



SEIU Healthcare

United for Quality Care

VIA E-MAIL

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January 14, 2013

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Illinois Health Facilities and Services Review Board

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RE: Opposition to Project No. 12-093: Fresenius Medical Care Streeterville

Dear Ms. Avery,

Board Chair:
Flora Johnson

Vice-Chairs:
Faith Arnold
Bernita Drayton
Francine Rico
Alberta Walker

On behalf of Service Employees International Union Healthcare Illinois/Indiana (SEIU HCII), I submit this letter of opposition to the Fresenius certificate of need ("CON") permit request and urge the Illinois Health Facilities and Services Review Board ("HFSRB") to deny Project Number 12-093. SEIU HCII represents 91,000 health care and child care workers and we feel that it is important for all health care providers to share a commitment to quality care that allows workers to perform at the highest level and patients to achieve the best possible outcomes.

Fresenius Medical Care has a thoroughly documented pattern of fraudulent and deadly practices, which have led to strong punitive actions taken against it by various federal agencies. Fresenius's poor quality of care recently led to a formal notice of expulsion from Medicare and Medicaid. Fresenius is being investigated by the F.D.A. for covering up the risk of death from one of its products, and faces a Class 1 product recall and a flood of lawsuits by the families of patients who died from using this product. Fresenius pled guilty to "a wide-ranging conspiracy to defraud Medicare" and paid a healthcare fraud settlement larger than any in previous U.S. history. A former Fresenius manager alleges in an ongoing False Claims Act suit that Fresenius continued to commit fraud after the settlement, and failed to abide by the terms of its Corporate Integrity Agreement.

All of this evidence demonstrates that Fresenius lacks the character to provide a proper standard of health care services to the community, and therefore fails to fulfill the criteria for Certificate of Need approval. SEIU HCII therefore earnestly requests that the Board deny Project Number 12-093.

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There are Exhibits attached to this Letter of Opposition. They are:

- Exhibit A: Statement of Deficiencies, Tennessee Dept. of Health, Fresenius Medical Care West Nashville, Oct. 25, 201
- Exhibit B: *NBC Chicago* story, "Gaytan Family vs. Fresenius Medical Care." Apr. 26, 2012.
- Exhibit C: Second Amended Complaint from *Gaytan v. Fresenius Medical Care North America*
- Exhibit D: FDA Recall Announcement, Fresenius Medical Care North America, Naturalyte and Granuflo Acid Concentrate, Mar. 29, 2012
- Exhibit E: DOJ Announcement of Criminal Pleas and Civil Settlements
- Exhibit F: First Amended Complaint, *U.S. ex rel. Drennen v. Fresenius Medical Care Holdings, Inc.*

Fresenius's Poor Quality of Care Has Led to a Formal Notice of Expulsion from Medicare/Medicaid and a Seven-Figure Settlement in Chicago

Serious quality of care issues at a Fresenius clinic recently led to a formal notice of expulsion from federal health care programs from the Center for Medicare and Medicaid Services. On November 9, 2012, *The Tennessean* reported:

A West Nashville dialysis center is facing expulsion from the federally funded Medicare and Medicaid programs after state health inspectors found multiple violations that placed patients in immediate jeopardy, including serious injury or death. ***A formal notice of expulsion from the two federal programs effective Nov. 17 was issued this week to Fresenius Medical Care-West Nashville by the Centers for Medicare & Medicaid Services.*** The notice follows a 76-page inspection report that found one patient at the facility lost so much blood she became nonresponsive and had to be revived and rushed to a nearby hospital. According to the notice, the federal government will no longer pay for Medicare or Medicaid patients as of Nov. 17.¹

The scathing 76-page Statement of Deficiencies from the Tennessee Department of Health is attached to this letter as Exhibit A. It is a catalogue of myriad quality-of-care and sanitation problems. It opens with the following statement:

"[T]he facility was found to be out of compliance with the following Conditions for Coverage: 494.40 Water & Dialysate Quality, 494.60 Physical Environment, 494.80 Patient Assessment, 494.90 Patient Plan of Care, 494.110 Quality Assess and Performance Improvement, 494.150 Responsibilities of the Medical Director, and 494.180 Governance. The ... citations resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodialysis at the facility and were cited as IMMEDIATE JEOPARDY." (emphasis in original)

Fresenius' poor quality of care has also stirred public concern, and led to a seven-figure settlement, in Chicago, where Project Number 12-093 is being proposed. In March 2009, a Chicago-area woman died after something went "terribly wrong" at Fresenius Medical Care in Berwyn. Teresa Gaytan had been living in a nursing home for about a year, but her five grown children wanted to bring her home, so they arranged for outpatient treatments at Fresenius-Berwyn. But in just her second week home, during her

third dialysis treatment, Fresenius called to report Ms. Gaytan was being rushed to the hospital. At the hospital, daughter Angela Gaytan spoke with the doctor: "I remember the doctor sitting down and just putting his head down, and he said something had gone terribly wrong with her dialysis at the center." ⁱⁱ

NBC Chicago reports that Fresenius would not give the family, nor *NBC*, information about what happened:

"I asked what happened, and they wouldn't tell me. ... We would try to call the facility to get answers from them because obviously something happened there. ... They weren't giving us answers," [Angela] Gaytan said. ... Fresenius Medical care would not comment on Teresa Gaytan's case, citing privacy concerns. ⁱⁱⁱ

Gaytan's family had to file suit in order to get answers. *NBC Chicago* reports:

According to the Gaytan family's complaint, there was a series of mistakes which led to the woman's death: A patient care technician did a reversal of her dialysis lines (which he was not qualified to do); the lines weren't secured properly and Gaytan began hemorrhaging, and then the alarms – which were supposed to signal that something was wrong -- were ignored.

"There were many, many mistakes," said [Gaytan's attorney]. "But even among those many mistakes, if somebody had done something at one step of the process along the way, that could have turned the whole thing around." ^{iv}

Fresenius eventually entered into a seven-figure settlement with the Gaytan family. ^v The *NBC Chicago* story, and the Second Amended Complaint from the Gaytan family's lawsuit, which lays out the family's claims, are attached as Exhibits B and C respectively.

Fresenius Being Investigated by F.D.A. for Covering Up the Risk of Death from its Products, Faces a Class 1 Product Recall and a Flood of Lawsuits from Families of Patients Who Died

The New York Times ^{vi} and *Chicago Tribune* ^{vii} reported this June that the F.D.A. is investigating Fresenius for potentially violating federal law. Fresenius failed to inform customers of a potentially-lethal risk connected to Granuflo, a Fresenius-manufactured product used in both Fresenius and non-Fresenius clinics. The *New York Times* reports:

Last November, Fresenius's medical office sent an internal memo to doctors practicing in the company's dialysis centers, warning them that failure to properly use one of the company's products appeared to be contributing to a sharp increase in the risk of patients dying suddenly from cardiac arrest.

"In light of these troubling findings," the memo said, doctors should take corrective action. "This issue needs to be addressed urgently," the memo added later.

But Fresenius, which is based in Germany, did not immediately warn other centers that use the product, which is known as GranuFlo. It did so only in late March after the F.D.A. received, anonymously, a copy of the internal memo and questioned the company about it.

“Personally, I’m troubled by the fact that Fresenius on its own initiative didn’t notify its entire customer base of this particular concern,” Steven Silverman, director of compliance for the F.D.A.’s medical devices division, said in an interview this week.

Mr. Silverman said the agency could issue a warning letter to Fresenius if it determined the company should have reported the safety concerns. But even if the company had no legal obligation, he said, **“Candidly, I just think it’s bad business and not in the interest of public health to sit on information about risks.”**

Dr. Thomas F. Parker III, chief medical officer at Renal Ventures, a dialysis chain that uses Fresenius products, agreed. “If the data was sufficient to warn their doctors, then all users of the product should have been made aware of it,” he said.^{viii}

On June 27, 2012, the FDA classified Fresenius’s action to change the labeling on its GranuFlo products as a Class 1 recall. The FDA states: **“Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.”**^{ix} The F.D.A. recall notice is attached as Exhibit D.

Fresenius’s GranuFlo cover-up has led to a flood of lawsuits against Fresenius, resulting from the untimely deaths of multiple Fresenius patients who were administered GranuFlo. These lawsuits were filed in various districts and by various law firms across the country.^x

Fresenius Pleads Guilty to Fraud, Pays Largest Health Care Fraud Settlement in U.S. History – Currently Facing New Fraud Allegations

Fresenius was forced to pay \$486 million in fines and penalties, and top executives pled guilty to felony crimes, when the Department of Justice found that, in its own words, “the company engaged in a wide-ranging conspiracy to defraud Medicare and other federal healthcare programs.” This was the largest fine and penalty awarded in a healthcare fraud case in U.S. history.^{xi}

Fresenius pled guilty to the following: conspiracy to submit false claims for certain lab tests; conspiracy to offer and pay kickbacks to induce dialysis facilities to order laboratory blood testing services to be paid by Medicare; and obstructing government agencies in the administration of various health care and health insurance programs including Medicare. Fresenius paid three separate criminal fines, each of which exceeded the largest health care criminal penalty previously paid. The Fresenius divisions responsible for the fraud were permanently excluded from participation in Medicare. Multiple high-level Fresenius executives pled guilty to felony crimes. Fresenius also had to enter a Corporate Integrity

Agreement, including mandatory audits and reporting to the government.^{xii} The Department of Justice announcement of this settlement is attached as Exhibit E.

Fresenius is now facing new accusations of fraud. A former Fresenius area manager has filed a False Claims Act suit on behalf of the United States, claiming that for at least eight years,^{xiii} the company overcharged Medicare for blood tests. He alleges that ***Fresenius continued committing fraud the year after its record-setting settlement, and did not comply with the Corporate Integrity Agreement.*** As stated in the First Amended Complaint:

Fresenius deliberately and/or recklessly billed the Government for tests that were not medically necessary and not supported by medical documentation. Fresenius represented to the Government that these tests were medically necessary and/or had supporting medical documentation, when, in fact, these tests were not medically necessary, were in excess of the tests authorized under [federal] requirements, and for which Fresenius had no medical documentation or physician orders. Fresenius concealed its fraudulent business practices, continues to withhold overpayments made by the Government, and this concealment has prevented the Government from discovering this systematic fraud.^{xiv}

Fresenius was not abiding by the provisions of the [Corporate Integrity Agreement]. Specifically, Fresenius did not have policies and procedures in place to ensure adherence to [federal] guidelines and the documentation of medical necessity and medical reasonableness with respect to its laboratory services. Fresenius did not have any internal controls designed to enable Fresenius to identify patterns of receiving reimbursement for medically unnecessary tests. Fresenius did not obtain the required documentation of medical necessity from the ordering physician or, if such documentation was unavailable, provide the services free of charge; instead it billed and received payment from Medicare. Fresenius did not notify the OIG of the resulting overpayments.^{xv}

The court has rejected Fresenius's Motion to Dismiss,^{xvi} and the case is ongoing. The First Amended Complaint is attached as Exhibit F.

Fresenius's Fraudulent and Deadly Practices, and the Adverse Actions Taken Against It By the Federal Government, Disqualify it from CON Approval

The Health Facilities and Services Review Board uses multiple criteria in determining whether to approve a project. Based on the above evidence, Fresenius falls far short of meeting at least two of these criteria, and the project should therefore be denied.

Criteria Failure #1: 1110.230(a): Background of Applicant. "An applicant must demonstrate that it is fit, willing and able, and has the qualifications, background and ***character, to adequately provide a proper standard of health care service for the community.*** [20 ILCS 3960/6] In evaluating the qualifications, background and character of the applicant, ***HFPB shall consider whether adverse action has been taken against the applicant,*** or against any health care facility owned or operated by the applicant, directly or

indirectly, within three years preceding the filing of the application.”^{xvii} An “adverse action” means “a disciplinary action taken by Illinois Department of Public Health, Centers for Medicare and Medicaid Services, or any other State or federal agency against a person or entity that owns and/or operates a licensed or Medicare or Medicaid certified healthcare facility in the State of Illinois. These actions include, but are not limited to, all Type A violations. A “Type A” violation means a violation of the Nursing Home Care Act or 77 Ill. Adm. Code 300, 330, 340, 350 or 390 that creates a condition or occurrence relating to the operation and maintenance of a facility presenting a substantial probability that death or serious mental or physical harm to a resident will result therefrom.” 77 Ill. Adm. Code 1100.220.

Fresenius fails to meet this criterion for two primary reasons:

- 1) Its cover-up of the deadly problems with Granuflo, and its history of fraudulent practices, demonstrate that Fresenius does not have the proper “character to adequately provide a proper standard of health care services”; and
- 2) The Center for Medicare and Medicaid Services formal notice of expulsion from Medicare, based upon “a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodialysis,” and the F.D.A. Class 1 recall, which “involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death,” constitute “adverse actions” by the federal government.

Criteria Failure #2: 1110.230(b): Purpose of the Project. “The applicant shall document that the project will provide health services that improve the health care or well-being of the market area population to be served.”^{xviii} Fresenius fails to meet this criterion based on its recent, thoroughly documented quality-of-care failures at its West Nashville facility, its gross negligence in the death of Teresa Gaytan from her treatment at Fresenius-Berwyn, and the indifference to the general well-being of the public demonstrated by its Granuflo cover-up.

For the above reasons, SEIU HCII earnestly requests that the Board deny Project Number 12-093. Thank you for your time and consideration.

Sincerely,



Sharon Post

Research Director

SEIU Healthcare Illinois/Indiana

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- ⁱ Walter F. Roche, Jr. "West Nashville dialysis center put patients at risk." *The Tennessean*, Nov. 9, 2012. (Emphasis added.)
- ⁱⁱ Katy Smyser, "Gaytan Family vs. Fresenius Medical Care." *NBC 5 Chicago*, Apr. 26, 2012.
- ⁱⁱⁱ Katy Smyser, "Gaytan Family vs. Fresenius Medical Care." *NBC 5 Chicago*, Apr. 26, 2012.
- ^{iv} Katy Smyser, "Gaytan Family vs. Fresenius Medical Care." *NBC 5 Chicago*, Apr. 26, 2012.
- ^v Katy Smyser, "Gaytan Family vs. Fresenius Medical Care." *NBC 5 Chicago*, Apr. 26, 2012.
- ^{vi} Andrew Pollack, "Dialysis Company's Failure to Warn of Product Risk Draws Inquiry." *New York Times*, June 14, 2012.
- ^{vii} "Fresenius on U.S. regulator's radar over dialysis." *Chicago Tribune*, June 15, 2012.
- ^{viii} Andrew Pollack, "Dialysis Company's Failure to Warn of Product Risk Draws Inquiry." *New York Times*, June 14, 2012. Emphasis added.
- ^{ix} FDA Medical Device Recall - Fresenius Medical Care North America, Naturalyte and Granuflo Acid Concentrate. Available at: <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm309990.htm>.
- ^x See, e.g., *Williams v. Fresenius USA Inc et al*, Northern Dist. of Alabama, Case No. 2:12-cv-02576-KOB; *Bishop v. Fresenius USA, Inc. et al*, Southern Dist. of Georgia, Case No. 6:12-cv-00086-BAE-GRS; *Kirk v. Fresenius Medical Care Holdings, Inc. et al*, Eastern Dist. of New York, Case No. 1:12-cv-05981-FB-CLP; *Tozzi v. Fresenius Medical Care Holdings, Inc. et al*, Dist. of New Jersey, Case No. 2:12-cv-07469-FSH-PS; *Harvey v. Fresenius Medical Care Holdings, Inc. et al*, Middle Dist. of Georgia, Case No. 4:12-cv-00328-CDL; *Johnson v. Fresenius Medical Care North America Inc. et al*, Dist. of Massachusetts, Case No. 1:12-cv-12295-JLT.
- ^{xi} Deputy Attorney General. "Announcement of Criminal Pleas and Civil Settlements". January 19, 2000. <http://www.justice.gov/archive/dag/speeches/2000/nmichaelhealthremarks.htm>
- ^{xii} Deputy Attorney General. "Announcement of Criminal Pleas and Civil Settlements". January 19, 2000. <http://www.justice.gov/archive/dag/speeches/2000/nmichaelhealthremarks.htm>
- ^{xiii} First Amended Complaint, ¶ 41, *United States of America ex rel. Christopher Drennen v. Fresenius Medical Care Holdings, Inc.*, Case No. 09-10179-GAO.
- ^{xiv} First Amended Complaint, ¶ 32, *United States of America ex rel. Christopher Drennen v. Fresenius Medical Care Holdings, Inc.*, Case No. 09-10179-GAO.
- ^{xv} First Amended Complaint, ¶ 37, *United States of America ex rel. Christopher Drennen v. Fresenius Medical Care Holdings, Inc.*, Case No. 09-10179-GAO.
- ^{xvi} Opinion and Order, Mar. 6, 2012, *United States of America ex rel. Christopher Drennen v. Fresenius Medical Care Holdings, Inc.*, Case No. 09-10179-GAO.
- ^{xvii} State of Illinois Health Facilities and Services Review Board, Staff Report on Fresenius Medical Care East Aurora, February 28, 2012, p. 8.
- ^{xviii} State of Illinois Health Facilities and Services Review Board, Staff Report on Fresenius Medical Care East Aurora, February 28, 2012, p. 11.

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

PRINTED: 11/08/2012
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 442615	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 10/25/2012
NAME OF PROVIDER OR SUPPLIER FRESENIUS MEDICAL CARE WEST NASHVILLE			STREET ADDRESS, CITY, STATE, ZIP CODE 242 ORLANDO AVENUE NASHVILLE, TN 37209		
(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	<p>INITIAL COMMENTS</p> <p>A recertification survey was conducted 10/8/12 through 10/25/12. An entrance conference was conducted on 10/8/12 at 10:38 AM with the Operations Manager. A telephone exit conference was conducted at 10:10 AM on 10/25/12 with the Regional Vice President, Director of Operations, Technical Operations Manager, Regional Quality Manager, Director of Education, North Nashville Operations Manager, Clinic Manager, and Director of Regulatory Affairs.</p> <p>Based on review of facility policy, document review, QAPI minutes, By-laws, Governing Board minutes, medical record review, observation and interview, the facility was found to be out of compliance with the following Conditions for Coverage: 494.40 Water & Dialysate Quality, 494.60 Physical Environment, 494.80 Patient Assessment, 494.90 Patient Plan of Care, 494.110 Quality Assess and Performance Improvement, 494.150 Responsibilities of the Medical Director, and 494.180 Governance.</p> <p>The Conditions for Coverage 494.40 Water & Dialysate Quality, 494.60 Physical Environment, 494.90 Patient Plan of Care and 494.110 Quality Assess and Performance Improvement, 494.150 Responsibilities of the Medical Director and 494.180 Governance citations resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodialysis at the facility and were cited as IMMEDIATE JEOPARDY.</p> <p>The following abbreviations were used in the statement of deficiencies:</p>	V 000			
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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V 000	Continued From page 1 & - and > - greater than < - less than AED - Automatic External Defibrillator AM - before noon Approx - approximately bicarb - bicarbonate BP - blood pressure cc - cubic centimeters cfu - colony forming unit CMS - Centers for Medicare & Medicaid Services c/o - complaint of CPR - cardiopulmonary resuscitation DBP - diastolic blood pressure DI - Deionization dist - distribution DOO - director of operations ER - emergency room EU - Endotoxin Unit H - hour H2O - water Hct - hematocrit HD - hemodialysis Hgb - hemoglobin Hr - hour IDT - Interdisciplinary Team LPN - Licensed Practical Nurse MD - Medical Doctor mg - milligrams ml - milliliter min - minimum NS - normal saline P - pulse PCT - Patient Care Technician PM - after noon PO - by mouth POC - plan of care Pt/pt - patient	V 000			

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V 000	Continued From page 2 QAI - Quality Assessment Improvement QAPI - Quality Assessment Performance Improvement RN - Registered Nurse RO - reverse osmosis RP - Random Patient SBP - systolic blood pressure SW - Social Worker sys - system tech - technician TRMT - treatment u - units uf - ultrafiltration VS - vital signs WDS - water delivery system	V 000			
V 111	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to maintain a clean and sanitary environment as evidenced by untidy and soiled conditions inside the water treatment room for 2 of 4 (10/15/12 and 10/16/12) observation days. The findings included: 1. Observations in the water treatment room on 10/15/12 and 10/16/12 revealed the following: A hose with an open end was connected to the bicarbonate distribution tank and looped over the pump mixer. The piping from the water source had insulation	V 111			

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V 111	Continued From page 3 exposed. White substances were noted around the bicarbonate tanks and the flooring around the tanks. The walls behind the acid storage tanks had a build-up of grime and dust. A copper pipe behind the acid tank had thick green build-up around the outside of the pipe. Brown streaks were noted on the walls behind and above the primary acid tank and a piece of wall missing. 2. During an interview in the water room on 10/15/12 at 4:25 PM, the Biomed Technician stated, "...If I mixed the bicarb, I would clean up afterwards..." 3. During an interview in the water room on 10/16/12 at 12:00 PM, the Technical Supervisor verified the water room was very dusty.	V 111			
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 (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	V 117			

