

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

PRINTED: 10/29/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052699	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/23/2009
NAME OF PROVIDER OR SUPPLIER HIGH DESERT DIALYSIS INC			STREET ADDRESS, CITY, STATE, ZIP CODE 1007 WEST AVE M-14 #B PALMDALE, CA 93551	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
V 000	INITIAL COMMENTS Surveyor: 15727 The following reflects the findings of the Department of Public Health during a re-licensure visit.	V 000		
V 111	Representing the Department of Public Health: Sylvia Villaflores, REHS, HFE I Rosalinda Ramos, RN, HFEN 494.30 INFECTION CONTROL The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation, interview and record review, the facility failed to monitor a sanitary environment to minimize the transmission of infectious agents within the unit. Findings: During an observation tour on July 22, 2009, at 7:35 a.m., on top of the sink counter near station 1, there was a rectangular plastic container with cover of 1% bleach, a rectangular plastic container labeled for dirty clamps, and a rectangular plastic container for clean clamps. At the same time during an interview, the director of nursing stated the container with 1% bleach was for the wipes used for disinfecting the machines and chairs after each treatment. He further stated that was where they set up the containers.	V 111		

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 111	Continued From page 1	V 111			
V 115	<p>A review of the facility's policy and procedure entitled Disinfecting Fistula Clamps and Hemostats revealed following the hemodialysis treatment as part of the clean up procedure, take the hemostats and fistula clamps away from the station and place them in their respective basins behind the nurses' station to soak and disinfect.</p> <p>There were no basins behind the nurses' stations for the dirty hemostats and fistula clamps to soak and disinfect.</p> <p>494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation and interview, a facility staff failed to close the gown in front while in the treatment area.</p> <p>Findings:</p> <p>During an observation on July 22, 2009, at 7:45 a.m., a certified hemodialysis technician was observed in the treatment area wearing a gown with the front open. The staff member was observed going to a patient in station 8. The same staff member proceeded to the reuse room</p>	V 115			

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V 115	Continued From page 2 and then came back out to the treatment area. The front of the gown remained open.	V 115			
V 116	During an interview on July 22, 2009, at 12:15 p.m., the same staff member was in the reuse room. She stated aside from patient care she was assigned to reuse for the day. 494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. -- Nondisposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient. -- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation and interview, the facility staff failed to ensure that items taken into the dialysis station used for a patient should not be taken back to the common storage area. Findings: On July 21, 2009, at approximately 8 a.m., during the tour of the treatment area, the PCT was observed took a roll of tape from the common	V 116			

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V 116	Continued From page 3 supply area. The PCT brought the roll of tape to hemodialysis station 2 for patient use. After using the tape, the PCT took the same roll of tape back to the common storage area and mix with other clean supplies.	V 116			
V 117	On the same day, at a later time, the PCT when asked indicated that he was not aware that he returned the roll tape with other clean supplies. 494.30(a)(1)(i) CDC RR-5 AS ADOPTED BY REFERENCE Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled. When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station. Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview and record review, the facility staff failed to ensure that multi-dose vial medications were dated and	V 117			

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V 117	<p>Continued From page 4</p> <p>initialed when first opened. Also the facility failed to ensure that there were no expired medications alongside with current medications in use. Also to ensure that a dedicated medication preparation area to prevent cross contamination. Also medications should not be accessible to unauthorized persons in the facility.</p> <p>Findings:</p> <p>On July 21, 2009 at approximately 9:05 a.m., during the medication storage observation, the following was observed:</p> <p>a. The medication refrigerator-</p> <p>1. There was an accumulation of ice in the freezer.</p> <p>There was a bottle of Humulin R opened on February 20, 2009.</p> <p>There was a bottle of Tubersol-Tuberculin Purified Protein Derivative Mantoux opened on June 2, 2009. According to the Manufacturer ' s insert stipulated a vial of Tubersol which had been entered and in use for 30 days should be discarded because oxidation and degradation may have reduced the potency. A bottle of Procrit (M) opened and undated</p> <p>At approximately 12 noon, interview with the DON, he stated that multi-dose vial medication should be dated upon opening and insulin medication should be discarded after days when initially used.</p> <p>In the medication cabinet by the nurses station- There were 23 bottles of 25% Mannitol Injection with expiration date of June 1, 2009. There was a vial of 125 mg of Solu-Medrol with expiration date of</p>	V 117			

