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BENICIA DIALYSIS	**560 FIRST STREET SUITE D103 BENICIA, CA 94510**

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V 000	INITIAL COMMENTS Surveyor: 14067 The following reflects the findings of the Department of Public Health during a RECERTIFICATION Survey from 3/16/09 - 3/20/09. Representing the Department of Health Services:Beverly VandeWeg, Health Facilities Evaluator Nurse (HFEN) and Edwin Hoffmark HFEN. Census 62 Abbreviations: Registered Nurse - RN Licensed Vocational Nurse - LVN Master in Social Work - MSW Licensed Clinical Social Worker - LCSW Registered Dietitian - RD Patient Care Technician - PCT Cardiopulmonary Resuscitation - CPR Patient Care Plan - PCP Quality Assurance - QA - (aka CQI) Peritoneal Dialysis - PD Blood Flow Rate - BFR Dialysate Flow Rate - DFR Preventive Maintenance - PM Central Venous Catheter - CVC Personal Protective Equipment - PPE Degree - ° Fahrenheit - F Centers for Disease Control - CDC End Stage Renal Disease - ESRD Transpacific Renal Network-17 - ESRD Network Cubic Centimeter - cc Milligram - mg milliliter - ml Automated External Defibrillator - AED	V 000		

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

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

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V 000	Continued From page 1 History and Physical - H&P Governing Body - GB	V 000		
V 101	494.20 COMPLIANCE WITH FED/STATE/LOCAL LAWS The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation, document review, and staff interview, the facility failed to comply with the State health and safety regulations of the Plumbing Code. Findings: During the initial tour observation on 3/16/09 at 8:30 a.m., the schematic diagram of the Water Treatment System piping installed in the facility was not posted at the nurses' station as required by the California Code of Regulations, Title 24, Section 613.8 of the California Plumbing Code. Staff stated during an interview that there had not been a schematic diagram posted at the nurse's station of the water system since the facility started treating patients.	V 101		3/22/09
V 110	494.30 CFC-INFECTION CONTROL This CONDITION is not met as evidenced by: Surveyor: 14067 Based on document review, observations, and staff interviews, the facility failed to ensure that	V 110		6/25/09

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V 110	Continued From page 2 services are provided in a sanitary and safe environment. Findings: 1. The facility failed to provide and monitor a sanitary environment to minimize the transmission of infectious agents within the facility (See V 111). 2. The facility failed to ensure that staff used protective personal equipment (PPE) when caring for patients' or touching the patients' equipment in the dialysis station and treatment area (See V 113). 3. The facility failed to ensure that the patient handwashing sink was stocked with paper towels for drying and accessible for patient use (See V114). 4. The facility failed to ensure that staff clean and disinfect contaminated surfaces, medical devices, and equipment in between patients (See V 122). 5. The facility failed to ensure staff are trained in infection control practices (See V 132). 6. The facility failed to ensure that all medications that are available for patient use are not expired (See V 143). The cumulative effect of these systemic failures resulted in the facility's failure to maintain a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.	V 110		
V 111	494.30 IC-SANITARY ENVIRONMENT The dialysis facility must provide and monitor a	V 111		6/25/09

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V 111	Continued From page 3	V 111		

sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

This STANDARD is not met as evidenced by:
Surveyor: 14067
Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that the environment was kept clean and sanitary by monitoring the patient care area and all equipment used in the patient care area to minimize the potential transmission of infectious agents within the facility that could affect 62 patients.

Findings:

On 3/16/09 at 10 am, observation of the patient care area revealed the following:

1. At Stations 11 and 14, water was noted on the floor. Patients walked near the water at Station 14. This had the potential for patients to slip and fall, causing an injury. Staff walked passed the water on the floor and did not mop it up to prevent an accident.

2. Two (2) Oxygen Concentrators (a device used to provide oxygen therapy) were observed in the patient care area. Both concentrators were dirty (brown substance on the top & sides), hair was noted on the shelf, and also tape residue. One (1) concentrator was being used by a patient at Station 2. Upon inquiry regarding who is responsible for cleaning the concentrators, LVN/PCT F stated that she did not know who was responsible for cleaning the concentrators.

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V 111	Continued From page 4	V 111		

3. Television (TV) monitors that are attached to the ceiling were dusty. Administrative Staff A stated that she did not know the last time the TVs had been cleaned. The facility has a contracted janitorial service and they are only responsible for cleaning the floors, inside of the windows, walls, and the counters behind the dialysis stations.

4. The metal computer stands were dirty, dusty, and rusty. The computer key board covers (plastic) were dirty and the dirt was easily scraped off using the tip of a writing pen.

5. The dialysis machines were dirty, dusty, and with tape residue on the front and sides of the machine. The intravenous (IV) pole stored near the emergency exit doors was observed as being rusty. There was debris (dust, hair) around the wheels.

6. The large red Biohazard container had a white substance splattered on the lid and down the front and sides. During a concurrent interview, Administrative Staff B stated that staff are responsible for keeping the container clean and this is to be done at the end of each day and as needed during the day.

7. On 3/18/09 at 9:15 am, LVN/PCT F brought a floor fan into the patient care area and placed it in front of the patient at Station 2. The fan was blowing air directly on the patient. LVN/PCT F was asked to turn off the fan for inspection. Inspection of the fan revealed that the blade edges were covered with a heavy layer of dust. The metal wire protective cage was also covered with dust. Upon inquiry regarding how often the fan was cleaned, LVN/PCT F stated that she did not know. During a concurrent interview,

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V 111	Continued From page 5 Administrative Staff A stated that she had recently told the staff not to bring fans into the patient care area because the fans blow dust all around and it's an infection control issue. 8. During observations on 3/16/09, 3/17/09, 3/18/09, and 3/19/08, one (1) gallon acid containers were placed directly on the floor in front of the dialysis machines. The floors were discolored (gray) where the containers sit. Located on the bottom of the dialysis machines is a concentrate container shelf. The purpose of this shelf is to hold the containers of fluid concentrates needed for dialysis. The shelf was cracked or had large holes in the shelf, allowing the concentrates to leak on to the floor. There also was fluid on the container shelf, along with bottle caps and debris. Staff stated during a concurrent interview that they do not use the shelves because they have holes and they leak, and it is more convenient to sit the container on the floor in front of the machine. 9. During observations on 3/17/09, 3/18/09, 3/19/09, and 3/20/09, the black foot rest that slides in and out from under the dialysis chair was dirty with an cumulation of dust, dirt, and debris. Upon inquiry regarding who is responsible for keeping the foot rest clean, staff stated that they do not clean the foot rest when they clean the chair between patients or at the end of the day and that it could be the janitor that cleans the facility at night. 10. During observations on 3/17/09, 3/18/09, 3/19/09, 3/20/09, in the patient bathroom that is adjacent to the patient care area, yellow staining was at the base of the toilet. On 3/20/09 at 8 am, Administrative Staff B stated that there is a	V 111		

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V 111	Continued From page 6 contracted janitorial service that cleans the clinic after hours of operation and the janitorial service is responsible for making sure the bathroom is clean. 11. During observation on 3/18/09 at 5 pm, the portable blood pressure metal stand stored near the large exit door, was rusty and the wheels were covered with dust and debris. Staff stated, during a concurrent interview, that they are to clean the patient's equipment when they have the time. The Hoyer lift (metal) stored near the medication room was rusty and dusty. 12. During observation on 3/20/09 at 8 am, the formica counter top (a plastic laminate sheeting that is used as counter tops) in the PD training room was discolored with a yellow substance around the sink. The nurse's station counter tops and the reuse counter tops were discolored and some were peeling. Administrative Staff A corroborated the above findings, stating that it was hard to keep the counter tops clean and it was hard to ensure that they got disinfected properly . Surveyor: 21966 13. During a care observation on 3/16/09 at 9:20 a.m., Patient 26 used a gloved hand to hold pressure on her right graft puncture site, then after leaving the station, preceded to touch/hold hands with other patients' at Stations 3, 6, 9, and 12. Patient 26 then left the treatment area without washing her hands.	V 111		
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE	V 113		6/25/09

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V 113	Continued From page 7	V 113		

Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.

