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| T 000 | INITIAL COMMENTS<br><br>PFI # 4525<br>OPERATING CERTIFICATE # 7002140<br><br>NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A COMPLAINT/ RE-LICENSURE SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.<br><br>NY00061423<br>NY00060918<br><br>The facility has a patient census of 171 including:<br>161 incenter hemodialysis patients<br>3 CAPD patients<br>10 home hemodialysis patients<br><br>On 8/14/08 at 12:45 PM, a determination of an immediate threat to patient safety was made due to the potential for serious patient harm in regards to the presence of debris resembling blood in the internal transducer protectors of the hemodialysis machines.<br>Cross refer to T2049.<br><br>Upon further inspection of the internal transducer protectors of all 28 hemodialysis machines currently in use in the treatment room, it was determined by the Owner/Operator that 17 | T 000 | | |

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| T 000 | Continued From page 1<br><br>machines did not pass visual inspection of the internal transducer protectors by the facility Biomed staff and were subsequently removed from service. The facility was able to operate with only 11 machines to care for 161 patients. The Owner/Operator made a decision to voluntarily close the facility after arrangements were made to transfer all the patients to other certified ESRD facilities.<br><br>On 8/15/08 at 9:00 PM. the facility reported that all patients were transferred out. Tour of the facility confirmed 0 census. | T 000 | | |
| T2008 | 751.2 (b) ORGANIZATION AND ADMINISTRATION. Operator.<br><br>The responsibilities of the operator shall include but not be limited to:<br>(b) ensuring that all patients receive quality health care and services provided in accordance with generally accepted standards of professional practice.<br>This Regulation is not met as evidenced by:<br>The Governing Body is not maintaining its full legal authority and responsibility for the governance and operation of the End Stage Renal Disease (ESRD) facility as evidenced by the scope and severity of the deficiencies noted below:<br><br>The Governing Body does not ensure that the facility maintains a safe environment for the care of their patients as related to the presence of blood observed in the internal transducer protectors of two hemodialysis machines.<br><br>THE PRESENCE OF BLOOD IN THE INTERNAL TRANSDUCER PROTECTOR HAS THE POTENTIAL TO AFFECT THE HEALTH AND | T2008 | | |

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| T2008 | Continued From page 2<br>SAFETY OF 161 HEMODIALYSIS PATIENTS RESULTING IN AN IMMEDIATE THREAT TO PATIENT SAFETY.<br>Cross refer to T2049.<br><br>PHL 2805 [redacted]<br><br>The Governing Body does not exercise its legal authority regarding oversight of contracted services.<br>See T2029.<br><br>The Governing Body failed to follow facility policy to complete annual performance evaluations of staff timely and that employees health files are complete.<br>See T2092, T2091, T2090.<br><br>The Governing Body failed to ensure that each patient had a timely short term care plan and long term care program developed by the multidisciplinary team and that each patient was offered opportunity to participate in their care plan and choice of treatment modality.<br>See T2669, T2128, T2114.<br><br>Following the facility's decision to voluntary close the facility, there is no evidence that the | T2008 | | |

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| T2008 | Continued From page 3<br><br>Governing Body made reasonable efforts to seek certified ESRD facilities close to the patient's homes or in Manhattan with consideration to the patients' preference or convenience.<br>See T2670.<br><br>The Governing Body failed to ensure that all patients are treated with consideration, respect, recognition of their individuality and the need for privacy in treatment. Moreover, the Governing Body does not ensure that all patients are afforded the right to make informed decisions regarding their care.<br>See T2162.<br><br>The Governing Body does not ensure that patients are treated in a safe and clean environment. Moreover, the Governing Body failed to implement policies and procedures concerning patient safety and therefore did not direct the staff to conduct all required machine safety tests prior to initiation of dialysis.<br>See T2032, T2672<br><br>The Governing Body does not ensure that the Medical Director responsible for care of the ESRD patients provides adequate direction, supervision and oversight regarding patient care.<br>See T2120, T2047.<br><br>The Governing Body does not ensure that the Nurse in charge of nursing services and the Medical Director fulfills their responsibilities to the nature of the patient population and the professional structure of the unit in the planning and the delivery of the patient services.<br>See T2031. | T2008 | | |
| T2029 | 751.2 (o) ORGANIZATION AND ADMINISTRATION. Operator. | T2029 | | |

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| T2029 | Continued From page 4<br><br>The responsibilities of the operator shall include but not be limited to:<br>(o) the approval of all written agreements and/or contracts.<br><br>This Regulation is not met as evidenced by:<br>Based on observation of care, document review and staff interview: the Governing Body does not exercise its legal authority regarding oversight of contracted services.<br><br>Findings include:<br><br>This was evident in that the Governing Body has engaged in an Administrative Services contract with a management company regarding the day to day operations of the facility. Based on the egregious and repetitive findings with regard to infection control violations and care of the patients by the contracted staff, the Governing Body has not fulfilled it's responsibilities to ensure that the contracted service is in compliance with Federal and Local law.<br>Cross refer to T2008, T2049, T2672, T2031. | T2029 | | |
| T2031 | 751.2 (q) ORGANIZATION AND ADMINISTRATION. Operator.<br><br>The responsibilities of the operator shall include but not be limited to:<br>(q) the provision of staff, space, facilities, supplies and equipment for all functions and services adequate to meet the health care and safety needs of its patient population and to facilitate the efficient operation of the center.<br><br>This Regulation is not met as evidenced by:<br>Based on observation of care and review of medical records and staff interview: The facility | T2031 | | |

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| T2031 | Continued From page 5<br>did not ensure that patients received the correct dialysate bath as prescribed by the physician.<br><br>On 8/12/08 at approximately 11:50 AM, the surveyor observed patient MR #38 at station #27 on machine #3 receiving 2.0 Potassium (K) dialysate bath from a central dialysate delivery system. However, a review of the Flowsheet revealed that the physician ordered a 1.0 K dialysate bath and that patient started treatment at 10:40 AM. The RN (employee #14) was informed and confirmed that the patient was on the wrong bath. The RN immediately made the correction. However, the patient was receiving the incorrect dialysate bath for over an hour.<br><br>On 8/12/08 at approximately 11:57 AM, the surveyor observed patient MR #39 at station #11 on machine #18 receiving 1.0 K bath from a central delivery system. However, a review of the Flowsheet revealed that the physician ordered a 2.0 K bath and that the patient started treatment at 11:25 AM. The RN (Employee #9) was informed and confirmed that the patient was on the wrong bath. The RN immediately made the correction. However, the patient was receiving the incorrect dialysate bath for over 30 minutes.<br><br>On 8/13/08 at approximately 11:25 AM, the surveyor observed patient MR #40 at station #4 on machine #33 receiving 2.0 K bath from a central delivery system. However, a review of the Flowsheet revealed that the physician ordered a 1.0 K dialysate bath and that the patient started treatment at 11:17 AM. The RN (Employee #13) was informed and confirmed that the patient was on the wrong bath. The RN immediately made the correction.<br><br>It was observed that the facility uses plastic jugs | T2031 | | |

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| T2031 | Continued From page 6<br>to delivery a 3.0 K bath. It was also observed that as a matter of routine, these jugs remain on the machines throughout the day regardless whether the current patient is using a 3.0 K bath. This practice creates a risk of placing the patient on the wrong bath and is also an infection control issue because the jug has a potential to be exposed to the patient's blood and is not cleaned between patients. This was observed all days of the survey when patient care was in process.<br><br>THIS IS A REPEAT CITATION FROM THE 8/06 RE-LICENSURE SURVEY<br><br>The facility was cited on 8/31/06 for containers of acid concentrate with the wrong potassium strength being left on machines from previous patients. In the facility plan of correction dated 10/12/06 it was stated that "Specialty bath containers will be removed immediately following treatment...". There is no evidence that this plan was implemented and followed up in the facility's QAPI program.<br><br>Based on observation of care and staff interview: the facility does not provide leadership and supervisory support services to staff to ensure when needed in accordance with generally accepted standards of nursing practice, the immediate availability of a registered professional nurse or ancillary staff for care of all patients. During all days of the survey, while the facility was fully operational (prior to voluntary closure) 8/12/08 and 8/13/08, critical patient care alarms were not attended to by the staff. Furthermore, patients mute alarms unsupervised in an effort to control the distressing noise from the machines. Staff not answering high level alarms (i.e. blood | T2031 | | |

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| T2031 | Continued From page 7<br>pressure/blood pump stopped) for this extended period of time, has a potential for patient harm.<br><br>Findings include:<br><br>During survey dates of 8/12/08 to 8/20/08, hemodialysis machines were observed alarming with a visual red light on and an audio alarm sounding. These alarms are for signs and symptoms of dialysis related problems that require immediate intervention.<br>It was observed that the staff did not respond timely to the alarms.<br><br>For example:<br><br>On 8/12/08 machines at the following stations were observed with blood pressure monitors alarming either high or low blood pressures:<br>Station # 5 Machine #22 from 3:10 PM to 3:20 PM (staff responded after 10 min)<br>Station #28 Machine #17 from 11:15 AM to 11:20 AM (staff responded after 5 min.)<br>Machines #8, 9, 10, 11, 13 from 2:40 PM to 2:52 PM (staff responded after 12 min.)<br>Machine #12 from 3:00 PM to 3:10 PM (staff responded after ten min.)<br><br>When the surveyor informed the Patient Care Technician (PCT) (Employee #19), the PCT pressed the re-set button on the machines and responded that patient's blood pressure was high. However, the surveyor pointed out that according to machine #9 the patient's blood pressure was actually low.<br><br>On 8/12/08 machines at the following stations were observed with machines alarming blood pump stopped:<br>Station #15 from 11:15 AM to 11:20 AM (staff | T2031 | | |