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V 117	<p>Continued From page 5</p> <p>March 2009</p> <p>3. There was a bottle of 50 mg Protamine Sulfate with expiration date of March 2009.</p> <p>4. There were two (2) bottles of 1 gm Calcium Chloride with expiration date of July 1, 2009.</p> <p>There was a bottle of 1 % Lidocaine HCL opened on July 7, 2009. The label indicated it was a single dose vial.</p> <p>At approximately 12 noon, interview with the DON, he stated that single dose vial medication should be discarded after it ' s use on that day.</p> <p>In the Peritoneal Dialysis Training Room there were 29 boxes of Hectorol with expiration date of March 2009.</p> <p>On July 21, 2009, at approximately 11:30 a.m., RN 1 was observed preparing medications in the nurse station. There were containers of pens and pencils, staplers, office supplies and patients charts. The nurse station was also used by staff to document and review patient charts. On July 22, 2009, at approximately 7:30 a.m., RN 2 was observed preparing medication along side the sink area above the medication storage cabinet across from the nurse station. An interview with the DON, he sated that the designated medication preparation area was the area across from the nurse station and not the nurses station. He further stated to prevent cross contamination during medication preparation was to use the designated medication preparation area at all times.</p> <p>3. On July 22, 2009, at approximately 3;15 p.m., RN 2 was observed to have left syringes,</p>	V 117			

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V 117	Continued From page 6 needles and medications Lidocaine and Heparin by the nurses station unattended. The needles and medications were potentially accessible to the paramedics, patients and other staff members who were at the nurses station at that time.	V 117		
V 122	494.30(a)(4)(ii) PROCEDURES FOR INFECTION CONTROL [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: 11683 Based on observation and interview, the facility failed to ensure that contaminated surfaces, equipment and supplies should be cleaned and disinfected after use. Findings: On July 21 and 22, 2009, at various times 8 a.m., 11:20 a.m. and 2 p.m., the following was observed: The patients ' medical charts were placed on top of the hemodialysis machines while patients receive treatment. The facility staff come to the station and document on the medical record then move to the next chart and so on. At the termination of the treatment the medical records were placed back to the rack without cleaning and/or sanitizing the charts. At the beginning of hemodialysis treatment a wet	V 122		

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V 122	Continued From page 7 disposable cloth was placed on every hemodialysis machine exposed at the initiation of treatment through termination. In an interview with the licensed nurse, she stated that the wet disposable towels were used to cleanse the machine at termination of treatment. A used nasal cannula tubing was found placed in between the pages of the medical record of Resident 3. In an interview with the licensed nurse, it was stated that nasal cannula tubing was single use at the facility. A funnel was exposed and hanging above the thrash can by the cart with jugs of dialysate. There were towels on the floor between two hemodialysis machines during treatment. In an interview with the licensed nurse, it was stated that towels were placed on the floor during priming for unexpected drip an/or leak of intravenous solution.	V 122			
V 187	494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE 8 Environment: schematic diagrams/labels Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction. Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow. If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range. This STANDARD is not met as evidenced by:	V 187			

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V 187	Continued From page 8 Surveyor: 15727 Based on observation, interview and record review, the facility failed to label major water system components to describe its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range. Findings: During an observation tour of the water treatment room on July 21, 2009, at 9:40 a.m., in the reverse osmosis room, a flow chart was posted on the wall. The schematic diagram indicated the major components and arrows to show direction of flow was indicated. The water system showed arrows to show the direction of flow of the water system. However, there was no label to include the function of each component and how performance is verified and what action to take in the event performance is not within the acceptable limit. At the same time during an interview, the technical manager stated he was not aware the function of each component had to be labelled to include how performance is verified and what action to take in the event performance is not within the acceptable limit.	V 187			
V 190	494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE 5.2.4 Softeners: auto regen/timers/salt/salt level Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as "regeneration," which involves exposure of the resin bed to a saturated sodium chloride solution.	V 190			

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V 190	<p>Continued From page 9</p> <p>5.2.4 Softeners Refer to RD62:2001, 4.3.10 Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.</p> <p>The face of the timers used to control the regeneration cycle should be visible to the user.</p> <p>6.2.4 Softeners Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.</p> <p>The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation and interview, the facility failed to monitor the brine tank to ensure that a saturated salt solution exists in the brine tank.</p> <p>Findings: During an observation on July 22, 2009, at 10:05 a.m., the brine tank had the water level above the salt pellets.</p>	V 190			

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V 190	Continued From page 10	V 190		
V 234	<p>At the same time during an interview, the certified hemodialysis technician stated salt pellets had to be added.</p> <p>494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE</p> <p>5.4.4.3 Bicarbonate concentrate mixing systems: not overmixed Overagitating or overmixing of bicarbonate concentrate should be avoided, as this can cause CO2 loss and can increase pH.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation, interview and record review, the facility failed to not overmix the bicarbonate concentrate.</p> <p>Findings:</p> <p>During an observation on July 22, 2009, at 12:00 p.m., a certified hemodialysis technician (CHT) was observed emptying one at a time 1 big bag and 7 small bags of dry powder bicarbonate into the bicarbonate mixing tank filled with water.</p> <p>At the same time during an interview, the CHT stated it would take approximately 15 minutes to mix until the mixture is clear.</p> <p>A review of the facility's policy and procedure on Bicarbonate Mixing revealed mix for a minimum of 5 minutes, then turn off the mixing motor. The rationale was the quality of the mixture will be altered by overmixing and may begin to cause the powder to precipitate out.</p> <p>In reference to ANSI/AAMI RD52: 2004</p>	V 234		