This STANDARD is not met as evidenced by:
Surveyor: 14067
Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that all staff use disposable gloves when caring for the patients' or touching patients' equipment at the dialysis station and failed to ensure that staff wash their hands after the removal of their gloves and between each patient or station with the potential of the transmission of contaminates (blood and body fluids) between patients.

Findings:

1. During observations on 3/16/09 at 8:30 am, PCT K did not use gloves when responding to an alarming machine at Station 14. At 9 am, PCT K responded to another alarming machine at Station 12. PCT K put on gloves and responded to the alarming machine. PCT K did not wash his hands after removing his gloves and after he delivered care to the patient at Station 9.

2. During observation on 3/19/09 at 7:30 am, PCT K was responding to alarming machines, carrying a one (1) gallon container from the patient care area to the storage area. PCT K was not wearing gloves when responding to the alarming machines or carrying the container from the patient care area to the storage area.

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V 113	Continued From page 8 The policy and procedure titled, "Infection Control For Dialysis Facilities," dated December 2008, was reviewed on 3/17/09 at 5 pm. The policy read that the dialysis facilities would provide a safe, clean environment for all patients and staff, to prevent the spread of infections or bloodborne pathogens. Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station, and will remove gloves and wash hands or perform hand hygiene between patient and/or stations. Gloves should be worn when: Potential for exposure to blood, dialysate, and other potentially infectious substances. Appropriate PPE (personnel protective equipment) will be worn whenever there is the potential for contact with body fluids, hazardous chemicals, contaminated equipment and environmental surfaces, for example, reuse room patient care areas. Appropriate lab coats or gowns will be worn at all times when on the treatment floor.	V 113		
V 114	494.30(a)(1)(i) IC-SINKS AVAILABLE A sufficient number of sinks with warm water and soap should be available to facilitate hand washing. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that the designated patient handwashing sink was available for patient use at all times. The handwashing sink is used by patients to wash their access site prior to treatment and wash hands after treatment. Paper towels were not provided so that patients could dry themselves	V 114		6/25/09

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V 114	Continued From page 9	V 114		

and the sink was blocked with equipment preventing access to the sink. This poses the potential for an increased risk of infection if patients do not wash their access site prior to dialysis or their hands after treatment.

Findings:

During observation on 3/18/09 at 9:30 am, no paper towels were available in the paper towel dispenser at the patients handwashing sink. A patient entered the patient care area and walked over to the sink to wash his access site. There were no paper towels available to dry the access site. The patient went to the nurse's station and tore off a section of paper towel from the large roll of paper towel and dried his access site. The patient made a comment to a PCT and a nurse, that if they wanted the patients' to wash their access site at the handwashing sink, there needed to be paper towels available to dry their access. The RN and the PCT did not make any attempt to refill the paper towel dispenser. The paper towel dispenser remained empty (between 9:30 am to 5:30 pm). Upon inquiry regarding refilling the paper dispenser, RN E stated that she believed that a key was needed to open the dispenser and she did not have the key, and she did not have time to look for the key. The large roll of paper towels at the nurse's station was being used by both patients and staff. The roll of paper towel was wet after pieces were torn off to dry hands and access sites.

At approximately 11:40 am, a patient was brought into the patient care area to Station 14 in a wheelchair. The patient was assisted into the chair. The attendant placed the wheelchair in front of the patients' handwashing sink, making

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V 114	Continued From page 10 the sink inaccessible for patients' to wash their access site or hands. At approximately 2 pm, the wheelchair remained placed in front of the sink. The policy and procedure titled, "Infection Control for Dialysis Facilities," dated December 2008 was reviewed on 3/17/09 at 5 pm. The policy indicated that the patients are encouraged to wash their access arm upon entering the treatment area prior to the initiation of dialysis and wash their hands after holding their own sites post dialysis as applicable. Sinks should be easily accessible and readily available in the treatment area and in other appropriate areas such as the reuse room, medications area, home training room, and isolation area/room. The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. Soap and a supply of paper towels protected from contamination must be available at each sink.	V 114		
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that all staff use Personal Protective	V 115		6/25/09

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Equipment (PPE) when caring for the patients', when touching patients' equipment, or when exposed to potentially hazardous or infectious substances in the treatment area or at the dialysis station. The failure to use PPE and wash hands between each patient or station has the potential for the transmission of contaminates (blood and body fluids) between patients.

Findings:

During observation on 3/18/09 at 7:10 am, PCT K was not wearing PPE while in the treatment area. PCT K was responding to alarming machines, and carrying a one (1) gallon container from the patient care area to the storage area. PCT K was not wearing gloves when responding to the alarming machines or when carrying the container from the patient care area to the storage area. PCT K did not wash his hands when he returned to the patient care area from the storage area. In addition, PCT K was wearing a stocking knit hat while providing care to dialyzing patients. PCT K removed his knit hat after Administrative Staff B made the request. PCT K took off the knit hat and put it on the computer stand at Station 8. PCT K was wearing a impermeable gown backwards (worn buttoned down the front). During a concurrent interview, Administrative Staff A stated that it was not acceptable to be in the patient care area without wearing PPE. There are too many risks involved with exposure to blood and body fluids.

The policy and procedure titled, "Infection Control For Dialysis Facilities," dated December 2008, was reviewed on 3/17/09 at 5 pm. The policy read that the dialysis facilities would provide a safe, clean environment for all patients and staff, to

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V 115	Continued From page 12 prevent the spread of infections or bloodborne pathogens. Teammates will wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station, and will remove gloves and wash hands or perform hand hygiene between patient and/or stations. Gloves should be worn when: Potential for exposure to blood, dialysate, and other potentially infectious substances. Appropriate PPE will be worn whenever there is the potential for contact with body fluids, hazardous chemicals, contaminated equipment and environmental surfaces, for example, reuse room, patient care areas. Appropriate lab coats or gowns will be worn at all times when on the treatment floor.	V 115		
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to ensure that staff thoroughly clean and disinfect contaminated surfaces, medical devices, and equipment between patients, which has the potential for the transmission of bloodborne pathogens for 62 of 62 patients. Findings:	V 122		6/25/09

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1. During observation on 3/16/09 at 9:05 am, a random PCT was cleaning the dialysis machine using a bleach solution pad, but was not removing the visible tape residue from the machine. At 9:20 am, a random PCT cleaning the dialysis chair at Station 13, did not clean and disinfect between the seat and the back of the chair or between the seat and the armrests of the chair. At 9:50 am, a random PCT cleaning the chair at Station 8, did not clean and disinfect between the seat and the back or the seat and the armrests of the chair.

2. During observation on 3/17/09 at 9 am, a random PCT cleaning the dialysis chair at Station 6, did not clean and disinfect between the seat cushion and the back of the chair or between the seat cushion and the armrests of the chair.

3. On 3/18/09 at 11 am, observation revealed that a random PCT cleaning the dialysis chair at Station 8. The PCT did not clean between the seat and the back of the chair or between the seat and the armrests of the chair. At 10:50 am, observation revealed that a random PCT cleaning the dialysis chair at Station 14. The PCT did not clean and disinfect between the seat and the back of the chair or between the seat and the armrests.

