID: 001554

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

MEDICARE/MEDICAID PROVIDER NO.
(L1) 342627

STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CHARLOTTE EAST DIALYSIS
(L4) 3204 SHARON AMITY
(L5) CHARLOTTE, NC (L6) 28205

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 10/01/2010 (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
02 SNF/NF/Dual 06 LAB 10 NF 14 CORF
03 SNF/NF/Distinct 07 X-Ray 11 IMR 15 ASC
04 SNF 08 OPT/SP 12 RHC 16 HOSPICE

FISCAL YEAR ENDING DATE: (L35)
12/31

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

12. Total Facility Beds Stations 16 (L18)

13. Total Certified Beds Stations 16 (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: * Code: B* (L12)

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

14. LTC CERTIFIED BED BREAKDOWN

18 SNF	18/19 SNF	19 SNF	ICF	IMR
(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):
A recertification survey was conducted onsite September 22-October 1, 2010. As a result of the survey in conjunction with a Life Safety Code survey, an immediate jeopardy (IJ) was indentified on October 1, 2010 at 1130. The IJ was no removed during the recertification survey. Condition level deficiencies were identified in 494.180 Governance, 494.30 Infection Control and 494.60 Physician Environment. Standard level deficiencies were also identified in 494.40 Water and Dialysate Quality, 494.50 Reuse, 494.80 Patient Rights 494.140 Personnel Qualifications. A plan of correction was requested.

17. SURVEYOR SIGNATURE
Ralph Mills RN
Date: 10/11/2010 (L19)

18. STATE SURVEY AGENCY APPROVAL Date:
7 (L20)

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

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

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
01/30/2003
(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.
00101
(L31)

30. REMARKS

a. RO RECEIPT OF CMS-1539
(L32)

32. DETERMINATION OF APPROVAL DATE
(L33)

DETERMINATION APPROVAL

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE & MEDICAID SERV S

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
342627	CHARLOTTE EAST DIALYSIS

Type of Survey (select all that apply) [I]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply) [A]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. 14819	09/22/2010	10/01/2010	0.50	0.00	1.00	0.00	4.00	0.50
2. 15546	09/22/2010	10/01/2010	1.00	0.00	19.00	0.00	13.00	10.50
3. 26594	09/22/2010	10/01/2010	0.50	0.00	4.00	0.00	1.50	0.50
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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ENTERS FOR MEDICARE & MEDICAID SERV ..S

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Provider/Supplier Number	Provider/Supplier Name
342627	CHARLOTTE EAST DIALYSIS

Type of Survey (select all that apply)

I	D			

A Complaint Investigation
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E Initial Certification
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Extent of Survey (select all that apply)

A				

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
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SURVEY TEAM AND WORKLOAD DATA

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Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
Team Leader ID 1. 15546	10/26/2010	10/26/2010	1.00	0.00	3.00	0.00	5.00	2.00
2. 13743	10/26/2010	10/26/2010	0.50	0.00	1.00	0.00	0.00	0.00
3.								
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13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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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
	345327	A. BUILDING ______ B. WING ______	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 on-site recertification survey was conducted on September 22 through October 1, 2010. During the survey, concerns were found in the Life Safety Code and a complaint intake was generated for a Life Safety Code survey. The survey on September 30, 2010 from the Life Safety Code survey team resulted in an Immediate Jeopardy (IJ) identification on October 1, 2010 at 1130. The IJ was identified when the facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire. The lack of the fire alarm system or a battery powered smoke detector in the building created a physical environment that increased the risk for harm during fire in the health and safety of patients, visitors and staff while at the facility resulting in immediate jeopardy. The IJ was not removed onsite during the recertification survey. The Conditions for Coverage 494.180 Governance, 494.30 Infection Control and 494.60 Physical Environment were not met.	V 000	V000- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon	
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility failed to implement and maintain an effective infection control program. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or	V 110	permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. The Governing Body will meet monthly x 3 or more often as required to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi- annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Charles Deppenden | TITLE: Administrator | (X6) DATE: 10-15-10

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.

OCT 18 2010

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3304 SHARON AMITY CHARLOTTE, NC 28205

(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 110	Continued From page 1 blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The cumulative affect of these systemic problems resulted in the facility's inability to ensure the provision of quality infection control practices for dialysis patients. The findings include: A. The facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0117 B. The facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0120 C. The facility failed to ensure that staff implemented standard infection control	V 110	V110- Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is place to install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. Plexiglas barriers will be placed to prevent potential cross contamination. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers . Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need for appropriate cleaning and disinfecting of vascular clamps. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. cont pg 3	10-15-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345337	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3104 SHARON AMITY CHARLOTTE, NC 28205

(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 110	Continued From page 2 precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments. ~Cross refer to 494.30(a)(4)(ii) Infection Control - Tag V0122 D. The facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing. ~Cross refer to 494.50(b)(1) Reuse of Hemodialyzers and Bloodlines - Tag V0331 E. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. ~Cross refer to 494.60(b) Physical Environment - Tag V0409 F. The facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. ~Cross refer to 494.30(a)(1)(i) Infection Control - Tag V0114.	V 110	V110 cont. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as pf 09/29/10.The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	10-18-10
V 114	494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by:	V 114		

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	342527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3264 SHARON AMITY CHARLOTTE, NC 28205

(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 114	Continued From page 3 Based on facility policy review, observations and staff interview, the facility failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. The findings include: A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink." Observation on 09/23/2010 at 1300 in the patient treatment area revealed that a paper towel dispenser located for the patients to wash their access sites at the exit area had no available paper towels for use after handwashing. The observation revealed that the paper towels were located in a machine with a sensor to dispense the towels. After washing hands was observed by a patient and surveyor, it was noted that the sensor was not working and no paper towels were available. An interview with the facility's registered nurse during the observation on 09/23/2010 at 1300 revealed that the paper towel dispenser was not working. The interview revealed that paper towels would have to be obtained in a different fashion until the sensor was fixed.	V 114	V114 Paper towels in the dispenser were replaced and threaded properly. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation 10/14/10. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3 weeks, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement ManagementMeetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10/18/10.
V 117	494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas	V 117		

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	342527	A. BUILDING ______ B. WING ______	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3304 SHARON AMITY CHARLOTTE, NC 28205

(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 117	Continued From page 4 should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients. The findings include: 1. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled." Observation on 09/22/2010 at 1028 in the patient	V 117	V117 Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height around the medication prep area to further designate this space as a clean area. FA is responsible for ongoing compliance with POC.	10-18-10

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	343537	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5204 SHARON AMITY CHARLOTTE, NC 28210

(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 117	Continued From page 5 treatment area revealed that a medication cart filled with medications and other unused supplies along with syringes was located directly beside the handwashing sink used by patients to wash their access sites. The sink was designated for patient hand washing and had a sign that was written as "Patients must wash access sites" and located at the base of the sink. The observation further revealed that no splash guard or barrier was noted to prevent water splashes on the medications and supplies. An interview on 09/22/2010 at 1000 with the facility's nursing staff revealed that the patient medications and unused supplies are stored on the cart was kept beside the handwashing sink. The interview revealed that the staff has always kept the medications and supplies in this location due to lack of space. The interview also confirmed that the supplies and medications can get wet from patients and staff washing hands. The interview revealed that the staff had not considered the potential contamination of the medications or supplies. An interview with the facility administrator on 09/22/2010 at 1240 revealed that the supplies and medications should be prevented from being wet or contaminated from people washing their hands at the nearby sink. 2. A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Clean areas should be designated for the preparation, handling, and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where supplies and equipment are handled."	V 117		

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	342837	A. BUILDING _____ B. WING _____	10/5/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5224 SHARON AMITY CHARLOTTE, NC 28205