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V 117	Continued From page 4 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 observation and interview, the facility failed to maintain a clean area for storage of supplies. The findings included: During a tour of the facility treatment area on 10/15/12 beginning at 2:39 PM, the following was observed in a cabinet under the sink in Bay 1: Betadine, air freshener, lotion, blood glucose test strips, glucose monitoring control solution, a ziplock bag of blood collection tubes, disinfectant spray and a patient alarm to detect wetness. During an interview on 10/15/12 at 2:39 PM, PCT #4 stated the cabinet was a "catch all."	V 117			
V 175	494.40 CFC-WATER & DIALYSATE QUALITY This CONDITION is not met as evidenced by: Based on review of facility Bylaws, policy, disinfection logs, culture and endotoxin reports, observation and interview, the facility failed to ensure the Medical Director was responsible for ensuring the water treatment and dialysate preparation equipment and distribution systems were maintained in a manner that provided an acceptable quality of water for preparation of dialysate, failed to ensure the salt pellets were	V 175			

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V 175	<p>Continued From page 5</p> <p>maintained above the level of the brine solution in the tank, failed to ensure the disinfection program was effective to ensure bacteria levels remained below allowed contamination and failed to ensure a corrective action plan was developed and implemented to prevent the recurrent growth of bacteria in the water treatment system for 19 of 19 (4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012) months reviewed.</p> <p>The facility's failure to ensure acceptable water quality for the provision of hemodialysis treatment resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all hemodialysis patients and placed them at risk for serious infection and death.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 1. The Medical Director failed to assure interventions were developed and implemented to maintain water contamination levels below the action level to provide safe hemodialysis treatments. Refer to V 179. 2. The facility failed to ensure the salt pellets were maintained above the level of the brine solution in the tank. Refer to V 190. 3. The facility failed to ensure an effective corrective action plan was developed and implemented to determine the root cause and to control the elevated water culture and endotoxin levels. 	V 175			

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V 175	Continued From page 6	V 175			
V 179	Refer to V 274. 494.40(a) BACT OF H2O-MEDICAL DIRECTOR RESPONSIBLE 4.1.2 Bacteriology of water: med dir resp The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels. This STANDARD is not met as evidenced by: Based on facility Bylaw and policy review, culture and endotoxin reports, disinfection logs and interview, the Medical Director failed to demonstrate responsibility for maintaining water treatment and diaysate preparation equipment and distribution systems that provided water used to prepare dialysate within allowable limits to ensure the safety of the patients receiving hemodialysis for 19 of 19 (4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012) months reviewed. The Medical Director's failure to demonstrate responsibility for maintaining the water treatment system placed all the patients receiving	V 179			

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V 179	<p>Continued From page 7</p> <p>hemodialysis at risk of exposure to contaminated water and resulted in a SERIOUS AND IMMEDIATE THREAT to their health and safety.</p> <p>The findings included:</p> <p>Review of the facility's Bylaws revealed, "...Medical Director Duties. The Medical Director is directly and actively responsible for the creation, on-going improvement and preservation of high quality professional care of patients at the Facility. The Medical Director is responsible for planning, organizing, conducting and directing the professional services of the Facility and, to that end, has specific duties and authorities...The Medical Director is responsible for the delivery of patient care and outcomes in the Facility and is accountable to the Company [company initials], Medical Department, Governing Body and CMS, for the quality of medical care provided to patients... Ensure that all policies and procedures relative to patient admissions, patient care (including, but not limited to, patient comprehensive assessments, plans of care and patient rights and responsibilities), infection control, and safety are made available to all medical staff members and non-physician practitioners and that they are adhered to by all individuals who treat patients in the Facility..."</p> <p>Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", documented, "...Water cultures will be monitored using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO</p>	V 179			

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V 179	<p>Continued From page 8</p> <p>or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml... Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..."</p> <p>Review of the bacterial cultures and endotoxin testing results and disinfection logs for the water treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12 revealed culture and/or endotoxin levels outside the allowable and/or action limits as follows:</p> <p>4/2011 - Pre-disinfection samples drawn on 4/3/11 revealed water cultures and endotoxin levels were < the action level. The water treatment system was disinfected by the facility on 4/3/11 and 4/4/11. Following this disinfection the water culture samples drawn on 4/6/11 were > the allowable limit. The water treatment system was disinfected again on 4/17/11. The post-disinfection samples drawn on 4/20/11 continued to have water culture > the allowable limit.</p> <p>There was no documentation the Medical Director reviewed and monitored the elevated water cultures during the month of April 2011.</p> <p>5/2011 - Pre-disinfection samples drawn on 5/1/11 had endotoxin level > the action level. The water treatment system was disinfected 5/1/11.</p>	V 179			

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V 179	<p>Continued From page 9</p> <p>The post-disinfection samples drawn 5/4/11 revealed the endotoxin levels continued to be > the action level. Pre-disinfection samples drawn 5/13/11 had endotoxin level > action level. The water treatment system was disinfected 5/15/11. The post-disinfection samples drawn on 5/18/11 continued to have endotoxin level > the action level. There was no documentation of further disinfection or action plans for the continued elevated endotoxin levels on 5/4/11 and 5/18/11. The pre-disinfection samples drawn on 5/27/11 had endotoxin level at the action level. The water treatment system was disinfected on 5/29/11. Review of the facility hemodialysis schedules and treatment records revealed patients continued to dialyze during the month of May with the elevated endotoxin levels.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin levels during the month of May 2011.</p> <p>6/2011 - Post-disinfection samples drawn 6/1/11 had water culture and endotoxin levels > the allowable limit. The water treatment system was disinfected 6/12/11. Post-disinfection sample on 6/15/11 had a water culture > the allowable limit. The disinfection log documented, "... 6/17/11 Due to improving results, disinfect schedule changed to every three weeks ..." Water cultures on 6/29/11 had > action level and > allowable limit. There was no documentation if the samples drawn on 6/29/11 were pre-disinfection or post-disinfection.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of</p>	V 179			

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V 179	<p>Continued From page 10 June 2011.</p> <p>7/2011 - Pre-disinfection samples drawn on 7/3/11 had water culture levels > the allowable limit, and endotoxin level > action level. The water treatment system was disinfected 7/3/11. Post-disinfection samples drawn on 7/7/11 continued to have water cultures > action level and > the allowable limit. There was no documentation of further action plans or disinfection for the continued elevated water cultures. A water sample drawn on 7/12/11 had a water culture > the allowable limit. Pre-disinfection samples drawn 7/22/11 had water cultures > the action limit and > the allowable limit. The water sample also had endotoxin levels > the action level. The water treatment system was disinfected on 7/24/11.</p> <p>There was no documentation the Medical Director had monitored the elevated water culture and endotoxin levels during the month of July 2011.</p> <p>8/2011 - A water sample drawn 8/12/11 had water cultures > the allowable limits, and endotoxin > the action level. The water treatment system was disinfected on 8/21/11.</p> <p>There was no documentation the Medical Director reviewed and monitored the elevated water culture and endotoxin levels during the month of August 2011.</p> <p>9/2011 - Pre-disinfection samples drawn on 9/11/11 had water cultures > the action level. The water treatment system was disinfected.</p> <p>There was no documetation the Medical Director</p>	V 179			

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V 179	<p>Continued From page 11</p> <p>had reviewed and monitored the elevated water culture and endotoxin levels during the month of September 2011.</p> <p>10/2011 - Pre-disinfection samples drawn 10/16/11 had culture > the action level and endotoxin level > allowable limits. The water treatment system was disinfected 10/16/11.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water cultures and endotoxin levels during month of October 2011.</p> <p>11/2011 - Pre-disinfection samples drawn 11/25/11 revealed the GRNFLO-FEED-BEFORE sample port water culture was 92 CFU/ml . The water treatment system was disinfected 11/27/11. Post-disinfection samples drawn 11/30/11 revealed: RO, 1 permeate sample port water culture was 180 CFU/ml, the endotoxin level was 0.43 EU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of Novemeber 2011.</p> <p>12/2011 - Water samples drawn 12/7/11 revealed the RO, 1 permeate sample port water endotoxin level was 0.40 EU/ml. Pre-disinfection samples drawn 12/18/11 revealed the RO 1, permeate sample port water endotoxin was 0.39 EU/ml. The water treatment system was disinfected 12/18/11. Post-disinfect water samples drawn 12/20/11 revealed the RO 1, permeate sample port water endotoxin level was 0.26 EU/ml. Water samples drawn 12/27/11 revealed the RO</p>	V 179			

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V 179	<p>Continued From page 12</p> <p>1, permeate sample port water endotoxin level was 0.26 EU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin during the month of December 2011.</p> <p>1/2012 - Pre-disinfection samples drawn 1/13/12 revealed the Acid mixer 1, feed sample port water culture was 116 CFU. H2O Delivery System (WDS) 1, Ultrafilter pre 1 sample port water culture was 56 CFU/ml. The Acid Mixer 1, feed sample port water culture was 116 CFU/ml. The water treatment system was disinfected 1/15/12. Post-disinfection samples drawn 1/18/12 revealed the RO 1, permeate sample port water endotoxin level was 0.27 EU/ml. A water sample drawn 1/27/12 revealed the Acid mixer 1, feed sample port water culture was 166 CFU/ml. RO 1, permeate sample port water culture was 120 CFU/ml. A leak in the loop was repaired and the water treatment system was disinfected 1/29/12. A water sample drawn 1/30/12 revealed the Acid mixer 1, feed sample port water endotoxin level was 4.56 EU/ml. H2O delivery system (WDS) 1, Ultrafilter pre 1 sample port water culture was 50 CFU/ml, the endotoxin level was 1.81 EU/ml. Solution Delivery System (SDS) End of Loop sample port water endotoxin level was 1.17 EU/ml. A water sample drawn 1/31/12 revealed the RO 1, permeate sample port water endotoxin level was 0.36 EU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of January 2012.</p>	V 179			

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V 179	<p>Continued From page 13</p> <p>2/2012 - Pre-disinfection samples drawn 2/9/12 revealed the Acid mixer 1, feed sample port water culture was 142 CFU/ml. H2O Delivery system (WDS) 1, ultrafilter pre 1 sample port water endotoxin level was 0.50 EU/ml. RO 1, permeate sample port water endotoxin level was 0.35 EU/ml. RO 2, polished sample port water endotoxin level was 0.32 EU/ml. Acid mixer 1, feed sample port water culture was 142 CFU/ml. The water treatment system was disinfected 2/12/12. Post-disinfection samples drawn 2/15/12 revealed the RO 1, polished sample port water endotoxin level was 0.56 EU/ml. RO 1, permeate sample port water endotoxin level was 0.45 EU/ml. Pre-disinfection samples drawn 2/26/12 revealed the RO 1, permeate sample port water endotoxin level was 0.32 EU/ml. Acid mixer 1, feed sample port water culture was 90 CFU/ml. A Granuflo conversion kit was installed, and the water treatment system was disinfected 2/26/12. Post-disinfection samples drawn 2/29/12 revealed the RO 1, permeate sample port water endotoxin level was 0.58 EU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of February 2012.</p> <p>3/2012 - Pre-disinfection samples drawn 3/11/12 were unable to be processed by the laboratory. The water treatment system was disinfected 3/12/12. Post-disinfection samples drawn 3/14/12 revealed the RO 1, permeate sample port water endotoxin level was 0.66 EU/ml. A repeat sample drawn 3/28/12 revealed RO 1, polished sample port water endotoxin level was 1.00 EU/ml. RO 1, permeate sample port water</p>	V 179			

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V 179	<p>Continued From page 14</p> <p>endotoxin level was 0.93 EU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated endotoxin levels during the month of March 2012.</p> <p>4/2012 - Pre-disinfection samples drawn 4/3/12 revealed the RO 1, permeate sample port water endotoxin level was 1.86 EU/ml. RO 1, polished sample port water endotoxin level was 1.58 EU/ml. The water treatment system was disinfected 4/3/12. Post-disinfection samples drawn 4/4/12 revealed the RO 1, permeate sample port water endotoxin level was 0.69 EU/ml. The water treatment system sample ports were flushed with alcohol on 4/9/12. A validation sample drawn 4/10/12 revealed the RO 1, polished sample port water culture was > 200 CFU/ml. Pre-disinfection samples drawn 4/12/12 - Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, feed sample port water culture was 164 CFU/ml. The water treatment system was disinfected 4/15/12. Post-disinfection samples drawn 4/17/12 revealed the Distribution loop 1, return sample port water endotoxin level was 0.96 EU/ml. RO 1, permeate sample port water endotoxin level was 0.40 EU/ml. Repeat samples drawn 4/24/12 revealed the RO 1, permeate sample port water endotoxin level was 0.50 EU/ml. HD machine 3, outlet sample port water culture was 58 CFU/ml. The sample port of the RO 1, permeate was disinfected on 4/26/12. Post-disinfection sample drawn 4/26/12 revealed the RO 1, permeate sample port water endotoxin level was 0.84 EU/ml. Ultrafilter 1, feed sample port water the endotoxin level was 1.04 EU/ml.</p>	V 179			

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V 179	<p>Continued From page 15</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin level reports dated 4/3/12, 4/4/12, 4/10/12, 4/17/12, and 4/26/12 during the month of April 2012.</p> <p>5/2012 - A sample drawn 5/1/12 revealed the RO 1, permeate sample port water endotoxin level was 0.54 EU/ml. Distribution loop 1, return sample port water culture was 182 CFU/ml. Ultrafilter 1, feed sample port water culture was 160 CFU/ml. A repeat sample drawn 5/10/12 revealed the Distribution loop 1, return sample port water culture was > 200 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. RO 1, permeate sample port water endotoxin level was 0.53 EU/ml. Distribution loop 1, return sample port water culture was > 200. Ultrafilter 1, feed sample port water culture > 200 CFU/ml. The sample ports were moved and a leak in the water loop was repaired 5/12/12. The water treatment system was disinfected 5/13/12. Post-disinfection samples drawn 5/15/12 revealed the Ultrafilter 1, feed sample port water endotoxin level was 1.68 EU/ml. RO 1, permeate sample port water endotoxin level was 0.69 EU/ml. Distribution loop 1, return sample port water endotoxin level was 2.06 EU/ml. Acid mixer 1, feed sample port water endotoxin level was 2.68 EU/ml. Ultrafilter 1, outlet sample port water endotoxin level was 1.28 EU/ml. Bicarb mixer 1, feed sample port water endotoxin level was 2.22 EU/ml. A leak in the water loop was repaired, and the tank and loop was disinfected 5/16/12. Repeat water samples drawn 5/18/12 revealed the RO 1, permeate sample port water endotoxin level was 0.65 EU/ml. Acid mixer 1, feed sample port water endotoxin level was 1.19 EU/ml. The</p>	V 179			

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V 179	<p>Continued From page 16</p> <p>tank and loop were disinfected 5/23/12. Post-disinfection samples drawn 5/25/12 revealed the RO 1, permeate sample port water endotoxin was 0.61 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 0.98 EU/ml. Pre-disinfection samples drawn 5/30/12 revealed the Bicarb dist sys, return sample port water culture was > 200 CFU/ml, the endotoxin level was 1.01 EU/ml. RO 1, permeate sample port water endotoxin level was 0.94 EU/ml. Distribution loop 1, return sample port water culture was 64 CFU/ml. Ultrafeed 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 1.07 EU/ml. The tank and loop were disinfected 5/30/12.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of May 2012.</p> <p>6/2012 - Pre-disinfection samples drawn 6/1/12 revealed the RO 1, permeate sample port water endotoxin level was 0.58 EU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Bicarb mixer 1, feed sample port water culture was 140 CFU/ml. The DI bypass hoses, pump outlet hose, post UF sample port, bicarb feed sample port, were replaced, and leaks to DI monitor were repaired. The water treatment system was disinfected 6/3/12. Post-disinfection samples drawn 6/5/12 revealed the Sample port 2, outlet water culture was 110 CFU/ml. Sample port 3, outlet water culture was > 200 CFU/ml, the endotoxin level was 1.23 EU/ml. Sample port 4, outlet water culture was > 200 CFU/ml. Sample port 5, outlet water culture was > 200 CFU/ml. Sample port 6, outlet water culture was 70</p>	V 179			

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V 179	<p>Continued From page 17</p> <p>CFU/ml. Sample port 7, outlet water culture was 128.0 CFU/ml. Repeat samples drawn 6/14/12 revealed the RO 1, polished sample port water endotoxin level was 1.14 EU/ml. Sample port 1, outlet sample port water culture was 70 CFU/ml, the endotoxin level was 9.60 EU/ml. Sample port 2, outlet, endotoxin level was 4.24 EU/ml. Sample port 3, outlet water endotoxin level was 1.70 EU/ml. Sample port 4, outlet, water endotoxin level was 1.06 EU/ml. Sample port 5, outlet water endotoxin level was 5.36 EU/ml. Sample port 6, outlet water endotoxin level was 3.54 EU/ml. Sample port 7, outlet water culture was > 200 CFU/ml, the endotoxin level was 4.27 EU/ml. Repeat samples drawn 6/19/12 revealed the Bicarb mixer 1, feed sample port water culture 54 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml, the endotoxin level was 0.96 EU/ml. Pre-disinfection samples drawn 6/25/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected on 6/27/12.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture and endotoxin levels during the month of June 2012.</p> <p>7/2012 - Post-disinfection samples drawn 7/6/12 revealed the Ultrafilter 1, feed sample port water culture was 128 CFU/ml. A sample drawn 7/10/12 revealed the Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was ></p>	V 179			

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V 179	<p>Continued From page 18</p> <p>200 CFU/ml. Bicarb mixer 1, feed sample port water culture was > 200 CFU/ml. Pre-disinfection samples drawn 7/15/12 revealed the Distribution Loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Acid Mixer 1, feed sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected 7/15/12. A sample drawn 7/31/12 revealed the Distribution loop 1, return sample port water culture was > 200 CFU/ml. Ultrafilter 1, feed sample port water culture was 158 CFU/ml. Acid Mixer 1, feed sample port water culture was 180 CFU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of July 2012.</p> <p>8/2012 - Pre-disinfection samples drawn 8/5/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution Loop 1, return sample port water culture was > 200 CFU/ml. The water holding tank and loop were disinfected 8/5/12. Pre-disinfection sample drawn 8/17/12 revealed the Ultrafilter 1, feed sample port water culture was > 200 CFU. The 500 gallon holding tank was replaced with a 250 gallon unit on 8/18/12. The tank and the loop were disinfected 8/19/12. Post-disinfection sample drawn 8/29/12 revealed the Ultrafilter 1, feed sample port water culture was 150 CFU/ml.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of August 2012.</p> <p>9/2012 - Water samples drawn 9/6/12 revealed</p>	V 179			

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V 179	<p>Continued From page 19</p> <p>the Distribution Loop 1, return sample port water culture was 132 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Water samples drawn 9/11/12 revealed the Ultrafeed 1, feed sample port water culture was > 200 CFU/ml. Storage tank 1, feed sample port water culture was 102 CFU/ml. Distribution loop 1, return sample port water culture was 184 CFU/ml. Pre-disinfection samples drawn 9/16/12 revealed the Ultrafilter 1, outlet sample port water culture was 180 CFU/ml. Ultrafilter 1, feed sample port water culture was > 200 CFU/ml. Distribution loop 1, return sample port water culture was > 200 CFU/ml. The hemodialysis RO and loop were disinfected 9/16/12. Pre-disinfection samples drawn 9/26/12 revealed the Ultrafilter 1, feed sample port water culture was 74 CFU/ml. The water holding tank and loop were disinfected 9/26/12.</p> <p>There was no documentation the Medical Director had reviewed and monitored the elevated water culture levels during the month of September 2012.</p> <p>10/2012 - A water sample drawn 10/3/12 revealed the Ultrafilter 1, feed sample port water culture was 140 CFU/ml. The water treatment system was disinfected 10/10/12. Post-disinfection samples drawn 10/12/12 revealed the Ultrafilter 1, feed sample port water culture was 126 CFU.</p> <p>There was no documentation the Medical Director had reviewed and monitored the the elevated water culture levels for 10/2/11 and 10/12/12.</p> <p>During an interview in the conference room on</p>	V 179			

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V 179	<p>Continued From page 20</p> <p>10/16/12 at 4:35 PM, the Technical Supervisor verified there had been water problems since February 2012.</p> <p>During an interview in the conference room on 10/16/12 at 4:55 PM when the Director of Operations was asked if she felt the patients had been at risk for any problems related to the water, she stated, "...we looked at infections... looked at validations... did seek and try to resolve it... [have] piece of mind in that dialysate is clear..."</p> <p>During an interview in the water room on 10/18/12 at 10:37 AM, the Technical Operations Director stated the next step was to replace the loop.</p> <p>During a telephone interview from the conference room on 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware.</p> <p>The Medical Director failed to ensure the development and implementation of an action plan to determine the root cause of the elevated bacteria and endotoxins in the water used to prepare dialysate, and to ensure the elevated levels were treated in a manner to ensure patient safety for the months of 4/2011, 5/2011, 6/2011, 7/2011, 8/2011, 9/2011, 10/2011, 11/2011, 12/2011, 1/2012, 2/2012, 3/2012, 4/2012, 5/2012, 6/2012, 7/2012, 8/2012, 9/2012, and 10/2012 resulting in IMMEDIATE JEOPARDY. Review of the facility hemodialysis schedules and treatment records revealed patients continued to dialyze during the months of 4/2011 - 10/2012 when the water cultures and/or endotoxins were elevated</p>	V 179			

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V 179	Continued From page 21 demonstrating the IMMEDIATE JEOPARDY situation continues.	V 179			
V 190	<p>494.40(a) SOFTENERS-AUTO REGENERATE/TIMERS/SALT LVL</p> <p>5.2.4 Softeners: auto regen/timers/salt/salt level Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution.</p> <p>5.2.4 Softeners Refer to RD62:2001, 4.3.10 Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.</p> <p>The face of the timers used to control the regeneration cycle should be visible to the user.</p> <p>6.2.4 Softeners Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.</p> <p>The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.</p>	V 190			