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| T2031 | Continued From page 8<br><br>responded after 5 min)<br>Station #14 Machine #31 from 11:15 AM to 11:20 AM (staff responded after 5 min)<br>Station #29 Machine #29 from 11:22 AM to 11:28 AM (staff responded after 5 min)<br><br>On 8/12/08 station #28 machine #17 for patient in MR#36 was observed alarming low conductivity at 3:01 PM after the patient was changed to a 3K Bath after initiation of treatment. The RN (Employee #1) and PCT were observed repeatedly muting the machine at least three times until approximately 3:30 PM when the Biomedical technician came to check the machine. The machine continued to alarm low conductivity. The surveyor notified the Clinical Nurse Coordinator (Employee # 20) and the patient was eventually transferred to another station at approximately 4:00 PM.<br><br>Based on Medical record review, staff interview and policy and procedure, the facility failed to ensure that patients receive safe and accurate doses of medication.<br>This was evident in:<br>3/7 Home Hemodialysis patients records MR #26, 29, 30.<br>8/15 incenter hemodialysis records MR # 2, 3, 5, 7, 8, 9, 10, 14.<br><br>Findings include:<br><br>On 8/17/08 at 10:30 am, review of home hemodialysis records revealed the following medication errors.<br>Review of MR# 29. On 2/27/08 the physician | T2031 | | |

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| T2031 | Continued From page 9<br>wrote an order for Venofer 200 mg IV push x 5 doses. The order does not note if it is to be given each treatment, weekly or monthly etc. Review of the patient's treatment sheet indicates that the patent was given three doses within six days. There is no evidence that the patient received 5 doses as per the physician's order.<br>On 2/2/08 the physician ordered heparin bolus of 2000 units, the treatment flow sheets dated 8/1/08-8/7/08 recorded that the patient received heparin 1500 units.<br><br>Review of MR #26. On the treatment sheet dated 8/9/08, the physician ordered that the patient was to receive 2000 units of heparin bolus. Review of the patient's treatment sheet revealed that the patient did not administer any heparin on that day. The treatment sheet was reviewed by the nurse (Employee #15) however no comment was noted by the nurse that the medication was not given.<br><br>Review of MR #30. On the treatment sheet dated 8/14/08, the physician order states that the patient is to receive 3500 units of heparin bolus. Review of the patient's treatment sheet revealed that the patient did not administer any heparin. The treatment sheet was reviewed by the nurse (Employee #15) however no comment was noted by the nurse that the medication was not given.<br><br>On 8/17/08 at 10:45 am, the home hemo dialysis nurse (Employee #15) was interviewed and confirmed the above findings.<br><br>In-center Hemodialysis:<br>Zemplar was neither administered neither per protocol nor per physician orders for the following patients. | T2031 | | |

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| T2031 | Continued From page 10<br><br>Review of MR #2 hemodialysis flow sheets for 7/1/08-7/15/08, showed that the patient received Zemplar 10 mcg. On 7/17/08-7/31/08, the patient received Zemplar 11 mcg.<br>The medical record had no evidence of a physician's order for Zemplar 10 mcg or 11 mcg. The most current physician's order dated 4/18/08, instructs the nurse to administer "Zemplar 12.0 mcg IV push 3xqw."<br><br>Review of MR #3 hemodialysis flow sheets for the following:<br>On 7/17/08-7/31/08, the patient received Zemplar 17 mcg IVP.<br>On 8/2/08-8/5/08, the patient received no Zemplar.<br>On 7/22/08, the physician wrote "Hold Zemplar". Even though the physician wrote an order on 7/22/08 to hold the Zemplar, the patient continued to receive Zemplar until 7/31/08. This was more than one week after the physician ordered it to be "held."<br><br>Review of MR #7 revealed the following: the dialysis flowsheets dated 6/13/08 to 7/15/08 documented that 13 mcg of Zemplar was administered. On 7/17/08 the dose was changed to Zemplar 17 mcg and was administered. According to the patient's iPTH level the dose should have stayed the same.<br><br>Review of MR #8 revealed the following: the dialysis flow sheets dated 7/17/08 to 8/12/08 documented that Zemplar 10 mg was administered. According to the patient's iPTH level the dose should have increased.<br><br>Review of MR #9 revealed the following: on 1/28/08 the physician ordered Zemplar 7 mcg | T2031 | | |

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| T2031 | Continued From page 11<br>every week. The dialysis flow sheets dated 7/31/08 to 8/7/08 documented that Zemplar 4 mcg was administered.<br><br>Review of MR #14 revealed the following: on 4/18/08, the physician ordered 4/18/08 "Zemplar 3.0 mcg IV push qtx.". Review of MR#14 hemodialysis flow sheet for 7/2/08-7/16/08, showed that the patient received Zemplar 2.0 mcg.<br>On 6/11/08, the physician ordered "Zemplar 2.0 mcg IV push qtx". On 7/18/08-8/13/08, the patient received Zemplar 3.0 mcg.<br><br>Epogen was not administered as ordered for the following patients.<br><br>Review of MR #5 revealed the following: on 7/15/08 the physician ordered Epogen 9900 units TIW. However on 8/11/08 the nurse administered Epogen 8800 mg.<br><br>Review of MR #10 revealed the following: on 6/11/08 the physician ordered Epogen 15400 units TIW. However on 8/12/08 the nurse administered Epogen 14300 mg.<br><br>On 8/15/08 at 10:30 am, review of the facility's policy and procedure "Medication Policy" it was revealed that medications are administered as prescribed and no medications are given without an order from the physician or allied health professional.<br><br>Upon Interview on 8/15/08 at 11:30 am, the Clinical Nurse Coordinator (Employee #20) acknowledged the above findings and stated that currently they do not have a protocol for Epogen dosing. But, they use the facility protocol for | T2031 | | |

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| T2031 | Continued From page 12<br><br>Zemplar dosing. She also stated that the Zemplar doses are calculated by the dietician as per Ca, PHO4, and IPTH lab values, then she enters in the computer system (snappy).<br><br>Upon interview on 8/18/08 at 3:00 PM the Dietician (Employee #33) stated that a year ago she was instructed to do the Zemplar calculation by the Facility Administrator and the Nephrologist. She stated that she receives instructions from the clinical specialist on the unit. She also stated that sometimes she calculates the dose for Zemplar based on her own judgement and expertise.<br><br>Upon interview on 8/18/08 at 12:40 PM, the Clinical Nurse Coordinator (Employee # 20) stated the dietician adjusts the dose for Zemplar and, without checking the dose, she enters the dose into the facility data base as an order for medication.<br><br>Based on observation of care and staff interview: in an effort to control expected and usual bleeding from the patient's needle sites, staff routinely wrap the patient's access sites with guaze and tape in a tourniquet fashion then leave the patients unsupervised to attend to other patients. This was observed in MR #39, 45, 46.<br><br>Findings include:<br><br>On 8/12/08 at approximately 3:10 PM, a PCT (Employee # 19) was observed wrapping tape around the arm of patient MR # 39.<br><br>On 8/12/08 at approximately 3:20 PM, interview with patient MR #46 revealed that this is the way the staff usually tape his arm. | T2031 | | |

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| T2031 | Continued From page 13<br><br>The surveyor notified the Clinical Nurse Coordinator (Employee # 20) who immediately went over and spoke to the PCT (Employee # 19) and had him removed the tape.<br><br>On 8/13/08 at approximately 9:50 AM, a PCT (Employee # 10) was observed wrapping tape around the arm of patient MR # 45. | T2031 | | |
| T2032 | 751.2 (r) ORGANIZATION AND ADMINISTRATION. Operator.<br><br>The responsibilities of the operator shall include but not be limited to:<br>(r) ensuring that all equipment is maintained in safe and working order.<br><br>This Regulation is not met as evidenced by:<br>Based on observation, document review and staff interview: the facility does not ensure that the internal pressure transducer protectors are inspected and replaced if necessary during routine preventive maintenance. This was evidenced by two out of the four internal transducer protectors observed by the surveyors on 08/13/08 at approximately 4:30 PM which had reddish brown residue in the tubing and on the filter inside the dark blue plastic housing of the transducer protector.<br><br>Furthermore, the facility does not ensure that the external transducer protectors are monitored during treatment for blood or fluid contamination and that they are changed and inspected according to facility policy. Cross refer to T2049.<br><br>Findings include:<br><br>During the tour of the equipment repair room on 08/13/08 at approximately 4:30 PM, the surveyors | T2032 | | |

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| T2032 | Continued From page 14<br><br>noted the Chief Technician (Employee # 16) working on two machines in the repair room. The surveyors also noted that there were four internal transducers placed on top of the two machines (machine #37 and machine #16) that were in the room .Two out of the four transducer protectors had reddish brown residue in the tubing and this had penetrated to the filter inside the dark blue plastic covering of the transducer protector. Upon interview, the Chief Technician stated that those contaminated internal transducers were removed from machine #37 and machine #16. These findings were brought to the attention of the facility staff including the Medical Director immediately.<br><br>However, during a visual inspection of the internal transducer protectors on the dialysis machines conducted on 08/14/08 at approximately 4:00 PM revealed that the transducer protector tubing on some machines (e.g. machines #30 and 34) had a tie wrap around it as opposed to the original tubing installed by the manufacturer with a metal clamp. This indicated that the facility had changed these internal pressure transducer protectors and its' tubing some time in the past. There is no documented evidence available to indicate the reasons for the change of these transducer protectors.<br><br>Review of 2007 dialysis machine repair logs on 08/19/08 at approximately 10:30 AM revealed that internal pressure transducer protectors were replaced on six dialysis machines. But there is no documented evidence available to indicate that these transducer protectors were inspected and changed during the transducer replacements. Upon interview of the Chief Technician (Employee #16) on 08/18/08 at approximately 10:00 AM, it was stated that this employee did not | T2032 | | |