(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 117	Continued From page 6 Observation on 09/22/2010 at 1550 revealed the medication preparation area used by the facility. The observation revealed that the preparation area is located on a wheeled cart (Craftsman brand) with the medication vials located on top of the cart with a cleared area noted. Observation revealed the medication preparation area (cart) was stationary and located directly beside of the facility's designated handwashing sink for patients to wash their access sites. Observation revealed that the facility had a sign on the sink that was written as "Patients must wash access sites" located at the base of the sink. The observation further revealed that no barrier and splash guard was present to prevent potential cross contamination during medication preparation. No separate clean area was observed for patient medication preparation. An interview on 09/22/2010 at 1555 during the observation with the facility's registered nurse revealed that the cart was the area where the facility's nursing staff prepares patients medications. The interview revealed that she never thought of the potential splashing of water from handwashing sink on the clean medication preparation area. An interview on 09/22/2010 at 1650 with the facility's administrative staff revealed that the potential cross contamination has to be corrected and that lack of space is a problem at the facility.	V 117		
V 120	494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the	V 120		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	342827	A. BUILDING _____ B. WING _____	10/07/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 120	Continued From page 7 dialysis machines' pressure monitors. If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse. Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients. This STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility staff failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients whose dialysis machines were observed to have wet or blood tinged external transducer protectors (Patient stations #1,11). The findings include: A review of the facility's policy "Changing Transducer Protectors" (revision date of 12/2008) revealed "External transducer protectors will be inspected for the presence of blood or saline every 30 minutes during patient treatment and	V 120	V120 The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect the external transducers for the presence of blood or saline every 30 minutes during patient treatment. The external transducer protector is to be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift, and then this will be included in monthly infection control audit going forward. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-7-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	34[illegible]37	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3324 SHARON AMITY CHARLOTTE, NC 28205

(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 120	Continued From page 8 included in the monitoring process. The external transducer protector will be replaced whenever blood or saline is observed in contact with the patient side of the transducer protector." 1. Observation on 09/22/2010 at 1605 for the patient in station #1 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector. 2. Observation on 09/22/2010 at 1610 for the patient in station #11 during tour revealed the patient's external transducer protector was noted to be contaminated with blood. Observation at 1610 through 1645 revealed that no staff member inspected or changed the transducer protector. 3. An interview on 09/22/2010 at 1650 with the facility's registered nurse in the patient treatment area revealed that the staff should change the bloody transducers and check the back of the transducer to make sure that the machine is not contaminated. 4. An interview with the facility's administrative staff on 09/22/2010 at 1655 revealed that the transducer protectors should be immediately changed and checked by staff when they become bloody.	V 120		
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control practices by implementing- (A) And maintaining procedures, in accordance with applicable State and local laws and accepted	V 122		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	343937	A. BUILDING ______ B. WING ______	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 122	Continued From page 9 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 facility policy review, observations and staff interview, the facility failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments. The findings include: A review of the facility's policy "Infection Control for Dialysis Facilities" (revision date 03/2010) revealed "Equipment if accessible to patients and teammates including outside of sharps containers and all work surfaces will be wiped clean with a bleach solution of the appropriate strength after completion of procedures, after spills of blood, throughout the day, and after each treatment. Any areas contaminated with visible blood or body fluids are cleaned promptly with a well wrung out wipe using 1:10 bleach solution." 1. a. Observation on 09/22/2010 at 1013 in the patient treatment area revealed that a rolling wheeled cart with a total of six (6) acid bath jugs on the cart had noted dialysate powder (white in color and chalky)and dust noted on the cart. 1. b. Observation on 09/22/2010 at 1806 revealed trash (paper wrappers) scattered on the patient treatment area floor near patient stations #4 and	V 122	V122- The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor and blood stains and blood stains are cleaned when they occur. Carts will be replaced by 10/15/2010; removed the existing soap dispensers and mounting brackets and replaced with disposable bottle-type dispensers. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need for appropriate cleaning and disinfecting of vascular clamps. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward Results of audits will be reviewed in Quality Improvement Management Meetings(QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	343627	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3224 SHARON AMITY CHARLOTTE, NC 28205

(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 122	Continued From page 10 911. Observation further revealed three trash cans in the patient treatment area that were full and overflowing with trash. 1. a. Observation on 09/22/2010 at 1615 revealed that two automated (GOJO Brand) soap dispensers in the facility's service area at handwashing sinks designated as clean had caked rusted buildup observed directly under the dispensers. No observed evidence of cleaning the dispensers was observed. An interview with the facility administrator on 09/22/2010 revealed that the area should remain free from clutter and dirty buildup around supplies. The interview also revealed that the trash should be cleaned up by the staff. No reason was given as to why the areas were not cleaned by the staff. 2. Observation on 09/22/2010 at 1020 in the patient treatment area revealed that vascular clamps used for patient vascular access sites were located in a container of 1:100 bleach disinfectant and had visible clotted blood on the clamp heads. The observation further revealed that the clamps were not fully submerged in the disinfectant bleach. An interview with the facility administrator on 09/22/2010 at 1215 revealed that the clamps should be below the level of bleach solution according to the facility policy. 3. Observation on 09/22/2010 at 1015 in the patient treatment area revealed blood stains on top of the needle sharps container located directly beside the patient dialyzing in station #14. The blood stains were located on top of the sharps	V 122		

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	342677	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3306 SHARON AMITY CHARLOTTE, NC 28205

(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 122	Continued From page 11 container from 1015 through 1155 without staff observed to clean the stains. An interview with the facility administrator on 09/22/2010 at 1210 revealed that the blood stains should be cleaned when they occur or soon as possible.	V 122		
V 166	494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 5.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 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.	V 166		

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	342537	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5844 SHARON AMITY CHARLOTTE, NC 28208

(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 196	Continued From page 12 This STANDARD is not met as evidenced by: Based on facility policy review, the facility's total chlorine testing log review and staff interview, the facility failed to ensure regularly performed testing to monitor the total chlorine in its water system used in patient hemodialysis and failed to provide color blindness testing in 2 of 4 sampled staff members that test the facility's water system for the presence of chlorine (staff #1,5). The findings include: A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed "Total Chlorine testing is done on a daily basis prior to the first patient treatment and every four (4) hours until all activities that require use of dialysis quality water are completed." A review on 09/23/2010 of the facility's "Routine Total Chlorine Testing Log" for 02/15/2010 revealed that the facility staff failed to document Chlorine testing every 4 hours. The review revealed that for 02/15/2010, the facility staff documented Chlorine testing at 0300, 0540, 1345 and 1740. The review further revealed that the facility staff wrote a time of 0945 on the log but failed to document any results, initials or signatures for the Chlorine testing. The review revealed that the 0945 testing for Chlorine was not documented as completed. An interview with the facility's biomed technician on 09/23/2010 at 1400 revealed that the total chlorine checks should be done every 4 hours with a 15 minute extra window of time given. The interview revealed that some times the nursing staff does not fully document on the water log	V 196	V196- The CSS in-serviced the teammates on the importance of completing the water system total chlorine monitoring every 4 hours per policy 2-07-04 "Daily Water Total Chlorine Monitoring" and documenting on the appropriate log. FA/designee will be checked daily for 7 days then weekly on going. Color blindness testing was completed on the 2 RN's cited and it was found that they did have testing and results are in teammates files. Color blindness testing will be done on all new hires and annually there after. Facility Administrator will spot check 25% of teammates file monthly for 3 months and annually there after. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-18-10

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	343327	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3324 SHARON AMITY CHARLOTTE, NC 28208

(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 196	Continued From page 13 record. A review of the facility's policy "Daily Water System Total Chlorine Monitoring" (revision date 03/2010) revealed that the facility uses the "Lamotte SL-MW Test Kit Colorimeter" for the chlorine testing in its water system. The policy also revealed that the staff instructions include "Holding the Octa-Slide Viewer so that non-direct light enters the back of the comparator. Match the test tube color standard on the Octa-Slide and read the ppm value on the Octa-Slide standard that matches color of the test tube sample." 1. A review of the facility's personnel file for staff nurse #1 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed. 2. A review of the facility's personnel file for staff nurse #3 on 09/23/2010 revealed that the registered nurse did test the facility's water system for total chlorine when needed. The review revealed that the registered nurse failed to have any documented color blindness testing completed. 3. An interview on 09/23/2010 at 1400 with the facility administrator revealed that these staff nurses did not have any documented color blindness testing in her personnel file. The interview revealed no reason as to why these staff nurses did not have any testing done. The interview also revealed that these nurses do check the water system for chlorine and should have color blind testing to ensure that each nurse	V 196		

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	34187	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3304 SHARON AREA CHARLOTTE, NC 28209

(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 186	Continued From page 14 can read the color matches.	V 186		
V 331	494.60(b)(1) REPROCESSING-TRANSPORTATION & HANDLING 11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party. This STANDARD is not met as evidenced by: Based on facility policy review, observation, refrigerator temperature log review and staff interview, the facility failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing. The findings include: A review of the facility policy "Reuse of Dialyzers" (revision date 09/2008) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reuse is begun. Refrigerated dialyzers may be stored for up to 39 hours prior to being reprocessed. The refrigerator used for contaminated dialyzer storage is maintained between 36-50 degrees Fahrenheit."	V 331	V331 Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	9-30-10