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V 190	Continued From page 22 This STANDARD is not met as evidenced by: Based on policy review, observation and interview, the facility failed to follow their policy for monitoring salt pellets in the brine tank for 3 of 4 (10/15/12, 10/16/12, and 10/18/12) observation days. The findings included: 1. Review of the facility's "Water Treatment Equipment" policy revealed, "...The top level of the salt pellets in the brine tank must be maintained above the level of the brine solution in the tank..." 2. Observation in the water room on 10/15/12 at 4:25 PM revealed the salt pellets inside the brine tank were below the solution level. 3. Observation in the water room on 10/16/12 at 4:15 PM revealed the salt pellets inside the brine tank were below the solution level. 4. Observation in the water room on 10/18/12 at 10:19 AM revealed the Technical Operations Manager opened the brine tank lid and observed salt pellets piled on one side allowing water to be visible. 5. During an interview in the water room on 10/15/12 at 4:30 PM, the Biomed Technician stated, "...that is supposed to be checked daily by whoever checks the chlorine at the beginning of the day..." 6. During an interview in the water room on	V 190			

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V 190	Continued From page 23 10/16/12 at 12:00 PM, the Technical Supervisor stated, "...the system regenerates on non nocturnal nights and the next morning would fill with salt if needed..." 7. During an interview in the water room on 10/16/12 at 12:00 PM, the Biomed Technician stated, "...there should be more salt. The person who checked the tank this morning didn't add it..." 8. During an interview in the water room on 10/18/12 at 10:19 AM the Technical Operations Manager was asked by the surveyor if the salt was leveled out would it be above the level of the water? He stated, "Needs more salt."	V 190			
V 274	494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety. This STANDARD is not met as evidenced by: Based on facility policy review, culture and endotoxin reports, and facility Quality Assessment and Performance Improvement (QAI) Incenter Hemodialysis Meeting Minutes, the facility failed to develop and implement a corrective action plan that ensured patient safety when bacterial and endotoxin results identified recurrent levels outside the allowable limits and action levels in the water treatment system used to prepare water for dialysis for 19 of 19 (4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12) months reviewed.	V 274			

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V 274	Continued From page 24 Failure of the Quality Assessment and Performance Improvement committee to develop and implement a corrective action plan for the recurrent elevated microbial levels resulted in a SERIOUS AND IMMEDIATE THREAT to all patients receiving hemodialysis and placed them at risk for complications including serious infection and death. The findings included: Review of the facility "Quality Assessment and Performance Improvement Program (QAPI)" policy revealed, "The Quality Assessment and Performance Improvement (QAI) Program encompasses all aspects of patients care ... is responsible for monitoring, problem solving, and reporting ... The QAI Program is designed and implemented to objectively, systematically, and comprehensively monitor, evaluate, and improve the quality and appropriateness of patient care and services by identifying opportunities and resolving identified problems ... The facility QAI Committee establishes priorities, develops and implements improvement projects based on established priorities and monitors these projects for effectiveness ... The Technical Services Representative is responsible for: Identification of improvement opportunities; Reporting on technical related issues, including water and dialysate ... The facility must take immediate, appropriate actions to address any serious threats and ensure patient safety. Examples of urgent priorities which could pose a threat to the health and safety of our patients and require immediate correction include ... Dangerous levels of contaminant in product water ... Elements to be	V 274			

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V 274	<p>Continued From page 25</p> <p>reviewed in the QAI meeting include ... Technical Operations, including water and dialysate quality and safety ..."</p> <p>Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", documented, "...Water cultures will be monitored using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml... Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..."</p> <p>Review of the bacterial cultures and endotoxin testing results for the water treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12, and 10/12 documented culture and/or endotoxin levels outside the allowable or action levels.</p> <p>Review of the QAI meeting minutes dated 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12 and 9/12 revealed no documentation the elevated water cultures and endotoxin levels were tracked and trended to determine a root cause for the continued elevated water cultures and endotoxin levels. There was no documentation an action plan was developed</p>	V 274			

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V 274	Continued From page 26 and implemented to ensure the water cultures and endotoxins were maintained within the acceptable parameters. Attached to the QAPI meeting minutes were communication summaries used by the technicians to show the summary of water cultures and endotoxin levels elevated outside of the allowable limits. Under the section of the QAPI meeting minutes titled, "Water/Dialysate Quality Monitoring: Microbiology and Water Chemical Analysis" in the area stating "Is disinfection required more than monthly...", the answer was marked "No"; the area titled "Improvement Area" was marked "No."	V 274			
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Based on facility policy review, medical record review, observation and interview, the facility failed to maintain visibility of vascular access sites and line connections at all times. The facility's failure to maintain access and line visibility provided an opportunity for a disconnected line to be undetected leading to excessive blood loss for Pt #7 and resulting in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Pt #7 and for all patients receiving hemodialysis at the facility and placed them at risk for serious complications including death. The findings included:	V 400			

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V 400	Continued From page 27 1. The facility failed to maintain visibility of vascular access sites and bloodline connectors during hemodialysis treatments resulting in Pt #7 experiencing excessive blood loss due to a disconnected access line. Refer to V 407.	V 400			
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Based on facility policy review, medical record review, observation and interview, the facility failed to maintain visibility of hemodialysis access sites and line connections during treatment for 2 of 17 (Pt #7 and 14) sampled patients and 4 (RP #1, 2, 3 and 4) Random Patients. The facility's failure to adequately visualize and monitor Pt #7's vascular access during treatment on 9/18/12 resulted in excessive blood loss of approximately 1500 ml. The facility's failure to adequately visualize and monitor hemodialysis access sites and bloodlines resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility placing them at risk for serious complications including death. Continued disregard for maintaining visibility and monitoring vascular access sites demonstrates the IMMEDIATE JEOPARDY continues. The findings included:	V 407			

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V 407	<p>Continued From page 28</p> <p>1. Review of the facility's policy and procedure, "Patient Monitoring During Patient Treatment" documented, "POLICY: Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary... Vital Signs/Mental Status: Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently, as needed.... Access: Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure access remains uncovered throughout the treatment. Documentation: Documentation of monitoring will be completed on the treatment record."</p> <p>Review of the facility policy, "Patient Safety Checks" documented, "Purpose: The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications. Responsibility: direct Patient Care Staff (based on job description, licensure, certification, Federal/State regulations). Policy: Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTIONS SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES."</p> <p>2. Medical record review for Pt #7 revealed an admission date of 3/1/06 with diagnosis of End Stage Renal Disease. Her pre treatment vital signs at 9:32 AM on 9/18/12 were blood pressure 117/78 and pulse 121 R (regular). Review of the Treatment Sheet dated 9/18/12 revealed the patient's treatment was started at 9:43 AM and</p>	V 407			

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V 407	<p>Continued From page 29</p> <p>the Pre-Treatment Nursing Assessment was completed at 9:46 AM (after the start of the treatment). The RN Evaluation documented no unusual findings.</p> <p>There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM. At 11:12 AM, the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting comfortably."</p> <p>The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "9/18/12 15:57 (3:57 PM) RN Evaluation-No unusual findings noted. Notes: at aprox 1210 pt became non responsive O2 applied, 911 called, 2000 ml of saline given and 2 cordial thumps administered, 20 compressions given, became responsive, was alert and responsive at time of departure. Aprox 1500 ml blood loss." Her post dialysis vital signs at 12:20 PM documented a blood pressure of 109/57 and pulse 144 IR (irregular).</p> <p>Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech that she was feeling short of breath and asked if he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation</p>	V 407			

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V 407	<p>Continued From page 30</p> <p>of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss. The lines were reconnected and CPR, rinse back with normal saline administration continued. Patient opened her eyes and was alert and oriented. Patient was sent to the emergency room by ambulance."</p> <p>Review of the hospital's consultation report dated 9/18/12 documented, "A stat hemoglobin [the oxygen-carrying pigment of the red blood cell] was 7.4 with hematocrit [the volume of packed red cells in a blood specimen] of 22.8. The most previous hematocrit that I have available from last week was 36."</p> <p>Review of the patient's lab reports revealed on 8/21/12 HCT was 39.2 [normal range 37-47]. On 8/28/12 her Hgb was 12.3 [normal range 12-16] and on 9/4/12 her Hgb was 12.1. On 9/18/12 at 9:40 AM prior to needle dislodgement, her Hgb was 12.5 and on 9/27/12 her Hgb was 10.3.</p> <p>Review of the IDT evaluation dated 2/24/12 revealed no documentation of concerns with the patient covering her access site. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered.</p> <p>Review of the Plan of Care signed by the IDT on 2/24/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered. Review of the 6 Month Patient Plan of Care Updated dated 8/10/12 revealed no documentation to address concerns with the patient keeping her access covered</p>	V 407			

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V 407	<p>Continued From page 31</p> <p>during treatments. Review of the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation to address concerns with the patient keeping her access covered during treatments.</p> <p>During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, "I was doing blood pressures on that section of patients. I had just checked her [Pt #7]. She coughed a funny cough. She had been coughing because I had given her an emesis basin earlier because she was spitting up. When she coughed funny I called for the nurse. She came over and saw that [patient] was gasping for air. She reclined her in the chair all the way. The chairs go into Trendelenburg [position where the patient is flat on a table or bed, with head positioned 30-40 degrees downward] position and started CPR. I started rinse back, and another nurse came over to help. We didn't notice her bleeding. [Patient] always kept her access covered. She said she was cold."</p> <p>During a telephone interview with the Medical Director on 10/18/12 at 3:00 PM, the Medical Director stated he was aware of the blood loss incident with this patient and an investigation was conducted that revealed the facility did not follow their protocol for using the correct lines. A manual line was used instead of a twister access line.</p> <p>Failure of the facility to maintain visibility of the hemodialysis access site and monitor for bleeding for at the access site resulted in loss of approximately 1500 cc of blood for Pt. #7.</p>	V 407			

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V 407	Continued From page 32 3. Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt. 4. Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections. 5. Observations on 10/15/12 beginning at 2:17 PM revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site. 6. Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites covered by a blanket.	V 407			
V 500	494.80 CFC-PATIENT ASSESSMENT This CONDITION is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to follow policies for monitoring blood pressures and administration of normal saline for cramping. The findings included: 1. The facility failed to follow its policies for hypertension and hypotension parameters for treatment and normal saline administration for	V 500			

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V 500	Continued From page 33 cramping. Refer to V 504	V 500			
V 504	494.80(a)(2) PA-ASSESS B/P, FLUID MANAGEMENT NEEDS The patient's comprehensive assessment must include, but is not limited to, the following: Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Based on policy review, medical record review and interview, the facility failed to follow policies for the treatment of blood pressures out of parameters and treatment of cramping for 7 of 17 (Pt #1, 4, 6, 7, 8, 12 and 17) sampled patients. The findings included: 1. Review of the facility's "Blood Pressure Management Treatment Parameters" policy revealed, "...Hypertension SBP > 190 and/or DBP > 110...Intradialytic Hypertension...If asymptomatic administer 0.1 mg Clonidine per MD order...Check BP in 1 hour. If BP decreasing continue to monitor. If BP still elevated above parameters administer second dose of Clonidine 0.1 mg PO ...Check BP again in 1 hour. If BP still elevated 1 hour after second dose notify MD for further orders...Post Treatment...If asymptomatic administer 0.1 mg Clonidine per MD order. Check BP in 1/2 hour. If BP decreasing patient may be discharged. If BP is still above parameters notify MD for further orders...Hypotension SBP <100...Pre Treatment...If asymptomatic initiate treatment and	V 504			

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V 504	<p>Continued From page 34</p> <p>administer 200 ml Normal Saline in addition to normal prime...If BP decreasing notify MD...Post Treatment...administer additional 200 ml NS...Check BP in 5 minutes...If BP increasing patient may be discharged..."</p> <p>2. Review of the facility policy, "Treatment of Muscle Cramping" revealed, "Follow the steps below to treat muscle cramps during the hemodialysis treatment...Reduce target goal, or turn UF button "off". 2. Take blood pressure, as muscle cramps commonly occur in conjunction with hypotension. 3. If blood pressure is low, give 100 ml. normal saline per procedure...to replace fluid and sodium to the bloodstream and tissues...4. Repeat bolus of normal saline in 100 ml. increments, if necessary for hypotension. Maximum of 500 ml. normal saline..."</p> <p>3. Medical record review for Pt #1 revealed the following elevated blood pressure readings which were not treated: 8/29/12 - BP's of 210/72 at 11:33 AM, 192/79 at 12:03 PM, 168/112 at 1:13 PM. 8/31/12 - BP's of 200/79 at 11:11 AM, 197/80 at 12:05 PM, 204/78 at 12:46, 193/76 at 1:31 PM, 166/144 at 1:55 PM. 9/3/12 - BP's of 198/87 at 11:33 AM, 196/80 at 12:37 PM, 202/79 at 1:40 PM and 193/85 at 2:47 PM. 9/12/12 - BP's of 204/77 at 11:10 AM, 205/83 at 11:39 AM, 196/81 at 12:40 PM, 194/72 at 1:03 PM, 196/77 at 2:02 PM. 9/21/12 - BP's of 197/98 at 12:11 PM, 204/82 at 2:00 PM and 211/93 at 2:30 PM. 9/24/12 - BP's of 208/91 at 11:22 AM and 198/85 at 12:35 PM. 9/26/12 - BP's of 217/91 at 11:06 AM, 211/91 at</p>	V 504			

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V 504	<p>Continued From page 35</p> <p>11:07, 210/96 at 11:34 AM and 197/88 at 12:11 PM.</p> <p>4. Medical record review for Pt #4 revealed the following elevated blood pressure reading which was not treated: 9/11/12 - BP of 166/112 on the post vital signs evaluation.</p> <p>5. Medical record review for Pt #6 revealed the following elevated blood pressure readings which were not treated: 8/29/12 - BP of 225/107 at 12:06 PM. 9/12/12 - BP of 173/138 at 2:28 PM.</p> <p>6. Medical record review for Patient #7 documented on the Hemodialysis Flowsheet dated 8/7/12, "11:50 AM ...pt complained of mild cramping, goal reduce and rn is aware. 12:11 PM blood pressure 58/43 Patient alert; pt not feeling well 200 ns giving reduced goal to 3000. 12:15 PM Patient alert; 200 ns giving will continue to monitor." Review of the LPN's documentation on the Post Dialysis Vitals and Evaluation revealed at 1:22 PM the patient's blood pressure was 80/57 and her heart rate was 113. The LPN documented the patient was discharged home at 1:39 PM. At 2:55 PM on the Post Assessment Nursing Evaluation, the RN documented, "Post assessment done, pt sent to [name of local hospital] for low bp and increased hr per [name of nurse practioner]. [Patients doctor name] aware."</p> <p>Further medical record review for Pt #7 revealed the following decreased blood pressure readings which were not treated: 8/28/12 -BP's of 76/54 at 12:07 PM, 79/55 at 12:32 PM, 78/55 at 1:04 PM, and 82/51 at 1:26</p>	V 504			

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V 504	<p>Continued From page 36</p> <p>PM.</p> <p>9/1/12 - BP's of 73/56 at 12:01 PM, and 73/51 at 12:39 PM.</p> <p>9/4/12 - BP's of 76/54 at 10:37 AM, 70/50 at 10:52 AM, 79/56 at 11:06 AM, 76/57 at 11:18 AM, 74/58 at 11:36 AM, 80/58 at 12:11 PM, and 77/55 at 12:35 PM.</p> <p>8. During an interview in the Biomed room on 10/8/12 at 3:43 PM, the DOO stated, "...we recognized we have blood pressure issues...got special permission from technical to see where we could post parameters [on the hemodialysis machines]..."</p> <p>9. Medical record review for Patient #8 documented on the Hemodialysis Flowsheet dated 6/1/12, "18:05 [6:05 PM] c/o cramping. uf goal is cut back to min. 300 cc ns is given by RN's advice continue to monitor" There was no documentation that the patients blood pressure was taken and addressed. On 6/6/12 at 5:32 PM, "pt states cramping uf goal was reduced to minimum team leader gave 200 ml of ns bp stable."</p> <p>10. Medical record review for Patient #12 documented on the Hemodialysis Flowsheet dated 2/2/12, "pt c/o cramping in hands goal decreased to 3800 150 ml NS given bp stable. (b/p 139/45)". On 2/11/12 at 12:32 PM the Hemodialysis Flowsheet documented, "patient b/p is low (81/38) nurse notified patient was given 150 cc of saline per nurse patient uf goal was reduced from 3500 to 300 per nurse. On 2/21/12 the Hemodialysis Flowsheet documented, "11:47 AM c/o cramping gave 200 ml ns and decreased goal to 3690. 11:50 AM pt c/o cramping no</p>	V 504			

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V 504	Continued From page 37 easing gave 200 ml ns pt stated subsided." 11. Medical record review for Patient #17 documented on the Hemodialysis Flowsheet dated 9/28/12, "Multidisciplinary Notes: 7:40 b/p stable but pt cramping in right calf, ankle and foot. 400 cc ns given without relief, will continue to monitor." The patient's treatment ended at 9:57 AM and there was no other documentation to address the patient cramping. The facility failed to adhere to its policies and procedures for hypertension, hypotension, and muscel cramping.	V 504			
V 540	494.90 CFC-PATIENT PLAN OF CARE This CONDITION is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to develop measurable timetables, monitor patients pre/during/post dialysis, obtain patients input in POC, failed to implement a POC within timeframe after admission and failed to revise the POC to address patients non compliance with keeping accesses visible during treatments. The facility's failure to address and to revise the POC to include interventions for vascular access visibility and the failure to adhere to its own policies for patient monitoring resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility and placed them at risk for potential death due to excessive blood loss.	V 540			

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V 540	Continued From page 38 The findings included: 1. The facility failed to develop measurable timetables for the POC. Refer to V 541. 2. The facility failed to include interventions for vascular access visibility in the POC and adequately monitor patients during dialysis, complete pre and post assessments and respond to hypertension/hypotension during treatments. Refer to V 543. 3. The facility failed to document the patients participation in the POC. Refer to V 556. 4. The facility failed to implement a POC within 30 days or 13 treatments after admission. Refer to V 557. 5. The facility failed to revise the POC to address patients non compliance with keeping accesses uncovered. Refer to V 559	V 540			
V 541	494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes	V 541			

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V 541	Continued From page 39 specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards. This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to develop a POC with measurable timetables for 1 of 17 (Pt #17) sampled patients. The findings included: Medical record review for Pt #17 documented a 90 day POC dated 9/28/12 by the IDT. Review of the care plan problems for Blood Pressure & Fluid Management, Anemia Management, and Dialysis Access revealed no documentation of measurable time tables to meet goals. During an interview on 10/17/12 at 5:05 PM, the Director of Operations verified that the POC did not have measurable time tables.	V 541			
V 543	494.90(a)(1) POC-MANAGE VOLUME STATUS The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; This STANDARD is not met as evidenced by: Based on facility policy review, medical record review and interview, the facility failed to develop a POC that was individualized to include interventions to ensure vascular access sites remained visible, failed to ensure patients were	V 543			

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V 543	<p>Continued From page 40</p> <p>adequately monitored during dialysis, and failed to ensure assessments were completed before and/or after dialysis for 13 of 17 (Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15 and 17) sampled patients.</p> <p>The facility's failure to develop an individualized POC that included interventions to ensure vascular accesses were uncovered and visible throughout the hemodialysis treatment and monitored per policy resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of Patient #7 when she had excessive blood loss. This resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving hemodilaysis at the facility and placed them at risk for potential death due to excessive blood loss.</p> <p>The findings included:</p> <p>1. Review of the facility's "Comprehensive Interdisciplinary Assessment and Plan of Care" policy revealed, "...The patient's individualized comprehensive Plan of Care must include, but limited to the following: Dose of Dialysis... Provide necessary care and services to manage the patient's volume status... Vascular Access... Provide vascular access monitoring... Psychosocial Status... Provide necessary monitoring and social work interventions, including counseling services and appropriate referrals... Patient Education and Training... Include education and training for patients and family members or caregivers as applicable.... Updates to Plan... The Assessment/Update section of the Plan of Care should be updated monthly for patients identified as stable, but that</p>	V 543			

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V 543	<p>Continued From page 41</p> <p>are not meeting the expected goal within the established timeframe. If the patient is stable, but is NOT meeting the Plan of Care goals in specific areas, but is still within the established timeframe, then those areas should be reviewed and the Plan of Care revised, or changes documented elsewhere in the medical record, such as in the progress notes or attending physicians extender orders... Plan of Care discussions may be scheduled with the interdisciplinary team to review the Plan of Care and revise as indicated..."</p> <p>2. Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..."</p> <p>3. Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... The purpose of this policy is to provide direction for monitoring dialysis patients during treatment to ensure patient safety... Monitor the patient at the initiation of treatment and every 30 minutes, or more frequently as necessary... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed. Observe for changes in the patient's respirations, heart rate and blood pressure. Verify and react to unusual findings such as atypical blood pressure readings. Access: Observe and document at the initiation of dialysis and at every safety check that</p>	V 543			