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| T2032 | Continued From page 15<br><br>do a detailed check of the internal pressure transducer protectors during the routine Preventive Maintenance checks and that the clinical care providers did not inform this employee at any time about a contaminated external transducer protector that would warrant an inspection of the internal pressure transducer protectors.<br><br>During inspections of the internal pressure transducer protectors on all the machines in the unit on 08/15/07 at approximately 3:17 PM, an inspection of the internal pressure transducer protector of machine #12 (not in use) revealed that the tubing of the internal transducer protector on the venous side of the machine was heavily contaminated with dark black residue.<br><br>Based on review of documents and staff interview, the facility failed to ensure that an established program for preventive maintenance of the dialysis machines was implemented in accordance with the manufacturer's guidelines and acceptable standard of practice. This was evident in all 40 machines at the unit.<br><br>Findings include:<br><br>Based on review of Preventative Maintenance (PM) records for the 40 dialysis machines in the unit on 08/14/08 at approximately 10:30 AM, the facility did not provide documented evidence of proper PM checks conducted in 2007 for these dialysis machines in the facility. The surveyor was provided with Service Order documents which noted "time for PM" under the heading 'Service Requested' and "PM performed" under the heading "Work Performed". These documents failed to indicate the type of PM (Quarterly or | T2032 | | |

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| T2032 | Continued From page 16<br><br>Annual) performed on each machine. The completed manual PM checklists for Fresenius 2008H and 2008K Preventive Maintenance Procedures were not available at the facility to indicate the different maintenance tasks and checks performed at 1000 and 4000 hour interval PM for each machine in the year 2007.<br><br>Furthermore, there was no documented evidence available to indicate that a visual inspection for contamination of the internal pressure transducer protectors were conducted during any Annual PM checks for any machine, as required by the manufacturer (Fresenius) of the dialysis machines.<br>Cross refer to T2049 and T2070.<br><br>In addition, during the tour of the facility on 08/12/08 at approximately 10:30 AM, it was noted that the facility was using polyurethane coiled (Fre-Thane) tubing on the dialysis machines for the delivery of acid and bicarb solutions. Upon review of the specification of these coiled tubings provided to the surveyor by the facility on 08/18/08 at approximately 3:30 PM, it was noted that these tubings can only withstand temperatures between-40 degree Fahrenheit and 165 degree Fahrenheit (74 degree celsius). But during the heat disinfection of the dialysis machines, hot water passing through the dialysate lines reaches a temperature of 84 degrees celsius. Therefore it was determined that this Fre-Thane Coils used for the delivery of acid and bicarb to the machine did not meet the heat resistivity requirement for the heat disinfection of these machines and therefore has the potential of causing machine leaks during treatments of patients. This finding was conveyed to and confirmed by the Acting Regional Bio-medical Administrator (Employee #23) of the facility. | T2032 | | |

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| T2032 | Continued From page 17<br><br>Based on observations, document review and staff interview, it was determined that the facility failed to implement policies and procedures concerning patient safety and therefore did not direct the staff to conduct all required machine safety tests prior to initiation of dialysis. This was evident in 28/28 machines in use.<br><br>Findings include:<br><br>During observation of care and review of the patient treatment record for patient (MR # 9) at station #17 machine #38 on "Snappy" (a computerized system to document treatment orders and medications) on 08/08/08 at approximately 10:37 AM, it was noted that the the manual conductivity test readings were exactly the same readings displayed by the machine.<br><br>At another instance on 08/12/08 at approximately 10:40 AM, a staff nurse (Employee #28) was observed copying the machine conductivity readings and documenting it under manual conductivity test readings without actually performing the manual test with an independent meter. Upon interview of this employee on 08/12/08 at approximately 10:45 AM, it was revealed that the staff were directed to copy the conductivity readings displayed on the dialysis machines and the Ph range was either left blank or documented as 7.0, as the machine did not display it..<br><br>Also, on 08/12/08 at approximately 3:00 PM, the surveyors observed a staff nurse (Employee #1) change the acid bath from 2K to 3K for a patient (MR# 36) on machine #17 located at station #28 | T2032 | | |

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| T2032 | Continued From page 18<br><br>during the course of treatment. This staff member did not check the conductivity of the dialysate with an independent meter after the change of bath. At approximately 3:05 PM, the machine was observed to be alarming with a conductivity of 12.9 mS/cm and was functioning in bypass mode. The facility staff including the Biomedical Technician (Employee #16) tried to fix the problem with the machine, but none of the staff members tried to verify the actual conductivity of the dialysate with the conductivity reading displayed by the machine.<br><br>The manufacturer of the dialysis machines recommend that manual conductivity tests be conducted prior to each treatment in order to verify the dialysate conductivity measured by the internal cell in the machine agrees with an external meter within 0.1mS/cm. | T2032 | | |
| T2047 | 751.4 (b) ORGANIZATION AND ADMINISTRATION.<br><br>Medical director.<br>The operator shall appoint a medical director who:<br>(b) is delegated the authority and is responsible to the operator for the professional, organizational and administrative aspects of the adequacy and quality of care provided to patients in the center.<br><br>This Regulation is not met as evidenced by:<br>Based on review of facility documents and staff interview: The Medical Director does not ensure that the polices and procedures governing the facility are developed and implemented to ensure the achievement and maintenance of minimal standards of care of the ESRD patient as required. | T2047 | | |

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| T2047 | Continued From page 19<br><br>The Medical Director does not direct and oversee quality assurance initiatives in that previous deficiencies and citations are not followed through and monitored through the facility's QAPI program.<br>See T2141.<br><br>There is no evidence of a routine review or evaluation of the adequacy and appropriateness of the medical care provided for patients.<br>Cross refer to T2128, T2167, T2114.<br><br>The Medical Director failed to ensure that an annual history and physical examination is completed for each patient.<br>See T2120.<br><br>The Medical Director failed to ensure that all employees whose job responsibilities include oversight of the water treatment system, are trained according to their assigned duties.<br>See T2101.<br><br>The Medical Director does not ensure that patients receive their prescribed treatment.<br>See T2031.<br><br>The Medical Director does not ensure that patients participating in the facility's home dialysis program are assessed and monitored on an ongoing basis by the facility staff and are provided with required follow-up and support services.<br>See T2688.<br><br>The Medical Director failed to monitor the quality of water and dialysate for the home hemodialysis patients.<br>See T2692. | T2047 | | |

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| T2049 | Continued From page 20 | T2049 | | |
| T2049 | 751.4 (d) ORGANIZATION AND ADMINISTRATION.<br><br>Medical director.<br>The operator shall appoint a medical director who:<br>(d) develops and recommends to the operator policies and procedures governing patient care in accordance with generally accepted standards of professional practice.<br><br>This Regulation is not met as evidenced by:<br>Based on observation of care, interview with staff and review of facility documents: it was determined that the Governing Body failed to ensure the health and safety of the patients as related to the presence of debris resembling blood observed in the internal transducer protectors in two of the four hemodialysis machines in the Biomed machine repair room. Machine # 37 and 16 had dried encrusted reddish brown debris on the venous internal transducer protector. Cross refer to T2032.<br><br>THE PRESENCE OF BLOOD IN THE INTERNAL TRANSDUCER PROTECTOR HAS THE POTENTIAL TO AFFECT THE HEALTH AND SAFETY OF 161 HEMODIALYSIS PATIENTS RESULTING IN IMMEDIATE THREAT TO PATIENT SAFETY.<br><br>On 8/14/08 at approximately 12:45 PM, the acting facility administrator (Employee # 24) was notified that the facility was determined to have an immediate threat to patient safety.<br><br>Transducer protectors are a barrier between blood in the tubing and the transducer in the machine. They connect to the machine's venous and/ or arterial ports via a small tubing segment | T2049 | | |

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| T2049 | Continued From page 21<br><br>on top of the drip chamber. Transducer port lines have a small line clamp in the middle. The transducer protector connects to the end of these lines and is the link between the machine and the blood tubing set (drip chambers). Transducer protectors use membranes that are hydrophobic when wetted, to keep fluid from passing through. If these filters get wet, they prevent air flow. Wetted or clamped transducer protectors cause pressure reading errors. A loose or damaged transducer protector on a pre-pump arterial chamber port could allow air into the bloodline circuit. In April 2001, the Centers for Disease Control and Prevention (CDC) made recommendations. These require centers to change wet transducer protectors right away and inspect the machine side of the protector for contamination or wetting. If a fluid breakthrough is found on the removed transducer protector, the machine's internal protector must be inspected by a qualified technician.<br><br>These recommendations have been taken from Centers for Disease Control and Prevention. MMWR. Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients. April 27, 2001 (RR-5), Vol 50.<br><br>External transducer protectors contaminated with blood has the potential to contaminate the machine internal transducer protector and luer connection. If the internal transducer protector is not changed and the machine is not properly disinfected, there can be cross contamination of patient's blood in subsequent treatments. Based on the following findings it was revealed that the at least two internal transducer protectors were contaminated with debris resembling blood at this facility. | T2049 | | |

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| T2049 | Continued From page 22<br><br>Findings include:<br><br>On 8/12/08 at 2:30 PM, machine #38 (MR # 9) was observed alarming that the venous pressure was high. At the same time it was also observed that the external transducer protector was filled with blood. Although staff did respond to the venous alarm, no action was taken regarding the external transducer protector that was wet with blood. At 3:10 PM upon interview, regarding what to do if there is a wet transducer protector, a Patient Care Technician (Employee # 12) stated that if staff notice blood in the transducer protectors it should be changed. However, the surveyor did not observe the PCT notify the Nurse and/or change the external transducer protector. At 4:00 PM, the patient continued the treatment with the blood filled transducer. Upon interview regarding the wet external transducer, the nurse (Employee # 14) assigned to MR # 9 stated that he had not noticed the bloody external transducer protector prior to the surveyor bringing to his attention and that the PCT did not inform him of it either. He stated that he would "flush it" now. He then left to perform another task in the unit.<br><br>Upon termination of the patient's treatment it was observed that the PCT (Employee # 12) did not check the machine side of the external transducer protector prior to discarding the used bloodlines. This was brought to the attention of the Biomed staff (Employee #16 and #23) and a request was made to have the internal transducer checked on this machine.<br><br>On 8/12/08 at approximately 4:30 PM upon interview, the Clinical Nurse Coordinator (Employee # 20) stated that in the event that an | T2049 | | |