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	343837	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3504 SHARON AMY CHARLOTTE, NC 28205

(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 331	Continued From page 16 Observation on 09/22/2010 at 1100 in the patient treatment area revealed a total of seven (7) patient used dialyzers inside of the storage refrigerator used for reuse storage. Inspection of the thermometer revealed that the temperature was 56 degrees Fahrenheit at 1105. The observation of the outside of the refrigerator revealed that a handwritten notation was placed on the front of the refrigerator that was written as "Temperature should be 36 degrees F (Fahrenheit) - 56 degrees F." An interview during the observation at 1105 with a patient dialysis care staff member confirmed that the temperature was 56 degrees F and it should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times. A review on 09/22/2010 of the refrigerator log for 09/2010 revealed that the facility's refrigerator temperature limits should be "35 degrees F to 46 degrees F." The review of the 09/2010 log revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review for 09/01/2010 revealed documentation by staff of the refrigerator temperature to be a range of 32- 38 degrees F. On 09/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 09/22/2010 (date of observation) revealed that the temperature reading was documented as 30-44 degrees F. An interview with the registered nurse in the patient treatment area on 09/22/2010 at 1155 revealed that the refrigerator has constantly been a concern with the temperature readings. The interview revealed "Everytime we put hot dialyzers	V 331		

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	342647	A. BUILDING _____ B. WING _____	10/11/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2324 SHARON AMITY CHARLOTTE, NC 28211

(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 331	Continued From page 16 in that refrigerator, the temperature goes in the 50s." An interview with the facility administrator on 09/22/2010 at 1210 revealed that he was not aware of the elevated temperature readings of the reprocessing storage refrigerator. The interview revealed that the staff had not informed him of the elevated temperature changes.	V 331		
V 340	494.50(b)(1) DIALYZER GERM=90% CONC/CAPS DISINFECT 11.4.1.4 Chemical germicidal procedure: = 90% conc/port caps disinfected If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration. The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer. This STANDARD is not met as evidenced by: Based on facility policy review, observations and staff interview, the facility's reuse staff failed to ensure that reuse dialyzer caps were cleaned and disinfected by appropriate immersion in a germicide before reassembling of the reprocessed dialyzers. The findings include: A review of the facility's policy "Cleaning and	V 340	V340- The CSS in-serviced reuse teammates on policy 6-04-03 Cleaning and Disinfection of Reuse Supplies with emphasis on the need to fully immerse the caps below the germicide surface level. Facility Administrator will monitor submersion of caps per policy for 7 days then once a week for 2 weeks, then monthly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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	343377	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3235 SHARON AMITY CHARLOTTE, NC 28205

(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 340	Continued From page 17 Disinfection of Reuse Supplies Policy" (origination date 08/2008) revealed "Reuse supplies will be cleaned and disinfected with a 1% peracetic acid solution for a minimum of 30 minutes. Blood and dialysate port caps, barrier adapters, extension tubing must be disinfected for a period of 30 minutes but no greater than 24 hours prior to use." Observation on 09/22/2010 at 1005 in the facility's reprocessing room revealed that reprocessing caps and port caps used for patient reprocessed dialyzers were placed in two 1% peracetic acid (germicide) solution plastic containers located in the designated dirty section for disinfection. The observation revealed that the caps in both containers of the disinfectant were not fully immersed below the disinfectant germicide surface level. The observation was during a time when no staff was present in the reprocessing area. An interview on 09/22/2010 at 1520 with the facility's reuse technician revealed that the containers with the caps should have the caps fully below the level of the disinfection surface. The interview revealed no reason as to why the caps in both containers were not below the disinfectant surface level.	V 340	V400-Physical Environment Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. * The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than 10-18-10. The fire system was ordered on the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. *In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. cont pg 19	*10-22-10 for Fire system
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Based on observations as referenced in the Life Safety Report of a complaint investigation completed 09/30/2010, facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the	V 400		*12-31-10 for additional physical plant work

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	342837	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3214 SHARON AMITY CHARLOTTE, NC 28205

(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 400	Continued From page 18 facility failed to maintain a physical environment that decreased the potential risks to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure the health and safety of patients, staff and visitors at the dialysis facility. The findings include: A. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying	V 400	V400 cont. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits, cont . pg 19	9-30-10 *10-22-10 for Fire system *12-31-10 for additional physical plant work 10/07/10

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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
	342937	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5224 SHARON AMITY CHARLOTTE, NC 28205

(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 400	Continued From page 19 conditions each quarter in place of only inservicing staff on the fire drills; and failed to remove storage in the front corridor of the facility next to the lobby at the side exit door. ~Cross refer to 494.60(e)(1) Physical Environment Fire-Safety and Life Safety Code- Tag V0417 B. The facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or unpassable. ~Cross refer to 494.60(d) Physical Environment - Tag V0408 C. The facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. ~Cross refer to 494.60(b) Physical Environment - Tag V0403.	V 400	V400 cont. The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0"ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work 10-1-10 09/30/10.
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 on facility policy review, observations,	V 403		

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	342827	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	9224 SHARON AMITY CHARLOTTE, NC 28205

(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 20 refrigerator temperature log review and staff interview, the facility failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reused dialyzers. This deficient practice placed all patients participating in the reprocessing program at risk for exposure to contamination from bacterial growth in the dialyzers. The findings include: A review of the facility policy "Reuse of Dialyzers" (revision date 08/2009) revealed "Dialyzers are reprocessed within two (2) hours or stored in a designated reuse refrigerator to retard bacterial growth until reprocessing is begun. Refrigerated dialyzers may be stored for up to 36 hours prior to being reprocessed. The refrigerator used for contaminated dialyzer storage is maintained between 36-50 degrees Fahrenheit." Observation on 09/22/2010 at 1100 in the patient treatment area revealed that the facility had a refrigerator in the patient treatment area that was used to store reused dialyzers at a temperature to inhibit potential bacterial growth. The observation revealed a total of seven (7) patient used dialyzers inside of the refrigerator used for the reuse storage. The observation at 1105 of the thermometer revealed that the temperature was 56 degrees Fahrenheit. The observation of the outside of the refrigerator revealed that a handwritten note was placed on the front of the refrigerator indicating "Temperature should be 36 degrees F." An interview during the observation at 1105 with patient dialysis care staff member revealed that	V 403	V403 Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the teammates on Policy 6-01-08 Reuse of Dialyzers with emphasis on dialyzer storage in reuse refrigerator including the temperature required to be maintained between 36-50 degree Fahrenheit and actions to take if temperature is out of range. Proper documentation of a single temperature to be recorded was also reviewed. Facility Administrator or designee will review the log everyday for 3 days, weekly on each shift x3 weeks, and then the log will be monitored daily by the charge nurse on an on-going basis. Results of audits will be reviewed in Quality Improvement Management Meetings(QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	9-30-10

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	342627	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	1334 SHARON AMITY CHARLOTTE, NC 28205

(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 21 the temperature was 88 degrees F and that the temperature should not be that high. The staff member revealed that the temperature in the refrigerator had been elevated for a while and was not able to give specific dates or times. A review on 09/22/2010 of the refrigerator log for 09/2010 revealed that the facility's refrigerator temperature limits should be "36 degrees F to 46 degrees F." The review of the log for 09/2010 revealed that the staff had documented temperature checks as ranges instead of a single documented temperature. Review of 09/01/2010 revealed documentation by the staff that the refrigerator temperature to be a range of 32- 35 degrees F. On 09/07/2010 the range of the temperature was documented as 32-42 degrees F. Review of the log for 09/22/2010 (date of observation) revealed that the temperature reading was documented as 30-48 degrees F. An interview on 09/22/2010 at 1330 with the facility administrator revealed that the temperatures of the refrigerators should be monitored every day and that the exact temperature should be documented. The interview also revealed that the raisa storage refrigerator should not be greater than 50 degrees F. The interview further revealed that the log used by the staff was meant for use for refrigerators containing medications, and that the limits on the log were set for medication storage, instead of showing the highest degree of 50 F.	V 403		
V 408	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten	V 408		

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	343527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3234 SHARON AMITY CHARLOTTE, NC 28205