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V 543	<p>Continued From page 42</p> <p>all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment; Observe and ensure: Tape is secure; Needles are intact; No bleeding or infiltration is noted... Documentation of monitoring will be completed on the treatment record. Appropriate interventions in response to changes in vital signs, treatment parameters, or machine adjustments shall be documented in the treatment record..."</p> <p>4. Review of the facility's "Patient Evaluation Pre Dialysis Treatment" policy revealed, "...The purpose of this policy is to provide guidance on evaluating the patient prior to initiating the dialysis treatment... [name of company] patient care staff will complete a pre dialysis evaluation prior to initiation of patient treatment... Performing an evaluation pre dialysis will assist the Clinician in identifying potential problems that may arise during dialysis treatment... Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record... Facilities in states that require nursing assessments for all patients should continue to perform and document the assessments as required..."</p> <p>5. Review of the facility's "Patient Evaluation Post Dialysis Treatment" policy documented, "...The purpose of this policy is to provide guidance on evaluating the patient after the dialysis treatment... [name of company] patient care staff will complete an evaluation post dialysis treatment on every patient... Patient assessment is a nursing responsibility and cannot be</p>	V 543			

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V 543	<p>Continued From page 43</p> <p>delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record... Facilities in states that require nursing assessments for all patients should continue to perform and document the assessments as required..."</p> <p>6. Review of the facility's "Monitoring the In-center Nocturnal Dialysis Patient" policy revealed, "...Nocturnal hemodialysis patients will have blood pressure and pulse obtained and documented at a frequency of not less than every two hours...the dialysis extracorporeal circuit and dialysis machine safety checks will be monitored and documented every 30 minutes during the patient's treatment..."</p> <p>7. Medical record review for Pt #7 revealed the treatment flow sheet documented the following on 8/28/12: treatment was initiated at 10:04 AM, the RN preassessment was done at 11:15 AM and VS were not documented every 30 minutes. On 9/1/12, 9/4/12 and 9/6/12 VS and safety checks were not documented every 30 minutes. On 9/11/12 treatment was initiated at 9:34 AM. Review of the flowsheet revealed a physician's order to increase blood pressure checks to every 15 minutes. VS were not documented every 15 minutes. On 9/18/12 treatment was initiated at 9:43 AM. The RN preassessment was not done until 9:46 AM.</p> <p>Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech</p>	V 543			

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V 543	<p>Continued From page 44</p> <p>that she was feeling short of breath and asked if he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss. The lines were reconnected and CPR, rinse back with normal saline administration continued. Patient opened her eyes and was alert and oriented. Patient was sent to the emergency room by ambulance."</p> <p>Review of the IDT evaluation dated 2/24/12 revealed no documentation Pt #7 covered her access during the hemodialysis treatment. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation Pt #7 covered her access during treatment.</p> <p>Review of the Plan of Care dated 2/24/12, the 6 Month Patient Plan of Care updated 8/10/12, and the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation by the IDT that Patient #7 kept her access covered during treatments.</p> <p>During a telephone interview on 10/23/12 at 2:10 PM PCT #5 was asked about Pt #7's blood loss on 9/18/12. PCT #5 stated, "... We didn't notice her bleeding... [Pt #7] always kept her access covered. She said she was cold..."</p> <p>The facility's failure to ensure visibility of the vascular access site and to monitor the access per policy and ensure the Plan of Care was individualized with interventions to keep vascular</p>	V 543			

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V 543	<p>Continued From page 45</p> <p>accesses uncovered during hemodialysis treatment resulted in SEVERE AND IMMEDIATE THREAT to the health and safety of Patient #7 and all patients receiving hemodialysis at the facility and placed Patient #7 at risk for potential death due to excessive blood loss.</p> <p>8. Medical record review for Pt #1 revealed the 9/21/12 treatment flow sheet documented treatment was initiated at 11:30 AM. The RN preassessment was not done until 3:05 PM and VS were not documented every 30 minutes.</p> <p>9. Medical record review for Pt #3 revealed the treatment flow sheets did not document VS every 30 minutes on 8/29/12, 9/7/12, 9/12/12, and 9/17/12. Rview of the treatment flowsheets did not documet safety checks every 30 minutes on 9/12/12 and 9/17/12.</p> <p>10. Medical record review for Pt #4 revealed the treatment flow sheet dated 9/1/12 documented treatment was initiated at 9:45 AM. The RN preassessment was not done until 10:03 AM and VS were not documented every 30 minutes. On 9/6/12 treatment was initiated at 10:00 AM. The RN preassessment was not done until 10:14 AM and VS were not documented every 30 minutes. On 9/8/12 and 9/11/12 the patient's VS were not documented every 30 minutes. On 9/15/12 treatment was initiated at 10:21 AM. The RN preassessment was not done until 2:49 PM and VS were not documented every 30 minutes. On 9/20/12 treatment was initiated at 10:38 AM and the first VS were documented at 12:08 PM.</p>	V 543			

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V 543	Continued From page 46 11. Medical record review for Pt #6 revealed the treatment flow sheets documented VS were not done every 30 minutes on 8/29/12, 9/12/12, 9/21/12, 9/24/12 and 9/26/12 and safety checks were not documented every 30 minutes on 8/29/12, 9/12/12, 9/21/12 and 9/24/12. On 9/12/12 treatment was initiated at 11:49 AM. the RN preassessment was documented at 8:37 PM. On 9/21/12 treatment was initiated at 10:51 AM, and there was no preassessment documented. 12. Medical record review for Pnt #8 revealed the treatment flow sheets did not document VS every 30 minutes on 6/1/12. 13. Medical record review for Pt #9 revealed the treatment flow sheets did not document VS every 30 minutes on 1/20/12 and 1/30/12. 14. Medical record review for Pt #11 revealed the treatment flow sheets did not document VS every 30 minutes on 7/3/12, 7/5/12 and 7/7/12. 15. Medical record for Pt #13 revealed the treatment flow sheet did not document VS every 30 minutes on 5/19/12. 16. Medical record review for Pt #14 revealed the treatment flow sheets did not document VS every 30 minutes on 9/14/12, 9/21/12 and 10/12/12. 17. Medical record review for Pt #15 revealed the treatment flow sheets did not document VS and safety checks every 30 minutes on 9/28/12 and 10/15/12. 18. Medical record review for Pt #17 revealed the	V 543			

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V 543	Continued From page 47 treatment flow sheets did not document VS every 30 minutes on 9/24/12, 9/26/12, 9/28/12, 10/1/12, 10/5/12 and 10/15/12 and safety checks were not documented every 30 minutes on 9/24/12. 19. Medical record review for Pt #2 revealed he received In-center nocturnal hemodialysis. The treatment flow sheets did not document VS every 2 hours on 8/19/12, 8/26/12, and 9/13/12. The treatment flowsheet did not document safety checks every 30 minutes 8/23/12, 8/26/12, 8/30/12, 9/2/12, 9/6/12, 9/13/12, 9/20/12 and 9/23/12. There was no RN documentation of a post assessment on 8/30/12 20. During an interview in the Biomed room on 10/8/12 at 2:15 PM, the Director of Operations stated, "...the system we now have takes the vital signs...they have to look at the blood pressure, acknowledge it before it crosses over..."	V 543			
V 547	494.90(a)(4) POC-MANAGE ANEMIA/H/H MEASURED Q MO The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs. This STANDARD is not met as evidenced by: Based on policy review, medical record review and interview, the facility failed to ensure Heparin was administered as ordered by the physician for	V 547			

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V 547	<p>Continued From page 48 2 of 17 (Pt #'s 3 and 15) sampled patients.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 1. Review of the facility's "Heparinization" policy revealed, "...Stopping the Heparin Pump...It is recommended the heparin pump be stopped: 30 minutes prior to the end of treatment in accordance with a physician order on patients dialyzing through a fistula or graft..." 2. Review of the facility's Physician Order Documentation" policy revealed, "...General Policy...Nurse practice acts require nurses to carry out treatment care, medication administration...based on physician orders..." 3. Medical record review for Pt #3 revealed the pt had an AV graft and a physician's order dated 9/20/11 for "...Heparin 1000U/H3.5 ...Every Sched TRMT..." <p>Review of the treatment flowsheets for Pt #3 revealed the Heparin infusion was not discontinued within 30 minutes prior to the end of dialysis treatment as follows: 8/29/12 - treatment was completed at 10:05 AM and the Heparin infusion was completed at 10:05 AM. 9/3/12 - treatment was completed at 10:07 AM and the Heparin infusion was completed at 10:07 AM. 9/7/12 - treatment was completed at 10:12 AM and the Heparin infusion was completed at 10:12 AM. 9/12/12 - treatment was completed at 10:16 AM and the Heparin infusion was completed at 10:16 AM.</p>	V 547			

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V 547	<p>Continued From page 49</p> <p>9/17/12 - treatment was completed at 10:07 AM and the Heparin infusion was completed at 10:31 AM.</p> <p>9/19/12 - treatment was completed at 10:03 AM and the Heparin infusion was completed at 10:15 AM.</p> <p>5. Review of the medical record for Pt #15 revealed a physician order dated 6/27/12 for "...Heparin...1,000 Units/ml Systemic- Infusion Rate 500 units per hour (1500 units during first three hours of treatment). Turn Heparin Pump Off 60 min prior to end of treatment..." Scheduled hours of treatment 4.0.</p> <p>Review of the treatment flowsheets for Pt #15 revealed the Heparin infusion was not discontinued within 60 minutes prior to the end of dialysis treatment and Pt #15 did not receive 1500 units of heparin as ordered: On 8/31/12 the treatment was completed at 2:42 PM, the Heparin infusion was completed at 2:42 PM with total Heparin infused 2,025.000. On 9/24/12, the flowsheet documented total Heparin infused was 2208.330. On 10/1/12 treatment was completed at 3:02 PM, the Heparin infusion was completed at 3:03 PM and the total Heparin infused was 2,033.330. On 10/15/12 treatment was completed at 2:06 PM, the Heparin infusion was completed at 6:10 PM and the total Heparin infused was 4,225.00.</p> <p>8. During an interview in the biomed room on 10/8/12 at 3:20 PM, the DOO verified the Heparin infusions were not stopped 30 minutes prior to end of treatment as ordered and stated, "...My guess is she documented when she did the post assessment..."</p>	V 547			

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V 556	<p>494.90(b)(1) POC-COMPLETED/SIGNED BY IDT & PT</p> <p>The patient's plan of care must-</p> <p>(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and</p> <p>(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.</p> <p>This STANDARD is not met as evidenced by: Based on policy review, record review and interview, the facility failed to include the patient in the plan of care for 2 of 17 (Pt's #3 and 17) sampled patients.</p> <p>The finding included:</p> <p>1. Review of the facility's "Comprehensive Interdisciplinary Assessment and Plan of Care" policy revealed, "...Plan of Care Requirements...The Plan of Care must be signed by team members including the patient or patient designee. If the patient is unable or chooses not to sign the Plan of Care, this must be documented on the Plan of Care along with the reason the signature was not provided..."</p> <p>2. Medical record review for Pt #3 documented a Plan of Care was developed by the IDT on 5/4/12. There was no indication by signature of the patient, that the patient had been involved in or approved the Plan of Care. There was no documentation why the patient had not been involved in or approved the Plan of Care.</p>	V 556			

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V 556	Continued From page 51 3. Medical record review for Pt #17 documented the patient was admitted to the facility on 7/25/12 for ESRD. A plan of care was developed by the IDT on 9/28/12. As of 10/18/12, there was no indication by signature of the patient, that the patient had been involved in or approved her Plan of Care. There was no documentation why the patient had not been involved in or approved the Plan of Care. In an interview on 10/17/12 at 5:05 PM, the Director of Operations verified that the patient had not been involved in her care planning process.	V 556			
V 557	494.90(b)(2) POC-INITIAL IMPLEMENTED-30 DAYS/13 TX Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to initiate a plan of care within 30 days or 13 treatments after admission for 1 of 17 (Pt #17) sampled patients. The findings included: Medical record review for Pt #17 documented she was admitted to the facility for chronic dialysis on 7/25/12. The first IDT Plan of Care was signed as a 90 day POC on 9/28/12.	V 557			

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V 557	Continued From page 52	V 557			
V 559	<p>During an interview in the conference room on 10/17/12 at 5:05 PM, the Director of Operations verified there was no POC within 30 days or 13 treatments after admission for chronic dialysis.</p> <p>494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC</p> <p>If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must-</p> <ul style="list-style-type: none"> (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section. <p>This STANDARD is not met as evidenced by: Based on medical record review and interview, the facility failed to adjust the POC to reflect the patient's current condition related to refusal to keep access visible for 1 of 17 (Pt #7) sampled patients.</p> <p>The facility's failure to assess and implement a POC to address access visibility resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of Pt #7 all patients receiving hemodialysis at the facility and placed them at risk for potential death due to excessive blood loss.</p> <p>The findings included:</p>	V 559			

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V 559	Continued From page 53 Medical record review for Pt #7 revealed the patient was admitted to the facility on 3/1/06 with diagnosis of End Stage Renal Disease. Review of the IDT evaluation dated 2/24/12 revealed no documentation of concerns with the patient covering her access site. Review of the Comprehensive Social Worker Assessment dated 8/7/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered. Review of the Plan of Care signed by the IDT on 2/24/12 revealed no documentation that the patient was non-compliant with keeping her access uncovered. Review of the 6 Month Patient Plan of Care Updated 8/10/12 revealed no documentation to address concerns with the patient keeping her access covered during treatments. Review of the Monthly Patient Plan of Care dated 9/14/12 revealed no documentation of concerns with the patient keeping her access covered during treatments and no update to the POC since the occurrence on 9/18/12. Review of the Post Dialysis Vitals and Evaluation section of the Treatment Record dated 9/18/12 documented, "Post vitals unable to complete-patient emergency." Review of the facility's event form dated 9/26/12 and completed by the Director of Operations documented, "Brief Summary of Incident: On September 18, 2012 [Pt #7] was receiving her dialysis treatment. She told the patient care tech that she was feeling short of breath and asked if	V 559			

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V 559	Continued From page 54 he would put her chair back (head down). The patient became unresponsive. CPR was initiated, Normal Saline was administered as her blood was rinsed back and 911 called. During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..." In a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, "I was doing blood pressures on that section of patients. I had just checked her [Patient #7]. She coughed a funny cough. She had been coughing because I had given her an emesis basin earlier because she was spitting up. When she coughed funny I called for the nurse. She came over and saw that [patient] was gasping for air. She reclined her in the chair all the way. The chairs go into Trendelenburg [position where the patient is flat on a table of bed, with head positioned 30-40 degrees downward] position and started CPR. I started rinse back, and another nurse came over to help. We didn't notice her bleeding. [Patient] always kept her access covered. She said she was cold."	V 559			
V 625	494.110 CFC-QAPI The facility's failure to ensure a POCs was developed and implemented to address access visibility, even after Pt #7 experienced excessive blood loss, continued to place Pt #7 and all patients in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all the patients receiving hemodialysis and placed them at risk for potential death.	V 625			

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V 625	Continued From page 55 This CONDITION is not met as evidenced by: Based on policy review, document review, record review and interview, the facility failed to ensure the QAPI committee provided effective quality assessment and performance activities that identified, prioritized and corrected major problems. The facility's failure to identify and address problems concerning vascular access visualization, monitoring of patient's during hemodialysis treatments and failure of the water treatment program to ensure testing results remained below allowable contamination levels resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the hemodialysis patients and placed them at risk for the potential of death and other complications from adverse events. The findings included: 1. The facility QAI program failed to trend results of testing for water used to prepare dialysate and develop a correction action plan effective in ensuring bacterial and endotoxin levels were maintained within acceptable parameters. Refer to V 627. 2. The facility QAI program failed to identify and take action to correct staff failure to follow facility policy and procedure for monitoring patients during hemodialysis treatments and patient failure to maintain vascular access site visibility during treatments. Refer to V-634.	V 625			
V 627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT	V 627			

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V 627	<p>Continued From page 56</p> <p>The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p> <p>This STANDARD is not met as evidenced by: Based on review of facility policy, water culture and endotoxin reports, water system disinfection logs, QAI meeting minutes and interview, the facility failed to ensure water testing results for recurrent elevated levels of bacterial growth and the presence of elevated levels of endotoxins were analyzed and addressed with a corrective action plan to ensure patient safety for 19 of 19 (4/2011-10/2012) months reviewed.</p> <p>The facility's failure to analyze the recurrent elevated levels of bacterial and endotoxins for a root cause and to implement corrective actions that eliminated the cause resulted in a SERIOUS AND IMMEDIATE THREAT to all patients receiving hemodialysis at the facility and placed them at risk for complications including serious infection and death. Facility hemodialysis schedules and treatment records indicate patient's continue to dialize during the months of 4/11 - 10/12 demonstrating the IMMEDIATE JEOPARDY continues.</p> <p>The findings included:</p> <p>Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes", revealed, "....Water cultures will be monitored</p>	V 627			

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V 627	<p>Continued From page 57</p> <p>using the following action level and allowable limits; Bacteria RO or DI Product - Action level 20 CFU/ml and Allowable limit 50 CFU/ml. Bacteria RO Distribution - Action level 50 CFU/ml and Allowable limit 200 CFU/ml. Endotoxin RO or DI Product Action level .25 EU/ml and Allowable level 1 EU/ml. Endotoxin RO Distribution - Action level 1 EU/ml and Allowable limit 2 EU/ml..."</p> <p>Review of the bacterial cultures and endotoxin testing results for the water treatment system for the months of 4/1011 - 10/2012 revealed culture and/or endotoxin levels outside the allowable or action level during each of the 19 months reviewed.</p> <p>Review of the QAI minutes from April 2011 through September 2012 revealed there was no documentation that the QAI committee trended or developed plans of action for the recurrent bacterial and endotoxins that were above the allowable or action levels.</p> <p>During an interview in the conference room on 10/16/12 at 4:35 PM, the Technical Supervisor verified he was aware there had been water problems since February 2012.</p> <p>During an interview in the conference room on 10/16/12 at 4:55 PM when the Director of Operations was asked if she felt the patients had been at risk for any problems related to the water, she stated, "...we looked at infections... looked at validations... did seek and try to resolve it... [have] piece of mind in that dialysate is clear..."</p> <p>During a telephone interview in the conference on</p>	V 627			

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V 627	Continued From page 58 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware.	V 627			
V 634	Refer to V179 and V274. 494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification. This STANDARD is not met as evidenced by: Based on policy review, meeting minutes, document review, medical record review, observation and interview, the facility failed to ensure the QAPI committee identified and took action to minimize the number of occurrences and limit the number of patients affected by staff failure to follow facility policies and procedures for monitoring patients during hemodialysis treatments and failure of patients to maintain vascular access site visibility during treatments for 13 of 17 (Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17) sampled patients and 4 (RP #1, 2, 3, and 4) random patients observed. The facility's failure to identify and address these problems resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the hemodialysis patients and placed them at risk for the potential of death and other complications. The continued disregard for adherence to policy and procedure without intervention by the QAI	V 634			

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V 634	<p>Continued From page 59</p> <p>committee demonstrated the IMMEDIATE JEOPARDY continues.</p> <p>The findings included:</p> <ol style="list-style-type: none"> Review of the facility's "Quality Assessment and Performance Improvement Program" policy revealed, "The Quality Assessment and Performance Improvement (QAI) Program encompasses all aspects of patient care... The QAI Program is designed and implemented to objectively, systematically, and comprehensively monitor, evaluate, and improve the quality and appropriateness of patient care and services by identifying opportunities and resolving identified problems... Improvement projects will be prioritized by the QAI Committee... Examples of urgent priorities... Failure to provide adequate observation of patient, patient vascular access, or patient equipment." Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed... Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment... Documentation of monitoring will be completed on the treatment record..." <p>Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30</p>	V 634			

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V 634	<p>Continued From page 60</p> <p>minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..."</p> <p>Review of the facility's "Patient Evaluation Pre Dialysis Treatment" policy revealed, "...patient care staff will complete a pre dialysis evaluation prior to initiation of patient treatment... Patient assessment is a nursing responsibility and cannot be delegated to unlicensed patient care staff... The assessment must be documented in the patient's medical record..."</p> <p>3. Medical record review for Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17 from 1/20/12 through 10/15/12 revealed 9 incidents of the preassessment being performed after treatment had been initiated, 42 incidents of VS not being performed and documented timely according to policy and 20 incidents of safety checks not being performed and documented according to policy.</p> <p>4. Medical record review for Pt #7 revealed her 9/18/12 treatment was started at 9:43 AM and the Pre-Treatment Nursing Assessment was completed at 9:46 AM (after the start of the treatment). There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM when the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting</p>	V 634			

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V 634	<p>Continued From page 61</p> <p>comfortably." The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "...at aprox 1210 pt became non responsive... Aprox 1500 ml blood loss."</p> <p>Review of the facility's event form dated 9/26/12 revealed, "During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..."</p> <p>During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, [Pt #7] always kept her access covered. She said she was cold."</p> <p>5. Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt. Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections.</p> <p>Observations on 10/15/12 beginning at 2:17 PM revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site.</p> <p>Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites</p>	V 634			