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| T2049 | Continued From page 23<br><br>external transducer protector is wet with blood during the course of a patient's treatment, the staff are to inspect the machine side of the protector and if there was breakthrough of blood or fluid, the machine must be pulled off the treatment floor and inspected by the Biomed staff.<br><br>On 8/13/08 at approximately 10:00 AM review of the facility policy and procedure: 1-03-11 "Changing Transducer Protectors" notes that external transducer protectors (ETP) will be inspected for the presence of blood or saline every 30-60 minutes during patient treatment and included as part of the monitoring process. The ETP will be replaced prior to each patient use. If the ETP becomes contaminated with blood or saline, the teammate will replace the external transducer protector. The back of the wet ETP and the machine pressure module luer locks will be visually inspected for blood or saline contamination prior to placing the new sterile ETP on the machine. If the back of the ETP or the machine pressure module luer locks are contaminated with blood or saline, the machine will be removed from service after completion of the current patient's treatment..... Both external and internal transducer protectors will be changed and the machine will be disinfected prior to use.<br><br>On 8/13/08 at approximately 1:00 PM the facility was instructed by the surveyors to check the internal pressure transducer protectors of the facility's 28 machines (that were currently in use by patients) at the end of all patient treatments.<br><br>On 8/14/08 at approximately 9:30 AM, the Acting Facility Administrator (Employee # 24) stated that after checking all the machines the previous | T2049 | | |

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| T2049 | Continued From page 24<br><br>evening, it was determined by the Biomed staff that 17 of the 28 machines had some evidence of debris or stains in the internal transducer protectors. It had also been observed by the surveyors in the presence of the facility staff (Employee # 25, 22, 26, 24, 21) that two of the four transducer protectors observed on top of the two machines in the Biomed machine repair room (machine # 37, 16) had dried debris resembling blood on the venous internal transducer protector. The Acting Facility Administrator (Employee # 24) had also told the surveyor that a decision was made by the facility to temporarily close the facility and that currently arrangements were being made to transfer all of the patients to other ESRD facilities.<br><br>On 8/14/08 at approximately 10:00 AM, a review of the hemodialysis machine Preventative Maintenance (PM) logs did not indicate that it was the facility's routine to document whether the internal transducer protector was visually inspected as part of the scheduled PMs.<br>Cross refer to T2032. | T2049 | | |
| T2066 | 751.5 (a) (10) ORGANIZATION AND ADMINISTRATION.<br><br>Operating Policies and Procedures.<br>The operator shall ensure:<br>(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:<br>(10) the establishment and implementation, in consultation with a qualified social worker, of a plan, consistent with available community and center resources, to provide or arrange for the provision of social work, psychological and health educational services that may be necessary to | T2066 | | |

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| T2066 | Continued From page 25<br>meet the treatment goals of its patients.<br><br>This Regulation is not met as evidenced by:<br>Based on review of policies and procedures, medical records and patient interviews: it was determined that the social worker failed to conduct a complete psychosocial assessments for patients with ESRD. The social worker failed to assess the patients current psychosocial needs, review the patients progress and provide adequate follow-up for patients with significant social issues. This was evident in 5/15 in-center hemodialysis medical records and 2/10 home dialysis medical records reviewed.<br><br>Findings include:<br><br>In-center hemodialysis patients:<br>MR# 1 is a 87.2 (b) ear old gentleman who began having hemodialysis at this facility since 87.2 (b) During interview on 8/12/08 at 10:30 AM, the patient, (MR #1) stated that he had only a 2nd grade education. He cannot read, and can only write his name. The surveyor observed that the nursing staff asked him to sign an early termination notice. When asked what he was signing, and if someone explained the possible effect on his care, the patient responded that he was not sure what he was signing and no one explained the implications of getting off the dialysis machine early. Review of the medical record showed that the last social work assessment was completed on 12/7/07. The social work assessments had no information regarding the patient's literacy, or the death of the patient's wife. The patient lost his wife six months prior to this assessment. The social worker failed to explore patient's recent loss, address the literacy issue, and assist patient in making informed decision about his care. | T2066 | | |

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| T2066 | Continued From page 26<br><br>Similar findings in in-center MR #2, #13, #14, #15.<br><br>Home dialysis patients:<br>Review of medical record #29 shows [redacted] ear old patient with a history of "chronic non-compliance." She was transferred to this facility o[redacted] and is in the home hemodialysis program. Review of the patient's medical record showed a social work assessment from the previous dialysis facility. Patient had several significant social issues including the fact that she was granted guardianship of a niece with Down Syndrome. This happened after the death of her sister several years ago. The social worker at this facility completed a "psychosocial update" on 1/15/08. Review of the psychosocial update showed no evidence that the social worker discussed this issue with the patient. Whether or not the patient still has guardianship of her niece. Whether or not this relationship may have an impact on her illness, i.e. possible non-compliance. The social worker did not explore the reason/reasons for the patient's non-compliance, and her ability to do dialysis at home. The social worker did not explore whether or not this patient has any social support systems.<br><br>MR #34 is [redacted] ear old individual with a history of IVDA. She started dialysis i[redacted] using the continuous ambulatory peritoneal dialysis (CAPD) program. The patient was removed from the program due to "poor compliance and multiple episodes of peritonitis." The patient then went to the hemodialysis program, but also developed problems with infection and was removed from that program. She came to the CAPD program at | T2066 | | |

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| T2066 | Continued From page 27<br>this facility on 10/07. The physician's note states that the patient is not compliant with medications. Review of the "psychosocial update" dated 3/10/08 & 5/19/08, showed no evidence that the social worker conducted an assessment of the patient's current social situation. The social worker did not identify or address the patient's history of drug abuse, non-compliance and ability to do dialysis at home.<br><br>The social work policy and procedure titled "SOCIAL WORK INTERVENTION AND DOCUMENTATION REQUIREMENTS', states that the social work documentation is individualized to reflect the specific social work needs of the patient, current and/or anticipated social work problems, education provided to the patient, implementation of planned intervention, patient comprehension and response to treatment/intervention. | T2066 | | |
| T2070 | 751.5 (a) (14) ORGANIZATION AND ADMINISTRATION.<br><br>Operating Policies and Procedures.<br>The operator shall ensure:<br>(a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:<br>(14) ensuring that emergency equipment and staff prepared to care for emergencies are provided in accordance with the services provided at the center, and equipment is maintained in working condition.<br><br>This Regulation is not met as evidenced by:<br>Based on observation and staff interview: the facility does not ensure that emergency | T2070 | | |

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| T2070 | Continued From page 28<br>equipment is readily available for patient use.<br><br>Findings include:<br><br>On 8/12/08 at approximately 10:30 AM, it was observed that the patient emergency cart was stored in a corner of the treatment room. It was also observed that the emergency cart could not easily be moved out because it was blocked by several other pieces of patient care equipment including one manual sphygmometer, two oxygen tanks, an IV pole and two oxygen concentrators.<br><br>This was brought to the attention of the Facility Administrator (Employee # 27). On 8/13/08 at approximately 2:00 PM, it was again observed that the same equipment was blocking access to the patient emergency equipment. | T2070 | | |
| T2090 | 751.6 (d) (4) ORGANIZATION AND ADMINISTRATION. Personnel.<br><br>The operator shall ensure:<br>(d) that a record of the following tests, procedures and examinations is maintained for all employees:<br>(4) ppd (Mantoux) skin test for tuberculosis prior to employment and no less than every year thereafter for negative findings. Positive findings shall require appropriate clinical follow-up but no repeat skin test.<br><br>This Regulation is not met as evidenced by:<br>Based on review of employee health files and interview, the facility did not determine the tuberculosis status prior to employment and/or at least annually. This was evident in 3/19 employee health files reviewed (Employee #2, #3, and #12).<br><br>Findings include: | T2090 | | |

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| T2090 | Continued From page 29<br><br>Review of health records for employees #2, #3, and #12 lacked documentation of screening for tuberculosis.<br><br>On 8/15/08 at approximately 3:30 PM, the Clinical Nurse Coordinator (CNC) (Employee #20) was informed of the findings and CNC provided no additional information. | T2090 | | |
| T2091 | 751.6 (d) (5) ORGANIZATION AND ADMINISTRATION. Personnel.<br><br>The operator shall ensure:<br>(d) that a record of the following tests, procedures and examinations is maintained for all employees:<br>(5) an annual, or more frequent if necessary, health status reassessment to assure freedom from a health impairment which is a potential risk to the patients or might interfere with the performance of duties.<br><br>This Regulation is not met as evidenced by:<br>Based on review of employee health files and interview, the facility failed to ensure that employees health files are complete and contain health assessments prior employment and/or annually and certificate of Rubella/Rubeola immunization. This was evident in 8 of 19 employee health files. (Employees #1, #2, #3, #5, #7, #12, #14, and #19)<br><br>Findings include:<br><br>The facility did not ensure that health files contained pre-employment and subsequent annual health status assessment.<br><br>Review of health files for Employee #1, #3, #5, | T2091 | | |