(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 408	Continued From page 22 the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. This STANDARD is not met as evidenced by: Based on observations, fire safety reports review and staff interview, the facility failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit passageway was blocked or unpassable. The findings include: Observation on 09/22/2010 at 1015 during tour of the facility's patient treatment area revealed that the facility had a total of sixteen (16) total stations for hemodialysis treatments. The facility hemodialysis station locations were against the four (4) walls of the patient treatment area. The observation of the facility's fire safety emergency evacuation route revealed that the facility had one emergency exit leading directly into a hallway from the patient treatment area. The exit route led to a door with a fire exit sign leading out to the facility's lobby area and main exit doors. The observation further revealed that there was no other exit location or emergency evacuation route in the patient treatment area. Observation revealed that only one (1) exit route/egress existed in the patient treatment area for patients, visitors and staff. No other doors or exits were observed in the patient treatment area.	V 408	V408- *The current Patient Station #7 will be relocated. A minimum 5'-0" portion of the Treatment Chase will be demolished to provide a clear path to a New 3'-0" Exit Only Door with Panic Hardware. A minimum 5'-0"ADA Accessible Sidewalk will be installed to connect this new door to the existing parking area. After installed the emergency evacuation plan will be updated to reflect the exit routes. A copy of Certificate of Occupancy has been requested from the city of Charlotte, original architect and general contractor. Going forward any fire inspections will be kept on file in the facility. FA is responsible for ongoing compliance with POC. *The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than 10-18-10. The fires system was ordered on the day of the survey.The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	10-13-10 *12-31-10 for additional physical plant work

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	342827	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2304 SHARON ABBEY CHARLOTTE, NC 28208

(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 408	Continued From page 23 An interview on 09/22/2010 at 1110 with the facility's registered nurse in the patient treatment area revealed that that there was only one way out of the patient treatment area of the facility. The interview revealed, "I have never thought about it, but if there was a fire, the only way out would be through the that area (staff indicating by pointing to the one exit) there." The interview revealed that the staff were trained in fire drills to use the one exit in the treatment area to evacuate the patients. The interview also revealed that the facility administration did not instruct the staff what to do if that one fire exit route was blocked with fire or other objects. A review of the local fire marshall reports on 09/23/2010 revealed that no report could be found at the facility where any fire marshall or local fire inspection was done at the facility to determine fire safety compliance. No documentation could be produced by the facility that revealed any fire safety inspections were conducted at the facility. An interview on 09/23/2010 at 1000 with the facility administrator and regulatory staff revealed that the facility could not find or produce a fire marshall or local county/city report for any past inspection of the the facility's fire safety. The interview revealed that the facility should have one on file, but the administrative staff were unable to produce this document during the survey.	V 408	V417- 1.The fire system was ordered on the day of the survey. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10 2. The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. 3. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. 4. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof	*10-22-10 for Fire system
V 417	494.30(a)(1) PE-FIRE SAFETY-LIFE SAFETY CODE 2000 (1) Except as provided in paragraph (a)(2) of this section, by February 9, 2009, The dialysis facility must comply with applicable provisions of the	V 417	deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer devise. cont pg 25	

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	342827	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2304 SHARON AMITY CHARLOTTE, NC 28205

(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 417	Continued From page 24 2000 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference at §403.744 (a)(1)(i) of this chapter). This STANDARD is not met as evidenced by: Based on observation on Thursday 9/30/10 between 8:30 AM and 11:00 AM the following was noted: 1) The facility did not have a fire alarm system nor was there any battery powered smoke detector found in the building. 2) The Server Room is lined with a plywood interior finish on the walls which does not comply with the required fire resistance rating for the area. 3) Facility is approximately 7600 sq. ft. in size and does not have a smoke barrier separating the building into two separate smoke compartments. 4) The facility has Bio Hazard Storage room is not self closing nor fire-rated. 5) The emergency battery operated light located next to the re-use room was not operational when tested. 6) The facility inservices the staff on Fire Drills each quarter in place of holding Fire drills being held at unexpected times under varying conditions. 7) There is storage in the front corridor next to the lobby to the side exit door, partially blocking the exit.	V 417	V417 cont. 5. This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. 6. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. 7. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. *The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues.	*12-31-10 for additional physical plant work
V 463	494.70(a)(12) PR-RECEIVE SERVICES OUTLINED IN POC The patient has the right to- (12) Receive the necessary services outlined in	V 463		

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	343837	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3304 SHARON AMITY CHARLOTTE, NC 28205

(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 483	Continued From page 28 the patient plan of care described in §484.60; This STANDARD is not met as evidenced by: Based on facility policy review, clinical record review, patient interview and staff interview, the facility failed to include the patient in the facility's interdisciplinary team annual meeting involving the patients plan of care for 2 of 7 sampled patient records (Patient #1,2). The findings include: A review of the facility policy "Patient Assessments and Plan of Care" (revision date 03/2010) revealed "The patient plan of care will be completed by the facility's interdisciplinary team, including patient or personal representative and be signed by team members including the patient or the patient's personal representative." A review on 09/22/2010 of the open clinical record for patient #1 revealed that the patient was admitted to the facility on 09/02/2005. The review of the clinical record revealed that an "Annual Care Plan" meeting was scheduled for Wednesday 03/03/2010 for the patient. A review of the form inviting the patient was found in the clinical record of the patient. The review of the form revealed that the facility's dietician signed the staff signature portion and dated it 03/03/2010 but failed to obtain a patient signature that she would either attend or not attend the meeting. The space was not completed and left blank but the staff member (dietician) had signed the staff signature witness section. No documentation was found where the patient received individualized care and a chance to participate in her plan of	V 483	V463- Policy #1-01-07 Patient Assessment and Plan of Care" was reviewed with the interdisciplinary team (IT) with emphasis on the need to include the patient/patient designee in the development of the plan of care unless the patient declines. Each patient will be given a written and verbal invitation to the care plan meeting as care plans become due. Patients will be asked to sign invitation and note if they will attend. If patient declines the invitation the plan of care a member of the IDT will review with them and ask for their signature on the plan. If the patient refuses to sign, this will be noted in the record as well. FA/designee will audit all plans of care completed x 3months and then 10% of those completed quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-18-10

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	342827	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	1224 SHARON AMITY CHARLOTTE, NC 28204

(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 463	Continued From page 26 care meeting. An interview with patient #8 on 09/22/2010 at 1040 during the facility tour and observation revealed that the patient had not been invited by the facility staff to her plan of care meetings. The interview revealed "I am usually told they happened, but the staff does not really invite me to attend. I would try to make it if possible. I usually sign the paper after the meeting happens." An interview with the facility administrator on 09/22/2010 at 1529 revealed that that this form should have indicated whether the patient was going to attend or not, that the staff should not sign this form before the patient signed, and that patients are invited to the meetings and usually sign the form.	V 463		
V 502	494.80(a)(1) PA-ASSESS CURRENT HEALTH STATUS/COMORBIDS The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions. This STANDARD is not met as evidenced by: Based on facility policy review, clinical record review and staff interview, the facility failed to ensure that registered nurses met the clinical needs of patients by failing to document and reassess as needed (PRN)medication administration in in 5 of 5 sampled patients receiving PRN medication (Patients #1,2,3,4,6).	V 502	V502- The Required documentation for the administration of PRN medication to include the reason given and effectiveness of the medication was reviewed with RN's. Facility Administrator will monitor documentation of PRN meds once a week for 3 weeks then complete random audits quarterly. Results of audits will be reviewed in Quality Improvement Management Meetings (QIFMM) and addressed as necessary. FA is responsible for ongoing compliance with POC.	10-15-10

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	342527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5304 SHARON AMITY CHARLOTTE, NC 28205

(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 502	Continued From page 27 The findings include: 1. A review on 09/22/2010 of the clinical record for patient #1 revealed that the patient was admitted to the facility on 03/02/2005 for chronic hemodialysis. A review of the patient treatment sheets for 08/16/2010 and 08/27/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/16/2010 at 1706 and on 08/27/2010 at 1430 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 2. A review on 09/23/2010 of the clinical record for patient #2 revealed that the patient was admitted to the facility on 10/20/2008 for chronic hemodialysis. A review of the patient treatment sheets for 08/24/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/24/2010 at 1148 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at	V 502		

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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
	342127	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2244 SHARON AMITY CHARLOTTE, NC 28208