During observation on 3/16/09 at 9:05 am and at 9:20 am, on 3/17/09 at 9 am and at 10:50 am, and on 3/18/09 at 11 am, when the PCTs cleaned the dialysis chairs between patients and at the end of the day, the PCTs did not clean the footrests, that are attached underneath the chairs. The footrests were dusty, had debris, and were stained. On 3/18/09 at 4 pm, during interview, a random PCT stated that she does not

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V 122	Continued From page 14 clean the footrests. Upon inquiry regarding how dirty the footrests were, the random PCT stated that she is not sure who responsibility it is to clean them. During a concurrent interview, Administrative Staff A stated that it is the responsibility of the PCTs to make sure that the chairs are kept clean and that would include the footrests.	V 122		
V 132	494.30(a)(1)(i) IC-TRAINING & EDUCATION Infection Control Training and Education Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that all staff demonstrated knowledge of infection control policies/procedures and practices by implementing the policy and procedure titled, "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) And Administration of Heparin," using proper techniques in the cleaning of the access sites prior to the cannulation (the introduction of the needles into the access sites). This has the potential to result in infection of the patient's access site if proper disinfection techniques are not followed. Findings: 1. During observation on 3/18/09 at 9:45 am, PCT	V 132		6/25/09

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V 132	Continued From page 15 H did not use proper technique in cleaning the access site for one (1) random patient. PCT H used only alcohol prep pads to clean the patient's access site. PCT H used one (1) alcohol prep pad for each access site. Upon inquiry as to why she was using only alcohol, PCT H stated that the patient did not like the color of the Betadine® (Povidone Iodine). PCT H used a circular motion; rubbing in a circular motion multiple times. PCT H did not move from the center outward. Concurrently, PCT H stated that she only needed to use one (1) alcohol prep pad for each access site and she let the alcohol dry completely before inserting the needles. PCT H stated that she followed the policy and procedure with the cleaning of the sites. 2. On 3/18/09 at 10:50 am, PCT H did not use proper technique in cleaning the access site on a second random patient. PCT H used two (2) alcohol prep pads and two (2) Betadine® prep pads for both access sites. PCT H used a circular motion; rubbing in a circular motion multiple times. PCT H did not move from the center outward. PCT H allowed the Betadine® to dry for appropriately 1 1/2 minutes (Betadine® needs to be thoroughly dry to be effective as a disinfectant). Concurrently, PCT H stated that she let the Betadine® dry for five (5) seconds. After a moment, PCT H then stated that it was five (5) minutes. PCT H stated that she is following the clinic's policy and procedure for the use of Betadine®. 3. On 3/19/09 at 11:30 am, PCT K did not use proper technique in cleaning the access site of a random patient. PCT K used a swiping motion of the alcohol and Betadine® (moving back and forth instead of a circular motion moving from the	V 132		

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V 132	Continued From page 16	V 132		

center outward) over the access sites. PCT K allowed the Betadine® to dry approximately 2 minutes. Concurrent interview with PCT K revealed that he had used the swiping motion technique at the other dialysis clinic.

On 3/19/09 at 5:15 pm, Administrative Staff A stated that she did not believe that the staff had any current training or educational in-service around the policy and procedure titled, "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) And Administration of Heparin." Administrative Staff B stated that all the PCTs are current with their mandatory training in Infection Control. Upon inquiry regarding what is covered in the infection control training, Administrative Staff B stated the training dealt with topics such as; Hepatitis B & C, HIV, Chain of Infection, How to break the chain of infection, Safety Practices, Handwashing, Biohazards, PPE, etc. Administrative Staff B stated that the mandatory training did not cover the general clinic's policy and procedures, which would include, "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) And Administration of Heparin."

On 3/20/09, personnel files were reviewed and indicated that the PCTs were current with the mandatory Exposure Control/Infection Control. The personnel files did not reflect any training regarding the clinic's general policy and procedures.

The policy and procedure titled, "AV Fistula or Graft Cannulation With Safety Fistula Needles (SFN) And Administration of Heparin," was reviewed on 3/18/09 at 4:35 pm, The policy read that staff was to use at least four (4) alcohol prep pads per site and the effective contact time was

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V 132	Continued From page 17 60 seconds. There was no air drying time required. Staff is to use at least one (1) Povidone Iodine (Betadine®) prep pad per site. The effective contact time is 60 seconds and the air drying time is 3 minutes. When staff is using alcohol they are to clean the sites using a circular rubbing motion, center out. When staff is using Povidone Iodine prep pads they are to use a circular rubbing motion for 1 minute, moving from the center out. Allow to dry for 2-3 minutes. Iodine works to kill bacteria on the skin and needs to be completely dry for the microbial effect to work.	V 132		
V 143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV MEDS [The facility must-] (2) Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to: 1. Have a mechanism in place to ensure expired medications are not available for patient use. This failure created the potential for 5 of 5 peritoneal dialysis patients and 62 of 62 hemodialysis patients to receive outdated or expired medications and, 2. Ensure that licensed staff used aseptic technique when dispensing an intravenous medication from a vial of Venofer/Iron Sucrose for one (1) Hemodialysis patient. Findings: 1. During observation on 3/20/09 at 7:50 am, in	V 143		6/25/09

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V 143	Continued From page 18	V 143		

the cabinet above the sink in the PD training room two (2) vials of Gentamicin (antibiotic) had expiration dates as follows: March 1, 2008 and July 1, 2008, and were available for patient use. During concurrent interview, Administrative Staff A stated that the expired drugs should have not been available for the patients use and should have been discarded once expired.

The facility has five PD patients who could potentially use the medications.

Surveyor: 21966

2. During observation on 3/16/09 at 4:30 pm, 16 vials of Epogen were stored on the nursing station counter, at room temperature, and in direct light. The vials were accessible to unauthorized persons.

During observation on 3/17/09 at 3:30 pm, 36 vials of Epogen were stored on the nursing station counter, at room temperature, and in direct light. The vials were accessible to unauthorized persons.

RN E stated during an interview on 3/18/09 at 3:25 pm, that she would bring all of the injectable medications (including the Epogen) out of the medication room at 7:30 am and then after the last treatment was started (around 3:45 pm) would then put all of the medication back into the medication room or the medication room refrigerator.

Review of the medication package insert provided by the facility, on 3/18/09, revealed the manufacturer guidance for the storage of Epogen as: STORAGE Store at 2° to 8° C (36° to 46° F).

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V 143	Continued From page 19 Do not freeze or shake. Protect from light. Amgen Inc. 2009. The failure to follow the manufacturer's storage guidance poses the potential that the medication will loose efficacy and potency. Administrative Staff A stated during an interview on 3/19/09 at 4:30 pm, that the licensed staff need to store Epogen in the refrigerator at all times. The facility has 62 hemodialysis patients who could potentially use the Epogen. 3. During observation on 3/17/09 at 3:37 pm, RN E failed to wipe (disinfect) the injection port of the vial of Venofer/Iron Sucrose with an alcohol swab, touched the injection port of the vial with her gloved finger, and then touched the metal band surrounding the top of the vial Venofer/Iron Sucrose with the tip of the needle used to draw up the Venofer/Iron Sucrose into the syringe for a patient's use.	V 143		
V 331	494.50(b)(1) REPROCESSING-TRANSPORTATION & HANDLING 11 Reprocessing 11.1 Transportation and handling Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described	V 331		6/25/09

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in this recommended practice shall be validated and documented by the responsible party.

This STANDARD is not met as evidenced by:
Surveyor: 14067
Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that all used dialyzers and tubing were placed in a leakproof bag for transport from stations to the reprocessing or disposal area. This had the potential for contamination due to spillage of blood and/or body fluids when transported without being placed in a leakproof bag.

Findings:

During observation on 3/16/09 at 9 am and 10 am, a PCT carried used dialyzers and tubing from Station 13 to a large red biohazard receptacle near Station 5 (which is across the clinic). The PCT disposed of the tubing and normal saline bags into the receptacle. The PCT then capped the dialyzer's ports, placed the dialyzers into bags and put the dialyzers into the adjacent refrigerator for storage. There was a Biohazard receptacle adjacent to Station 13.