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| T2091 | Continued From page 30<br>#7, #12, and #19 revealed that the most recent annual health assessments were completed over one to two years ago.<br><br>Review of health files for employees #3 and #7 whose date of hire were 4/4/07 and 9/12/07, respectively, lacked documentation of a pre-employment health screening and/or annual assessment.<br><br>Review of files for employees #2, #3, #7, and #14 lacked evidence of Rubella and/or Rubeola titer or vaccination.<br><br>On 8/15/08 at approximately 3:30 PM, the Clinical Nurse Coordinator (Employee #20, CNC) was informed of the findings. On 08/18/08, the surveyor was presented with health assessments dated 8/18/08 for employees #1, #5, #7, #12 and #19. The CNC confirmed that these health status assessments were not completed timely. The CNC did not provide any other additional information.<br><br>THIS IS A REPEAT CITATION FROM THE 8/06 RE-LICENSURE SURVEY<br><br>The facility stated in the plan of correction submitted 10/12/07 that "The FA or designee will audit 100% of the personnel files for new employees monthly and 25% of current employees quarterly, to ensure that all have a current health assessment...". There is no evidence that his plan was fully implemented. | T2091 | | |
| T2092 | 751.6 (e) ORGANIZATION AND ADMINISTRATION. Personnel.<br><br>The operator shall ensure:<br>(e) that a personnel file is maintained for each | T2092 | | |

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| T2092 | Continued From page 31<br>employee.<br><br>This Regulation is not met as evidenced by:<br>Based on review of policy and procedure, personnel files and staff interview: the facility failed to follow facility policy to complete annual performance evaluations timely for 8 of 19 employee files reviewed (#3, #6, #9, #12, #13, #17, #18, and #19).<br><br>Findings include:<br><br>Review of personnel files on 8/13/08 - 8/15/08 lacked evidence that performance evaluations were completed timely for the following employees:<br><br>Employee #03 most recent performance evaluation was completed on 04/27/07.<br>Employee #09 most recent performance evaluation was completed on 05/29/06.<br>Employee #12 most recent performance evaluation was completed on 04/09/07.<br>Employee #13 most recent performance evaluation was completed on 05/16/06.<br>Employee #17 most recent performance evaluation was completed on 10/12/02.<br>Employee #18 most recent performance evaluation was completed on 08/30/02.<br>Employee #06 most recent performance evaluations was completed on 02/18/05 and then on 9/30/07.<br>Employee #19 most recent performance evaluations was completed in 10/2005 and then on 9/30/07.<br><br>The facility policy entitled: Compliance As An Element of Performance Evaluations Policy 3-03-01 states that "In order to communicate to teammates New York Licensed Operator | T2092 | | |

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| T2092 | Continued From page 32<br>commitment to its compliance with all applicable federal and state laws and regulations, all New York teammates will be assessed annually against performance standard relative to their promotion of and adherence to DaVita Code of Conduct and Policies and Procedures".<br><br>On 8/15/08 at approximately 3:30 PM, the Clinical Nurse Coordinator (CNC) (Employee #20) was informed of the findings. The CNC confirmed that performance evaluations should be done annually but no additional information was provided regarding the eight employees. | T2092 | | |
| T2101 | 751.6 (k) ORGANIZATION AND ADMINISTRATION. Personnel.<br><br>The operator shall ensure:<br>(k) that each employee, as applicable, receives on-the-job training necessary to perform his/her duties.<br><br>This Regulation is not met as evidenced by:<br>Based on observations, interviews and review of documents, the Medical Director failed to ensure that all the employees whose job responsibilities include oversight of the water treatment system, are trained according to their assigned duties.<br><br>Findings include:<br><br>Interviews were conducted with one Patient Care Technician (Employee # 11) and a Maintenance / opening Technician (Employee # 18) on 08/12/08 and 08/13/08 at approximately 12:00 PM and 1:35 PM respectively. There employees were noted to be responsible for the maintenance and monitoring of the water treatment system, regarding testing of Chlorine/Chloramine.<br>The interviews revealed that the staff were not | T2101 | | |

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| T2101 | Continued From page 33<br><br>aware of:<br>(a) the purpose of the tests<br>(b) the contaminants in the water that require monitoring<br>(c) the AAMI limits for the contaminants.<br>(d) the testing procedure using the La Motte DPD1 and DPD3 tablets<br>Both the employees were unclear whether the reading was to be taken after the tablet had been fully dissolved or during the effervescent stage, immediately after dropping the tablet in the water sample. These two employees were also not sure of the contaminant that was tested for after adding both DPD1 and DPD 3 tablets to the water sample.<br><br>The above mentioned Patient Care Technician when interviewed regarding the documentation of results in chlorine/chloramine log, it was stated that it will be documented as "L.1" Thus it was concluded that this employee was documenting the results without a proper understanding of the results and its significance. | T2101 | | |
| T2114 | 751.7 (d) ORGANIZATION AND ADMINISTRATION.<br><br>Medical record system.<br>The operator shall:<br>(d) ensure that the medical record for each patient contains and centralizes all pertinent information which identifies the patient, justifies the treatment and documents the results of such treatment.<br><br>This Regulation is not met as evidenced by:<br>Based on review of medical record, policy and procedure and staff interview: the facility failed to complete or revise the Short Term Care Plan as necessary to ensure that it provides for the | T2114 | | |

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| T2114 | Continued From page 34<br>patients' ongoing needs. This was evident in that the following care plans were not completed at least every six months as required:<br>14/15 of incenter hemodialysis patients,<br>2/3 Peritoneal dialysis patients.<br><br>Findings include:<br><br>In center hemodialysis.<br>MR# 1. The short term care plan was last done 1/07.<br>MR# 2. The short term care plan was last done 10/07.<br>MR# 3. The short term care plan was last done 11/29/07.<br>MR# 4. The short term care plan was last done 10/07.<br>MR# 5. The short term care plan was last done on 10/13/06.<br>MR# 6. The short term care plan was last done on 4/30/07.<br>MR# 7. The short term care plan was last done on 9/28/07.<br>MR# 8. The short term care plan was last done 9/21/07.<br>MR# 9. The patient started dialysis at this unit 11/27/07. There was no care plans in the medical record.<br>MR # 10. The patient started dialysis at this unit in 5/15/08. There was no care plans in the record.<br>MR# 11. The short term care plan was last done 8/2007,<br>MR# 12. The short term care plan was last done on 1/08.<br>MR# 14. The patient started dialysis in this facility on 10/30/06, there was no care plans in the record.<br>MR# 15. The short term care plan was last done on 10/07. | T2114 | | |

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| T2114 | Continued From page 35<br><br>PD Program<br>MR # 32. The short term care plan that was last done "Oct. 2007"<br>MR # 33. The short term care plan that was last done "12/4/07"<br><br>On 8/15/08 at approximately 1:00 PM, a review of the facility policy and procedure # 1-01-07 entitled "Development of Patient Care Plans and Long Term Programs" noted that the multidisciplinary team and the patient develop the Patient Care Plan (PCP).... The plans for stable patients are reviewed every six months...The PCP is initiated on the day of admission and completed within 30 days...<br><br>Upon interview on 8/15/08 at 11:30 am, the Medical Director (Employee# 21) acknowledged the above findings and did not give an answer to why it was not done timely. | T2114 | | |
| T2120 | 751.7 (e) (5) ORGANIZATION AND ADMINISTRATION.<br><br>Medical record system.<br>The operator shall:<br>(e) ensure that the following are included in the patient's record as appropriate:<br>(5) physical examination reports.<br><br>This Regulation is not met as evidenced by:<br>Based on staff interview and review of the medical record, and policy and procedure: the facility failed to complete an annual history and physical examination for each patient. 6/15 Medical Records reviewed had no evidence of an initial and /or annual physical examination of ESRD patients. MR # 1, 2, 9, 12, 13, 14. | T2120 | | |

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| T2120 | Continued From page 36<br>Findings include:<br><br>Review of MR #1, 2, 9, 12, 13 had evidence that the facility failed to complete an annual physical examinations in more than one year. The medical records showed that the last history and physical exams for the above mentioned patients were completed on 5/06, 9/06, 10/06, and 12/06.<br><br>Review of MR #14 showed that this patient began having hemodialysis at the facility on 87.2 (b) He has a medical history of HTN, CAD, DM, and CVA and 87.2 (b) 87.2 (b) The medical record does not reflect any evidence that this patient had an initial or annual medical examination.<br><br>During interview on 8/15/08 at 2:10 PM, with the Attending Physician (Employee #30) acknowledged that he does not complete history and physicals for all his patients. He states that he, "cannot get all the patients to his office to complete their history and physicals".<br><br>The facility policy and procedure states that the Physician should complete an initial and annual history and physical examination. | T2120 | | |
| T2128 | 751.7 (e) (13) ORGANIZATION AND ADMINISTRATION.<br><br>Medical record system.<br>The operator shall:<br>(e) ensure that the following are included in the patient's record as appropriate:<br>(13) progress note(s).<br><br>This Regulation is not met as evidenced by:<br>Based on review of the facility's policies and procedures and medical records: there was no | T2128 | | |

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| T2128 | Continued From page 37<br><br>evidence that each patient had a short term care plan developed by the multidisciplinary team. This was evident in 3/3 (100% sample) medical records reviewed of peritoneal dialysis patients and 1/7 home hemodialysis patients.<br><br>Findings include:<br><br>PD Program<br>MR # 32 The short term care plan that was done "Oct. 2007" there was no input from Medicine.<br>MR # 33 The short term care plan that was done "12/4/07" there was no input from Medicine.<br>MR # 34 The short term care plan was last done "2/2008" there was no input from Medicine and Nursing.<br><br>Home Hemodialysis<br>MR # 26 The short term care plan was last done "3/2008" there was no input from the physician.<br><br>On 8/15/08 at approximately 1:00 PM, a review of the facility policy and procedure # 1-01-07 entitled "Development of Patient Care Plans and Long Term Programs" noted that the multidisciplinary team and the patient develop the Patient Care Plan.... The plans for stable patients are reviewed every six months. | T2128 | | |
| T2141 | 751.8 (a) ORGANIZATION AND ADMINISTRATION.<br><br>Quality assurance program.<br>PHL 2805<br>[redacted] | T2141 | | |