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V 634	Continued From page 62 covered by a blanket. 6. Review of the Adverse Event Summary for Hemodialysis for 2012 documented 8 patients with blood loss >100 ml from February 2012 through September 2012. 7. Review of the QAI meeting minutes from 3/16/12 (February 2012) until September 2012 revealed the QAI committee failed to identify staff failure to adhere to facility policy for monitoring patients during hemodialysis treatment, failure to ensure visibility of vascular access during hemodialysis treatment, or blood loss as areas for improvement.	V 634			
V 692	494.140(e)(1),(2) PQ-PCT-STATE REQUIREMENTS & HS DIPLOMA Patient care dialysis technicians must- (1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and (2) Have a high school diploma or equivalency; This STANDARD is not met as evidenced by: Based on Tennessee Code for Practice of Professional Nursing, medical record review and interview, the facility failed to monitor PCT's to assure they did not administered NS to 2 of 17 (Patient ' s #8 and #13) sampled patients. The findings included: 1. Tennessee Code Annotated 63-7-103 Practice of Professional Nursing Defined (a) (1) documented, "Practice of professional nursing	V 692			

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V 692	Continued From page 63 means the performance for compensation of any act requiring substantial specialized judgement and skill based on knowledge of the natural, behavioral and nursing sciences, and the humanities, as the basis for application of the nursing process in wellness and illness care." Review of the Tennessee Board of Nursing Position Statement RE: Practice: Deligation of Medication Administration documented, "Authority: Tennessee Code Annotated 63-7-101 (license required to practice nursing)...Position: The Tennessee Board of Nursing will not approve a program for unlicensed persons to administer medication since such would reduce the quality of care which exists and may lower standards as recognized..." 2. Medical record review for Patient #8 revealed on 6/1/12 PCT #1 documented, "c/o cramping - uf goal is cut back to minimum 300 cc NS is given by RN's advice continue to monitor." 3. Medical record review for Patient #13 revealed on 5/10/12 at 9:17 AM, PCT #2 documented, "bp low 100 cc n/s rins [rinse] back. Cut uf to min." Review of the treatment sheet dated 5/12/12 revealed PCT #3 documented, "pt b/p is 92/67 m requested that the pt goal be reduced to minimum and 150 cc of saline be given." 4. In an interview at the nurses' station on 10/9/12 at 2:45 PM, the Director of Operations verified that the PCT gave NS per documentation.	V 692			
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR	V 710			

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V 710	<p>Continued From page 64</p> <p>This CONDITION is not met as evidenced by: Based on Governing Bylaws, facility policy and procedure, document review, medical record review, observation and interview, the Medical Director failed to demonstrate responsibility for ensuring delivery of quality patient care and clinical outcomes.</p> <p>The Medical Director's failure to ensure water quality was maintained, POC's were individualized and revised to reflect current patient safety issues, QAPI identified and corrected serious problems and staff adherence to policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all facility hemodialysis patients. Review and observations during the survey revealed these issues have not been corrected and demonstrates the IMMEDIATE JEOPARDY continues.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 1. The Medical Director failed to ensure the quality of the water used to prepare dialysate had water culture and endotoxin levels below the action levels and failed to ensure a cause for the continued elevated levels was identified and effective corrective actions were implemented and the problem resolved. Refer to V179, V274 and V627. 2. The Medical Director failed to ensure policies and procedures were followed for hemodialysis accesses sites and blood line connections to remain visible and monitored during treatment. Refer to V407 	V 710			

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V 710	Continued From page 65 3. The Medical Director failed to ensure POC's were individualized to include concerns for visibility and monitoring of patient's during treatment. Refer to V543 and V559 4. The Medical Director failed to ensure the QAPI committee identified variances and developed and implemented a corrective action plan to ensure the health and safety of all patients receiving hemodialysis. Refer to V634 and V712. 5. The Medical Director failed to ensure staff adhered to facility policies and procedures. Refer to V190, V407, V504, V547, V556 and V557.	V 710			
V 712	494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. This STANDARD is not met as evidenced by: Based on policy review, meeting minutes review, document review, medical record review and interview, the Medical Director failed to ensure the QAPI committee developed and implemented action plans to ensure the health and safety of patients receiving hemodialysis. The Medical Director's failure to demonstrate responsibility for QAPI intervention to maintain the water treatment system and to ensure adherence to facility policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all the	V 712			

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V 712	<p>Continued From page 66 patients receiving hemodialysis.</p> <p>The findings included:</p> <p>1. Review of the facility's policy "Quality Assessment and Performance Improvement Program (QAPI)" revealed "... The Medical Director is th Chairperson of the QAI Committee and is responsible for the overall effectiveness of the facility QAI Program and communication with the Governing Body of the status of QAI activities... The Medical Director will communicate with the Governing Body regarding QAI activities. The Governing Body will review information related to significant problems identified and their causes, and provide guidance and support for proposed needed corrections..."</p> <p>Review of the facility's Bylaws revealed, "...Medical Director Duties. The Medical Director is directly and actively responsible for the creation, on-going improvement and preservation of high quality professional care of patients at the Facility... The Medical Director is responsible for the delivery of patient care and outcomes in the Facility..."</p> <p>Review of the facility's policy, "Microbiological Monitoring of Water Used for Dialysis Purposes" revealed, "....Test results exceeding the Action Level or allowable limits - Promptly (within 48 hours) notify the Medical Director...Discuss with Medical Director, the creation of an action plan when test results indicate that the "Allowable limits" have been exceeded..."</p> <p>Review of the bacterial cultures and endotoxin testing results and disinfection logs for the water</p>	V 712			

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V 712	<p>Continued From page 67</p> <p>treatment system during the months of 4/11, 5/11, 6/11, 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12, 8/12, 9/12 and 10/12 revealed culture and/or endotoxin levels outside the allowable and/or action limits. There was no documentation the Medical Director reviewed and monitored the elevated water cultures.</p> <p>During a telephone interview from the conference room on 10/18/12 at 3:00 PM, the surveyor asked the Medical Director if he was aware of the issues with the water culture and endotoxin levels being out-of-range for the past year. The Medical Director stated he was aware.</p> <p>Review of the QAI meeting minutes dated 7/11, 8/11, 9/11, 10/11, 11/11, 12/11, 1/12, 2/12, 3/12, 4/12, 5/12, 6/12, 7/12 and 9/12 revealed no documentation the elevated water cultures and endotoxin levels were tracked and trended to determine a root cause for the continued elevated water cultures and endotoxin levels. There was no documentation an action plan was developed and implemented to ensure the water cultures and endotoxins were maintained within the acceptable parameters.</p> <p>Attached to the QAPI meeting minutes were communication summaries used by the technicians to show the summary of water cultures and endotoxin levels elevated outside of the allowable limits.</p> <p>Under the section of the QAPI meeting minutes titled, "Water/Dialysate Quality Monitoring: Microbiology and Water Chemical Analysis" in the area stating "Is disinfection required more than</p>	V 712			

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V 712	<p>Continued From page 68</p> <p>monthly...", the answer was marked "No"; the area titled "Improvement Area" was marked "No."</p> <p>2. Review of the facility's "Patient Monitoring During Patient Treatment" policy revealed, "... Vital signs will be monitored at the initiation of dialysis and every 30 minutes, or more frequently as needed... Observe and document at the initiation of dialysis and at every safety check that all connections are secure and visible... Ensure that bloodlines are secured to the patients... Ensure access remains uncovered throughout the treatment... Documentation of monitoring will be completed on the treatment record..."</p> <p>Review of the facility's "Patient Safety Checks" policy revealed, "... The purpose of this policy is to provide guidance on safety checks to prevent, detect and treat complications... Safety checks will be performed pre treatment and every 30 minutes or more frequently as needed once the treatment has begun. CAUTION: VASCULAR ACCESS, NEEDLE/CATHETER INSERTION SITES, BLOODLINE CONNECTIONS AND PATIENT'S FACES SHOULD BE VISIBLE AT ALL TIMES..."</p> <p>Medical record review for Patients #1, 2, 3, 4, 6, 7, 8, 9, 11, 13, 14, 15, and 17 from 1/20/12 through 10/15/12 revealed 42 incidents of VS not being performed and documented timely according to policy and 20 incidents of safety checks not being performed and documented according to policy.</p> <p>Medical record review for Pt #7 revealed her 9/18/12 treatment was started at 9:43 AM and the Pre-Treatment Nursing Assessment was</p>	V 712			

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V 712	<p>Continued From page 69</p> <p>completed at 9:46 AM (after the start of the treatment).</p> <p>There was no documentation of vital signs, access checks or safety checks from 9:43 AM until 11:12 AM when the PCT documented the patient's vital signs (BP-100/68 P-117) and that the patient was alert and resting comfortably. At 12:07 PM, vital signs were documented (BP-94/70 P-114) by the PCT and that the patient was, "alert, denies complaints, resting comfortably." The Post Dialysis Vitals and Evaluation section of the Treatment Record documented, "Post vitals unable to complete-patient emergency." The Nursing Evaluation documented, "...at aprox 1210 pt became non responsive... Aprox 1500 ml blood loss."</p> <p>Review of the facility's event form dated 9/26/12 revealed, "During initiation of CPR it was noted that the venous needle and line had become separated and the patient had experienced blood loss..."</p> <p>During a telephone interview on 10/23/12 at 2:10 PM, PCT #5 stated, [Pt #7] always kept her access covered. She said she was cold."</p> <p>Observations on 10/15/12 beginning at 1:45 PM revealed Pt #14 receiving hemodialysis with his access covered by the sleeve of his shirt.</p> <p>Observations on 10/15/12 beginning at 1:52 PM revealed RP #1 was covered with a blanket from the knees to shoulders. The patient was continuously observed from 1:52 PM to 3:10 PM and the staff did not uncover or assess the patient's access site or line connections.</p> <p>Observations on 10/15/12 beginning at 2:17 PM</p>	V 712			

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V 712	Continued From page 70 revealed RP #2 notified the PCT that she was cramping. The nurse was observed to give the patient a normal saline bolus. During this time the patient's access site was covered with a quilt. Neither the nurse nor the PCT uncovered the access site. Observations on 10/17/12 beginning at 8:20 AM revealed RP #3 and RP #4 were receiving hemodialysis treatment with their access sites covered by a blanket. Review of the Adverse Event Summary for Hemodialysis for 2012 documented 8 patients with blood loss >100 ml from February 2012 through September 2012. Review of the QAI meeting minutes from 3/16/12 (February 2012) until September 2012 revealed the QAI committee failed to identify staff failure to adhere to facility policy for monitoring patients during hemodialysis treatment, failure to ensure visibility of vascular access during hemodialysis treatment, or blood loss as areas for improvement.	V 712			
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by:	V 715			

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V 715	<p>Continued From page 71</p> <p>Based on Bylaws review, facility policy review, medical record review, observation and interview, the Medical Director failed to ensure staff adhered to facility policies and procedures for medication preparation, vascular access visualization, monitoring during treatment, B/P and cramping management and Heparin administration.</p> <p>The Medical Director's failure to demonstrate responsibility for staff adherence to policies and procedures concerning vascular access visibility and monitoring of patient's during treatment resulted in SERIOUS AND IMMEDIATE THREAT to the health and safety of all the patients receiving hemodialysis at the facility.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 1. Review of the facility By-laws revealed, "...The Medical Director is responsible for the delivery of patient care and outcomes in the Facility and is accountable to the Company [company initials], Medical Department, Governing Body and CMS, for the quality of medical care provided to patients... Ensure that all policies and procedures relative to patient admissions, patient care (including, but not limited to, patient comprehensive assessments, plans of care and patient rights and responsibilities), infection control, and safety are made available to all medical staff members and non-physician practitioners and that they are adhered to by all individuals who treat patients in the Facility..." 2. Review of the facility policy and procedure, "Medication Preparation and Administration" revealed, "Labeling Vials: When preparing 	V 715			

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V 715	<p>Continued From page 72</p> <p>medications if the vial is not used immediately in its entirety, the nurse must place the date and time the vial was opened on the medication label along with the nurse initials."</p> <p>Observations during a tour of the treatment area on 10/15/12 at 1:45 PM at machine #20 revealed a syringe filled with a clear liquid was infusing. There was no label on the syringe indicating what was inside, when it was drawn up or whom. Observations in the locked medication drawer during tour of the treatment area on 10/15/12 at 2:42 PM revealed syringes for 11 different patients labeled with the medication name, patient names and the date 0/15/12. There was no time or initials to indicate who drew the medication into the syringes.</p> <p>During an interview in the conference room on 10/18/12 at 10:20 AM the Director of Operations verified the correct procedure for medication administration is to label the drugs with name, initials and time the medication was drawn into the syringe.</p> <p>3. Review of facility policies, "Patient Monitoring During Patient Treatment", Patient Safety Checks", facility incident report, medical record review and interview revealed the Medical Director failed to ensure the policies and procedures visual monitoring of the vascular access and bloodline connections, VS and safety checks.</p> <p>Failure of the Medical Director to ensure the policies and procedures for monitoring patients during hemodialysis treatment resulted in Pt #7 experiencing excessive blood loss. Refer to V407 and V543.</p>	V 715			

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V 715	Continued From page 73 4. Review of facility policies "Blood Pressure Management Treatment Parameters" and "Treatment of Muscle Cramping" revealed the Medical Director failed to ensure patients who experienced hypertension or hypotension, and/or muscle cramping during hemodialysis treatment were treated according to policy. Refer to V 504. 5. Review of facility policy "Comprehensive Interdisciplinary Assessment and Plan of Care" revealed the Medical Director failed to ensure staff followed facility policies and procedures to individualize the POC for Pt #7's covered vascular accesses and bloodlines durring the dialysis treatment. Refer to V543 and V559. 6. Review of the facility "Heparinization" policy revealed the Medical Director failed to ensure the staff discontinued heparin infusion according to policy. Refer to V547.	V 715			
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on Bylaws, Governing Body meeting minutes, policy review, medical record review, water culture and endotoxin levels, disinfection logs, observation and interview, the Governing Body failed to ensure water used to prepare dialysate was maintained below action level to ensure health and safety of patients who received hemodialysis and failed to find a cause for the continued elevated bacterial cultures and endotoxins, maintain visibility and monitor patient	V 750			

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V 750	<p>Continued From page 74</p> <p>accesses during treatment, and ensure the facility followed policies and procedures to ensure the health and safety of all patients who received hemodialysis at the facility.</p> <p>The Governing Body's failure to ensure the water was free of bacteria, POC's were individualized to address the current needs of the patient, QAPI program identified issues and put actions into place for correction and staff adherence to policies and procedures resulted in a SERIOUS AND IMMEDIATE THREAT to the health and safety of all patients receiving dialysis. Record review, observations and interviews during the survey revealed these occurrences had not been corrected and demonstrated the IMMEDIATE JEOPARDY situation continues.</p> <p>The findings included:</p> <ol style="list-style-type: none"> 1. The Governing Body failed to ensure processes were followed to determine the cause of recurrent elevated levels of bacteria and endotoxins in the water used to prepare dialysate and ensure the levels were maintained below action levels to ensure the health and safety of all patients who received hemodialysis in the facility. Refer to V179, V274 and V627. 2. The Governing Body failed to ensure patients' hemodialysis accesses were visible and monitored throughout treatment. Refer to V407. 3. The Governing Body failed to ensure the patient's POC was individualized to address covered hemodialysis access during treatment. Refer to V543 and V559. 	V 750			

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V 750	Continued From page 75 4. The Governing Body failed to ensure the QAPI committee trended events that compromised the health and safety of all patients and put action plans in place to ensure the health and safety of all patients receiving hemodialysis. Refer to V634 and V712. 5. The Governing Body failed to ensure staff followed facility policies and procedures to maintain the health and safety of all patients who received hemodialysis. Refer to V407, V504, V543, V547, V559, and V557.	V 750			

UNIT 5 INVESTIGATES

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Gaytan Family vs. Fresenius Medical Care

Teresa Gaytan, 65, died following a series of mistakes at a Berwyn dialysis clinic, a now-settled lawsuit alleged

By Katy Smyser | Thursday, Apr 26, 2012 | Updated 3:09 PM CST

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Teresa Gaytan, second from right, died following a series of mistakes at a Berwyn dialysis clinic, a now-settled lawsuit alleged.

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Teresa Gaytan's children wanted her to come home.

The 65-year-old mother of five had been living for about a year in a nursing home, dealing with congestive heart failure and kidney failure. But her five children -- all adults -- wanted to care for her themselves. After making arrangements for outpatient treatment at a local dialysis center, they were able to bring her back to the home where she'd raised all her children.

"It was just... complete," said her daughter, Angela Gaytan. "We were able to eat together, laugh together. It's the sense of being complete

with her there."

DOCUMENTS

Gaytan needed dialysis three days each week, so her children arranged for her to get

Gaytan Family Second Amended Complaint

Illinois Dept. of Public Health Report for RCG MidAmerica Berwyn

treatment at Fresenius Medical Care in Berwyn. She'd gone for two treatments during her first week home, and on March 5, 2009, she went in for her third.

"About three hours later, we got a call," her daughter recalled. "They said they were rushing my mother to the hospital. I asked what happened, and they wouldn't tell me."

The family went to the hospital to find their mom completely unresponsive.

"I remember the doctor sitting down and just putting his head down, and he said something had gone terribly wrong with her dialysis at the center," said Angela Gaytan.

Two days later, she said, the doctors confirmed there was nothing more that could be done, and the family took their mother off of life-support. She died on March 10th, 2009.

"We would try to call the facility to get answers from them because obviously something happened there. ... They weren't giving us answers," Gaytan said.

So the Gaytan family sought out Chicago attorneys Joseph Lopez and Mark Parts, who ended up filing suit against Fresenius Medical Care. Through discovery and depositions, they pieced together a narrative of what they believed happened to Teresa Gaytan, which they outlined in their [Second Amended Complaint in their lawsuit](#).

According to the Gaytan family's complaint, there was a series of mistakes which led to the woman's death: A patient care technician did a reversal of her dialysis lines (which he was not qualified to do); the lines weren't secured properly and Gaytan began hemorrhaging, and then the alarms -- which were supposed to signal that something was wrong -- were ignored.

"There were many, many mistakes," said Parts. "But even among those many mistakes, if somebody had done something at one step of the process along the way, that could have turned the whole thing around."

Fresenius Medical Care would not comment on Teresa Gaytan's case, citing privacy concerns. The company eventually came to a seven-figure settlement with the Gaytans, but admitted no wrongdoing.

RELATED STORIES

- [How to Be a Living Kidney Donor](#)
Harvey Mysel, who created the Living Kidney...

For families like the Gaytans -- trying their best to figure out where to send a loved one for the complicated process of dialysis -- [ProPublica's dialysis facility tracker gives information on mortality statistics and infection rates](#). It spells out information and statistics that the government has collected for years from dialysis clinics, but never made public until ProPublica pushed to get it a few years ago.

But physicians and nephrologists repeatedly stress that a kidney patient needs to consider far more than just these statistics. They point out that getting dialysis is not like buying a car or a house, where you can compare miles per gallon or room sizes and simply choose the "best."

Dialysis involves all kinds of variables, including how sick you are, where you live, what kind of insurance you have, how old you are, and your likelihood for getting a kidney transplant.

According to several nephrologists that Unit 5 consulted, all those factors can mean that the best clinic for you is not necessarily one of the "top" clinics on ProPublica's tracker.

The Fresenius clinic in Berwyn, where Teresa Gaytan went, currently ranks about average for mortality and infection rates in the most current figures posted by ProPublica. The Fresenius corporation owns dozens of dialysis clinics in the Chicago area, and while a few of their clinics have relatively high rates of mortality and infection, several Fresenius clinics have some of the lowest death and infection rates in the area, according to the figures published by ProPublica.



Supreme Court Takes Up Gay Marriage

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USEFUL LINKS

- [ProPublica Dialysis Facility Tracker](#)

For example, Fresenius' dialysis clinic in Chicago's Garfield neighborhood ranks well on ProPublica's tracker. It is run by Dr. Brian Duffy, who points out that he has his offices inside his dialysis unit, so he is able to see his patients as often as 12 times a month.

But Dr. Duffy points out that every doctor will have a slightly different way of running a dialysis clinic.

"It's my setup, where we see them all the time," he said. "I know there are other practitioners that have nurse practitioners or physicians' assistants who will communicate with [the doctors] as to what the situation is. So Fresenius doesn't mandate any number of visits. ... It's really what the physician thinks is appropriate."

In the end, that appears to be the best way to use ProPublica's tracker as well – as one more tool to share with your doctor, as you decide together what the most appropriate dialysis facility is for you.

That's something Angela Gaytan said she'd advise anyone in her situation trying to do the best for a loved one who needs dialysis.

"Just do your homework," she said. "Don't rush."

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42778

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

ANGELA GAYTAN, as Special Administrator)
of the Estate of TERESA GAYTAN,)
)
Plaintiff,)

v.)

09 L 3786

3011
2800-1

FRESENIUS MEDICAL CARE NORTH AMERICA,)
RENAL CARE GROUP, INC., DIALYSIS CENTERS)
OF AMERICA -- ILLINOIS, INC., FRESENIUS MEDICAL)
CARE HOLDINGS, INC., FRESENIUS MEDICAL)
CARE AG & CO. KGaA, BONIFACIO GALARIO,)
NAPAPORN KHUMPOR, ELIZABETH BOYLE,)
BETTE ANDERSON, MELITA LAROCO, and)
DR. WILLIAM WISE,)

JURY DEMAND

Defendants.)

SECOND AMENDED COMPLAINT

Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan ("Plaintiff"), by her attorneys, Parts & Spencer, Ltd., and Joseph R. Lopez, Ltd., for her Second Amended Complaint at Law against Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, Bonifacio Galario, Napaporn Khumpor, Elizabeth Boyle, Bette Anderson, Melita Laroco, and Dr. William Wise, ("Defendants"), states as follows:

1. Angela Gaytan has been appointed as Special Administrator of the Estate of Teresa Gaytan, deceased.
2. Angela Gaytan is a resident of Cook County, Illinois.