On 3/18/09 at 10 am, a second PCT carried a used dialyzer and tubing from Station 14 to a large red biohazard receptacle adjacent to Station 5 (which is across the clinic). The PCT disposed of the tubing and the normal saline bag into the receptacle. The PCT then capped the dialyzer's ports, placed the dialyzer into a bag and put the dialyzer into the adjacent refrigerator for storage. There was a Biohazard receptacle adjacent to Station 13.

On 3/20/09 at 8 am, the policy and procedure

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V 331	Continued From page 21 titled, "Infection Control For Dialysis Facilities," dated December 2008, was reviewed and read, the purpose of the clinic is to provide a safe, clean environment for all patients and staff and to prevent the spread of infection or bloodborne pathogens. All potentially infectious waste will be placed in a sealable, leakproof biohazard waste bags that are clearly marked or colored. All extracorporeal disposable supplies such as blood lines will be placed in the red biohazard waste bags immediately after use. Upon completion of treatment, dialyzers will be capped, bagged, and taken to the appropriate area. The policy and procedure titled, "Reuse Of Dialyzers," dated March 2008, read that the staff are to transport and handle reuse dialyzers in a clean and sanitary manner using dialysis precautions. Prior to transport, reuse dialyzer blood ports are capped with the same caps removed prior to set up. The capped dialyzer is placed in a plastic bag and the bag is closed prior to transport to the reuse area.	V 331		
V 400	494.60 CFC-PHYSICAL ENVIRONMENT This CONDITION is not met as evidenced by: Surveyor: 14067 Based on observation, policy and procedure review, and staff interview, the facility failed to ensure that the physical environment was clean, sanitary, functional, and safe as follows. Findings: 1. The facility failed to ensure that the building was constructed equipped, and maintained to provide dialysis patients, staff, and the public a	V 400		6/25/09

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V 400	Continued From page 22 safe, functional. and comfortable treatment environment (See V 401). 2. The facility failed to ensure the building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public (See V 402). 3. The facility failed to maintain a comfortable temperature within the patient care area (See V 405). 4. The facility failed to ensure that all vascular access site and bloodline connections were visible throughout the patients' dialysis treatments (See V 407). 5. The facility failed to ensure that had a facility specific disaster/Emergency Plan (See V 408). 6. The facility failed to ensure that the emergency equipment was clean and complete (See V 413). 7. The facility failed to evaluate the effectiveness of the emergency preparedness plan and provide regular training to ensure that all staff are trained and competent in emergency procedures (See V 415). 8. The facility failed to contact and develop a communicative relationship with the local disaster management agency. This relationship will help expedite restoration of interrupted services due to an emergency or disaster (See V 416). The cumulative effects of these systemic problems resulted in the failure of staff to provide care in a clean, sanitary, and functional	V 400		

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V 400	Continued From page 23 environment and ensure the safety of the patients and others during dialysis.	V 400		
V 401	494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to:1. Ensure that equipment and patient personal items are kept off the floor. This posed the potential risk to patients for falls should they trip on the oxygen tubing and/or blankets on the floor. The also poses an infection control risk, and 2. Ensure that the medications were secured against loss, tampering, destruction, or unauthorized use. Finding: 1. During observation on 3/16/09 at 9:10 am, the patient sitting at Station 8 was using oxygen via nasal cannula (prongs that go into the nose). The patient removed the oxygen tubing and it fell to the floor. Staff did not pick up the oxygen tubing off the floor. At 9:30 am, the patient stood up from the chair and stood on the oxygen tubing that was lying on the floor. The patient's blanket was lying on the floor. Staff did not pick up the blanket off the floor until the patient was ready to leave the clinic. Concurrent interview with staff revealed that they did not pay attention to the oxygen tubing or the blanket being on the floor. Staff	V 401		6/25/09

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V 401	Continued From page 24	V 401		

acknowledged that there was a risk for the patient to get tangled up in the tubing and falling and that the blanket could get contaminated.

2. During observation on 3/18/09 at 7:45 am, the medication room door was left ajar. The medication room did not have constant surveillance or supervision by a licensed staff. The medication room was accessible to unauthorized persons and posed the potential for the diversion or tampering with medications.

Surveyor: 21966

3. During observation on 3/16/09 at 4:30 pm, 16 vials of Epogen were stored on the nursing station counter, at room temperature, and in direct light. The vials were accessible to unauthorized persons and were accessible for diversion and/or tampering.

During observation on 3/17/09 at 3:30 pm, 36 vials of Epogen were stored on the nursing station counter, at room temperature, and in direct light. The vials were accessible to unauthorized persons.

RN E stated during an interview on 3/18/09 at 3:25 pm, that she would bring all of the injectable medications (including the Epogen) out of the medication room at 7:30 am and then after the last treatment was started (around 3:45 pm) would then put all of the medication back into the medication room or the medication room refrigerator.

Review of the medication package insert provided by the facility, on 3/18/09, revealed the

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V 401	Continued From page 25 manufacturer guidance for the storage of Epogen as: STORAGE Store at 2° to 8° C (36° to 46° F). Do not freeze or shake. Protect from light. Amgen Inc. 2009. Administrative Staff A stated during an interview on 3/19/09 at 4:30 pm, that the licensed staff need to store Epogen in the refrigerator at all times.	V 401		
V 402	494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observations and patient and staff interviews, the facility failed to ensure that the entrance door to the lobby could accommodate the needs of persons who are physically disabled. This failure had the potential for an unsafe entrance into the facility. Findings: During observation on 3/16/09, 3/17/09, 3/18/09, 3/19/09, and 3/20/09, the handicap push plate activation switch on the outside of the front door required multiple attempts to get the activation switch to work properly to open the door. During interviews on 3/20/09, multiple random patients stated that it was difficult to enter the facility using the front door. The activation switch did not work all the time. The patients' stated that they would have to pull hard on the front door to get it to	V 402		6/26/09

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V 402	Continued From page 26 open. Two (2) patients stated that they felt it was dangerous for them to have to struggle to get the front door to open, because they do not have good balance and they were afraid of falling. During a concurrent interview, Administrative Staff B stated that she had brought it to the attention of the past Facility Administrator (FA) and she believed that it had been taken care of by the past FA.	V 402		
V 405	494.60(c)(2) PE-COMFORTABLE TEMPERATURE The dialysis facility must: (i) Maintain a comfortable temperature within the facility; and (ii) Make reasonable accommodations for the patients who are not comfortable at this temperature. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to maintain a comfortable temperature within the facility for patients' sitting at Station 13. This failure resulted in a patient wearing a hat and sunglasses during dialysis, thus reducing the staff's visibility of the patient's face and eyes to monitor during dialysis. Findings: During observation on 3/17/09 at 1 pm, the patient sitting at Station 13 had his face covered with a hat and was wearing sunglasses. The patient had requested that the air flow be redirected, so that the air would not be blowing down on him during dialysis. During a concurrent interview, PCT I stated that air from the air vent above Station 13 was blowing down on the	V 405		6/26/09

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V 405	Continued From page 27 patient and it made him cold, so he was covering up. PCT I stated that she told the patient that she had told RN D. PCT I stated it was approximately a month ago, that she told RN D that the patients' that sit at Station 13 get cold from the air blowing down on them.	V 405		
V 407	494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to; 1. Ensure that the patients' vascular access site and bloodline connections (arterial and venous) were visible to staff throughout dialysis treatments. This had the potential of accidental needle dislodgement or line disconnection that may go undetected, which could result in exsanguination (bleeding out) and death for 5 random patients and, 2. Ensure that two (2) random patients' faces and eyes were visible to staff during dialysis to ensure safety and surveillance. Findings: During observation on 3/16/09 at 2:30 pm, the access site and bloodline connection of a random patient sitting at Station 13 was covered and not visible to staff during dialysis. At 2:45 pm, the access sites of two random patients' sitting at Station 1 and Station 12 were covered and not visible to staff during dialysis.	V 407		6/25/09