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| T2141 | Continued From page 38 | T2141 | | |

PHL 2805

[redacted]

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| T2141 | Continued From page 39<br>PHL 2805 [redacted]<br>THIS IS A REPEAT CITATION FROM THE RE-LICENSURE SURVEY OF 8/31/2006.<br>PHL 2805 [redacted] | T2141 | | |

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| T2141 | Continued From page 40<br>PHL 2805<br>[redacted] | T2141 | | |
| T2162 | 751.9 (b) ORGANIZATION AND ADMINISTRATION.<br><br>Patients' rights. | T2162 | | |

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| T2162 | Continued From page 41<br><br>Policies and procedures shall be developed and implemented regarding the patients' rights. The operator shall have in effect a written statement of patients' rights which is prominently posted in patient care areas and a copy of which is given to the patient. Such statement shall include the patients' rights to:<br>(b) be treated with consideration, respect and dignity including privacy in treatment.<br><br>This Regulation is not met as evidenced by:<br>Based on observation and staff interview: the facility failed to ensure that all patients are treated with consideration, respect, recognition of their individuality and the need for privacy in treatment. 8/8 applicable patients observed with Central Venous Catheters (CVC) were not afforded privacy during dialysis treatment. MR# 1, 5, 6, 10, 12, 14, 37. 44.<br><br>Findings include:<br><br>On 8/12 and 8/13/08 while observing care, it was noted that during the initiation of hemodialysis treatments the staff failed to provide privacy to patients with CVC.<br>It was observed that the staff was using partial screen covering while attending to seven patients with CVC in their chest and leg area. The screen provided only frontal coverage. These patients were visible to other male and female patients that were seated on both sides of the screen. The surveyor observed that the patient's undergarments were exposed.<br><br>During interview on 8/12/08, two Registered Nurses (Employee # 4 and 14) acknowledged that this was a common practice in the facility and that they did not have enough screens for patients with CVC. | T2162 | | |

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| T2162 | Continued From page 42<br><br>During interview on 8/12/08, a patient (MR #1) stated that the staff usually uses a partial screen while attending to his CVC.<br><br>On 8/12/08 at 11:28 AM, it was observed that MR#44 was not treated with respect and privacy during dialysis treatment. Throughout the dialysis treatment it was observed that the patient's pants were dropped to her ankle with both of her legs and her underwear exposed. The patient had a dialysis access in her leg. The nurse had a partial screen which did not provide sufficient privacy. On several occasions, the surveyor asked the nursing staff to cover the patient. They responded that the facility does have sheets to cover this patient.<br><br>Based on review of medical records and interview, the facility did not ensure that all patients are afforded the right to make informed decisions regarding their care.<br><br>Findings include:<br><br>3/15 medical records (MR #1, 4, 15), reviewed had evidence that the facility had patients sign forms to end dialysis early without an explanation of the possible risks to their health.<br><br>Review of MR #15, had evidence that he had 31 early termination notices from 2/22/08 to 8/11/08. 21/31 early termination notices were not signed by this patient. The medical record had no explanation why this patient terminated his dialysis treatment early, thirty one times in an eight months period. | T2162 | | |

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| T2162 | Continued From page 43<br><br>The medical record had no information that the staff informed the patient of the risk involved in ending their dialysis treatments early.<br>In addition, there was no evidence that the medical staff discussed the issue of early terminations with the patient.<br><br>MR #1 had 18 early termination notices from 3/1/08 to 6/10/08. None of these notices were signed by the patient, the staff wrote that patient refused to sign.<br>MR #4 had 26 early terminations from 2/25/08 to 8/8/08.<br>13/26 early termination notices were not signed by the patient, the staff wrote that patient "refused".<br><br>The medical record had no explanation why these patients had that many early terminations in such a short period of time.<br><br>On 8/12/08 at 10:30 AM, the surveyor observed the staff asking patient MR #1 to sign a form to terminate the dialysis treatment early. After patient MR #1 signed this form, the surveyor asked him if he understood the form he just signed. He says he does not understand what he just signed. He says that he has a second grade education and is not able to read, he can only sign his name. He further stated that "if they ask me to sign something I just sign it".<br><br>Upon interview on 8/12/08 the Social Worker (Employee #29) when asked whether he was involved in the process of patient's request to sign early termination from the dialysis treatment, he stated that he was not involved in the process. When told about MR #1's inability to read, the social worker stated that he was not aware of this. He recently began working full time with the | T2162 | | |

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| T2162 | Continued From page 44<br>facility and had not had the opportunity to speak with all the patients. | T2162 | | |
| T2167 | 751.9 (g) ORGANIZATION AND ADMINISTRATION.<br><br>Patients' rights.<br>Policies and procedures shall be developed and implemented regarding the patients' rights. The operator shall have in effect a written statement of patients' rights which is prominently posted in patient care areas and a copy of which is given to the patient. Such statement shall include the patients' rights to:<br>(g) obtain from his/her health care practitioner, or the health care practitioner's delegate, complete and current information concerning his/her diagnosis, treatment and prognosis in terms the patient can be reasonably expected to understand.<br><br>This Regulation is not met as evidenced by:<br>Based on review of medical records and the facility's policies and procedures: there was no evidence that all patients are involved in the development of their short term care plans. This was evident in 3/3 (100% sample) medical records reviewed of peritoneal dialysis patients, 1/15 incenter hemodialysis patients and 2/7 home hemodialysis patients.<br><br>Findings include:<br><br>PD Program<br>MR # (32) The short term care plans that were done "Oct. 2007" and "April 2008" there was no evidence that the patient was involved.<br>MR # (33) The short term care plan that was done "6/2008" there was no evidence that the | T2167 | | |

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| T2167 | Continued From page 45<br>patient was involved.<br>MR # (34) The short term care plan was last done "2/2008" there was no evidence that the patient was involved.<br><br>In-center Hemodialysis<br>MR# 11. The short term care plan that was last done 8/2007 noted that there was no patient involvement.<br><br>Home Hemodialysis<br>MR# 25. The short term care plan that was last done 5/2008 noted that there was no patient involvement.<br>MR# 27. The short term care plan that was last done 1/2008 noted that there was no patient involvement.<br><br>On 8/15/08 at approximately 1:00 PM, a review of the facility policy and procedure # 1-01-07 entitled "Development of Patient Care Plans and Long Term Programs" noted that the multidisciplinary team and the patient develop the Patient Care Plan.... The plans for stable patients are reviewed every six months. | T2167 | | |
| T2669 | 757.1 (a) (4) CHRONIC RENAL DIALYSIS SERVICES.<br><br>Chronic renal dialysis services.<br>(a) (4) 405.2137 Condition. Patient long-term program and patient care plan, 42 CFR, 1988 edition.<br><br>This Regulation is not met as evidenced by:<br>Based on review of the medical records, policies and procedures and patient interview: the facility failed to complete a long term care program for each dialysis patient. The long term care program | T2669 | | |

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| T2669 | Continued From page 46<br>was not done or was not completed in the twelve month period as required. This was evident in 9/15 medical records reviewed for patients receiving in-center hemodialysis and 2/3 patients in the Home Peritoneal Program (PD).<br><br>On 8/12/08 to 8/15/08 medical records were reviewed for completion of the Long term-care programs.<br><br>Findings include:<br><br>In MR# 1, 2, 3, 4, 5, 11, 12, the long term care program was not completed every twelve months.<br><br>MR #10 and 14 had no long term care program.<br>MR # 10 started hemodialysis at this facility on 5/15/08.<br>MR # 14 started having hemodialysis at this facility on 10/30/06.<br><br>The facility policy and procedure states that the long term care program (LTCP) is completed within 30 days of the patient's admission and is updated every twelve months or more frequently as indicated by the patients response to treatment.<br><br>Furthermore, the long term care programs that were completed for the previous year did not address the patients' current transplant status and were not completed by all disciplines. Review of the facility kidney transplant list showed that MR #1, 4, 15 are on the kidney transplant list in "New York State". Even though these individuals are candidates for kidney transplant since 2000, 2003 and 2004, their current status were not addressed in the current long term care program. | T2669 | | |

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| T2669 | Continued From page 47<br><br>MR #1 long term care program for 6/18/2007 indicates that he is not a candidate due to "age of patient". Review of the "Transplant blood" log showed that the facility sent blood to the transplant hospital on 7/26/08 for MR #1. During interview on 8/12/08 at 10:30 AM, the patient MR# 1 stated he was not aware that he was on the kidney transplant list.<br><br>MR# 4 long term care program for 4/2007 had no information about his "current transplant status" or his transplant suitability. Both sections of the long term care program form was left blank. Review of the "Transplant blood" log showed that the facility sent blood to the transplant hospital on 7/25/08 for MR #4.<br><br>MR #15 had no information about his "current transplant status" in the long term care program. In the comment/plan section, someone wrote that patient was probably not medically suitable secondary to vascular disease. Review of the "Transplant blood" log showed that the facility sent blood to the transplant hospital on 7/25/08 for MR #15.<br><br>During interview on 8/12/08 at 12:20 PM, the patient MR# 3 was adamant about not wanting a kidney transplant. He stated that he had several medical problems and was not interested in having a kidney transplant. The long term care program indicated that patient was "considering options". The patient MR# 3 stated the staff did not discuss his plan of care with him.<br><br>PD Program<br>In MR # 34 the Long Term Program was done on 2/14/08 with no input from the physician, nurse or the patient nor does it discuss transplant as an | T2669 | | |