3. Plaintiff, Angela Gaytan, brings this action on behalf of the next-of-kin of Teresa Gaytan. This matter arises from an incident on March 5, 2009 at the Fresenius Medical Care dialysis center in Berwyn, Illinois, in which Teresa Gaytan sustained massive blood loss as a result of hemorrhage from the dialysis circuit during dialysis treatment at the center.

4. Teresa Gaytan left surviving her as next-of-kin at her death five adult children: Maria Mandujano, Martha Gaytan, Angela Gaytan, Julio Gaitan, and Carlos Gaitan.

5. Defendants Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, (the "Fresenius Defendants") are affiliated corporations and are doing business in Cook County, Illinois, engaged in providing dialysis services at the "Fresenius Medical Care" dialysis center at 2601 South Harlem in Berwyn, Illinois (hereinafter the "Fresenius Medical Care Berwyn dialysis center"). Defendants have operated in their own names as well as through their affiliates and subsidiaries and under various d/b/a designations, including but not limited to: the names identified as Defendants, "Fresenius Medical Care," "RCG Berwyn" and others.

6. In providing dialysis services at the Fresenius Medical Care Berwyn dialysis center, the clinical manager, clinical coordinator, physicians, nurses and dialysis technicians were employees and/or agents of the Fresenius Defendants and had a duty to possess and apply the knowledge and to use the skill and care which reasonably well qualified clinical managers, clinical coordinators, physicians, nurses and dialysis technicians would use in providing dialysis services.

7. On and preceding March 5, 2009, Bonifacio Galario was a patient care technician ("PCT") at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and at times prior thereto, Bonifacio Galario was an employee of the Fresenius Defendants involved in provision of dialysis treatment to Teresa Gaytan.

8. On and preceding March 5, 2009, Napaporn Khumpor was a nurse at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and at times prior thereto, Napaporn Khumpor was an employee of the Fresenius Defendants and was a nurse involved in provision of and supervision of dialysis treatment to Teresa Gaytan.

9. On and preceding March 5, 2009, Elizabeth Boyle was a nurse at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and at times prior thereto, Elizabeth Boyle was an employee of the Fresenius Defendants and a nurse involved in provision of and supervision of dialysis treatment to Teresa Gaytan.

10. On and preceding March 5, 2009, Bette Anderson was clinical coordinator at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and prior thereto, Bette Anderson was an employee of the Fresenius Defendants and was responsible for supervision and oversight of the program and policies relating to various aspects of the provision of dialysis treatment to Teresa Gaytan and other dialysis patients, including staffing, training, assessment, discipline, care provision, care monitoring, and others.

11. On and preceding March 5, 2009, Melita Laroco was clinical manager at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and prior thereto, Melita Laroco was an employee of the Fresenius Defendants and was responsible for supervision and oversight of the program and policies relating to various aspects of the provision of dialysis treatment to Teresa Gaytan and other dialysis patients, including hiring, staffing, training, assessment, discipline, care provision, care monitoring, and others.

12. On and preceding March 5, 2009, Dr. William Wise was a physician practicing at the Fresenius Medical Care Berwyn dialysis center operated by the Fresenius Defendants. On March 5, 2009, and prior thereto, Dr. Wise was an actual agent of, an apparent agent of and/or an employee of Fresenius Defendants providing dialysis care to patients at the Fresenius Medical Care Berwyn dialysis center. On March 5, 2009, and prior thereto, Dr. Wise was involved in providing medical care including dialysis to Teresa Gaytan and in overseeing the dialysis care provided to her by patient care technicians and nurses.

13. In the fall of 2008, deficiencies in monitoring dialysis treatment and other shortfalls in care at the Fresenius Medical Care Berwyn dialysis center were recognized and directions were provided to address those problems in order to provide for safe and appropriate care of dialysis patients at the facility. The necessary steps to provide for safe patient care, in areas including but not limited to monitoring of dialysis patients, were not being implemented and enforced as of March 5, 2009.

14. Notwithstanding a requirement that background checks of the employment history of new employees be made and documented, no such background checks were made

or documented when PCT Bonifacio Galario was hired by Clinic Manager Melita Laroco to work at the Fresenius Medical Care Berwyn dialysis center in 2008.

15. Assessment of PCT Bonifacio Galario in 2008 noted that he did not meet standards for performance competency with respect to areas such as appropriately responding to alarms and requesting assistance when necessary. These shortfalls were not remedied prior to March 5, 2009

16. Prior to March 5, 2009, complaints were received by Clinic Coordinator Bette Anderson and discussed by her with Clinic Manager Melita Laroco concerning performance of PCT Bonifacio Galario at the Fresenius Medical Care Berwyn dialysis center with respect to his failure to follow standard procedures; however, appropriate discipline was not undertaken to enforce compliance with such procedures, and his non-compliance with those procedures was known to be a problem in the time period leading up to March 5, 2009.

17. Prior to March 5, 2009, an incident occurred involving a patient under the care of Defendants PCT Bonifacio Galario and nurse Elizabeth Boyle at the Fresenius Medical Care Berwyn dialysis center who experienced bleeding from the catheter port. That incident was reported to management of the facility but was never investigated and no related discipline was undertaken.

18. On March 5, 2009, Teresa Gaytan presented at the Fresenius Medical Care Berwyn dialysis center for the purpose of receiving dialysis treatment.

19. During dialysis treatment of Teresa Gaytan on March 5, 2009, PCT Bonifacio Galario improperly conducted a reversal of the dialysis lines on Teresa Gaytan, a procedure that was supposed to be performed by a dialysis nurse.

20. During attachment of the catheter lines to the catheter port of Teresa Gaytan on March 5, 2009, PCT Bonifacio Galario did not connect them securely enough to preclude hemorrhage from the dialysis circuit.

21. During dialysis of Teresa Gaytan on March 5, 2009, PCT Bonifacio Galario did not properly attach the hemosafe clip, a device used to prevent disconnection of the dialysis lines.

22. Nurse rounding on Teresa Gaytan was not properly conducted and documented on March 5, 2009.

23. Physician rounding on Teresa Gaytan was not properly conducted and documented on March 5, 2009.

24. In providing dialysis treatment to Teresa Gaytan on March 5, 2009, the physician, nurses and patient care technicians involved in her care did not properly assess and document the condition of Teresa Gaytan and of the catheter access site.

25. In providing dialysis treatment to Teresa Gaytan on March 5, 2009, the physician, nurses and patient care technicians involved in her care did not ensure that the dialysis access site was open and visible and remained open and visible at all times.

26. During that dialysis treatment on March 5, 2009 at the Fresenius Medical Care Berwyn dialysis center, Teresa Gaytan suffered substantial blood loss through a disconnected catheter line, resulting in flow of blood onto her clothing and her chair, as well as significant pooling of blood on the floor of the dialysis center. As a result of her blood loss on March 5, Teresa Gaytan subsequently went into respiratory and cardiac arrest.

27. The last scheduled half hourly check of Teresa Gaytan was not conducted or documented prior to the eventual discovery of the blood loss by Teresa Gaytan on March 5, 2009.

28. In the time period leading up to the discovery of the blood loss from the catheter site, multiple alarms went off on the dialysis machine being used in treatment of Teresa Gaytan on March 5, 2009. PCT Bonifacio Galario responded to those alarms by talking to Teresa Gaytan and resetting the dialysis machine, but did not otherwise investigate the cause or check the integrity of the dialysis circuit.

29. Neither of the floor nurses on duty, Napaporn Khumpor and Elizabeth Boyle, responded to investigate the multiple alarms on the dialysis machine being used in treatment of Teresa Gaytan on March 5, 2009 until they were summoned after the last of those alarms.

30. PCT Bonifacio Galario did not request help from a nurse until the situation with Teresa Gaytan had progressed so far that there was a large pool of blood noticeable under her dialysis chair.

31. When called for help by PCT Bonifacio Galario, Napaporn Khumpor told him to reset the machine before investigating the cause of the problem or checking the integrity of the dialysis circuit.

32. Receipt of oxygen by Teresa Gaytan was delayed in the dialysis clinic because the oxygen tank that was supposed to be available on the floor in the event of an emergency was found to be empty.

33. Notwithstanding the pulseless condition of Teresa Gaytan on arrival of the Berwyn Fire Department ambulance, cardio-pulmonary resuscitation ("CPR") with

compression was not performed by the personnel of the Fresenius Medical Care Berwyn dialysis center as required by clinical emergency guidelines.

34. Delay in discovering the existence and severity of the emergency involving Teresa Gaytan resulted in delay in the arrival of the emergency personnel, including the Berwyn Fire Department ambulance that initiated CPR and transported Teresa Gaytan to MacNeal Hospital.

35. The ongoing loss of blood from the dialysis circuit eventually resulted in severe anoxic brain injury to Teresa Gaytan.

36. Teresa Gaytan was transported by ambulance to MacNeal Hospital, where she subsequently died on March 10, 2009 as a result of injuries sustained on March 5 at the Fresenius Medical Care Berwyn dialysis center.

37. Fresenius Defendants' death report reflects hemorrhage from the dialysis circuit as the sole cause of death of Teresa Gaytan.

COUNT I -- WRONGFUL DEATH

(Fresenius Medical Care North America)

38. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

39. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Fresenius Medical Care North America and its employees and agents had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

40. Notwithstanding these duties, Fresenius Medical Care North America and its employees and agents were guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;
- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (G) Failure to ensure that the catheter access site remained open and visible at all times;
- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (L) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (M) Failure to timely notify emergency response personnel;

- (N) Failure to follow appropriate procedures for hiring clinical personnel;
- (O) Failure to follow appropriate procedures for disciplining clinical personnel;
- (P) Failure to implement proper training of clinical personnel;
- (Q) Failure to provide for proper oversight of the dialysis facility;
- (R) Failure to properly staff the dialysis clinic;
- (S) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (T) Failure to perform CPR consistent with clinical guidelines;
- (U) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (V) Otherwise failed to uphold the standard of care.

41. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care North America, in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the

Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT II -- WRONGFUL DEATH

(Renal Care Group, Inc.)

42. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

43. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Renal Care Group, Inc., and its employees and agents had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

44. Notwithstanding these duties, Renal Care Group, Inc., and its employees and agents were guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;
- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (G) Failure to ensure that the catheter access site remained open and visible at all times;

- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (L) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (M) Failure to timely notify emergency response personnel;
- (N) Failure to follow appropriate procedures for hiring clinical personnel;
- (O) Failure to follow appropriate procedures for disciplining clinical personnel;
- (P) Failure to implement proper training of clinical personnel;
- (Q) Failure to provide for proper oversight of the dialysis facility;
- (R) Failure to properly staff the dialysis clinic;
- (S) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (T) Failure to perform CPR consistent with clinical guidelines;
- (U) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (V) Otherwise failed to uphold the standard of care.

45. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the

decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Renal Care Group, Inc., in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT III -- WRONGFUL DEATH

(Dialysis Centers of America -- Illinois, Inc.)

46. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

47. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Dialysis Centers of America -- Illinois, Inc., and its employees and agents had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

48. Notwithstanding these duties, Dialysis Centers of America -- Illinois, Inc., and its employees and agents were guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;

- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (G) Failure to ensure that the catheter access site remained open and visible at all times;
- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (L) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (M) Failure to timely notify emergency response personnel;
- (N) Failure to follow appropriate procedures for hiring clinical personnel;
- (O) Failure to follow appropriate procedures for disciplining clinical personnel;
- (P) Failure to implement proper training of clinical personnel;
- (Q) Failure to provide for proper oversight of the dialysis facility;
- (R) Failure to properly staff the dialysis clinic;

- (S) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (T) Failure to perform CPR consistent with clinical guidelines;
- (U) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (V) Otherwise failed to uphold the standard of care.

49. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dialysis Centers of America -- Illinois, Inc., in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT IV -- WRONGFUL DEATH

(Fresenius Medical Care Holdings, Inc.)

50. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

51. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Fresenius Medical Care Holdings, Inc., and its employees and agents had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

52. Notwithstanding these duties, Fresenius Medical Care Holdings, Inc., and its employees and agents were guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;
- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (G) Failure to ensure that the catheter access site remained open and visible at all times;
- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms

during dialysis of Teresa Gaytan;

- (L) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (M) Failure to timely notify emergency response personnel;
- (N) Failure to follow appropriate procedures for hiring clinical personnel;
- (O) Failure to follow appropriate procedures for disciplining clinical personnel;
- (P) Failure to implement proper training of clinical personnel;
- (Q) Failure to provide for proper oversight of the dialysis facility;
- (R) Failure to properly staff the dialysis clinic;
- (S) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (T) Failure to perform CPR consistent with clinical guidelines;
- (U) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (V) Otherwise failed to uphold the standard of care.

53. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care Holdings, Inc., in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT V -- WRONGFUL DEATH

(Fresenius Medical Care AG & Co. KGaA)

54. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

55. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Fresenius Medical Care AG & Co. KGaA and its employees and agents had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

56. Notwithstanding these duties, Fresenius Medical Care AG & Co. KGaA and its employees and agents were guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;
- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during

dialysis;

- (G) Failure to ensure that the catheter access site remained open and visible at all times;
- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (L) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (M) Failure to timely notify emergency response personnel;
- (N) Failure to follow appropriate procedures for hiring clinical personnel;
- (O) Failure to follow appropriate procedures for disciplining clinical personnel;
- (P) Failure to implement proper training of clinical personnel;
- (Q) Failure to provide for proper oversight of the dialysis facility;
- (R) Failure to properly staff the dialysis clinic;
- (S) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (T) Failure to perform CPR consistent with clinical guidelines;
- (U) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and

(V) Otherwise failed to uphold the standard of care.

57. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT VI -- WRONGFUL DEATH

(Bonifacio Galario Individually and as
Employee and Agent of Fresenius Defendants)

58. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

59. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Bonifacio Galario, individually and as an employee and agent of the Fresenius Defendants had a responsibility to exercise

ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

60. Notwithstanding these duties, Bonifacio Galario was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly secure the dialysis lines to the catheter port;
- (B) Failure to properly apply the hemosafe clip;
- (C) Failure to follow proper procedures for reversing the dialysis lines;
- (D) Failure by a patient care technician to request a nurse to reverse the dialysis lines or to inform other personnel of reversal of the lines;
- (E) Failure to maintain a secure dialysis connection;
- (F) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (G) Failure to ensure that the catheter access site remained open and visible at all times;
- (H) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (I) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (J) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (K) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (L) Failure to engage in appropriate remedial measures after receiving one or

more alarms during dialysis of Teresa Gaytan;

(M) Failure to timely notify emergency response personnel; and

(N) Otherwise failed to uphold the standard of care.

61. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bonifacio Galario and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT VII -- WRONGFUL DEATH

(Napaporn Khumpor Individually and as

Employee and Agent of Fresenius Defendants)

62. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

63. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Napaporn Khumpor, individually and as an employee and agent of the Fresenius Defendants had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

64. Notwithstanding these duties, Napaporn Khumpor was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (B) Failure to ensure that the catheter access site remained open and visible at all times;
- (C) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (D) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (E) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (F) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (G) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (H) Failure to timely notify emergency response personnel;
- (I) Failure to perform CPR consistent with clinical guidelines;

- (J) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (K) Otherwise failed to uphold the standard of care.

65. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Napaporn Khumpor and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT VIII -- WRONGFUL DEATH

(Elizabeth Boyle, Individually and as

Employee and Agent of Fresenius Defendants)

66. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

67. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Elizabeth Boyle, individually and as an employee and agent of the Fresenius Defendants had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

68. Notwithstanding these duties, Elizabeth Boyle was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (B) Failure to ensure that the catheter access site remained open and visible at all times;
- (C) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (D) Failure to appropriately respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (E) Failure to timely respond to one or more alarms occurring during dialysis of Teresa Gaytan;
- (F) Failure to provide proper assessment after receiving one or more alarms during dialysis of Teresa Gaytan;
- (G) Failure to engage in appropriate remedial measures after receiving one or more alarms during dialysis of Teresa Gaytan;
- (H) Failure to timely notify emergency response personnel;
- (I) Failure to perform CPR consistent with clinical guidelines;
- (J) Failure to properly supervise personnel providing dialysis services to Teresa

Gaytan; and

(K) Otherwise failed to uphold the standard of care.

69. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Elizabeth Boyle and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT IX -- WRONGFUL DEATH

(Bette Anderson, Individually and as

Employee and Agent of Fresenius Defendants)

70. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

71. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Bette Anderson, individually and as

an employee and agent of the Fresenius Defendants had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

72. Notwithstanding these duties, Bette Anderson was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (B) Failure to implement proper training of clinical personnel;
- (C) Failure to follow appropriate procedures for disciplining clinical personnel;
- (D) Failure to provide for proper oversight of the dialysis facility;
- (E) Failure to properly staff the dialysis clinic;
- (F) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (G) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (H) Otherwise failed to uphold the standard of care.

73. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bette Anderson and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT X -- WRONGFUL DEATH

(Melita Laroco, Individually and as
Employee and Agent of Fresenius Defendants)

74. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

75. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Melita Laroco, individually and as an employee and agent of the Fresenius Defendants had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

76. Notwithstanding these duties, Melita Laroco was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly monitor the status of Teresa Gaytan during dialysis;
- (B) Failure to follow appropriate procedures for hiring clinical personnel;
- (C) Failure to implement proper training of clinical personnel;
- (D) Failure to follow appropriate procedures for disciplining clinical personnel;

- (E) Failure to provide for proper oversight of the dialysis facility;
- (F) Failure to properly staff the dialysis clinic;
- (G) Failure to have all necessary emergency preparedness equipment in functional order, checked and documented on the floor of the dialysis center;
- (H) Failure to perform CPR consistent with clinical guidelines;
- (I) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (J) Otherwise failed to uphold the standard of care.

77. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Melita Laroco and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XI -- WRONGFUL DEATH

(Dr. William Wise Individually and as
Agent and/or Employee of Fresenius Defendants)

78. Plaintiff incorporates paragraphs 1 - 37 by reference as if fully set forth herein.

79. During and preceding Teresa Gaytan's dialysis treatment at the Fresenius Medical Care Berwyn dialysis center on March 5, 2009, Dr. William Wise, individually and as an agent and/or employee of the Fresenius Defendants had a responsibility to exercise ordinary care and caution in the diagnosis, care and treatment of Teresa Gaytan and other patients.

80. Notwithstanding these duties, Dr. William Wise was guilty of one or more of the following careless or negligent acts and/or omissions, which constitute a deviation from the applicable standard of care:

- (A) Failure to properly assess and document the status of Teresa Gaytan during dialysis;
- (B) Failure to ensure that the catheter access site remained open and visible at all times;
- (C) Failure to properly supervise personnel providing dialysis services to Teresa Gaytan; and
- (D) Otherwise failed to uphold the standard of care.

81. As a direct and proximate result of one or more of the aforementioned acts or omissions, Plaintiff's decedent suffered injuries that resulted in her death. As a result, the decedent's next of kin have suffered great losses of a personal and pecuniary nature, including but not limited to the loss of companionship and society of the decedent as well as

grief, sorrow and mental suffering as a result of Teresa Gaytan's death, subjecting the Defendant to liability pursuant to 740 ILCS 180/1, commonly referred to as the Wrongful Death Act.

WHEREFORE, Plaintiff respectfully requests that judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dr. William Wise and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA in an amount necessary to fully and fairly compensate the next-of-kin for their losses under the terms of the Wrongful Death Act, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XII -- SURVIVAL

(Fresenius Medical Care North America)

82. Plaintiff incorporates paragraphs 1 - 41 by reference as if fully set forth herein.

83. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care North America, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care North America, in an amount

necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XIII -- SURVIVAL

(Renal Care Group, Inc.)

84. Plaintiff incorporates paragraphs 1 - 37 and 42 - 45 by reference as if fully set forth herein.

85. As a direct and proximate result of one or more of the aforementioned acts or omissions of Renal Care Group, Inc., the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Renal Care Group, Inc., in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XIV -- SURVIVAL

(Dialysis Centers of America -- Illinois, Inc.)

86. Plaintiff incorporates paragraphs 1 - 37 and 46 - 49 by reference as if fully set forth herein.

87. As a direct and proximate result of one or more of the aforementioned acts or omissions of Dialysis Centers of America -- Illinois, Inc., the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting Dialysis Centers of America -- Illinois, Inc., to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dialysis Centers of America -- Illinois, Inc., in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XV -- SURVIVAL

(Fresenius Medical Care Holdings, Inc.)