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V 234	Continued From page 11 Requirements as adopted by Reference 42 CFR 494.40 (a) Overagitating or overmixing of bicarbonate concentrate should be avoided, as this can cause carbon dioxide loss and can increase pH.	V 234			
V 243	494.40(a) ANSI/AAMI RD52:2004 AS ADOPTED BY REFERENCE 6.5 Concentrate distribution: bicarb jugs rinsed daily/stored dry Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation, interview and record review, the facility failed to store empty bicarbonate concentrate jugs inverted at the end of each treatment day. Findings: During an observation on July 22, 2009, at 9:58 a.m., two empty bicarbonate jugs were stored horizontally on a rack. When the technician picked up one jug and tilted it over, a moderate amount of water poured out. At the same time during an interview, the technician stated that was how the empty bicarbonate jugs were stored at the end of the treatment day.	V 243			
V 306	494.50(b)(1) AAMI RD47:2002/A1:2003 ADOPTED BY REFERENCE 4.1 Dialyzer reprocessing manual: dialyzer	V 306			

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V 306	Continued From page 12 reprocessing manual The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to include the compilation of all specifications in the facility's reuse manual. Findings: On July 23, 2009, a review of the facility's reuse manual revealed the following: job description, reuse core curriculum, reuse policy and procedure, ECHO MR 1000 operations manual, forms used, QA and environmental safety. During an interview on July 23, 2009, at 8:35 a.m., the technical manager stated he was not aware that a compilation of all specifications should be included in the reuse manual.	V 306			
V 309	494.50(b)(1) AAMI RD47:2002/A1:2003 ADOPTED BY REFERENCE 5.2.2 Documentation: includes med dir certification	V 309			

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V 309	Continued From page 13 Each person performing procedures for the multiple use of dialyzers shall have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training shall be certified by the medical director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee having received the instruction. Retraining is necessary when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to show documentation that the reuse technicians were certified by the medical director. Findings: On July 23, 2009, a review of the employee files revealed 6 certified hemodialysis technicians who were reprocessing dialyzers did not have any record in their personnel files that the medical director had certified each of them on reuse. During an interview, on July 23, 2009, at 8:40 a.m., the technical manager stated he gave the training. He was not aware the medical director had to certify the technicians after the reuse training.	V 309		
V 318	494.50(b)(1) AAMI RD47:2002/A1:2003 ADOPTED BY REFERENCE ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR 494.50 (b)(1)	V 318		

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V 318	<p>Continued From page 14</p> <p>8 Physical plant and environmental safety considerations</p> <p>8.1 Reprocessing area and ventilation</p> <p>The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see [AAMI] 8.5).</p> <p>Table 1-OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated</p> <table border="1"> <thead> <tr> <th>Substance/material</th> <th>Limits (PEL)a</th> </tr> </thead> <tbody> <tr> <td>Acetic acid</td> <td>10 ppm TWAb</td> </tr> <tr> <td>Chlorine dioxide (syn: chlorine oxide)</td> <td>0.1 ppm TWA</td> </tr> <tr> <td>Citric acid</td> <td>None developed</td> </tr> <tr> <td>Formaldehyde</td> <td>0.75 ppm TWA 2 ppm STELc(15 min)</td> </tr> <tr> <td></td> <td>0.5 ppm action level</td> </tr> <tr> <td>Glutaraldehyde</td> <td>0.2 ppm ceiling NIOSH/OSHA</td> </tr> <tr> <td>Hydrogen peroxide</td> <td>1 ppm TWA</td> </tr> <tr> <td>Peracetic acid</td> <td>None developed</td> </tr> <tr> <td>Phenol</td> <td>5 ppm TWA</td> </tr> </tbody> </table> <p>ppm = parts per million a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to;</p>	Substance/material	Limits (PEL)a	Acetic acid	10 ppm TWAb	Chlorine dioxide (syn: chlorine oxide)	0.1 ppm TWA	Citric acid	None developed	Formaldehyde	0.75 ppm TWA 2 ppm STELc(15 min)		0.5 ppm action level	Glutaraldehyde	0.2 ppm ceiling NIOSH/OSHA	Hydrogen peroxide	1 ppm TWA	Peracetic acid	None developed	Phenol	5 ppm TWA	V 318		
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V 318	Continued From page 15 PELs can be TWAs or STELs. b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period. c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to perform the monthly vapor test. Findings: On July 21, 2009, a review of the facility's Maintenance and Testing Schedule for 2008 and 2009, revealed vapor testing was not done for June and July, 2009. At the same time during an interview, the technical manager stated he performed the vapor testing every month. However, he forgot to do the vapor test for the month of June and July, 2009. A review of the facility's policy and procedure on Acetic Acid Air Vapor Test revealed air in the reuse room is tested monthly for acetic acid vapors. A review of the facility's policy and procedure on Hydrogen Peroxide Air Vapor Test revealed air in the reuse room is tested monthly for hydrogen peroxide vapors.	V 318		
V 332	494.50(b)(1) AAMI RD47:2002/A1:2003 ADOPTED BY REFERENCE 11.2 Rinsing/cleaning: precleaning equipment/pressures 11.2.1 When precleaning is done, it is part of the	V 332		