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V 407	Continued From page 28 During observation on 3/17/09 at 7:30 am, the access sites and the bloodline connections of two random patients' sitting at Station 9 and Station 11 were covered and not visible to staff during dialysis. The patient at Station 9 also had his face covered. At 1 pm, the patient sitting at Station 13 had his face covered with a hat and was wearing sunglasses. Staff interviewed stated that the patients' get cold and they want to stay warm, so they put their arms under the blankets or jackets. Staff stated that they have in the past told the patients' that their access site and bloodline connection need to be visible during treatment, but the staff have not enforced the policy. On 3/18/09 at 9 am, during an interview, Administrative Staff A and Administrative Staff B stated that it is the Standard of Practice that all access sites and bloodline connections are to be uncovered and visible to the staff during dialysis. Administrative Staff A stated that a reminder is posted just outside of the patient care area. Administrative Staff B stated that it is the responsibility of the staff to implement the Standard of Practice.	V 407		
V 408	494.60(d) PE-EMERGENCY PREPAREDNESS-PROCEDURES The dialysis facility must implement processes and procedures to manage medical and non medical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.	V 408		6/23/09

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V 408	Continued From page 29 This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review and staff interview, the facility failed to develop and implement a comprehensive emergency plan, which addressed medical, other emergencies, and natural disasters. An emergency or natural disaster could have the potential to threaten the health and safety of the patients, staff, and the public. Findings: On 3/17/09 at 5 pm, a review of the Dialysis Facility Disaster Plan binder revealed that there had not been any implementation of a comprehensive disaster plan. During a concurrent interview, Administrative Staff B stated that she was not aware of any comprehensive disaster plan for this clinic. Administrative Staff B stated that the Dialysis Facility Disaster Plan Template had not been implemented, and which included the following: facility was to determine which kinds of disasters they would likely see, develop a relationship with the local and regional disaster planner, develop a relationship with local utilities, secure the facility to prevent injuries during a disaster, provide education to patients regarding evacuation procedures, staff disaster plan training, evacuation plan, have a disaster organizational structure, create a communications plan, have a written agreement with another dialysis facility, and disaster response and recovery.	V 408		
V 413	494.60(d)(3) PE-ER EQUIP ON PREMISES-02, AED, SUCTION	V 413		6/25/09

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V 413	Continued From page 30	V 413		

Emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, must be on the premises at all times and immediately available.

This STANDARD is not met as evidenced by:
Surveyor: 14067
Based on observation, document review, and staff interview, the facility failed to maintain a fully equipped, well maintained emergency cart and evacuation kits and failed to ensure that they were kept clean and ready to use. This failure had the potential of not being able to respond to patients' medical emergency timely for 62 patients.

Findings:

During inspection on 3/17/09, there was no backboard on the emergency cart and no oxygen adjacent to the emergency cart.

The emergency evacuation kit did not have a contents list located on the outside of the kit. Administrative Staff B was able to find the content list inside of the kit. The kit was not secured. The kit was dirty and dusty. Administrative Staff B stated during a concurrent interview that she did not know when the last time the kit had been cleaned. The Evacuation Kit Checklist did not match what was in the kit. The Evacuation Kit Checklist indicated that the kit had not been checked by staff in October 2008, November 2008, December 2008, January 2009, and February 2009. The last date the kit had been checked was September 2008. The initials at the bottom the checklist indicated that a non-licensed

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V 413	Continued From page 31 staff had checked the kit in August 2008 and September 2008. During concurrent interview, Administrative Staff B stated that staff checks the evacuation kit monthly to ensure that all supplies and medications in the quantity listed are present and at the same time are to check for out dated medications and supplies. A review of the Checklist revealed that the kit had been signed off as being completed monthly. The following was identified: a. 6 bottles of Heparin 5000 u/cc were listed. The 6 bottles of Heparin were missing from the kit b. 36 Sterile Catheter Caps were listed. Only 18 in the kit. c. 2 bottles Dextrose 50% Injection USP. Expiration date was listed as 4/09. The manufacturer's expiration date was stamped on the bottles as being 4/1/09. d. 2 Bite Blocks were listed. 5 were in the kit. e. 23 packages of sterile 4x4s were listed. No 4x4s were in the kit. f. 12 Masks were listed. Only 6 were in the kit. g. 10 IV tubing sets were listed. Only 7 were in the kit. h. 3 - 10 ml Syringes were listed. 25 were in the kit. i. 3 - 30 ml Syringes were listed. 6 were in the kit. j. 10 sterile gloves were listed. None were in the	V 413		

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V 413	Continued From page 32 kit. k. 3 - 1 inch paper tape was listed. 12 were in the kit. l. 3 - 1 inch plastic tape were listed. 12 were in the kit. m. 24 hemostats (Blue clamps) were listed. 21 were in the kit. n. 3 scissors were listed. 2 were in the kit. o. 10 Emergency survival blankets were listed. 3 were in the kit. p. Flashlight batteries were in the kit. The expiration dates of the batteries were not listed. q. Radio batteries were in the kit. The expiration dates were not listed. r. 13 Fistula needles were in the kit. They were not listed on the check list. s. AA batteries were in the kit and not on the check list. Administrative Staff B corroborated the above findings.	V 413		
V 415	494.60(d)(4)(ii) PE-ANNUAL EVAL-EMERGENCY/DISASTER PLANS The facility must- Evaluate at least annually the effectiveness of the emergency and disaster plans and update them as necessary;	V 415		6/26/09

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V 415	Continued From page 33 This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review, policy and procedure review, and staff interview, the facility failed to evaluate the effectiveness of the emergency and disater plans on an annual basis to ensure that each employee is trained properly and correctly carry out emergency procedures. Findings: 1. On 3/20/09 at 9 am, a review of 11 employee personnel files had no documented evidence that fire safety drills and/or mock codes had been held on an annual basis to determine the employees's skill level for medical and non-medical emergencies. 2. On 3/20/09 at 11 am, the fire drill log was reviewed. The facility had not conducted periodic fire drills/disaster drills. Administrative Staff A corroborated the above finding. Administrative Staff B stated during a concurrent interview that she could not locate any documentation that fire drills or mock codes had been conducted. The policy and procedure titled, "Fire/Disaster Drills," dated September 2007 was reviewed on 3/19/09 at 5 pm. The policy read that fire drills are to be conducted quarterly in order that all teammates are familiar with the appropriate steps which are to be followed during a fire. Drills for natural disaster, power failure, or medical emergency should be reviewed individually on an annual basis.	V 415		
V 416	494.60(d)(4)(iii) PE-CONTACT LOCAL EOC ANNUALLY The facility must-	V 416		6/26/09

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V 416	Continued From page 34 (iii) Contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review and staff interview, the facility failed to ensure that they had contacted the local disaster management agency at least annually to ensure that the agency is aware of the dialysis facility's needs in the event of an emergency. Findings: The facility's disaster binder was reviewed on 3/19/09 at 7:30 am. The binder had no documented evidence that the facility had contacted and developed a communicative relationship with the local disaster management agency on an annual basis. This is to ensure that in case of an interruption of services during an emergency, the local agency would help expedite restoration of services and also be aware of the facility's needs in the event of an emergency. Concurrent interview with Administrative Staff A and Administrative Staff B corroborated the above finding.	V 416		
V 503	494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the	V 503		6/26/09