(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 502	Continued From page 28 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 3. A review on 09/20/2010 of the clinical record for patient #3 revealed that the patient was admitted to the facility on 12/29/2003 for chronic hemodialysis. A review of the patient treatment sheets for 09/18/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 09/18/2010 at 1422 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 4. A review on 09/22/2010 of the clinical record for patient #4 revealed that the patient was admitted to the facility on 03/11/2010 for chronic hemodialysis. A review of the patient treatment sheets for 09/20/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 09/20/2010 at 1807 the patient was administered the medication "Acetaminophen 650 milligrams" by mouth. No	V 502	V686 The facility will ensure qualified charge nurse is designated for each shift during hemodialysis treatments. The opening nurse is designated as the charge nurse for the day and this will be identified on the daily schedule on an ongoing basis. FA is responsible for ongoing compliance with POC.	10-15-10

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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
	342627	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	2304 SHARON AMITY CHARLOTTE, NC 28205

(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 602	Continued From page 29 other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication. 5. A review on 09/23/2010 of the clinical record for patient #8 revealed that the patient was admitted to the facility on 07/21/2009 for chronic hemodialysis. A review of the patient treatment sheets for 08/19/2010 revealed that the facility nursing staff administered a PRN medication to the patient without any documentation for the reason why administered and the reassessment of the medication effectiveness. The review revealed that on 08/19/2010 at 1445 the patient was administered the medication "Loperamide (anti diarrhea medication) 2 milligrams" by mouth. No other documentation was found regarding the administered medication and/or the effectiveness of the medication. An interview on 09/23/2010 at 1400 with the facility administrator revealed that the patient should have had documentation from the nursing staff for the reason that the PRN medication was administered and the effectiveness of the medication.	V 602	V750 Members of the Governing Body (GB) have met to review the Statement of Deficiencies (SOD) and formulate the following Plan of Correction (POC). The standards under the Conditions of Infection Control (V110); Physical Environment (V400); and Governance (V750 that are not met as well as other standards, contain specifics of corrective plans. The facility will ensure that the GB provides oversight and has systems in place to see that the facility is equipped and maintained to provide a safe, functional and comfortable environment and an effective infection control program is in place. Eliminated the use of a medication cart and the medication station has been relocated. A designated clean area was created for medication prep on one of the island nurse stations in the treatment area 09/29/10. A plan is in place to also install separation barriers 12" in height will also be installed around the medication prep area to further designate this space as a clean area. The Clinical Services Specialist (CSS) in-serviced the teammates on policy #1-03-11 "Changing Transducers Protectors" on 10/07/2010 with emphasis on the need to change and inspect wet and/or blood contaminated external transducers . Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift.3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the teammates on policy 1-04-08 "Utilizing Vascular Access Clamps" and policy 1-05-01 "Infection Control for Dialysis Facilities" on 10/7/2010 with emphasis on the need appropriate cleaning and disinfecting of vascular clamps. cont. pg 31	10-18-10
V 668	484.140(b)(3)(i)-(ii) PQI-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	V 668		

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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
	342527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3304 SHARON AMITY CHARLOTTE, NC 28205

(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 30 experience in providing nursing care to patients on maintenance dialysis; This STANDARD is not met as evidenced by: Based on facility policy review and staff interview, the facility failed to designate a charge nurse for each shift during hemodialysis treatments. The findings include: A review of the facility policy "Teammate Qualifications, Licensure and Adequate Teammate Staffing" (revision date of 12/2008) revealed "Charge Nurse Standards: The charge nurse responsible for each shift will be a registered nurse, licensed practical nurse/vocational nurse who meets the practice requirements in each State in which he or she is employed." An interview on 09/22/2010 at 0900 with the facility administrator revealed that the facility does not currently have a designated charge nurse during the hemodialysis treatments. The interview revealed "We do not have enough patients to have an established charge nurse. All of the staff knows we have a nurse that can handle things and who to report problems to." An interview on 09/22/2010 at 1900 with the facility administrator revealed that the facility does not have a official charge nurse but everyone knows the nurse role. The interview revealed that each shift does not have any formal or assigned charge nurse.	V 686	V750 cont.Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. The CSS in-serviced the team on the importance of maintaining a clean environment and ensuring trash is picked up from the floor. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x3 weeks, and then this will be included in monthly infection control audit going forward. Upon inspection, it was determined that this refrigerator was unable to maintain temperature within acceptable limits. The reuse refrigerator has been replaced and verified to be within acceptable limits as of 09/29/10. The CSS in-serviced the team on policy 6-01-08 "Reuse Policy" and reviewed refrigerator log with temp ranges. Paper towel dispenser at patient prep area is a battery powered hands free style dispenser. The dispenser was found to be inoperative. Replaced batteries and verified operation. Facility Administrator or designee will monitor team everyday for 3 days, weekly on each shift x 3weeks and then this will be included in monthly infection control audit going forward. *The facility has been diligently working on correcting all the issues cited since the survey. This report was received on 10-11-10 stating completion dates could be no later than 10-18-10. The fire system was ordered the day of the survey. The installation of the fire system is subject to the availability of the vendor who is working with the facility to expedite the process. An agreement is in place with a local vendor to install a smoke detection system and fire alarm system that meets local code on 10-22-10. cont pg 32	10-18-10 *10-22-10 for Fire system
V 750	404.1801 CPC-GOVERNANCE			

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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
	342627	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	7324 SHARON AMITY CHARLOTTE, NC 28226

(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 750	Continued From page 31 This CONDITION is not met as evidenced by: Based on facility policy review, observations, refrigerator temperature log review and staff interviews, it was determined that the facility's governing body failed to provide oversight and have systems in place to ensure the facility implemented and maintained an effective infection control program; and failed to ensure that the facility maintained a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is approximately 7600 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to conduct fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drill; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. The cumulative effect of these systemic problems resulted in the facility's inability to ensure safe and effective care for all dialysis patients, and the safety of staff and visitors.	V 750	V750 cont. In addition the physical plant issues will require more time as they are also dependent upon permits and vendor availability as well the fact that much of the work will have to be completed during non-operational hours. These issues have been evaluated by an architect and a plan to move forward is in place. Estimated time frame to complete is 9-12 weeks. We request your consideration in these particular issues. The Server Room's Plywood will be removed. The currently non-rated Walls will be upgraded to Minimum 1 Hour Fire Rated Partitions, in accordance with the attached sketches. This will allow the 1 Hour Fire Rating to run behind the plywood finishing material once reinstalled. Since the Facility is approximately 7,600 sq. ft. in size, the required Smoke Compartmentalization will be accomplished by extending the existing non-rated partitions to the Roof Deck, as indicated in the attached Sketches. This will provide the minimum 1,140 S.F. in either compartment as well as the minimum exiting requirements. New 1 Hour Smoke/Fire Partition and 20 Minute Fire Rated Doors will be installed at key locations in order to provide the needed pathway from exterior wall to exterior wall. Each door will also include a passage latch system, 1 Hour Fire Rated Frame, and Closer device. The Facility Bio Hazard Storage room is not self closing nor fire-rated. The facilities Bio Hazard Storage room will be separated from the Corridor by upgrading and extending the existing non-rated partition to the roof deck as a minimum 1 Hour Fire Resistant assembly. The Door between the Bio Hazard Storage room and the Corridor will be upgraded to a minimum 45 min. rated door with a minimum 1 hour Rated Frame and Closer devise. cont pg 33	*12-31-10 for additional physical plant work

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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	348627	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3324 SHARON AREA CHARLOTTE, NC 28205