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V 332	<p>Continued From page 16</p> <p>reprocessing procedures. All applicable requirements for design and maintenance of equipment included in this document should be adhered to for precleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation, interview and record review, the facility failed to maintain the water pressure at the rinsing/cleansing sink.</p> <p>Findings:</p> <p>During an observation on July 21, 2009, at 9:10 a.m., in the reuse room the pressure gauge for the water pressure had a reading of 26. The label on the gauge was 18-20.</p> <p>At the same time during an interview, Reuse Technician A stated the 18-20 water pressure was too low and would not pre-clean the dialyzer properly.</p> <p>During an observation on July 23, 2009, at 8:30 a.m., the pressure gauge for the water pressure had a reading of 24.</p> <p>At the same time during an interview, the Technical Manager stated the pressure was too high. He further stated the water pressure should be between 18-20 as indicated on the label.</p> <p>A review of the facility's policy and procedure entitled Reprocessing revealed after the dialyzer has been at the pressure rinse station in the designated of time the reuse tech will open the</p>	V 332			

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V 332	Continued From page 17 headers of the dialyzer and rinse off any residual clots of blood. There was no mention of the pressure the water should be at in the rinse station.	V 332			
V 334	494.50(b)(1) AAMI RD47:2002/A1:2003 ADOPTED BY REFERENCE 11.4.1.2 Dialyzer header cleaning and disinfection The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and O-rings shall be kept with their respective dialyzers. If the header cap is removed to clean the header space, cleaning shall be done with water meeting the requirements of these regulations related to allowable bacterial and endotoxin levels. Once the O-ring and the header cap are cleaned and before they are reassembled at the end of the dialyzer, they should be disinfected. The disinfectant shall not be rinsed and shall be allowed to remain on the dialyzer components as they are reassembled. If any cracking of the header occurs, the process should be evaluated. If the header space is cleaned with the header cap in place, it is necessary to ensure that the end of the fiber bundle is not damaged. If water is used, it shall meet the requirements of these regulations. If automated equipment is used, the manufacturer's instruction for use shall be followed.	V 334			

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V 334	Continued From page 18 This STANDARD is not met as evidenced by: Surveyor: 15727 Based on observation, interview and record review, the facility failed to disinfect the header cap before it was reassembled at the end of the dialyzer. Findings: During an observation on July 22, 2009, at 12:15 p.m., a certified hemodialysis technician was observed in the reuse room with dialyzers rinsing in the cleaning station. At the same time during an interview, the certified hemodialysis technician stated the header caps were removed and blood clots were rinsed off. The header caps were placed back at the end of the dialyzer. She stated the header caps were not disinfected before they were reassembled at the end of the dialyzer. A review of the facility's policy and procedure entitled Reprocessing revealed after the dialyzer has been at the pressure rinse station for the designated length of time, the reuse tech will open the headers of the dialyzer and rinse off any residual blood clots of blood. The header caps are then secured in place and the dialyzer is hooked up one of the stations on the reprocessing machinery where the machine will also put the dialyzer through a cleaning cycle. The facility's policy and procedure entitled Reprocessing did not include disinfecting the headers prior to reassembly at the end of the dialyzers.	V 334			
V 402	494.60(a) PHYSICAL ENVIRONMENT: BUILDING	V 402			