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| T2669 | Continued From page 48<br>option for the patient.<br>IN MR # 32 the Long Term Program was done on 10/31/07 with no input from the physician or the patient nor does it discuss transplant as an option for the patient. | T2669 | | |
| T2670 | 757.1 (a) (5) CHRONIC RENAL DIALYSIS SERVICES.<br><br>Chronic renal dialysis services.<br>(a) (5) 405.2138 Condition. Patients' rights and responsibilities, 42 CFR, 1988 edition.<br><br>This Regulation is not met as evidenced by:<br>Based on review of documents and staff interview: Following the facilities decision to voluntary close the facility, 161 incenter hemodialysis patients were moved to alternate facilities primarily in Brooklyn and the Bronx. As of 8/15/08 only eight patients were transferred to facilities not managed by this company and located in Manhattan. Although this facility is in Manhattan, there is no evidence that the facility made reasonable efforts to seek certified ESRD facilities close to the patient's homes or in Manhattan.<br><br>Findings include:<br><br>As of 8/18/08, according to a grid that was presented to the surveyor as to where the patients had been transferred to, all of the patients were initially assigned facilities that were owned and operated by the company that manages this facility without consideration of needs, distance, schedule of the patients.<br><br>For example:<br>MR # 5 lives in the Bronx and was assigned a facility in South Flushing Queens. | T2670 | | |

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| T2670 | Continued From page 49<br><br>MR # 38 lives in Manhattan and was assigned a facility in the Bronx.<br>MR # 41 lives in Brooklyn and was assigned a facility in the Bronx.<br>MR # 42 lives in Brooklyn and was assigned a facility in the Bronx.<br>MR # 43 lives in Manhattan and was assigned a facility in South Flushing Queens.<br><br>Upon interview on 8/15/08 at approximately 6:30 PM, the Acting Facility Administrator (Employee #24) stated that the patients must be sent to facilities that are owned and operated by the same contracted service as this facility because the required paper work for a proper transfer is not available. The medical records in this facility are not updated and/ or complete.<br><br>Upon interview on 8/15/08 at approximately 6:30 PM, the Director of Clinical Services (Employee # 34) stated that efforts have been made to reach out to facilities other than the contracted management service and in Manhattan. She then presented a document which stated that for example:<br>1. Beth Israel Medical Center "left message with answering service"<br>2. NYU Hospital "left message with answering service"<br>3. St. Luke's "left message with answering service"<br>4. Bellevue "no answer, several attempts"<br>etc..<br><br>On 8/18/08 at approximately 5:15 PM, upon interview patient MR #47 stated that he had not been informed that the facility was closed. He came in for treatment and although he lives in the Bronx he was told to go to South Flushing Queens on the fourth shift. The patient was upset | T2670 | | |

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| T2670 | Continued From page 50<br><br>because of the increased travel time. The surveyor worked out a schedule with the facility staff to get the patient a unit in Manhattan.<br><br>On 8/20/08 at approximately 10:30 AM upon interview, the patient MR #48 was crying and stated to the surveyor that he is all puffy and that he had not had dialysis since Friday and he was instructed to go to Columbia Dialysis. When he called Columbia he was told that they do not have any paperwork on him. He was then instructed to go to Lower Manhattan Dialysis Center. When he called Lower Manhattan, he was told that they also had no paperwork on him. He then went to St. Luke's Hospital and he was refused treatment because he was not an emergency. He then returned to this facility on 8/20/08 and complained to the surveyor. The surveyor intervened and arranged with the facility staff to transfer this patient to a Brooklyn unit near the patient's home. | T2670 | | |
| T2672 | 757.1 (a) (7) CHRONIC RENAL DIALYSIS SERVICES.<br><br>Chronic renal dialysis services.<br>(a) (7) 405.2140 Condition. Physical environment, 42 CFR, 1988 edition.<br><br>This Regulation is not met as evidenced by:<br>Based on tour of the facility, observation of care, document review and patient and staff interview: the facility does not ensure that patients are treated in a safe and clean environment.<br><br>Findings include:<br><br>The facility failed to ensure that an established program for preventive maintenance of the dialysis machines was implemented in accordance with the manufacturer's guidelines | T2672 | | |

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| T2672 | Continued From page 51<br>and acceptable standard of practice. This was evident in all 40 machines at the unit.<br>See T2032.<br><br>The facility failed to monitor the quality and quantity of the water entering and leaving the RO system in order to assess the proper functioning of all the components in the water treatment system.<br>See T2691.<br><br>The facility does not take standard precautions to ensure that patients that are Hepatitis B Virus (HBV) susceptible are protected from potential infection. The facility does not follow the Centers for Disease Control (CDC) recommended infection control practices for hemodialysis units as required.<br>Cross refer to U7046.<br><br>The facility does not ensure that the internal pressure transducer protectors are inspected for contamination and replaced if necessary during routine preventive maintenance.<br>See T2032. | T2672 | | |
| T2688 | 757.2 (c) CHRONIC RENAL DIALYSIS SERVICES.<br><br>General requirements.<br>The operator shall comply with the following requirements:<br>(c) Provision of chronic renal dialysis services in a patient's home by center or facility staff shall be based on a recommendation for such home treatment as a result of the coordinated evaluation of each patient's treatment in an approved center or facility and the recommendation of the patient's physician. The center or facility shall assume the responsibility to | T2688 | | |

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| T2688 | Continued From page 52<br><br>provide the patient's home treatment and to act as a backup for the patient's emergency needs. In addition to the specific requirements of this Chapter, chronic renal dialysis shall be provided by an approved center or facility in a patient's home in accordance with generally accepted standards of professional practice.<br><br>This Regulation is not met as evidenced by:<br>Based on review of medical records, facility documents and staff and patient interviews: the facility does not ensure that patients participating in the facility's home dialysis program are monitored on an ongoing basis by the facility staff and are provided with required follow up and support services. This is evident in 7/7 home hemodialysis patients and 3/3 peritoneal dialysis patients (100 % sample).<br><br>Findings include:<br><br>Home Hemodialysis Program<br><br>Patients who dialyzed at home using the Pureflow water treatment system did not have evidence of adequate monitoring of the product to ensure the purity of the water. This was evident in 7/7 patients in the home dialysis program MR # 25, 26, 27, 28, 29, 30, 31.<br>Cross refer to T2692.<br><br>All patients are not adequately assessed or monitored by the multidisciplinary team. Short term care plans are not completed as required.<br>Cross refer to T2128.<br><br>Patients do not receive clinical training and follow up by the health care team to safely perform treatments at home. This was evident in 1/1 applicable records reviewed in the Home | T2688 | | |

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| T2688 | Continued From page 53<br>Hemodialysis Program. MR # 29.<br><br>On 8/13/08 at approximately 1:00 PM an interview was conducted with patient MR # 29. The patient stated that she performs hemodialysis at home using the NX-Stage hemodialysis machine. She also uses the Pureflow water treatment system (which makes product water to mix dialysate using a deionization system). The patient stated that she has low blood pressure and that she was told by her physician to do less dialysis to bring her blood pressure up. She further stated that not too long ago she noticed fragments or clumps of matter floating around in her blood while she was on the machine. She went to see her vascular surgeon and he told her to stop using the button hole technique when cannulating the needles into her access. The surgeon also told her that the debris she saw in her blood was fragments of the graft.<br><br>On 8/14/08 at approximately 4:00 PM a review of the medical record for MR #29 was conducted. The patient initiated training for home hemodialysis using the NX-Stage machine on 9/25/07. She completed training on 10/15/07. The patient was trained to perform dialysis at home without a partner. A home visit was made on 7/9/07 and a follow up visit was done on 9/19/07. Although there is no documentation as to why a home visit was conducted in 7/07, upon interview, the training nurse (Employee #15) stated that the first visit did not pass. Regarding the second home visit conducted on 9/19/07, the nurse documents that the patient was in the "interim of fully cleaning up room" and that training the patient was "held up for the pt apt to be conducive for HH".<br><br>The nurse (Employee # 15) made three more | T2688 | | |

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| T2688 | Continued From page 54<br><br>home visits on 10/16/07, 11/21/07 and 1/17/08. On interview, the nurse stated that she went to the patient's house to draw samples for endotoxins (LAL) from the water treatment system. On 2/08 a result was obtained that the LAL was 59 EU/ml. Upon interview the nurse stated that she did not inform the physician about this high level of endotoxins in the water. She also stated that this was the first time that the patient had performed the sample herself. There was no evidence in the medical record that the patient had been trained to collect water samples for endotoxin testing. Nor was there an investigation as to why the result was so high. On 4/23/08, the patient called the dialysis unit to report that she had been admitted to the hospital. The medical record notes that the patient had rigors, shaking chills and fever 102 degrees Farenheit following initiation of dialysis treatment. Blood cultures revealed that the patient had a bacteremia and the culture test was positive for Acinetobacter. Upon discharge from the hospital, it was noted in the medical record that there were several entries from nursing regarding training the patient on how to properly perform Chlorine/ Chloramine testing and that this was a problem the day the patient got sick. Upon interview when asked the nurse stated that the acceptable level for Chloramine was 2.0 ppm. during training in the post exam the nurse trained the patient that the acceptable level for chloramines was 1.0 ppm (according to AAMI, the acceptable range for Chloramine is less than 0.1ppm).<br><br>The patient was trained to perform home hemodialysis without a partner. It was noted in the medical record that the patient is routinely severely hypotensive with blood pressures averaging 70/40. There is no evidence in the medical record that the physician assessed the | T2688 | | |

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| T2688 | Continued From page 55<br><br>appropriateness of training this medically unstable patient to perform hemodialysis at home alone prior to the initiation of training. Upon interview, the home nurse (Employee #15) stated that the patient has one of those "help I've fallen and I can't get up" devices at home. There is a progress note dated 4/16/08 which states that "Pt may safely dialyze and cannulate at home". Moreover, the patient is not adequately dialyzed as evidenced by a Blood Urea Nitrogen (BUN) value of 99 on 7/16/08.<br><br>On 8/1/08 the patient submitted a treatment flow sheet to the home nurse which recorded her pre dialysis blood pressure as 70/46. The patient did not take another blood pressure for the entire four hour treatment. Instead the patient documented that the "blood pressure cuff was no good. Batteries low. Couldn't use. No extra batteries". The home nurse signed the treatment sheet that she had reviewed it. There was no evidence of discussion with the patient or comment in the medical record regarding this. On 8/2/08, the patient's blood pressure was documented as 64/39.<br><br>The patient MR #29 has a arterio-venous graft (AVG) as an access to her blood stream to perform hemodialysis. According to the medical record the patient was taught to perform venipuncture using the button hole technique.<br><br>The button hole technique requires that patients place the needles into the same two needle puncture sites each treatment. This technique is only appropriate for use with native vessels. Repeated punctures into the same site with AVGs has a potential to cause aneurysms or pseudo-aneurysms of the artifical graft and breakdown of the graft material which could | T2688 | | |