(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 780	Continued From page 32 The findings include: A. For findings causing the Condition for Infection Control to be not met, see V110 and its associated tags. reprocessing; and failed to ensure that a clean area was designated to prevent potential cross-contamination of medications/supplies and for staff to prepare, handle and store medications to be administered to patients; failed to change and inspect contaminated external transducer protectors in 2 of 2 observed patients with wet or blood tinged external transducer protectors; failed to ensure that staff implemented standard infection control precautions by cleaning equipment surfaces with removal of trash from floors in the patient treatment area, appropriate cleaning and disinfecting of vascular clamps used in patient treatments and cleaning blood stains from work surfaces during patient hemodialysis treatments; failed to ensure that patient used dialyzers were adequately refrigerated to inhibit bacterial growth before reprocessing; and failed to ensure that patients had a supply of paper towels available at handwashing sinks in the patient treatment area. -Cross refer to 494.30 Infection Control Condition- Tag V0110 B. The facility failed to maintain a physical environment that decreased the potential risk to the health and safety of patients, visitors and staff. The facility failed to have a fire alarm system or a battery powered smoke detector in the building to ensure patient, staff and visitor safety in the event of a fire; failed to have a smoke barrier separating the building into two separate smoke compartments for a facility that is	V 780	V750 cont.This emergency battery operated light was repaired and operation verified by an outside vendor 10/07/10. This will be monitored to ensure it is in working order during monthly facility audits. Fire drill was conducted on 10/1/2010 and will be conducted quarterly at unexpected times by the Facility Administrator or designee. These fire drills will be documented and evaluated in QIFMM. Storage items have been removed from the corridor and relocated to the records storage area as of 09/30/10. Route will be monitored daily for 7 days then weekly for 2 weeks then monthly for 3 months by Facility Administrator or designee. Please review the attached MSDS Sheet for Renalin, Section 16 for Other Information. The NFPA Flammability Classification for this chemical is 0, thereby qualifying as a low hazard in accordance with NFPA 101 Section 6.2.2.2. NFPA 101 Section A6.2.2.4 for High Hazardous contents are described as the following "contents include occupancies where flammable liquids are handled or used or are stored under conditions involving possible release of flammable vapors; where grain dust, wood flour, or plastic dust, aluminum or magnesium dust, or other explosives are produced; where hazardous chemicals or explosives are manufactured, stored, or handled under conditions producing flammable flyings; and other situations of similar hazards." cont pg 34	10/07/10 09/30/10 12-31-10 for additional physical plant work

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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
	34527	A. BUILDING _____ B. WING _____	10/01/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	5234 SHARON AMITY CHARLOTTE, NC 28205

(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 750	Continued From page 33 approximately 7800 square feet in size; failed to have a hazardous storage area that is 1 hour fire rated construction and sprinklered when storing twelve (12) cases of highly flammable material (Renalin that is used for disinfection of dialyzers); failed to ensure that an emergency battery operated light located next to the re-use room was in operation; failed to hold fire drills at unexpected times under varying conditions each quarter in place of only inservicing staff on the fire drills; failed to remove storage in the front corridor of the facility next to the lobby at the side exit door; failed to ensure an effective emergency evacuation route for the facility's patients, staff and visitors to include an alternative fire exit route from inside the patient treatment area in the event of the one fire exit blocked by fire; and failed to monitor and maintain refrigerator temperatures to inhibit potential bacterial growth in stored reprocessed (reuse) dialyzers. ~Cross refer to 494.60 Physical Environment Condition- Tag V0400	V 750	V750 cont. The Storage Room is classified as a Low Hazard area in accordance with Section 6.2.2.2. Due to this, NFPA 101 Section 8.4.1 will require this area as well as the Janitor's Closet to be upgraded to the Minimum 1 Hour Fire Resistant Rating. This will be accomplished by upgrading the existing Non-Rated Partition and Doors according to the attached Sketches. The attached Sketches are respectfully submitted for your review and comments. Should you require additional information, please contact our office. The Governing Body will meet monthly x 3 to ensure compliance with POC. Further compliance to the POC will be reviewed during monthly QA meetings and reported to the Governing Body no less than semi-annually. The Facility administrator (FA) representing the GB will be responsible for ensuring implementation and ongoing compliance with this POC.	*12-31-10 for additional physical plant work

EPARTMENT OF HEALTH AND HUMAN . VICES — CENTERS FC IEDICARE & MEDICAID SERVICES

ID: OB2211

Facility ID: 001554

MEDICARE/MEDICAID CERTIFICATION AND TRANSMITTAL

PART I - TO BE COMPLETED BY THE STATE SURVEY AGENCY

MEDICARE/MEDICAID PROVIDER NO.
(L 342627
STATE VENDOR OR MEDICAID NO.
(L2)

3. NAME AND ADDRESS OF FACILITY
(L3) CHARLOTTE EAST DIALYSIS
(L4) 3204 SHARON AMITY
(L5) CHARLOTTE, NC (L6) 28205

4. TYPE OF ACTION: 6 (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 04/15/2009 (L34)

ACCREDITATION STATUS: ___ (L10)
0 Unaccredited 1 JCAHO
2 AOA 3 Other

7. PROVIDER/SUPPLIER CATEGORY 09 (L7)
01 Hospital 05 HHA 09 ESRD 13 FTIP
02 SNF/NF/Dual 06 LAB 10 NF 14 CORF
03 SNF/NF/Distinct 07 X-Ray 11 IMR 15 ASC
04 SNF 08 OPT/SP 12 RHC 16 HOSPICE

FISCAL YEAR ENDING DATE: (L35)
12/31

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

2. 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

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

B. Not in Compliance with Program Requirements and/or Applied Waivers: * Code: A1* (L12)

14. LTC CERTIFIED BED BREAKDOWN

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

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

16. STATE SURVEY AGENCY REMARKS (IF APPLICABLE SHOW LTC CANCELLATION DATE):
A complaint investigation was conducted onsite at the facility April 15, 2009. As a result of the investigation, a standard level deficiency was found in 494.30 Infection Control. A plan of correction was requested. Refer to intake #NC00054102.

17. SURVEYOR SIGNATURE
Robin McBrayer
Date: 06/01/2009 (L19)

18. STATE SURVEY AGENCY APPROVAL
Date: 6/2/09 (L20)

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

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

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 (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.
00000 (L31)

30. REMARKS

31. RO RECEIPT OF CMS-1539 (L32)

32. DETERMINATION OF APPROVAL DATE (L33)

DETERMINATION APPROVAL

Control Number: OB2211 (NC000541)

Department of Health and Human Services
Medicare/Medicaid/CLIA Complaint Form

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number: 3 4 2 6 2 7

Facility Name and Address:
CHARLOTTE EAST DIALYSIS
3204 SHARON AMITY
CHARLOTTE, NC 28205

3. Date Complaint Received: 0 3 0 6 0 9 (M M D D Y Y)

4. Receiving Component: 1 State Survey Agy. / [1] 2 RO

5. Date Acknowledged: 0 3 2 7 0 9 (M M D D Y Y)

6A. Source of Complaint: 1 [1] / 2 [ ] / 3 [ ]
1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants: 0 1

7. Allegations

	7.A. Category	7.B. Findings (To be completed following investigation)	7.C. Number of Complainants per Allegation
1	0 6	0 2	0 1
2			
3			
4			
5			

7.A. Category:
1 Resident Abuse
2 Resident Neglect
3 Resident Rights
4 Patient Dumping
5 Environment
6 Care or Services
7 Dietary
8 Misuse of Funds/ Property
9 Certification/Un-authorized Testing
10 Proficiency Test
11 Falsification of Records / Reports
12 Unqualified Personnel
13 Quality Control
14 Specimen Handling
15 Diagnostic Erroneous Test Results
16 Fraud/False Billing
17 Fatality/Transfusion Fatality
18 Other (Specify)
19 Life Safety Code
20 State Monitoring

7.B. Findings (To be completed following investigation):
01 Substantiated
02 Unsubstantiated/ Unable to Verify

8. Action (if multiple actions, indicate earliest action): [3]
1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify)
6 Other Action (Specify)
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by: [1]
1 State Survey Agency
2 RO
3 Other (Specify)

10. Complaint Survey Date: 0 4 1 5 0 9 (M M D D Y Y)

11. Findings (Under 7B Above)

12. Proposed Actions Taken by SA or RO

1: 0 4
2:
3:

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify)
23 Enforcement Action

13. Date of Proposed Action: 0 4 1 5 0 9 (M MD D Y Y)

14. Parties Notified and Dates

Party	Date
1. [1]	0 4 1 6 0 9
2. [2]	0 4 2 1 0 9
3. [ ]	

1 Facility
2 Complainant
3 Representative
4 Other (Specify)

(M M D D Y Y)

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567): (M MD DY Y)

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt: (M M D D Y Y)

17. CMS RO/MSA Action: [ ]
1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify)
14 Enforcement Action

18. Date of Final Action Sign-of: (M M D D Y Y)

CMS RO

FORM CMS-562 (1-93)

RECEIVED APR 29 2009

PRINTED: 04/15/2009
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
	342627	A. BUILDING _____ B. WING _____	C 04/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 147	494.30(a)(2) CDC RR-10 AS ADOPTED BY REFERENCE 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 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 the facility's policies and procedures, clinical record review, and staff interview, the facility's staff failed to change or clean an exit site	V 147	See Attached	5/15/09

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

Charlotte Sheppard RN/FA 4-24-09

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.