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V 402	Continued From page 19 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: 15727 Based on observation, interview and record review, the facility failed to maintain the building to ensure the safety of the patients, the staff and the public. Findings: During a tour of the facility on July 21, 2009, from 8:55 a.m. - 9:40 a.m., the following was observed: 1. The chairs in the waiting area had stains on the upholstery. 2. The door from the waiting area leading to the treatment area was partially open. The sign on the door read "Keep door closed." 3. In the treatment area, there were water stained ceiling tiles. 4. In the treatment area, there were station chairs with torn upholstery. 5. In the reuse room, the wall vent was dusty. The electric fan was thickly covered with dust. There was a detached section of the sink counter around the base of the faucet. The pedals for the faucet was non-functioning. The sink cabinet cover had a missing section. There were 4 water stained ceiling tiles. Eight floor tiles had missing sections creating an uneven surface. 6. In the hallway outside the reuse room, there was a water stained ceiling tile. 7. In the staff restroom, the ceiling tile was cracked. The base coving behind the toilet bowl	V 402		

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V 402	Continued From page 20 was missing. The ceiling vent was thickly covered. 8. In the janitorial closet, 5 gallon bottled water were stored on the floor. 9. In the supply room, there was a bulging water stained ceiling tile above the 2K tank. The section of the wall next to the 2K tank was damaged. The exit door had a missing section of the metal strip at the bottom of the door creating a gap. This was a possible entry point for rats and insects. 10. In the RO room, the cement floor had an uneven surface. There was a hole in the ceiling tile. The base coving behind the RO water system was detached approximately 4 feet long. The wall behind the carbon tanks was damaged. During an interview on July 21, 2009, at 9:15 a.m., the Technical Manager stated there was a leak in the roof and they would ask the owner of the building if repairs had been done so they could change the waterstained ceiling tiles. A review of the facility's policy and procedure on The Physical Plant revealed the areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.	V 402		
V 407	494.60(c)(4) PATIENT CARE ENVIRONMENT 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: 11683	V 407		

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V 407	Continued From page 21 Based on observation and interview, the facility staff failed to ensure the patients access sites was visible during hemodialysis treatment. Findings: On July 21, 2009, at approximately 9:05 a.m., during the tour of the treatment area, patients ' access sites were not visible in stations 4 and 8. On July 22, 2009, at approximately 7:30 a.m., it was observed that patients ' access site was not visible in stations 2 and 8. At 11:50 a.m. observation round, it was noted that the patients ' access site were not visible in station 6 and 10. The facility staff members were passing by the patients without reminding the patients about their access sites not being visible while receiving treatment. On July 22, 2009, at approximately 12 noon, during an interview with the DON, he stated that access sites should be visible during treatment.	V 407			
V 413	494.60(d)(3) EMERGENCY PREPAREDNESS 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: 11683 Based on observation, interview and record review, the facility staff failed to ensure that emergency equipment such as emergency cart, portable oxygen tank and emergency drugs were	V 413			

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V 413	Continued From page 22 secure, functional and readily available for use. Findings: On July 21, 2009, at approximately 11 a.m., during the medication storage observation, the following were noted: The emergency cart contained emergency medications and supplies had a broken, red, plastic lock. The emergency cart had a vial of 1:1000 Epinephrine with expiration date of July 1, 2009 and 3 packets of Life Patch for the defibrillator with expiration date of June 2009. The emergency cart had list of missing medications such as 2 bottles of 50 mg Protamine Sulfate, 2 bottles of 500 mg Solu-Cortef and 2 bottles of 100mg/2ml of Phenytoin (Dilantin). The emergency cart contained listed and unlisted extra medications such as Epinephrine, Narcan, Calcium Chloride, Diazepam, Solu-Cortef, Phenytoin Inj., Protamine Sulfate Inj. And normal saline. The Emergency Evacuation Kit had a missing bottle of 50 ml 50% Dextrose and extra bottles of 1000 units and 5,000 units of Heparin. The portable oxygen tank by the emergency cart did not have the gauge, tubing and other attachments available for immediate use.	V 413			
V 503	494.80(a)(2) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] (2) Evaluation of the appropriateness of the dialysis prescription,	V 503			

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V 503	Continued From page 23 This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview and record review, the facility staff failed to obtain a physician 's order for electrolyte composition of the dialysate for Patient 1. Also failed to follow physician 's order for blood /dialysate flow rates for Patients 1 and 3. Findings: 1. On July 21, 2009, at approximately 9 a.m., Patient 1 was observed receiving hemodialysis treatment via right subclavian catheter. The patient was dialyzing on a 2 Potassium (K) and a 2.5 calcium bath. The blood flow rate (BFR) was 400 and dialyzate flow rate (DFR) was 800. A review of the clinical record revealed that there was no physician 's order for electrolyte composition of the dialysate. On July 22, 2009, at approximately 1:50 p.m., during an interview with the DON, while reviewing the clinical record, it was noted that on a physician order dated June 30, 2009, an order for 2 K and 2.5 Ca bath was added to the existing physician 's order. (after presenting a copy of the physician order made the day before). A review of the daily treatment record dated July 2, 2009 through July 18, 2009, revealed that the BFR ranged from 200 to 400 and the DFR was 800. A review of the physician 's order dated January 2, 2009, indicated a DFR of 350 and DFR 750. 2. According to the clinical record, Patient 3 was	V 503			