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V 503	Continued From page 35 dialysis prescription, This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review and staff interview, the facility failed to ensure that the licensed staff evaluated the patients dialysis treatment orders and ensured the physician dialysis orders were implemented for the Blood Flow Rate (BFR) for 2 of 2 dialysis patients (Patients 1, 2). Findings: 1. On 3/18/09 at 10 am, review of the physician order for Patient 1 revealed that the Blood Flow Rate (BFR) was ordered to run at 350 ml/minute. A review of the treatment flowsheets revealed that the staff did not have the BFR at 350 ml/minute, instead had the BFR at either 300 or 400 as follows: a. On 2/27/09 BFR was documented at 300. b. On 3/6/09 BFR was documented at 350 for the first hour and then up to 400. Documentation indicated that the RN had received a verbal order from the physician to increase the BFR to 400, which was done at 1:44 pm. The verbal order for the BFR to be at 400 ml/minute was not written until 3/16/09 (10 days later). c. On 3/9/09, 3/11/09, and 3/13/09 documentation revealed that the BFR continued to be run at 400. d. On 3/16/09 the BFR was at 400 for the first hour of treatment and then the BFR was at 350. There was no documentation as to why the PCT	V 503		

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turned down the BFR or that the PCT notified the RN that the BFR was at 350.

On 3/19/09 at 8:45 am, during an interview, PCT H stated that the patient was new and she always started the patient's BFR lower then what is ordered. PCT H stated that she did not notify the RN that she was not following the physician's orders.

On 3/19/09 at 8:50 am, during an interview, PCT G stated that he did not look at the physician's order. PCT G stated that he increased the BFR to 400 to get the best outcome for the patient. He stated that he did not notify the RN and let him know that he was increasing the BFR. PCT G stated that he dropped the BFR on 3/16/09 from 400 to 350, because he looked at the order.

On 3/19/019 at 9 am, during an interview, RN D stated that he does not have the time to review the flowsheets thoroughly, that he only looks at the blood pressures and the pre and post weights, when he can.

2. On 3/19/09 at 9 am, review of the physician orders for Patient 2 revealed that the Blood Flow Rate (BFR) was ordered to run at 450 ml/minute. A review of the treatment flowsheets revealed that the staff did not have the BFR at 450 ml/minute as follows:

a. On 3/5/09, the BFR was documented at 350 for the first hour and then 310 to 210 for the rest of the treatment.

b. On 3/7/09, 3/10/09, and 3/12/09, the BFR was documented at 400.

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V 503	Continued From page 37 c. On 3/14/09, the BFR was documented at 400 for the first hour and then 350 for the rest of the treatment. The medical record had no documented evidence that the physician had written an order to change the BFR from 450 to 350.	V 503		
V 516	494.80(b)(1) PA-FREQUENCY-INITIAL-30 DAYS/13 TX An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review and staff interview, the facility failed to ensure that all comprehensive assessments be completed within the 30 day or 13 treatment timeframe for all patients (Patient 2, 3, 4, 5, 6, 8, 12,). This poses the potential that patients needs will not be met. Findings: 1. Review of Patient 2's medical record on 3/18/09 revealed that the patient was admitted to the facility on 6/17/08. The initial nursing assessment was completed on 1/26/09 (7 months late). 2. Review of Patient 3's medical record on 3/18/09 revealed that the patient was admitted to the facility on 10/21/08. The initial nursing assessment was completed on 1/23/09 (3 months late).	V 516		6/26/09

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V 516	Continued From page 38 3. Review of Patient 8's medical record on 3/18/09 revealed that the patient was admitted to the facility on 8/27/02. The Registered Dietician's (RD) initial assessment had been completed on 10/12/02 (2 months late). 4. Review of Patient 12's medical record on 3/18/09 revealed that the patient was admitted to the facility on 6/20/07. The medical record had no documented evidence that the initial nursing assessment had been done. The Medical Social Worker (MSW) initial assessment was not completed until 6/23/08 (a year late). Surveyor: 21966 5. Review of Patient 4's medical record on 3/19/09 revealed that the patient was admitted to the facility on 12/27/08. The initial nursing assessment was not completed (over 2 months late). Administrative Staff A stated during an interview on 3/19/09 at 1:55 p.m., that she could not find a nursing assessment in Patient 4's medical record. 6. Review of Patient 5's medical record on 3/19/09 revealed that the patient was admitted to the facility on 10/16/08. The initial nursing assessment was completed on 12/18/09 (1 month late). 7. Review of Patient 6's medical record on 3/19/09 revealed that the patient was admitted to the facility on 12/11/08. The initial nursing assessment was not completed. (2 months late).	V 516		

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V 516	Continued From page 39 RN D stated during an interview on 3/19/09 at 11:35 a.m., that he had started Patient 6's nursing assessment but had not completed it.	V 516		
V 692	494.140(e)(1),(2) PQ-PCT-STATE REQUIREMENTS & HS DIPLOMA Patient care dialysis technicians must- (1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and (2) Have a high school diploma or equivalency; This STANDARD is not met as evidenced by: Surveyor: 14067 Based on document review and staff interview, the facility failed to ensure that two (2) Patient Care Technicians (PCT) met all applicable State requirements for education, training, credentialing, and certification. This resulted in two (2) PCT working in the role as a PCT, which included the responsibility for direct patient care,to set up and take down machines, and administering anticoagulant medications, without having the requirements related to certification or registration. Findings: On 3/19/09 at 2 pm, during review of random treatment flowsheets,two (2) employees were administering Heparin (an anticoagulant that prevents clotting of the blood) to patients during dialysis. The professional title in the electronic records indicated that they were Licensed Vocational Nurse (LVNs) and not PCTs. During concurrent interview, Administrative Staff A and Administrative Staff B stated that they were aware	V 692		6/26/09

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V 692	Continued From page 40 that LVN G did not possess a current PCT certification since October 2008. Concurrent review of the Hemodialysis Education and Training Program dated October 24, 2008 revealed that LVN G had taken the training, but failed to send in the application to the PCT program for certification. LVN/PCT F had been employed as a PCT for approximately 4 years (between 2005 -2009) and had allowed her certification expire in 2000. Concurrent review of the directive sent to all clinics dated July 14, 2005, indicated that Sacramento Superior Court ruled that the scope of practice for the LVNs did not allow LVNs to administer intravenous (IV) medications. IV medication means fluid solutions of electrolytes, nutrients, vitamins, blood and blood products. The directive stated " ... Only Certified Hemodialysis Technicians (CHT) [same as Patient Care Technician] may administer heparin to patients with a fistula or graft. Therefore, all LVNs must be CHT certified ..."	V 692		
V 715	494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Surveyor: 14067 Based on personnel file review, policy and procedure review, and staff interview, the facility	V 715		6/26/09

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V 715		V 715		

Continued From page 41

failed to ensure that all employees demonstrated the ability to pass the Color Vision Evaluation for 2 of 10 employees. This poses the potential that staff may not be able to correctly interpret test strip results that are based on color results.

Findings:

On 3/20/09, a review of the personnel files revealed that the employees had been given a Color Vision Evaluation in 12/2/08. The Goodlite Pseudo-Isochromatic 16 Plate evaluation is used for checking for both red/green and blue/yellow deficiencies. The evaluation is intended to be use by a medical professional to qualify and quantify employees or patients for color vision deficiency. Documentation revealed that LVN G was screened on 12/2/08 and had color vision defect in 7 out of 9 plates (Plates 2, 3, 4, 5, 6, 7, and 8). The screening indicated that if an employee failed plates 1-7, they had some type of red/green color deficiency. Plate 8 determines the type and degree (mild or strong) of the defect and Plate 9 signifies the color of blue/yellow. Documentation revealed that RN D was screened on 12/2/08. Documentation revealed that he had color vision defect in Plate 3, 4, and 8. Plates 1, 2, 5, 7, 8, and 9 were normal.