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| T2688 | Continued From page 56<br>cause fatal exsanguinations.<br><br>There are multiple omissions of critical data in the medical record by nursing. For example, on 7/16/08 the patient was seen by the home nurse for the monthly clinic visit in which the patient's vital signs, including blood pressure was not taken. On 2/29/08, the patient was seen in clinic and was given the first dose of Venofer, no vital signs were taken. On 1/28/08 the patient was seen in clinic for monthly visit in which the nurse documents that the patient has facial puffiness, no weight was taken.<br><br>On 8/18/08 at 2:40 PM an interview was conducted with the home dialysis nurse (Employee # 15). The nurse stated that the physician assesses the patients for home hemodialysis. She also stated that she is aware that the patient (MR #29) is hypotensive and that the patient has refused to take a medication that was prescribed by the physician to raise the blood pressure. She stated the patient was advised to cut down on the number of treatments because of the hypotension. The nurse stated that she did not teach the patient to use the button hole technique despite what is written in the medical record. The nurse acknowledged the multiple omissions of documentation (vital signs, signatures, care plans etc.). The nurse also stated that she did not report the abnormal LAL level of 59 EU/ml to the physician.<br><br>On 8/20/08 at approximately 11:30 AM upon interview the attending physician (Employee #30) stated that he was aware that the patient was not adequately dialyzed and that the patient was probably not following the prescribed amount of dialysis. He also acknowledged that he knew that the patient performed self dialysis treatment | T2688 | | |

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| T2688 | Continued From page 57<br>alone at home and was very hypotensive. He also stated that he was not aware of the high endotoxin count in the water and that Acinetobacter could be a water bacteria. The Medical Director (Employee #21) was present during the interview and stated that he would reassess the appropriateness of this patient to perform home hemodialysis without a partner.<br><br>Home Peritoneal Dialysis Program<br><br>Patients are not adequately assessed or monitored by the multidisciplinary team. Short term care plans are not completed as required. This was evident in 3/3 records reviewed in the Peritoneal Home Program<br>Cross refer to T2114.<br><br>Patients do not receive clinical training and follow up by the health care team to safely perform treatments at home. This was evident in 1/1 records reviewed in the Peritoneal Home Program. MR #33.<br><br>For Example:<br><br>On 8/12/08 at approximately 11:00 AM an interview was conducted with patient MR #33. The patient stated that he performs Continuous Ambulatory Peritoneal Dialysis (CAPD) at home and does five exchanges a day. He started CAPD last November and was doing all right until June 2008 when he got an infection. He stated that, at that time, he had terrible pain in his abdomen and that the fluid that came out of him was cloudy. He stated that he was not sure what to do or what was wrong. He stated that he did not want to bother the home nurse. After five days the pain became unbearable and he called his sister. It | T2688 | | |

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| T2688 | Continued From page 58<br><br>was after that that he went to see the doctor and found out that he had an infection called peritonitis. He stated that during his training that it wasn't really explained to him about the signs and symptoms of peritonitis. He also went to Texas in July and there his catheter fell apart and he got another infection. He is still feeling sick and is currently on medicine. It was later revealed by the nurse (Employee #15) that the patient was admitted to the hospital with a fungal peritonitis and that his potassium was low from diarrhea from the antibiotics.<br><br>On 8/15/08 at approximately 5:00 PM a review of the medical record for MR #33 was conducted. The patient started training in the PD program on 10/15/07. There was no evidence that the patient was adequately trained to recognize peritonitis nor was there evidence that the patient was instructed as to what steps are to be taken in the event of possible peritonitis.<br><br>On 8/18/08 at 2:40 PM an interview was conducted with the home dialysis nurse (Employee # 15). The nurse stated that she did teach the patient (MR #33) about peritonitis. | T2688 | | |
| T2691 | 757.2 (f) CHRONIC RENAL DIALYSIS SERVICES.<br><br>General requirements.<br>The operator shall comply with the following requirements:<br>(f) The quality of water used to prepare dialysate shall be compatible with dialysis treatment.<br><br>This Regulation is not met as evidenced by:<br>Based on review of the daily Reverse Osmosis System (RO) monitoring log and staff interview, | T2691 | | |

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| T2691 | Continued From page 59<br>the facility failed to monitor the quality and quantity of the water entering and leaving the RO system in order to assess the proper functioning of all the components in the water treatment system.<br><br>Findings include:<br><br>During the review of the readings documented on the daily monitoring log on 08/12/08 at approximately 12:15 PM for that day in the water treatment room, it was noted that the RO product water flow rate was documented as 3.5 GPM at 5:00 AM that morning and the acceptable range provided on the log was >6 GPM. Upon reviewing the actual reading on the RO system, the flow rate of the product water was found to be at 7 GPM at 12:15 PM. There was no indication that the dialysis machines were alarming in the morning to indicate shortage of water.<br><br>Upon review of daily RO monitoring log for months 06/08 and 07/08 on 08/14/08 at approximately 11:30 AM, it was noted that the opening technicians were continuously documenting the product water flow rate as 3.5 GPM.<br><br>In addition, the conductivity reading for the product water coming out of the RO system and for the final product water in the loop was continuously being documented as 76-78mS/cm and N/A respectively for the last two months, while acceptable standard provided on the log is <30mS/cm.<br>Moreover, the initials of the teammates monitoring the RO and of the nurses (verifying that the results are within standards) are not legible on the log. | T2691 | | |

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| T2691 | Continued From page 60<br><br>The Patient Care Technician (Employee #11), responsible to check the functioning of the water treatment system on 08/12/08 was interviewed by the surveyor on the same day at 12:30 PM, regarding the readings documented on the daily monitoring log. During this interview it was revealed that this employee was not able to locate the flow meter on the RO System from which the reading was obtained. This finding was confirmed with the Biomedical Technician (Employee #16).<br><br>Thus it was determined that the employees were documenting these readings without the proper understanding of the location of the meters/gauges and the significance of their readings. | T2691 | | |
| T2692 | 757.2 (f) (1) CHRONIC RENAL DIALYSIS SERVICES.<br><br>General requirements.<br>The operator shall comply with the following requirements:<br>(f) The quality of water used to prepare dialysate shall be compatible with dialysis treatment. Water quality standards shall include but not be limited to the following:<br>(1) water shall be sampled for microbiological examination at least once each month, and for chemical examination at least once every three months.<br><br>This Regulation is not met as evidenced by:<br>Based on review of NX-Stage home hemodialysis patient's documents and staff interview: the facility failed to monitor the quality of water and dialysate on a monthly basis using culture measurements. This was evident in 7 of 7 (100% census) patient records ( MR #25, MR # | T2692 | | |

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| T2692 | Continued From page 61<br>26, MR # 27, MR # 28, MR # 29, MR # 30, MR #31 ) reviewed.<br><br>Findings include:<br><br>During the review of NX-Stage home hemodialysis program using Pure flow SL on 08/19/08 at approximately 11:40 AM, it was noted that the facility did not collect samples for water bacteriology or dialysate bacteriology on a monthly basis as required. Therefore there was no water or dialysate culture tests conducted by any patients on the Pureflow PAK used during their dialysis treatment. This was confirmed upon interview of the Nurse (Employee #15) assigned to train and monitor the Home Hemodialysis patients. This same employee who was responsible for the monitoring of home dialysis treatment was also not aware of the requirement to conduct culture test on the water generated by Pure Flow SL system and therefore had advised patients to bring the water samples during their clinic visits to test for endotoxins only. The microbiological quality of the water and dialysate should be analyzed monthly at the end of "SAK" life using cultures and endotoxin measurements.<br><br>During review of the home hemodialysis patient records, it was noted that 3 out of 7 patients did not send out water samples for endotoxin level testing on a monthly basis.<br>Examples are<br>MR # 25- the endotoxin test results were missing for 12/07 and 2/08<br>MR # 29- the endotoxin test results were missing for 12/07 and 1/07<br>MR # 27- the endotoxin test results were missing for 7/07, 8/07, 10/07, 12/07, 1/08, 2/08.<br><br>Also, upon review of the endotoxin test results for | T2692 | | |

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| T2692 | Continued From page 62<br><br>the water produced by the Pure Flow SL System used by a patient (MR # 29), it was revealed that the LAL (endotoxins) in the sample of water collected on 02/27/08 was at 59 EU/ml (AAMI recommendations that the endotoxin level be <2.0 EU/ml). The lab result was reported on 03/01/08 and there was no action or an investigation by the facility staff regarding the reasons for such high level of endotoxins in the water. It was noted that "to be repeated" was written on the lab report by someone in the facility without signing or dating it. Upon interview of the Physician (Employee 30) responsible for the care of this patient on 08/20/08 at approximately 10:30 AM, it was revealed that this Physician was not notified of the high LAL test results.<br><br>Therefore, it was determined that the facility failed to establish a system to ensure proper collection of the water samples and timely submission to the testing laboratory.<br>Upon notifying the Acting Facility Administrator (Employee #24) and the Director of Clinical Services (Employee #34 ) about these findings, the facility voluntarily suspended the use of Pure Flow and advised all of their Home Hemodialysis patients to use Sterile PAK for their treatment. | T2692 | | |