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V 503	Continued From page 24 admitted to the facility on November 12, 2002, with diagnosis of chronic glomerulonephritis. The hemodialysis order dated Janaury 1, 2009, indicated a dialysate flow rate (DFR) of 500-800 and blood flow rate (BFR) of 350-450. Review of daily treatment record dated July 10 through 20, 2009, documented BFR was between 200 to 300. An interview with the Director of Nursing on July 23, 2009, at 11 a.m., while reviewing the clinical record, indicated that the physician's order for the BFR should have been followed.	V 503		
V 504	494.80(a)(2) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] Blood pressure, and fluid management needs. This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to monitor the blood pressure of Patient 3. Findings: A review of the treatment record dated July 7, 9 and 11, 2009 revealed Patient 3's blood pressure was elevated after treatment. The patient was discharged after each treatment. There was no nursing documentation of the elevated blood pressure. There was no care plan developed for elevated blood pressure.	V 504		

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V 504	Continued From page 25 During an interview on July 22, 2009, at 9:07 a.m., the director of nursing stated there should have been nursing documentation regarding the elevated blood pressure of Patient 3 after each treatment.	V 504			
V 507	494.80(a)(4) ASSESSMENT CRITERIA [The patient's comprehensive assessment must include, but is not limited to, the following:] (4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s). This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility staff failed to ensure that an evaluation of Patient 1 and 3 ' s iron therapy (Venofer) was administered as ordered by the physician. Findings; 1. Patient 1 was admitted to the facility on January 15, 2009, with diagnosis of obstructive uropathy. A review of the monthly laboratory test results revealed that on May 26, 2009, the transferrin saturation (iron in the blood) was 15 % and for June 2009 was 17 %. The parameter should be greater than 20%. On May 30, 2009, the physician ordered Venofer 100 mg every treatment 5 doses. A review of the daily treatment record revealed that Venofer was not administered to the patient on June 9 and 11,	V 507			

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V 507	Continued From page 26 2009 and July 9 and 21, 2009. On July 22, 2009, at approximately 1:50 p.m., interview with the DON, he stated that Venofer should have been given to the patient on those treatment days. 3. Patient 3 was admitted to the facility on November 12, 2002, with diagnosis of glomerunephritis. A review of the monthly laboratory test results revealed that on May 25, 2009, the transferrin saturation was 14% and for the month of June 2009 was 13%. The parameter was greater that 20%. On June 29, 2009, the physician order Venofer 100 mg IV times 10 doses for transferrin saturation of 13%. Review of the daily treatment record revealed than July 8, 16 and 20, 2009, revealed that Venofer was not documented as being given on those tratment days. 2. Patient 3 was admitted to the facility on November 12, 2002, with diagnosis of chronic glomerulonephritis. A review of the monthly laboratory test results revealed transferrin saturation for June 2009 was 13% and for May 2009 was 14%. The parameter should be greater than 20% On July 1, 2009, the physician ordered Venofer 100 mg every treatment for 10 times. The daily treatment record revealed that on July 8, 16 and 20, 2009, Venofer was not administered as ordered.	V 507			
V 541	494.90 PATIENT PLAN OF CARE The interdisciplinary team as defined at \$494.80 must develop and implement a written,	V 541			

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V 541	<p>Continued From page 27</p> <p>individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to develop a comprehensive plan of care for Patient 1 and 3 and no coordinated care plan with the skilled nursing home for Patient 1 and 2.</p> <p>Findings:</p> <p>A review of the 3 patient medical records revealed there was no comprehensive care plans developed for Patient 1 and 3 and no coordinated care plan with the skilled nursing home for Patient 1 and 2. Patient 1 was admitted to the facility on August 6, 2008. Patient 2 was admitted to the facility on August 27, 2007. Patient 3 was admitted to the facility on November 13, 2008.</p> <p>During an interview on July 22, 2009, at 9:07 a.m., the director of nursing stated a care plan should have been developed.</p> <p>A review of the facility's policy and procedure on Patient Care Plans and Life Plan revealed there is a written patient care plan for each patient of the</p>	V 541			