Concurrent review of the policy and procedure titled, "Teammate Color Vision Evaluation," dated September 2007, read that the color vision evaluation was to establish guidelines for screening teammates for the ability to differentiate colors and for the use of test strips or kits utilizing color based readings.

During concurrent interview, Administrative Staff B stated that RENALIN® strips are a blue/gray to

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V 715	Continued From page 42 indicate the presence of Renalin. The PH strips are green + and orange + with the ranges listed on the bottle. Administrative Staff B stated that the policy is vague and the teammate should have been required to be tested by an outside physician or optometrist, since they did not pass the color screening provided by the company.	V 715		
V 725	494.170 CFC-MEDICAL RECORDS This CONDITION is not met as evidenced by: Surveyor: 14067 Based on observation, document review, policy and procedure review, and staff interview, the facility failed to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records. Findings: 1. The facility failed to create and maintain a complete and accurate record of care for every patient that is unique for that patient. Each patient's medical record should clearly portray the patient, the care provided by the facility personnel, and the outcomes of that care (See V 726). 2. The facility failed to ensure that the Medical Record storage area was secured, had controlled accessibility, and protected the medical records at all times (See V 727). 3. The facility failed to ensure that all medical records and those of discharged patients were completed promptly (See 729). The cumulative effects of these serious systemic	V 725		6/26/09

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V 725	Continued From page 43 problems identified resulted in the failure of the staff to ensure that all medical records are accurate, completed, and are accessible at all times.	V 725		
V 726	494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation, document review, policy and procedure review, patient and staff interview, the facility failed to create and maintain a complete and accurate record of care for every patient that is unique for that patient. Each patient's medical record should clearly portray the patient, the care provided by the facility staff (Pre-dialysis and Post-dialysis assessments) and the outcomes of that care for 11 of 62 patients (Patient 2, 4, 12, 14, 15, 17, 18, 19, 20, 21, & 22). This has the potential for the care needs of the dialysis patients not to be met. Findings: On 3/16/09, observation, document review, and staff interview revealed the following regarding Post-dialysis Assessments: 1. At 9:55 am, Patient 14 had been terminated from dialysis. Patient 14 left the clinic without the Registered Nurse (RN) completing a post-dialysis	V 726		6/26/09

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V 726	Continued From page 44	V 726		

assessment. During a concurrent interview, Patient 14 stated that the RN had listened to his heart, lungs, and checked for his ankles edema when he first arrived for dialysis. Patient 14 turned and left the clinic. At 9:57 am, the electronic record was reviewed, the post-assessment had not been completed.

2. At 10 am, Patient 17 had been terminated from dialysis. At 10:30 am, Patient 17 exited the patient's bathroom and left the clinic without a post-dialysis assessment. During a concurrent interview, Patient 17 stated that the RN had not listened to his lungs, heart, nor did the RN check his ankles for edema before he left the clinic. At 10:34 am the electronic record was reviewed, the post-assessment had not been completed.

3. At 9:40 am, Patient 12 had been terminated from dialysis. Patient 12 left the clinic without the RN completing a post assessment. During a concurrent interview, LVN G stated that the RN had not completed the post-dialysis assessment prior to the patient leaving the clinic. At 10:05, the electronic record was reviewed, the post-assessment had not been completed nor documented.

4. At 10:25 am, Patient 15 had been terminated from dialysis. Patient 15 left the clinic without the RN completing a post-assessment. The RN was taking care of another patient at Station 2 when Patient 15 left the clinic. At 10:26 the electronic record was reviewed and the post-assessment had not been completed nor documented.

On 3/17/09 at 8 am, review of the treatment flowsheets from 3/16/09 on the patients cited above, revealed the following discrepancies

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V 726	Continued From page 45 regarding the documentation of the Post-dialysis Assessments: a. Patient 17 had been terminated from dialysis at 10 am and left the clinic at 10:30 am. The post-assessment was documented as being completed at 10:05 am. b. Patient 12 had been terminated from dialysis at 9:40 am and left the clinic at 10:02 am. The post-assessment was documented as being completed at 9:45 am. c. Patient 15 had been terminated from dialysis at 10:02 am and left the clinic at 10:25 am. The post-assessment was documented as being completed at 10:15 am. On 3/17/09 at 9 am, Administrative Staff A, Administrative Staff B, and Administrative Staff L were notified by the survey team of the discrepancy and inaccurate documentation. On 3/17/09 at 9:48 am, RN D stated that the facility's policy and procedure indicated that only unstable patients were required to have post-dialysis assessments. Stable patients could leave the clinic after they weigh themselves and they did not require a post-dialysis assessment after they finished their dialysis treatment. RN D stated that he is very busy and does not have the time to do post-dialysis assessments regularly. Upon inquiry regarding the post-dialysis assessment documentation on the treatment flowsheets dated 3/16/09 on the above patients' that had been completed by him after the patients had left the clinic, RN D did not respond to the inquiry. RN D again stated that he is very busy and feels over whelmed with all that he is	V 726		

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V 726	Continued From page 46	V 726		

expected to do.

On 3/17/09 at 7:30 am, review of the treatment flowsheets from 3/16/09, revealed the following regarding the documentation of the Pre-dialysis Assessments:

d. Patient 18's treatment started at 10:44 am. A review of the treatment flowsheet revealed no documented evidence that the pre-dialysis assessment had been completed by the RN.

e. Patient 2's treatment started at 11:09 am. The pre-dialysis assessment was documented as being completed at 11:22 am (13 minutes after the initiation of dialysis). The PCT taking care of Patient 2 stated during a concurrent interview that the RN was busy with another patient. Patient 2 was identified by the staff as being unstable.

f. Patient 19's treatment started at 11:15 am. The pre-dialysis assessment was documented as being completed at 11:21 am (6 minutes after the initiation of dialysis).

g. Patient 20's treatment started at 10:10 am. The pre-dialysis assessment was documented as being completed at 10:20 am (10 minutes after the initiation of dialysis).

h. Patient 21's treatment started at 10:45 am. The treatment flowsheet revealed no documented evidence that the pre-dialysis assessment had been completed by the RN. LVN G stated during a concurrent interview " ...RN was busy with another patient, so I went ahead and began the dialysis. I did not wait for the RN to do the pre-dialysis assessment. "

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V 726		V 726		

Continued From page 47

i. Patient 22's treatment started at 9:40 am. The pre-dialysis assessment was documented as being completed at 9:47 am (7 minutes after the initiation of dialysis).

On 3/17/09 at 10 am, Administrative Staff A, Administrative Staff B,and Administrative Staff L were notified by the survey team of the discrepancy and inaccurate documentation.

On 3/18/09 at 11:30 am, RN E stated that it was the facility policy and procedure that the pre-dialysis assessment can be done within one (1) hour after the initiation of treatment. The post-assessments are done on patients' that are considered unstable. Stable patients' don't get post-assessments unless there is time. RN E stated that she does not always have time to do pre-dialysis assessments. There are a lot of Central Venous Catheters (CVC) and it takes time to do the dressing changes, replace the catheter caps and administer the medications, before the initiation of dialysis can start.

The policy and procedure titled, "Pre/Post Dialysis Treatment Data Collection," dated December 2006, indicated that the Pre/Post -dialysis assessments were to plan the dialysis treatment and for reviewing the patient's response to the treatment. A registered nurse will complete the patient assessment pre-dialysis (Cardiac status, respiratory status, and Peripheral edema).