88. Plaintiff incorporates paragraphs 1 - 37 and 50 - 53 by reference as if fully set forth herein.

89. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care Holdings, Inc., the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care Holdings, Inc., in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XVI -- SURVIVAL

(Fresenius Medical Care AG & Co. KGaA)

90. Plaintiff incorporates paragraphs 1 - 37 and 54 - 57 by reference as if fully set forth herein.

91. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care AG & Co. KGaA, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XVII -- SURVIVAL

(Bonifacio Galario, Individually and as

Employee and Agent of Fresenius Defendants)

92. Plaintiff incorporates paragraphs 1 - 37 and 58 - 61 by reference as if fully set forth herein.

93. As a direct and proximate result of one or more of the aforementioned acts or omissions of Bonifacio Galario, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bonifacio Galario and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XVIII -- SURVIVAL

(Napaporn Khumpor, Individually and as

Employee and Agent of Fresenius Defendants)

94. Plaintiff incorporates paragraphs 1 - 37 and 62 - 65 by reference as if fully set forth herein.

95. As a direct and proximate result of one or more of the aforementioned acts or omissions of Napaporn Khumpor, the Plaintiff's decedent, Teresa Gaytan, did suffer serious

injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Napaporn Khumpor and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XIX -- SURVIVAL

(Elizabeth Boyle, Individually and as

Employee and Agent of Fresenius Defendants)

96. Plaintiff incorporates paragraphs 1 - 37 and 66 - 69 by reference as if fully set forth herein.

97. As a direct and proximate result of one or more of the aforementioned acts or omissions of Elizabeth Boyle, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on

behalf of the next-of-kin, against Elizabeth Boyle and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XX -- SURVIVAL

(Bette Anderson, Individually and as

Employee and Agent of Fresenius Defendants)

98. Plaintiff incorporates paragraphs 1 - 37 and 70 - 73 by reference as if fully set forth herein.

99. As a direct and proximate result of one or more of the aforementioned acts or omissions of Bette Anderson, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bette Anderson and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XXI -- SURVIVAL

(Melita Laroco, Individually and as
Employee and Agent of Fresenius Defendants)

100. Plaintiff incorporates paragraphs 1 - 37 and 74 - 77 by reference as if fully set forth herein.

101. As a direct and proximate result of one or more of the aforementioned acts or omissions of Melita Laroco, the Plaintiff's decedent, Teresa Gaytan, did suffer serious injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Melita Laroco and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XXII -- SURVIVAL

(Dr. William Wise, Individually and as
Agent and/or Employee of Fresenius Defendants)

102. Plaintiff incorporates paragraphs 1 - 37 and 78 - 81 by reference as if fully set forth herein.

103. As a direct and proximate result of one or more of the aforementioned acts or omissions of Dr. William Wise, the Plaintiff's decedent, Teresa Gaytan, did suffer serious

injuries of a personal and pecuniary nature, including but not limited to, pain and suffering experienced as she was bleeding out through the dialysis circuit at the dialysis center, subjecting the Defendant to liability pursuant to 755 ILCS 5/27-6, commonly referred to as the Survival Statute.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dr. William Wise and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the Survival Statute, which substantially exceed the minimum jurisdictional amount of this Court.

COUNT XXIII -- FAMILY EXPENSE

(Fresenius Medical Care North America)

104. Plaintiff incorporates paragraphs 1 - 37, 38 - 41, and 82 - 83 by reference as if fully set forth herein.

105. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care North America, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care North America, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXIV -- FAMILY EXPENSE

(Renal Care Group, Inc.)

106. Plaintiff incorporates paragraphs 1 - 37, 42 - 45, and 84 - 85 by reference as if fully set forth herein.

107. As a direct and proximate result of one or more of the aforementioned acts or omissions of Renal Care Group, Inc., the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Renal Care Group, Inc., in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXV -- FAMILY EXPENSE

(Dialysis Centers of America -- Illinois, Inc.)

108. Plaintiff incorporates paragraphs 1 - 37, 46 - 49, and 86 - 87 by reference as if fully set forth herein.

109. As a direct and proximate result of one or more of the aforementioned acts or omissions of Dialysis Centers of America -- Illinois, Inc., the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dialysis Centers of America -- Illinois, Inc., in an amount

necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXVI -- FAMILY EXPENSE

(Fresenius Medical Care Holdings, Inc.)

110. Plaintiff incorporates paragraphs 1 - 37, 50 - 53, and 88 - 89 by reference as if fully set forth herein.

111. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care Holdings, Inc., the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Fresenius Medical Care Holdings, Inc., in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXVII -- FAMILY EXPENSE

(Fresenius Medical Care AG & Co. KGaA)

112. Plaintiff incorporates paragraphs 1 - 37, 54 - 57, and 90 - 91 by reference as if fully set forth herein.

113. As a direct and proximate result of one or more of the aforementioned acts or omissions of Fresenius Medical Care AG & Co. KGaA, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on

behalf of the next-of-kin, against Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXVIII -- FAMILY EXPENSE

(Bonifacio Galario, Individually and as
Employee and Agent of Fresenius Defendants)

114. Plaintiff incorporates paragraphs 1 - 37, 58 - 61, and 92 - 93 by reference as if fully set forth herein.

115. As a direct and proximate result of one or more of the aforementioned acts or omissions of Bonifacio Galario, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bonifacio Galario and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXIX -- FAMILY EXPENSE

(Napaporn Khumpor, Individually and as
Employee and Agent of Fresenius Defendants)

116. Plaintiff incorporates paragraphs 1 - 37, 62 - 65, and 94 - 95 by reference as if fully set forth herein.

117. As a direct and proximate result of one or more of the aforementioned acts or omissions of Napaporn Khumpor, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Napaporn Khumpor and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXX -- FAMILY EXPENSE

(Elizabeth Boyle, Individually and as
Employee and Agent of Fresenius Defendants)

118. Plaintiff incorporates paragraphs 1 - 37, 66 - 69, and 96 - 97 by reference as if fully set forth herein.

119. As a direct and proximate result of one or more of the aforementioned acts or omissions of Elizabeth Boyle, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Elizabeth Boyle and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully

and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXXI -- FAMILY EXPENSE

(Bette Anderson, Individually and as
Employee and Agent of Fresenius Defendants)

120. Plaintiff incorporates paragraphs 1 - 37, 70 - 73, and 98 - 99 by reference as if fully set forth herein.

121. As a direct and proximate result of one or more of the aforementioned acts or omissions of Bette Anderson, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Bette Anderson and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXXII -- FAMILY EXPENSE

(Melita Laroco, Individually and as
Employee and Agent of Fresenius Defendants)

122. Plaintiff incorporates paragraphs 1 - 37, 74 - 77, and 100 - 101 by reference as if fully set forth herein.

123. As a direct and proximate result of one or more of the aforementioned acts or omissions of Melita Laroco, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Melita Laroco and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

COUNT XXVIII -- FAMILY EXPENSE

(Dr. William Wise, Individually and as
Agent and/or Employee of Fresenius Defendants)

124. Plaintiff incorporates paragraphs 1 - 37, 78 -81, and 102 - 103 by reference as if fully set forth herein.

125. As a direct and proximate result of one or more of the aforementioned acts or omissions of Dr. William Wise, the Plaintiff's decedent, Teresa Gaytan, and her Estate did sustain losses in the form of medical, funeral, and burial expenses.

WHEREFORE, Plaintiff respectfully requests that the judgment be entered in favor of the Plaintiff, Angela Gaytan, as Special Administrator of the Estate of Teresa Gaytan, deceased, on behalf of the next-of-kin, against Dr. William Wise and Fresenius Medical Care North America, Renal Care Group, Inc., Dialysis Centers of America -- Illinois, Inc., Fresenius Medical Care Holdings, Inc., and Fresenius Medical Care AG & Co. KGaA, in an amount necessary to fully

and fairly compensate the Estate for all losses compensable under the terms of the family expense statute.

Attorneys for Plaintiff

A handwritten signature in black ink, appearing to read 'M. Parts', is written over a horizontal line.

Mark Parts
PARTS & SPENCER, LTD.
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Medical Devices

Fresenius Medical Care North America, Naturalyte and Granuflo Acid Concentrate

Recall Class: Class I

Date Recall Initiated: March 29, 2012

Product: Naturalyte and Granuflo Acid Concentrate

Serial numbers for Naturalyte Liquid Acid Concentrate range from:

08-0231-4, 08-1001-0, 08-1201-8, 08-1231-3, 08-1251-1, 08-1301-4, 08-2201-5, 08-2231-2, 08-2251-0, 08-2301-3, 08-2351-8, 08-3201-4, 08-3231-1, 08-3251-9, 08-3301-2, 08-4123-1, 08-4223-7, 08-4225-1, 08-4230-2, 08-4231-0, 08-4323-5, 08-4325-1, 13-1251-1, 13-2201-5, 13-2231-2, 13-2251-0, 13-3231-1, 13-3251-9, 13-4123-1, 13-4220-1, 13-4225-1, 13-4325-1

Serial numbers for Naturalyte GranuFlo (powder) Acid Concentrate range from:

OFD1201-3B, OFD1251-3B, OFD2123-3B, OFD2201-38, OFD2220-3B, OFD2223-3B, OFD2225-3B, OFD2231-3 B, OFD2251-3B, OFD2301-3B, OFD2323-3 B, OFD2325-3B, OFD3201-3B, OFD3231-3B, OFD3251-3B, OFD3301-3B

This concentrate was manufactured and distributed from January 2008 through June 2012.

Use: The Naturalyte and Granuflo Dry Acid Concentrate are used in the treatment of acute and chronic renal failure during hemodialysis. The concentrate is formulated to be used with a three-stream hemodialysis machine, which is calibrated for acid and bicarbonate concentrates.

Recalling Firm:

Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Reason for Recall:

The manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' Naturalyte Liquid and Granuflo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death.

FDA has issued a general safety communication related to inappropriate prescription and resultant alkali dosing errors in the dialysate concentrates used in hemodialysis.

Public Contact:

Consumers may contact the firm at 1-800-662-1237.

FDA District: New England District Office

FDA Comments:

On March 29, 2012, the firm sent an Urgent Product Notification to their clinics and customers. This notification provided clinicians with prescribing information regarding the Naturalyte Liquid and Granuflo Acid Concentrate.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)¹ either online, by regular mail or by FAX.

Additional Links:

- [FDA Safety Communication](#)²
- [Firm Urgent Product Notification](#)³

Page Last Updated: 11/19/2012

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U.S. Department of **Health & Human Services**

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Remarks of Eric H. Holder, Jr.

Deputy Attorney General

Announcement of Criminal Pleas and Civil Settlements

United States v. Fresenius (National Medical Care)

Boston, Massachusetts

January 19, 2000

Thank you. I am pleased to be here with my colleagues in law enforcement to announce the settlement of the largest health care fraud case in our nation's history. Today, the largest provider of dialysis services in the United States has agreed to pay \$486 million in criminal fines and in civil penalties to resolve allegations that the company engaged in a wide-ranging conspiracy to defraud Medicare and other federal health care programs. National Medical Care, now also known as Fresenius Medical Care, North America, has agreed to pay \$101 million, the largest criminal fine, and \$385 million, the largest civil recovery, in a health care fraud case to resolve allegations that the company submitted false claims for laboratory tests and conspired to pay illegal kickbacks. So you understand recovery here is well over two times loss to the government.

I would first like to thank the law enforcement agencies and Department of Justice components whose vigilance and dedication led to this record recovery. Here with me are Mark Pearlstein, Assistant United States Attorney in Boston; David Ogden, Assistant Attorney General for the Department's Civil Division; and June Gibbs Brown, Inspector General of the Department of Health and Human Services. I also want to recognize Barry Mawn, the Special Agent in Charge of the Federal Bureau of Investigation, for the FBI's tremendous investigative effort on this case. A truly remarkable team effort.

Today's landmark recovery comes as one more example of success in our fight against health care fraud -- a fight that has been a priority for the Administration and Justice Department since 1993. Through the dedicated efforts of the Justice Department and our federal and state law enforcement partners, we have made tremendous strides in rooting out health care fraud and abuse:

- The number of criminal health care fraud cases filed has risen steadily - from 246 cases in 1996 to more than 320 cases in 1998. Health care fraud convictions jumped from 177 to 219 in this same time period.
- Since 1996, we have recovered and returned more than \$2 billion in criminal fines and civil judgments and settlements to the Medicare Trust Fund - funds that are used to provide vitally needed health services to elderly and disabled Americans.
- Perhaps most important, improper payments in the Medicare program have been cut almost 50% - from more than \$23 billion in 1996 to just over \$12 billion in 1998. Through our vigorous enforcement efforts, we have saved the taxpayers billions of dollars.

Today's settlement should serve as a message to other health care providers that law enforcement is committed to detecting and eliminating fraud and will use a variety of

tools, both criminal and civil, to protect Medicare and other taxpayer-funded health care programs from fraud and abuse.

One such tool is criminal prosecution. Today, the United States filed criminal charges against three divisions of National Medical Care, which is headquartered in Lexington, Massachusetts and is the largest provider of dialysis services in the United States. The Medicare program and other federal and state health care programs pay for dialysis services to patients with end stage renal disease, a life-threatening condition that inhibits the operation of the patient's kidneys and affects many people in the United States.

The three divisions: LifeChem, Medical Products and Homecare, have agreed to plead guilty to various criminal charges. LifeChem has agreed to plead guilty to conspiracy to submit false claims for certain lab tests; Medical Products will plead guilty to conspiring to offer and pay kickbacks to induce dialysis facilities to order laboratory blood testing services from LifeChem to be paid by Medicare; and Homecare has agreed to plead guilty to obstructing government agencies in the administration of various health care and health insurance programs including Medicare.

National Medical Care will pay a total of \$101 million in criminal fines -- \$51.8 million for the LifeChem and Medical Products' criminal conduct, and \$49.3 million in criminal penalties for the Homecare conduct. Each of these fines exceeds the largest prior health care criminal penalty paid before.

Also on the criminal side, two high-level executives already have pleaded guilty to felony crimes, and three other executives currently are under indictment. Criminal prosecutions against individuals are especially important both in terms of our commitment to hold persons accountable for health care fraud and to serve as a deterrent to others who have responsibility for federal health care dollars.

In addition, the divisions of National Medical Care that plead guilty will be excluded permanently from participation in the Medicare program under an agreement subject to court acceptance.

On the civil side, National Medical Care has agreed to pay approximately \$385 million to resolve claims under the False Claims Act, under which the Department can seek damages and penalties against providers who knew that false or fraudulent claims were submitted to Medicare or other federal health programs.

From this civil recovery, private relators or whistleblowers will receive approximately \$65.9 million under provisions of the False Claims Act that allow individuals to file suits on behalf of the United States. The successful pursuit of other cases under the False Claims Act and through the cooperation of whistleblowers has resulted in more than \$2.9 billion in recoveries.

In addition, under today's civil settlement, the company and its divisions have agreed to comply with rigorous corporate integrity requirements, including mandatory audits and reporting to the government. These requirements should prevent further abuses of the Medicare program.

Today's record settlement would not have been possible without the powerful qui tam- or whistleblower - provisions in the False Claims Act. Under these provisions, individuals with knowledge of fraud against the government may file suits on behalf of the United States against wrongdoers. In turn, the whistleblowers are entitled to a portion of any recovery. In today's landmark case, whistleblowers will receive approximately \$65 million - the largest payment ever in a False Claims Act case. This payment is entirely appropriate given the essential role the whistleblowers played in the \$486 million recovery we announce today. I would like to thank Sen. Grassley, Cong. Berman, and others for their efforts in strengthening the False Claims Act in 1986. Those amendments have made the False Claims Act our most powerful and effective tool in rooting out and punishing fraud in government programs.

Again, today's record recovery represents an exceptional degree of teamwork among many agencies, including the Boston U.S. Attorney's office, which also handled the now-second

largest criminal fine in history in a previous case that also involved illegal conduct by a clinical laboratory. I commend the numerous individuals involved in this investigation for their tireless dedication to combating health care fraud and reiterate our pledge to hold accountable any company, any individual who attempts to defraud the citizens of the United States.

Thank you.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*
CHRISTOPHER DRENNEN

Plaintiffs,

vs.

Civil Action No. 09-10179 - GAO

FRESENIUS MEDICAL CARE HOLDINGS,
INC., d/b/a FRESENIUS MEDICAL CARE
NORTH AMERICA,

Defendant.

FIRST AMENDED COMPLAINT

Plaintiff and Relator Christopher Drennen, for his Complaint against Defendant Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America (“Fresenius”), alleges as follows:

I. Introduction

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false or fraudulent statements and claims made and presented by Fresenius and/or their agents and/or employees in violation of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended (“the Act” or “the FCA”). The violations of the Act involve claims for false and fraudulent billing to the United States Government (“Government”), including its Medicare and/or Medicaid programs and other Government healthcare programs, for clinical laboratory tests that are not reasonable and medically necessary including tests for (1) hepatitis B surface antigen; (2) hepatitis B surface antibody; and (3) ferritin.

2. The Act provides that any person who knowingly submits or causes to be submitted a false or fraudulent claim to the Government for payment or approval is liable for a

civil penalty of up to \$11,000 for each such claim submitted or paid, plus three times the amount of the damages sustained by the Government. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring an action for himself as Relator and for the Government, and for them to share in any recovery. Pursuant to the Act, Drennen seeks to recover damages and civil penalties arising from Fresenius's false and fraudulent billings to the Government's Medicare, Medicaid and other Government health care programs and the Government's agents in connection with the Government's payment of claims for hepatitis B and ferritin tests that were not reasonable and medically necessary, including without limitation because the tests were not supported by adequate medical documentation.

II. Parties

3. Drennen is a resident of Meridian, Mississippi. He is a former employee of Fresenius in Mobile, Alabama. Fresenius employed him as an area manager from January 2006 to January 2008, during which time he managed ten Fresenius dialysis clinics. Drennen brings this action for violations of 31 U.S.C. §§ 3729 *et seq.* on behalf of himself and the Government pursuant to 31 U.S.C. § 3730(b)(1). As set forth below in more detail, Drennen has direct and independent knowledge of false records, statements and/or claims that Fresenius presented to the Government.

4. Fresenius is a corporation headquartered in Waltham, Massachusetts. Fresenius is the nation's largest provider of dialysis services. The vast majority (by some estimates as high as 90% or more) of patients receiving dialysis services from Fresenius receive Government assistance for treatment.

III. Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28

U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Further, as set forth more fully herein, Drennen satisfies or has satisfied all of the conditions of 31 U.S.C. § 3730. Drennen has direct and independent knowledge of the fraudulent schemes described herein. His knowledge is set forth herein. He has voluntarily provided the information on which his allegations are based to the Government before filing the action. On December 11, 2008, prior to filing this action in February 2009, Drennen provided Lewis Morris, Office of Inspector General, Department of Health and Human Services, and Joyce Branda, Department of Justice, Director, Civil Frauds, with a draft of Drennen's disclosure statement, including the documentary evidence on which he based his allegations. Specifically, he provided the information on which he bases his allegations of fraudulent hepatitis B and ferritin testing. He also provided information regarding Fresenius's violations of its Corporate Integrity Agreement with the Government, and Fresenius's intentional and fraudulent concealments of overpayments. Fresenius has never, to Drennen's knowledge, publicly disclosed that it has billed the Government for hepatitis B and ferritin tests and received payments for those tests that were not reasonable and medically necessary and were not supported by medical documentation or physician's orders. To Drennen's knowledge, none of the allegations or transactions referenced herein have been disclosed prior to the filing and then ultimate unsealing of Drennen's complaint.

6. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a), which provides that "[a]ny action under section 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act proscribed by section 3729 occurred." Section 3732(a) also authorizes nationwide service of process. Defendant Fresenius resides in

and/or transacts business in the District of Massachusetts.

7. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant Fresenius can be found in, resides in, and transacts business in the District of Massachusetts, and because some of the violations of 31 U.S.C. § 3729 described herein occurred within this judicial district.

IV. Legal Background

8. The FCA provides, in pertinent part that any person who:

(a) (1)(A) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; ...or

(a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; ...
or

(a)(1)(G) knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, ... plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729.1

9. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended

¹ On May 20, 2009, after the Complaint was filed, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (“FERA”). Section 3729(a)(1)(B) was formerly § 3729(a)(2), and is applicable to this case by virtue of § 4(f) of FERA. Section 3729(a)(1)(A) was formerly § 3279(a)(1) of the statute prior to FERA, and as amended in 1986, remains applicable here. Section 3729(a)(1)(G) was formerly numbered as § 3279(a)(7) of the statute prior to FERA; the language of this section was amended by FERA, but the section, as amended in 1986 pre FERA, remains applicable here. For ease of reference, this Amended Complaint will use the numbering used in FERA.

by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to \$5,500 to \$11,000 for violations occurring on or after September 29, 1999.

10. The FCA defines a “claim” to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

11. The FCA, 31 U.S.C. § 3729(b)(1) provides that “(1) the terms ‘knowing’ and ‘knowingly’ – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.”

12. The FCA, 31 U.S.C. § 3729(b)(4) provides that “(4) the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

V. Government Healthcare Programs

13. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare Program, to pay for the costs of certain healthcare services. The program is overseen by the United States Department of Health and Human Services (“HHS”) through the Centers for Medicare and Medicaid Services (“CMS”). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and

conditions of the Medicare Program based on disability or affliction with certain diseases. *See* 42 U.S.C. §§ 1395 to 1395ccc. End stage renal disease and thus dialysis are among the disease states and services covered regardless of the patient's age. For purposes of this case, there are two general components to the Medicare program, Part A and Part B.

14. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers known as fiscal intermediaries ("FIs") (for Part A) or carriers (for Part B) or private insurance companies who administer the plans (for Part C) to administer and pay claims, directly or indirectly, from the Medicare Trust Fund.

15. The Medicaid program, as enacted under Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396, *et seq.*, is a system of medical assistance for indigent individuals. Though federally created, the Medicaid program is a joint federal-state program in which the United States provides a significant share of the funding for the program. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. The Medicaid Program is overseen by HHS through CMS. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

16. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. *See* 10

U.S.C. §§ 1071-1106; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted by DEFENDANT under the TRICARE program. The federal government, through its Departments of Defense and Veterans Affairs, also maintains and operates medical facilities including hospitals.