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V 541	Continued From page 28 facility.	V 541			
V 542	<p>494.90(a) DEVELOPMENT OF PATIENT PLAN OF CARE</p> <p>The interdisciplinary team must develop a plan of care for each patient.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the interdisciplinary team failed to develop and implement a written, individualized comprehensive plan of care that addressed the patient ' s needs based on comprehensive assessment for Patients 1 and 3.</p> <p>Findings:</p> <p>On July 22, 2009, during record review of patients' medical record revealed the following:</p> <p>1. Patient 1 was admitted to the facility on January 6, 2008, with diagnosis of obstructive uropathy. An interdisciplinary care plan was developed at the time of admission. However, for the year 2009, there was no documented evidence to indicate that the interdisciplinary team develop a care to address the patient's current needs.</p> <p>An interview with the DON, while reviewing the clinical record, he concurred that for the current year 2009, there was no interdisciplinary care plan developed to address the needs of the patient.</p> <p>2. Patient 2 was admitted to the facility on November 12, 2002, with diagnosis of chronic glomerulonephritis. The clinical record revealed a</p>	V 542			

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V 542	Continued From page 29 multidisciplinary care plan dated June 23, 2008. The multidisciplinary care plan failed to show written documentation that the nursing and the patient was involved.	V 542		
V 550	494.90(a)(5) DEVELOPMENT OF PATIENT PLAN OF CARE The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility staff failed to ensure that Patient 3 was evaluated for the appropriate vascular access type,taking into considerations, other risks factors, and whether the patient is a potential candidate for arteriovenous fistula placement. For Patient 3 the facility failed to document an action plan for a more permanent vascular access. Findings: Patient 3 was admitted to the facility on November 12, 2002, with diagnosis of glomerulonephritis. The dialysis treatment kardex for the year 2009 documented that since December 22, 2008, the patient had right subclavian catheter. The multidisciplinary care	V 550		

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V 550	Continued From page 30 plan dated June 23, 2008, did not have written documentation to indicate that the current catheter access was address and an action plan for a permanent vascular access. An interview with the Director of Nursing on July 23, 2009, at 11 a.m., while reviewing the clinical record indicated that there was no written evidence to indicate the patient had been not evaluated for a placement of a more permanent vascular access.	V 550			
V 551	494.90(a)(5) DEVELOPMENT OF PATIENT PLAN OF CARE The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on observation, interview and record review, the facility failed to ensure that patient ' s vascular access was monitored to prevent access failure for Patients 1 Findings: On July 21, 2009, at approximately 9 a.m. Patient 1 was observed receiving hemodialysis treatment via right subclavian catheter. A review of the daily treatment record dated July 2 through 17, 2009, revealed that it was not	V 551			

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V 551	Continued From page 31 consistently documented that the access site was assessed. Interview with the licensed nurse, she stated that the section under access site should not be left blank.	V 551			
V 586	494.100(b)(1) HOME DIALYSIS MONITORING The dialysis facility must - (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training; This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the dialysis facility failed to show written documentation in the medical record that the patient, the caregiver or both received and demonstrated adequate comprehension of the training for Patient 2. Findings: On July 23, 2009, at 7:30 a.m., a review of Patient 2's clinical record failed to show written documentation the facility had provided CAPD/CCPD Home Training to the patient, the caregiver or both. Also there was no written evidence to show that patient/caregiver had demonstrated competence in performing the home dialysis procedures and techniques for every aspect of the peritoneal dialysis. At 11 a.m., during an interview with the Director of Nursing, while reviewing the clinical record concurred that the written evidences of training provided and assessment of patient/caregiver competence were not found.	V 586			
V 589	494.100(c)(1)(i) SUPPORT SERVICES	V 589			

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V 589	Continued From page 32 Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care. This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility failed to show written documentation in the clinical record that an initial homevisit was conducted to monitor patient's home adaptation prior to initiation of treatment for Patient 2. Findings: Patient 2 was admitted to the facility on March 8, 2008, with diagnosis with chronic renal failure, diabetes mellitus and hypertension. Further review of the clinical record failed to show written documentation that a home visit was conducted. On July 23, 2009, at approximately 8 a.m., interview with the Director of Nursing, he stated that a homevisit was conducted to all patients prior to initiation of peritoneal dialysis treatment modality at home. The DON reviewed the clinical record and concluded that he could not find any written evidence to indicate that a homevisit was conducted.	V 589			
V 599	494.100(c)(2) SUPPORT SERVICES The dialysis facility must maintain a recordkeeping system that ensures continuity of	V 599			

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V 599	<p>Continued From page 33</p> <p>care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in §414.330(a)(2) of this chapter.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility failed to ensure the staff maintained a recordkeeping system that would ensure continuity of care for the in home hemodialysis Patient 2.</p> <p>FindingsL</p> <p>A review of Patient 2's clinical record revealed that the patient was on continuous ambulatory peritoneal (CAPD) . On March 16, 2009, the physician orders three (3) exchanges per day, four (4) hours dwell time, 2000 cc of fill volume and three (3) of 2.5% strength of Baxter Dianeal PD2 solution.</p> <p>Further review of the clinical record revealed that there was no home records for the months of January 2009, March 2009 and June 2009. The home records for the months of February 2009, April 2009 and May 2009 were not consistently filled out with the following vital information such as temperature, blood pressure, weight, blood sugar reading and amount of insulin administered, dextrose concentrate, volume exchanges and medications administered. Further review of the monthly visit notes from January 2009 through June 2009, there was no documented evidence to indicate that the PD</p>	V 599			