PRINTED: 04/15/2009
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
	342627	A. BUILDING _____ B. WING _____	C 04/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 147	Continued From page 1 of a patient's central venous catheter dressing 7 of 16 hemodialysis treatments (Patient #1). The findings include: Review of the facility's policy "Central Venous Catheter (CVC) Care" (revised on 04/2009) revealed that the purpose of the care was to reduce the risk of infection in the patient and to reduce trauma to the catheter and exit site while minimizing blood loss. The policy review also revealed that cuffed catheters with well-healed exit sites may not require a dressing but still require examination and cleaning of exit site each treatment. A clinical record review on 04/15/2009 for patient #1 revealed that the 32 year old patient had his first dialysis treatment at the facility 12/30/2004. The review revealed that the patient had "CVC right side femoral catheter" used for his hemodialysis treatments at the facility. The review of the patient's post treatment flow sheets on the dates of 03/10/2009, 03/26/2009, 03/28/2009, 04/04/2009, 04/07/2009, 04/11/2009 and 04/14/2009 revealed that no staff either changed the patient's CVC dressing or documented cleaning of the patient's dressing after his hemodialysis treatments. No documentation was found in the patient's clinical record where the facility's administration or the patient's physician was made aware of the patient not having his CVC catheter cleaned after each hemodialysis treatment. Staff interview on 04/15/2009 at 1010 with the facility's administrator revealed that he was not aware of the patient refusing catheter care after the 7 missed changing or cleaning of the exit site.	V 147	1. An in-service on Central Venous Catheter changes and initiation of treatment was Completed on 4-15-09 by the vascular Access Manager with attendance all pct's and RNs 2. Teammates will be observed by RN or Facility Administrator to assure company guidelines are adhered to. Teammates will be observed on 3 occasions. 3. Bi-weekly meetings between RN's and Facility Administrator will be held to discuss any concerns or issues pertaining to any patient or teammate. 4. Teammates and RN's are instructed to document any event that is a variation from company policy and procedure and/or any Physicians order 5. MD was fully aware of pt's refusal of dressing changes. On several MD visits, MD verbalized to pt. the importance of dressing changes performed in-center by RN	5-15-09

PRINTED: 04/15/2009
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
	342627	A. BUILDING _____ B. WING _____	C 04/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CHARLOTTE EAST DIALYSIS	3204 SHARON AMITY CHARLOTTE, NC 28205

(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 147	Continued From page 2 The interview also revealed that the staff should make the administration aware if the patient was refusing the medication and cleaning of the CVC catheter exit site. Reference intake #NC00054102.	V 147		

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE & MEDICAID SEP 'ES

FORM APPROVED

SURVEY TEAM COMPOSITION AND WORKLOAD REPORT

Provider/Supplier Number	Provider/Supplier Name
142627	CHARLOTTE EAST DIALYSIS

Type of Survey (select all that apply)

[A] [ ] [ ] [ ] [ ]

A Complaint Investigation
B Dumping Investigation
C Federal Monitoring
D Follow-up Visit
E Initial Certification
F Inspection of Care
G Validation
H Life Safety Code
I Recertification
J Sanctions/Hearing
K State License
L CHOW
M Other

Extent of Survey (select all that apply)

[D] [ ] [ ] [ ] [ ]

A Routine/Standard Survey (all providers/suppliers)
B Extended Survey (HHA or Long Term Care Facility)
C Partial Extended Survey (HHA)
D Other Survey

SURVEY TEAM AND WORKLOAD DATA

Please enter the workload information for each surveyor. Use the surveyor's identification number.

Surveyor ID Number (A)	First Date Arrived (B)	Last Date Departed (C)	Pre-Survey Preparation Hours (D)	On-Site Hours 12am-8am (E)	On-Site Hours 8am-6pm (F)	On-Site Hours 6pm-12am (G)	Travel Hours (H)	Off-Site Report Preparation Hours (I)
1. 15546	04/15/2009	04/15/2009	1.00	0.00	4.00	0.00	11.00	2.50
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								

Total SA Supervisory Review Hours..... 1.00

Total RO Supervisory Review Hours.... 0.00

Total SA Clerical/Data Entry Hours.... 0.50

Total RO Clerical/Data Entry Hours..... 0.00

Was Statement of Deficiencies given to the provider on-site at completion of the survey?.... No

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

FORM APPROVED
OMB 0938-0360

END STAGE RENAL DISEASE APPLICATION/NOTIFICATION AND SURVEY AND CERTIFICATION REPORT

PART I - APPLICATION - TO BE COMPLETED BY FACILITY

1. Name of Facility: Davita East
2. Provider Number: 3 4 2 6 2 7
3. Street Address: Charlotte / 3204 N. Sharon Amity
4. City: Charlotte
5. County: MECKLENBURG
6. State: NC
7. ZIP Code: 28205
8. Telephone No.: (704) 531-1990
9. Facsimile No.: (704) 531-8122
10. Fiscal Year Ending Date: 12/31/10
11. Name/Address/Telephone Number of Authorized Official
Name: CHARLES SHEPARD Address: 3204 N. Sharon Amity Charlotte NC-28205 Telephone No. (704) 531-1990
12. Type of Application/Notification: (V1) *(check all that apply and specify in Remarks section [see item 27])*
☐ 1. Initial ☐ 2. Expansion to new location ☐ 3. Change of ownership
☐ 4. Change of location ☐ 5. Expansion in current location ☐ 6. Change of services/operations
☑ 7. Other *(specify)* Recertification
13. Ownership (V2) ☑ For Profit ☐ Not for Profit ☐ Public
14. Is this Facility Hospital-Based *(check one)* (V3) ☐ Yes ☑ No *If Yes, hospital provider number* (V4) ☐☐☐☐☐☐
15. Is this Facility SNF-Based *(check one)* (V5) ☐ Yes ☑ No *If Yes, SNF provider number* (V6) ☐☐☐☐☐☐
16. Is this facility owned and/or managed by a multi-facility organization? (V7) ☑ Yes ☐ No *If Yes, name and address of parent organization*
Name: (V8) DAVITA Dialysis Address: 1423 Pacific Ave. Tacoma Washington 98401
17. Services Provided: (V9) *(check all that apply and specify in Remarks section [see item 27])*
☑ 1. Hemodialysis ☐ 2. Peritoneal Dialysis ☐ 3. Transplantation ☐ 4. Home Training: __ Hemodialysis __ Peritoneal Dialysis ☐ 5. Home Support: __ Hemodialysis __ Peritoneal Dialysis
18. Is Reuse Practiced? (V10) ☑ Yes ☐ No
19. Reuse System (V11) *(check all that apply)* ☐ 1. Manual ☐ 2. Semi-Automated ☑ 3. Automated
20. Germicide (V12) *(check all that apply)* ☑ 1. Formalin ☐ 2. Heat ☐ 3. Gluteraldehyde ☐ 4. Peracetic Acid Mixture ☐ 5. Other *(specify)* RENALIN
21. Number of Dialysis Patients
(V13) 78 Total Patients = (V14) ✓ Hemodialysis + (V15) __ Peritoneal Dialysis
22. Number of Stations *(check all that apply and include isolation stations under Total Stations)*
(V16) 16 Total Stations = (V17) ✓ Hemodialysis + (V18) __ Hemodialysis Training
23. Does the facility have isolation stations? (V19) ☐ Yes ☑ No
24. Total Number of Patients *(enter number of dialysis facility patients treated on each shift for full week prior to submission of this form)*

A. SUNDAY				B. MONDAY				C. TUESDAY				D. WEDNESDAY			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				16	16	14		16	16			16	16	14	
E. THURSDAY				**F. FRIDAY**				**G. SATURDAY**							
1	2	3	4	1	2	3	4	1	2	3	4				
16	16			16	16	14		16	16						

25. Total Number of patients followed at home (V20) ____

Control Number: OB2211 (NC00054102)

partment of Health and Human
edicare/Medicaid/CLIA Complaint Form

Part I - To Be Completed by Component First Receiving Complaint (SA or RO)

1. Medicare/Medicaid Identification Number

3 4 2 6 2 7

Facility Name and Address

CHARLOTTE EAST DIALYSIS
3204 SHARON AMITY
CHARLOTTE, NC 28205

3. Date Complaint Received

0 3 0 6 0 9
M M D D Y Y

4. Receiving Component

1 State Survey Agy.
[1] 2 RO

5. Date Acknowledged

0 3 2 7 0 9
M M D D Y Y

6A. Source of Complaint

1 [1]
2 [ ]
3 [ ]