Surveyor: 21966

5. Review of Patient 4's clinical record on 3/19/09. Patient 4 was identified with Heparin

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V 726	Continued From page 48 Induced Thrombocytopenia while in the acute hospital. Review of Patient 4's Physician Hemodialysis Orders and the chart cover sheet, revealed that Patient 4 had no allergies. Review of Post Treatment flowsheets dated 2/7/09 and 2/14/09, revealed under the section titled, "Medications & Ancillaries Administered," that Sodium citrate 4% solution was not administered and that heparin was administered to the catheter ports instead. Review of unsigned medication orders dated 2/23/09 revealed under notes: Allergic to any forms of heparin. Use normal saline for locking CVC ports. RN E stated during an interview on 3/19/09 at 4:03 pm., that she did not realize that Patient 4 was allergic to heparan. She stated that she could not find the Sodium Citrate and called RN D and was told to give heparin instead. RN E stated that she did not call the physician on either date.	V 726		
V 727	494.170(a) MR-PROTECT PT RECORDS FM LOSS/CONFIDENTIAL The dialysis facility must- (1)Safeguard patient records against loss, destruction, or unauthorized use; and (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following: (i) The transfer of the patient to another facility. (ii) Certain exceptions provided for in the law. (iii) Provisions allowed under third party payment contracts. (iv) Approval by the patient.	V 727		6/26/09

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V 727	Continued From page 49 (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program. This STANDARD is not met as evidenced by: Surveyor: 14067 Based on observation and staff interview, the facility failed to ensure that medical records were stored in a way that would ensure that they were not lost, stolen, destroyed, and retrieval. Findings: During observation and inspection on 3/16/09 and 3/17/09, the medical record room was left unlocked, thus not providing a secure room for the storage of the medical records. The medical records were stored in a manner that would have prevented the timely retrieval of requested medical records. There was loose filing; and the tops of the boxes were left off, thus not protecting the medical records from possible water damage. Boxes of medical records were stacked on top of each other in a disorganized manner. Administrative Staff B stated that they have a contracted janitorial service that cleans the facility after hours. Administrative Staff B stated that the medical records need to be stored where they are protected and in a manner that would allow them to be retrieved in a timely manner.	V 727		
V 729	494.170(b)(1) MR-COMPLETE RECORDS PROMPTLY (1) Current medical records and those of discharged patients must be completed promptly. This STANDARD is not met as evidenced by: Surveyor: 14067	V 729		6/26/09

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V 729	Continued From page 50 Based on document review, policy and procedure review, and staff interview, the facility failed to ensure that four of four patients discharged from the facility, records were completed promptly. Discharge summaries had not been completed for the patients (Patients 8, 23, 24, and 25). Findings: 1. On 3/18/09, review of Patient 8's closed medical record revealed that the patient was discharged from the facility on 10/1/08. The medical record had no documented evidence that a discharge summary had been completed. 2. On 3/20/09, review of Patient 23's closed medical record revealed that the patient was discharged from the facility on 1/29/09. The medical record had no documented evidence that a discharge summary had been completed. 3. On 3/20/09, review of Patient 24's closed medical record revealed that the patient was discharged from the facility on 1/27/09. The medical record had no documented evidence that a discharge summary had been completed. 4. On 3/20/09, review of Patient 25's closed medical record revealed that the patient was discharged from the facility on 2/11/09. The medical record had no documented evidence that a discharge summary had been completed. During concurrent interview, Administrative Staff A stated that the Standard of Practice for the facility is that the discharge summaries are to be completed with 30 days of discharge from the facility, which includes transfer from one facility to another.	V 729		

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V 729	Continued From page 51 The policy and procedure titled, "Discharge Summary Procedure: 3-02-01B," dated December 2008, indicated that the following needed to be completed upon discharge: reason for discharge, summary of treatment, and disposition at discharge.	V 729		
V 750	494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Surveyor: 14067 Based on observation, staff interview, policy and procedure review, the governing body failed in its responsibility for the governance and operation of the facility. Findings: The governing body has full legal authority and responsibility for the governance and operation of the facility. The ability of the health care team to provide a safe level of care to patients cannot be ensured as evidenced by the seriousness of the deficiencies cited throughout this document as follows: 1. The facility failed to provide and monitor for a sanitary, functional, and safe environment to minimize the transmission of infectious agents within the facility (See V 110 and V 400). 2. The facility failed to ensure that staff uses protective personal equipment (PPE) when caring for patients or touching the patient's equipment at the dialysis station (See V 113, V 114, and V 115). 3. The facility failed to ensure that staff clean and	V 750		6/26/09

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V 750	Continued From page 52 disinfect contaminated surfaces, medical devices, and equipment in between patients (See V 122). 4. The facility failed to ensure that all medications that are available for patient use are not expired (See V 143). 5. The facility failed to ensure that the initial comprehensive nursing, dietary, and social workers assessments were completed within 13 dialysis treatment or 30 calendar days (See V 516). 6. The facility failed to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records (See V 725, V 726, V 727, and V 729). 7. The facility failed to ensure that there was adequate number of qualified personnel present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients [patient assessment and monitoring per facility policy] (See V 757). The cumulative effects of these systemic problems resulted in the inability of the governing body to ensure the provision of quality care in a clean and sanitary environment, that medications administrated to the patients are safe for patient use, that medical records are accurarte and protected, and that there are adequate number of qualified personnel to met the needs of the patients.	V 750		
V 757	494.180(b)(1) GOV-STAFF # & RATIO MEET PT NEEDS	V 757		6/26/09

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V 757	Continued From page 53	V 757		

The governing body or designated person responsible must ensure that-
(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients;

This STANDARD is not met as evidenced by:
Surveyor: 14067
Based on medical record reviews, document review, and staff interview, the facility failed to ensure that whenever patients are undergoing dialysis, there is adequate number of personnel present, so that the patient/staff ratio is appropriate to the level of dialysis care being given and meet the needs of 10 of 10 patients (Patient 2,12, 14, 15, 17, 18, 19, 20, 21, and 22).

Findings:

1. The facility had a 4:1 PCT staffing ratio and a 13:1 RN staffing ratio.

On 3/17/09 at 9:48 am, RN D stated during an interview that the facility's policy and procedure indicated that only unstable patients were required to have post-dialysis assessments and that stable patients could leave the clinic after they weigh themselves and they did not require a post-dialysis assessment after they finished their dialysis treatment. RN D stated that he is very busy and does not have time to do post-dialysis assessments regularly. Upon inquiry regarding the post-dialysis assessment documentation on the treatment flowsheets dated 3/16/09 for patients (Patient 12, 14, 15, and 17) that had been completed by him after the patients had left

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	052810	A. BUILDING ______ B. WING ______	03/20/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BENICIA DIALYSIS	560 FIRST STREET SUITE D103 BENICIA, CA 94510

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 757		V 757		

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the clinic and patients stated that the RN did not do a post-assessment on them, RN D did not respond to the inquiry. RN D stated again that he is very busy and feels over whelmed with all that he is expected to do.

On 3/18/09 at 11:30 am, RN E stated that it was the facility policy and procedure that the pre-dialysis assessment can be done within one (1) hour after the initiation of treatment. The post-assessments are done on patients' that are considered unstable. Stable patients' don't get post-assessments unless there is time (Patient 2, 18, 19, 20, 21, 22). RN E stated that she does not always have time to do pre-dialysis assessments. There are a lot of Central Venous Catheters (CVC) and it takes time to do the dressing changes, replace the catheter tips and administer the medications, before the initiation of dialysis can start.

The Job Description - Charge Nurse - Chronic dated September 2008, indicated that the essential duties and responsibilities of the RN was to provide patient care, which included but not limited to physical assessment of the patients.

The policy and procedure titled, "Pre/Post Dialysis Treatment Data Collection," dated December 2006, indicated that the Pre/Post -dialysis assessments were to plan the dialysis treatment and for reviewing the patient's response to the treatment. A registered nurse will complete the patient assessment pre-dialysis (Cardiac status, respiratory status, and Peripheral edema).