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V 599	Continued From page 34	V 599			
V 626	<p>nurse discussed with the patient regarding the home record being incomplete in viatl information.</p> <p>494.110 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT</p> <p>The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.</p> <p>This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and interview, the facility failed to maintain and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The facility failed to demonstrate evidence of the quality improvement and performance improvement program for CMS review.</p> <p>Findings:</p> <p>On July 22, 2009, at 8 a.m., during an interview with the clinical manager, it was indicated that the governing body meeting was utilized as the Quality Assurance meeting for the facility.</p>	V 626			

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V 626	Continued From page 35 The QA committee was composed of medical director, chief executive officer, administrator, director of nursing/clinical manager and maintance/engineering. The committe was to meet every quarterly. The QA agenda consisted of clinical issues such as outcome indicator for hemodialysis , peritoneal dialysis, infection control, immunization, and vascular access; hospital review which included number aof hospitalizations related and non-related to dialysis;; facility technical support which included machine culture, equipment inspection, re-sue, safety check; staff issues which included inservices and education, concerns; census/mortality, satisfaction survey and medical record audit. A review of the QA minutes revealed that the facility did not have aQA meeting for the 3rd quarter (July, August and September 2008) and 4th quarter (October, November and December 2008). For the year 2009, the facility had one QA meeting on April 21, 2009, however, the written minutes and the sign sheet was not available for review.	V 626			
V 681	494.140 PERSONNEL QUALIFICATIONS All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.	V 681			

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V 681	Continued From page 36 This STANDARD is not met as evidenced by: Surveyor: 11683 Based on record review and staff interview, the facility failed to ensure that the dialysis staff met the personnel qualifications and demonstrated competencies necessary to meet the comprehensive needs of the patients. Findings: On July 22, 2009, at approximately 2:45 p.m., three (3) personnel files of dialysis staff members were reviewed and revealed the following: Registered Nurse (RN) 1 was hired on November 20, 2007, as a hemodialysis staff nurse. The personnel file did not have written evidence to indicate that an orientation, competency evaluation and infection control training prior to employee started work. RN 2 was hired on December 3, 2008, as hemodialysis staff nurse. The personnel file did not have written evidence to indicate that an orientation and competency evaluation prior to employee started work. At approximately 10 a.m., interview with the Director of Nurses (DON), he stated that orientation and competency evaluation were required of the staff members prior to start working. A review of the Human Resources Requirements to be done prior to start of work listed orientation and skills inventory checklist (competency evaluation).	V 681			
V 727	494.170(a) PROTECTION OF THE PATIENT'S RECORD	V 727			

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V 727	Continued From page 37 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) 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: 11683 Based on observation and interview, the facility failed to ensure that patient ' s records were safe from unauthorized access at all times. Findings: On July 21, 2009, at approximately 9:30 a.m. during the initial tour of the facility, it was observed that a bunch of papers containing patients' name, date of birth, diagnosis and account numbers were left on top of the bio hazard refrigerator. The bio hazard refrigerator was located in the hallway which was accessible to other patients, staff and visitors. At approximately 11 a.m., interview with the DON, he acknowledged that patients ' information should be protected from unauthorized access from others.	V 727		
V 753	494.180(a)(1) DESIGNATING A CEO OR ADMINISTRATOR	V 753		

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052699	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 07/23/2009
NAME OF PROVIDER OR SUPPLIER HIGH DESERT DIALYSIS INC			STREET ADDRESS, CITY, STATE, ZIP CODE 1007 WEST AVE M-14 #B PALMDALE, CA 93551	
(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 753	<p>Continued From page 38</p> <p>The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to-</p> <p>(1) Staff appointments;</p> <p>This STANDARD is not met as evidenced by: Surveyor: 15727 Based on interview and record review, the facility failed to include in the medical staff by-laws the appointment/reappointment for non-physician practitioners.</p> <p>Findings:</p> <p>A review of the physician files revealed the facility had one non-physician on staff. There was no documentation in the employee's file of the appointment to the medical staff.</p> <p>A review of the medical staff by-laws revealed no provision for appointment/re-appointment for non-physician practitioners.</p> <p>During an interview on July 23, 2009, at 11a.m., the director of nursing stated he was not aware there was no provision in the medical staff by-laws for non-physician practitioners.</p>	V 753		