1 Resident/Patient Family
2 Ombudsman
3 Facility Employee/Ex-Employ
4 Anonymous
5 Other

6B. Total Number of Complainants

0 1

7. Allegations

	7.A. Category	7.B. Findings (To be completed following investigation)	7.C. Number of Complainants per Allegation
1	0 6	0 2	0 1
2			
3			
4			
5			

7.A. Category:
1 Resident Abuse
2 Resident Neglect
3 Resident Rights
4 Patient Dumping
5 Environment
6 Care or Services
7 Dietary
8 Misuse of Funds/ Property
9 Certification/Un-authorized Testing
10 Proficiency Test
11 Falsification of Records / Reports
12 Unqualified Personnel
13 Quality Control
14 Specimen Handling
15 Diagnostic Erroneous Test Results
16 Fraud/False Billing
17 Fatality/Transfusion Fatality
18 Other (Specify)
19 Life Safety Code
20 State Monitoring

7.B. Findings (To be completed following investigation):
01 Substantiated
02 Unsubstantiated/ Unable to Verify

8. Action (if multiple actions, indicate earliest action)

[3]

1 Investigate within 2 working days
2 Investigate within 10 working days
3 Investigate within 45 working days
4 Investigate during next onsite
5 Referral (Specify)
6 Other Action (Specify)
7 None

Part II - To Be Completed By Component Investigating Complaint (SA or RO)

9. Investigated by

[1] 1 State Survey Agency
2 RO
3 Other (Specify) _____

10. Complaint Survey Date

0 4 1 5 0 9
M M D D Y Y

11. Findings (Under 7B Above)

12. Proposed Actions Taken by SA or RO

1: 0 4
2:
3:

1 Recommend Termination (23-day)
2 Recommend Termination (90-day)
3 Recommend Intermediate Sanction
4 POC (No Sanction)
5 Fine
6 Denial of Payment for New Admissions
7 License Revocation
8 Receivership
9 Provisional License
10 Special Monitor
11 Directed POC
12 Limitation of Certificate
13 Suspension of Certificate
14 Revocation of Certificate
15 Injunction
16 Civil Monetary Penalty
17 TA & Training for Unsuccessful PT
18 State Onsite Monitoring
19 Suspension of Part of Medicare Payments
20 Suspension of All Medicare Payments
21 None
22 Other (Specify) _____
23 Enforcement Action

13. Date of Proposed Action

0 4 1 5 0 9
M MD D Y Y

14. Parties Notified and Dates

1 Facility
2 Complainant
3 Representative
4 Other (Specify) _____

Party	Date
1. [1]	0 4 1 6 0 9
2. [2]	0 4 2 1 0 9
3. [ ]	

M M D D Y Y

15. Date Forwarded to CMS RO or Medicaid SA (MSA) (Attach HCFA-2567)

M MD DY Y

Part III - To Be Completed By Component Taking Final Close-Out Action (RO/MSA)

16. Date of CMS/MSA Receipt

M M D D Y Y

17. CMS RO/MSA Action

1 None
2 Termination (23-day)
3 Termination (90-day)
4 Intermediate Sanction
5 Move Routine Survey Date Forward
6 Limitation of Certificate
7 Suspension of Certification
8 Revocation of Certificate
9 Injunction
10 Civil Monetary Penalty
11 TA & Training For Unsuccessful PT
12 Cancellation of Medicare Approval
13 Other (Specify) _____
14 Enforcement Action

18. Date of Final Action Sign-off

M M D D Y Y

CMS RO

FORM HCFA-562 (1-93)

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

FORM APPROVED
OMB 0938-0360

END STAGE RENAL DISEASE APPLICATION/NOTIFICATION AND SURVEY AND CERTIFICATION REPORT

PART I - APPLICATION - TO BE COMPLETED BY FACILITY

1. Name of Facility: DaVita East Charlotte
2. Provider Number: 3 4 2 6 2 7
3. Street Address: 3204 N. Sharon Amity Rd.
4. City: Charlotte
5. County: Mecklenburg
6. State: NC
7. ZIP Code: 28205
8. Telephone No.: (704) 531-1990
9. Facsimile No.: (704) 531-8122
10. Fiscal Year Ending Date: 12/31
11. Name/Address/Telephone Number of Authorized Official
Name: Charles Sheppard Address: 3204 N. Sharon Amity Rd. Charlotte NC. Telephone No. (704) 531-1990
12. Type of Application/Notification: (V1) *(check all that apply and specify in Remarks section [see item 27])*
☐ 1. Initial ☐ 2. Expansion to new location ☐ 3. Change of ownership
☐ 4. Change of location ☐ 5. Expansion in current location ☐ 6. Change of services/operations
☑ 7. Other *(specify)* Complaint
13. Ownership (V2) ☑ For Profit ☐ Not for Profit ☐ Public
14. Is this Facility Hospital-Based *(check one)* (V3) ☐ Yes ☑ No *If Yes, hospital provider number* (V4) ☐☐☐☐☐☐
15. Is this Facility SNF-Based *(check one)* (V5) ☐ Yes ☑ No *If Yes, SNF provider number* (V6) ☐☐☐☐☐☐
16. Is this facility owned and/or managed by a multi-facility organization? (V7) ☐ Yes ☑ No *If Yes, name and address of parent organization*
Name: Address:
(V8)
17. Services Provided: (V9) *(check all that apply and specify in Remarks section [see item 27])*
☑ 1. Hemodialysis ☐ 2. Peritoneal Dialysis ☐ 3. Transplantation ☐ 4. Home Training: ___ Hemodialysis ___ Peritoneal Dialysis ☐ 5. Home Support: ___ Hemodialysis ___ Peritoneal Dialysis
18. Is Reuse Practiced? (V10) ☑ Yes ☐ No
19. Reuse System (V11) *(check all that apply)* ☐ 1. Manual ☑ 2. Semi-Automated ☐ 3. Automated
20. Germicide (V12) *(check all that apply)* ☐ 1. Formalin ☐ 2. Heat ☐ 3. Gluteraldehyde ☑ 4. Peracetic Acid Mixture ☐ 5. Other *(specify)* ___
21. Number of Dialysis Patients
(V13) 72 Total Patients = (V14) 72 Hemodialysis + (V15) ___ Peritoneal Dialysis
22. Number of Stations *(check all that apply and include isolation stations under Total Stations)*
(V16) 16 Total Stations = (V17) 16 Hemodialysis + (V18) ___ Hemodialysis Training
23. Does the facility have isolation stations? (V19) ☐ Yes ☐ No
24. Total Number of Patients *(enter number of dialysis facility patients treated on each shift for full week prior to submission of this form)*

A. SUNDAY				B. MONDAY				C. TUESDAY				D. WEDNESDAY			
1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
				16	16	8		14	13			16	16	7	

E. THURSDAY				F. FRIDAY				G. SATURDAY			
1	2	3	4	1	2	3	4	1	2	3	4
14	13			16	14	5		14	13		

25. Total Number of patients followed at home (V20) 0

26. Staffing	(V21) ☑ Registered Nurse	2.00	(V22) ☐ Licensed Practical Nurse	
(list full-time equivalents)	(V23) ☑ Social Worker	.25	(V24) ☐ Dietitian	.25
	(V25) ☐ Technicians	1.00	(V26) ☑ Others	.25

27. Remarks: *(Use this space for explanatory statements for Items 1–26)*

2(e information contained in this Application Survey and Certification Report (Part I) is true and correct to the best of my belief. 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. 405.2100 and 405.2180, respectively.

Signature of Authorized Official	Title	Date
Mark Sheppard	RN | Administrator	4-15-09

PART II TO BE COMPLETED BY STATE AGENCY

9. ESRD Provider Number *(if the facility has a provider number)* 3 4 2 6 2 7

0. Network Number (V27) 0 6

1. State Region (V28)	NCC	32. State County Code (V29)	590

3. Type of Survey (V30) *(check all that apply)* ☐ Initial ☒ Complaint ☐ Recertification ☐ Other

4. Survey Protocol (V31) *(check all that apply)* ☒ Basic ☐ Initial ☐ Supplemental ☐ Combination

5. Surveyor Name/Number *(print)*	Professional Discipline *(print)*
Ralph Mills, RN, BSN	Registered Nurse

i. Date of Survey

April 15, 2009

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