17. The Federal Employees Health Benefits Program (“FEHBP”) provides health care benefits for qualified federal employees and their dependents.

18. The Railroad Retirement Health Insurance Program provides health care benefits for railroad retirement beneficiaries over the age of 65. (Together these programs described in the preceding paragraphs shall be referred to as “Federal Health Care Programs” or “Government Health Care Programs”).

19. Reimbursement practices under all Government Health Care Programs are the same or closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

V. Defendant’s Fraudulent Business Practices

20. Fresenius is the country's largest provider of dialysis services. Most of these dialysis services are provided to patients who receive Government assistance for treatment. During the process of providing these services, Fresenius bills Government Health Care Programs for the dialysis services, including clinical laboratory testing, provided in the treatment of patients. At its dialysis clinics, Fresenius retains a Medical Director and contracts with

treating physicians for patient care at its clinics. Fresenius employs nurses and patient care technicians at its dialysis clinics, and these employees provide care to patients. Although both the physicians and nurses are responsible for patient care, Fresenius alone is ultimately responsible for billing Government Health Care Programs only for that clinical laboratory testing which is medically reasonable, necessary, and supported by medical documentation.

21. In regard to the testing performed by Fresenius, Title 33 of the Social Security Act, § 1862(a)(1)(A), allows Medicare coverage and payment for *only* those services that are considered to be medically reasonable and necessary. The Department of Health and Human Services, through the Centers for Medicare and Medicaid Services, publishes the "specific medical items, services, treatment procedures or technologies that can be paid for under Medicare" in its National Coverage Determinations manual ("NCD"). Unless specified in the NCD, an item, service, etc. is "not reasonable and necessary"² under § 1862(a)(1) of the Act and therefore cannot be paid under Medicare.

22. Similarly, other Government health care programs, such as Tricare, Medicaid, CHAMPUS, and the Railroad Retirement Health Insurance Program³ allow payment only for services, including testing, which are reasonable and medically necessary.

23. When submitting a claim to these Government health care programs Fresenius and other health care providers will certify that the service is medically reasonable and necessary and is supported by medical documentation. (A copy of CMS Form 1500 is attached as Exhibit

² The statutory phrase "reasonable and medically necessary" is sometimes referred to herein as simply "medically necessary."

³ All such programs, including Medicare may be collectively referred to herein "Government health care programs."

1.) The Government relies on these certifications when paying for claims submitted to it.

24. This action addresses fraudulent billing practices by Fresenius with respect to clinical laboratory testing for hepatitis B and ferritin.⁴ According to the NCD, Medicare and other Government health care programs have limited coverage for hepatitis B and the ferritin tests.

25. With respect to hepatitis B testing, Medicare and other Government Health Care Programs cover, upon admission to a dialysis facility, one hepatitis B surface antigen (HbsAG) test⁵ and one hepatitis B surface anti-body (HBsAb) test.⁶ Once a person has been admitted into a dialysis facility, coverage for hepatitis B testing depends on the patient's "serologic status" i.e., whether the patient's blood shows the need for further testing. Pursuant to the NCD, the following post-admission tests are covered:

Patient's Vaccination and Serologic Status	Testing Frequency	
	HbsAG	HbsAb
Unvaccinated and Susceptible to Hepatitis B	Monthly	Semiannually
Unvaccinated and positive for Hepatitis B infection (antigen test positive)	Annually	None

⁴Ferritin is a test used to determine the amount of iron in the blood.

⁵A hepatitis B surface antigen test is a test to determine whether a patient is infected with hepatitis B.

⁶A hepatitis B anti-body test is a test to determine whether a person has had prior exposure to hepatitis B, whether the person is no longer infected with hepatitis B, whether the person can pass the virus onto another person, and whether the person is protected from future infections of hepatitis B.

Unvaccinated but positive for Hepatitis B anti-bodies ⁷	None	Annual
Vaccinated and positive for Hepatitis B anti-bodies	None	Annual
Vaccinated but low level of or negative for Hepatitis B anti-bodies	Monthly	Semiannually

Per the NCD, no other hepatitis B testing should be billed or be paid for unless the testing is medically necessary and/or supported by medical documentation.

26. The NCD states that ferritin tests are to be done quarterly. Like hepatitis B testing, no additional ferritin testing should be billed or paid for unless the testing is medically necessary and/or medical documentation regarding medical necessity is provided.

27. The only way that the Government's health insurance programs can be properly billed for hepatitis B and ferritin tests which are done more frequently than the NCD's standards is if the test is medically reasonable and necessary and properly documented. If either condition fails, the provider's certification on claims submitted to the Government is false. Thus, although a Medical Director or treating physician at a Fresenius clinic may order tests consistent with the NCD requirements either through standing orders or otherwise, any additional tests must be documented as medically reasonable and necessary prior to submission to the Government.

28. Drennen alleges based on personal knowledge that Fresenius knew that these were the only hepatitis B and ferritin tests that Medicare and the other Government health programs considered medically necessary and thus properly payable under those programs.

⁷The NCD states that a "anti-HB positive" means "at least 10 sample ration units by radioimmunoassay or positive by enzyme immunoassay."

Nevertheless, as set forth below, Fresenius billed and likely continues to bill the Government for hepatitis B and ferritin tests that were not medically necessary or reasonable as defined in the NCD and for which Fresenius has no medical documentation for their medical necessity.

29. As set forth in further detail below, Drennen has direct independent knowledge that from May 2001 to May 2006, Fresenius performed HbsAg and HbsAb tests and billed Medicare for those tests even though the tests were not medically necessary or reasonable and which were not medically documented. Fresenius represented these tests as medically necessary and reasonable even though they were not. For example, Fresenius performed hepatitis HbsAb (hepatitis antibody) tests, billed for the tests, and received payment for those tests on a quarterly or monthly basis *even though* the patient tested positive for hepatitis B antibodies and *even though* medical necessity was not documented. As set forth in the coverage schedule above, only an annual HbsAb test is medically necessary and reasonable when the patient tests positive for hepatitis B antibodies, absent medical documentation for the need for more frequent tests.

30. Drennen also had knowledge, which he confirmed through area managers, that from at least 2006 to 2008, Fresenius performed ferritin tests at its Renal Group facilities and Florida Panhandle facilities, billed for the tests, and received payments for those tests monthly without any additional medical documentation. Despite the fact that only quarterly ferritin tests are "medically necessary" absent documentation of medical necessity, as set forth above, Fresenius claimed that these monthly tests were medically necessary and submitted them to the Government as such without any medical documentation, and received reimbursement for the tests.

31. Fresenius uses (and has used since at least 2001) a computer system known as "Proton" to track patient information and forward services performed, including testing, for

billing to Government Health Care Programs. Proton was used in all Fresenius dialysis clinics in the United States. Proton contains a database of Fresenius's patients. The data stored on each patient indicate whether the patient tested positive for hepatitis B antibodies and whether, despite that positive test, additional unnecessary tests were ordered and billed to Medicare without medical documentation. That data also indicates whether unnecessary ferritin tests were ordered and billed to Medicare without medical documentation or necessity. As described further below, Drennen reviewed literally hundreds, if not thousands of these records.⁸

32. The Government relies on Fresenius to issue non-fraudulent bills and to bill the Government only for medically necessary tests. Fresenius deliberately and/or recklessly billed the Government for tests that were not medically necessary and not supported by medical documentation. Fresenius represented to the Government that these tests were medically necessary and/or had supporting medical documentation, when, in fact, these tests were not medically necessary, were in excess of the tests authorized under the NCD requirements, and for which Fresenius had no medical documentation or physician orders. Fresenius concealed its fraudulent business practices, continues to withhold overpayments made by the Government, and this concealment has prevented the Government from discovering this systematic fraud.

33. Drennen initially discovered the fraudulent billing practices in May 2006. As area manager, Drennen's responsibilities included the review, investigation, and compliance with any audits performed on the facilities under his management. In May 2006, he received the

⁸Due to privacy laws, the names and medical information of the patients cannot be produced or set forth herein. However, as stated below, Drennen has provided a disclosure statement and relevant documents to the United States Attorney, and these can be produced to Defendant and/or the Court *in camera* if necessary. Further, some of these records are no longer in the possession of Drennen as he is no longer employed by Fresenius.

results of an audit of three of the Fresenius facilities in the Mobile, Alabama area - Port City, Prichard and Magnolia Grove-- from Mary Macaluso, an employee of Spectra Laboratories, Inc. (a wholly owned subsidiary of Fresenius). Drennen found that Fresenius was performing HbsAg and HbsAb tests and billing Medicare for those tests even though the tests were not medically necessary, were done more frequently than NCD requirements allow, and were done without medical documentation. The audit showed that Fresenius performed the hepatitis tests and billed for those tests *even though* patients tested positive for hepatitis B antibodies and had no documented medical reason for additional tests. As set forth above, only an annual HbsAb test may be billed to Medicare under those circumstances.

34. Upon receiving the audit results, Drennen reviewed data on Fresenius patients at all ten Mobile area facilities. Drennen reviewed Fresenius's computer database and confirmed the results of the audit. When reviewing the data on all ten of the facilities under his management, he discovered that the fraudulent conduct occurred throughout the Mobile area and that the conduct had been occurring for at least five years. He discovered that during the period May 1, 2005 through May 31, 2006 alone, 1,612 HBsAG tests and 962 HBs Antibody tests were billed to Medicare and paid by Medicare even though they were done more frequently than NCD requirements, were not medically unnecessary, and did not contain medical documentation or physician orders. Drennen contacted a manager in the Opelika area of Alabama and confirmed that similar overbilling without medical necessity or documentation had occurred in the facilities. It then became apparent to Drennen that because of Fresenius's nationwide practices and use of the nationwide system, Fresenius had submitted thousands, if not millions, of false claims to the Government.

35. In June 2006, Drennen informed his superiors, including Susan Stanfield,

Fresenius Alabama Region Vice President, of the false claims submitted to the Government. He reported to Ms. Stanfield that according to his estimates for the one-year period for the facilities in the Mobile area, the amount of fraudulent billing was \$40,338. He found that HBsAG tests were billed at \$15.04 and HBs Antibody billed at \$16.05. Ms. Stanfield contacted Kenny Ensley, East Division Compliance for Fresenius by e-mail. In her e-mail, Ms Stanfield acknowledged that Fresenius's procedures had been "misleading" and requested that a complete audit be done by the Compliance Department. Mr. Ensley acknowledged in e-mails that the funds must be "refunded back to Medicare." Another superior acknowledged that Fresenius must "notify the OIG [the Office of Inspector General] of the problem." Drennen made numerous requests to ensure that proper full-scale audits were done and that policy changes and refunds were made. To Drennen's knowledge, no refunds were ever made, and at the time he left Fresenius, it had not corrected the improper claims.

36. Drennen learned that the reason that OIG would have to be informed is that Fresenius had entered into a Corporate Integrity Agreement ("CIA") with the Government with respect to its billing practices that was in effect until January 2008. Fresenius had entered into this CIA as a result of a settlement in the year 2000 of a previous False Claims Act case filed against Fresenius. As part of the CIA and the settlement agreement, Fresenius agreed, among other things to the following:

- "Within 120 days of the effective date of this CIA, Fresenius shall review and, where appropriate, revise or develop written policies and procedures to address the specific obligations identified below regarding Fresenius's provisions of items and services and submission of claims to the Federal health care programs."
- "**Laboratory Services.** Fresenius shall have policies and procedures designed to ensure adherence to relevant Federal Rules relating to the provision of and reimbursement for clinical laboratory services. at a minimum, such policies and

procedures shall address the following issues in the manner prescribed below:

(1) Medical Necessity.

(a) Generally. (i) Fresenius shall ensure that it does not engage in any conduct or activities that causes the submission of claims to Federal health care programs for laboratory tests and/or services that lack medical necessity; (ii) Fresenius shall design and implement internal controls (1) designed to prevent Fresenius from receiving reimbursement for medically unnecessary tests and (2) designed to enable Fresenius to identify utilization patterns that may indicate Fresenius is receiving reimbursement for medically unnecessary tests; and (iii) Fresenius shall communicate to physicians that claims submitted for service will only be paid if the services are covered, reasonable and medically necessary for the beneficiary, given his or her clinical condition.

....

(c) If Fresenius is unable to obtain required documentation of medical necessity from the ordering physician after a good faith effort to obtain it, and therefore, is unable to claim reimbursement for a service from a Federal health care program, and the ordering physician has not provided an appropriately completed adverse beneficiary notice ("ABN"), Fresenius may choose to provide the service at no charge to the patient, the dialysis facility where the patient obtains the service, or the ordering physician, provided that Fresenius (1) undertakes to educate the ordering physician on the need to document medical necessity for tests that under Federal Rules or local medical review policy require a diagnosis code in order to obtain reimbursement or obtain an ABN and the potential for violations of sections 1128A(a)(5) and 1128B(b) of the Social Security Act for failure to provide required documentation, including an ABN, to the laboratory; and (2) monitors orders from such ordering physician to assess compliance with proper documentation requirements. In the event that a pattern of physician non-compliance continues notwithstanding these efforts, Fresenius shall either bill and obtain payment from the ordering physician, obtain payment from the dialysis facility with which the ordering physician is affiliated, or cease processing such physician's orders."

- *“Reporting of Overpayments.* If, at any time, Fresenius determines that it has received an overpayment from a Federal health care program, Fresenius shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct any operational or policy deficiencies on Fresenius’s part which may have caused the overpayments to occur, including preventing the underlying problem and the overpayments from recurring.

Reporting to OIG. If Fresenius determines that there is a Reportable Event, Fresenius shall notify the OIG within 30 days of such determination. Fresenius’s notification to the OIG shall include the following information; provided however, that if the Reportable Event does not involve an overpayment, the requirements of a and b below do not apply:

- a.. all of the information provided to the payor in returning the overpayment;
- b. the name and the address of the payor to whom the overpayment was returned;
- c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and program authorities;
- d. Fresenius’s actions to correct any operational or policy deficiency; and
- e. any further steps Fresenius plans to take to address such operational or policy deficiency and prevent it from recurring.”

37. The information that Drennen obtained through the course of his duties as area manager made clear that Fresenius was not abiding by the provisions of the CIA. Specifically, Fresenius did not have policies and procedures in place to ensure adherence to NCD guidelines and the documentation of medical necessity and medical reasonableness with respect to its laboratory services. Fresenius did not have any internal controls designed to enable Fresenius to identify patterns of receiving reimbursement for medically unnecessary tests. Fresenius did not obtain the required documentation of medical necessity from the ordering physician or, if such

documentation was unavailable, provide the services free of charge; instead it billed and received payment from Medicare. Fresenius did not notify the OIG of the resulting overpayments.

38. As set forth above, Drennen reviewed voluminous records when investigating the claims submitted by Fresenius to the Government.⁹ As set forth above, the number of improper tests for one year is more than 1,500. Despite the large volume of unnecessary tests, Drennen provides the following representative examples of the unnecessary and medically undocumented (e.g., no physician's orders) tests, as evidence of Fresenius's fraudulent conduct:¹⁰

Patient C.J.¹¹ - Mobile Clinic - 12 Antigen unnecessary tests at \$15.44 per test and 3 unnecessary Antibody tests at \$16.06 = \$233.46.

Patient J.M. - Mobile Clinic - 12 unnecessary Antigen tests at \$15.44 per test and 4 unnecessary Antibody tests at \$16.06 per test = \$249.52

Patient F.D. - East Mobile Clinic - (five month period only) - 4 unnecessary Antigen tests at \$15.44 per test = \$61.76

Patient W.M. - East Mobile Clinic - 12 unnecessary Antigen tests at \$15.44 per test and 3 unnecessary Antibody tests at \$16.06 per test = \$233.46.

Patient B.G. - Prichard Clinic - 13 unnecessary Antigen tests at \$15.44 per test and 3 unnecessary Antibody tests at \$16.06 = \$248.90.

Patient L.H. - Prichard Clinic - 11 unnecessary Antigen tests at \$15.44 per test and 3 unnecessary Antibody tests at \$16.06 per test

⁹As an ex-employee of Fresenius, Drennen no longer has access to many of the documents he reviewed in his investigation.

¹⁰All tests are taken from May 1, 2005 to May 31, 2006 unless otherwise noted.

¹¹All patients' names are withheld to comply with federal and state privacy laws.

= \$218.02.

Total for all six patients: \$1245.12.

39. As stated above, Drennen also investigated the frequency of ferritin testing and Fresenius' billing practices. In May and June, 2006 he contacted South Alabama Area Manager Ingrid Jackson and Area Managers, including Joan Dye, of the company which Fresenius had recently acquired, Renal Care Group. He requested information regarding ferritin testing. He learned that at Fresenius's former Renal Care facilities, patients were being tested monthly, and that the Government was billed for those tests monthly, which is more frequently than NCD requirements allow. He found no medical documentation or justification to support those additional tests. Drennen sought information and action from the Regional Vice President during his employment. However, no action was taken, nor was information provided.¹²

40. In his investigation, Drennen found that the false claims he identified resulted from a pattern and practice of conduct by Fresenius including, but not limited to, failing to input proper patient information into Fresenius's computer systems, failing to follow or develop standardized, written protocols, failing to follow NCD requirements, failing to submit claims with adequate medical documentation or physician orders, failing to develop its own standards, procedures, and requirements for compliance with Government statutes and regulations, and failing to follow the CIA. This pattern and practice applied nationwide pursuant to company policies, procedures and systems.

41. Defendant's violations of the Act listed herein and their concealment thereof, stem from at least 2001. Plaintiff believes and alleges that such violations are ongoing. Drennen has

¹²Unlike the hepatitis B testing information, Drennen does not have access to the ferritin testing documentation any longer.

provided the United States with a Disclosure Statement and evidence relating to his allegations prior to the filing of this action and has continued to cooperate and disclose information to the United States since filing the actions.

COUNT ONE
VIOLATIONS OF THE ACT
(31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B))

42. Plaintiff repeats and incorporates by reference the allegations made in paragraphs 1 through 41 of this Complaint.

43. This is a claim for treble damages and civil penalties under the Act, 31 U.S.C. §§ 3729-32, as amended.

44. Through the acts described above, Defendant and its agents and employees knowingly presented and caused to be presented to officers and employees of the Government false or fraudulent claims in order to obtain payment for unnecessary medical testing.

45. Through the acts described above, Defendant and its agents and employees knowingly made, used, or caused to be made or used, false records or statements to get such false or fraudulent claims paid by the Government.

46. The United States and its fiscal intermediaries, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees, paid and continue to pay Defendant for claims that would not be paid if the truth were known.

47. The United States and its fiscal intermediaries, unaware of the falsity of the records, statements, and claims made or submitted by Defendant, have paid claims for unnecessary medical testing that they would not have paid otherwise.

48. As a direct result of the Defendant's false records, statements, claims and omissions, the United States has been damaged in the amount of many millions of dollars in

monies paid for unnecessary medical testing.

49. The tolling provisions of 31 U.S.C. § 3731 make this Complaint timely with respect to all violations occurring within a ten-year period from the date of the filing of this action.

COUNT TWO
VIOLATIONS OF THE ACT
(31 U.S.C. §§ 3729(a)(1)(G) and 31 U.S.C. 3729(a)(1)(B))

50. Plaintiff repeats and incorporates by reference the allegations made in paragraphs 1 through xx of this Complaint.

51. This is a claim for treble damages and civil penalties under the Act, 31 U.S.C. §§ 3729-32, as amended.

52. Through the acts described above, Defendant and its agents and employees have knowingly made, used, or caused to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money to the Government.

53. Through the acts described above, Defendant has knowingly concealed or knowingly and improperly avoided or decreased an obligation to return overpayments to the Government.

54. As set forth herein, Defendant has knowingly retained overpayments to Government health care programs and knowingly concealed those overpayments from the Government. These overpayments were not withheld as a result of a statutory or regulatory process, but were willful receipts and withholding of overpayments to which Defendant is not entitled. Defendant has failed to take the required and appropriate steps to satisfy the obligation owed to the United States, refund or return such overpayments, or to inform Medicare or Medicaid or any other government health care program of the overbilling, and instead continues

to retain the same, and to overbill such programs.

55. As a direct result of the Defendant's false records, statements, claims and omissions, and failure to repay monies due to the United States, the United States has been damaged in the amount of many millions of dollars in monies paid for unnecessary medical testing.

56. The tolling provisions of 31 U.S.C. § 3731 make this Complaint timely with respect to all violations occurring within a ten-year period from the date of the filing of this action.

PRAYER

WHEREFORE, Plaintiff/Relator prays for judgment against Defendant as follows:

1. That Defendant ceases and desists from violating 31 U.S.C. §§ 3279-32, as amended;
2. That the Court enter judgment against the Defendant in an amount equal to the total of three times the amount of damages the United States has sustained as a result of the Defendant's actions, as well as a civil penalty against the Defendant in the amount of \$11,000.00 for each violation of 31 U.S.C. § 3729;
3. That Plaintiff/Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Act;
4. That Plaintiff/Relator be awarded all costs and expenses of this action, including attorney's fees; and
5. That the United States and the Plaintiff/Relator recover all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury.

Respectfully submitted this 1st day of July, 2011,
Counsel for Plaintiff/Relator Christopher Drennen

/s/ Edwin Lamberth
R. Edwin Lamberth (*pro hac vice*)

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CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the foregoing pleading on the following counsel on this 1st day of July, 2011 by filing this pleading with the Court's ECF system.

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/s/ R. Edwin Lamberth