

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

PRINTED: 05/26/2011  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>552623</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED  <b>02/03/2011</b>
NAME OF PROVIDER OR SUPPLIER  <b>PEGASUS DIALYSIS, LLC</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>3101 PEGASUS DRIVE SUITE 100 BAKERSFIELD, CA 93308</b>		
(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  The following reflects the findings by the California Department of Public Health during a Recertification survey.  Representing the Department:  26215, HFES 25558, HFES 27011, HFEN  Census:  92 Hemodialysis Patients 8 Peritoneal Dialysis Patients  Sample size:  9 Hemodialysis Patients 1 Peritoneal Dialysis Patients	V 000			
V 110	494.30 CFC-INFECTON CONTROL  This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility did not meet the Conditions for Coverage(CFC) for Infection Control by failing to:  1. Provide a sanitary environment in the unit (refer to V111).  2. Demonstrate proper glove and hand hygiene (refer to V113).  3. Wear gowns in patient care area (refer to V115).	V 110		5/18/11	

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 110	Continued From page 1 4. Dispose, dedicate, or disinfect items at dialysis station (refer to V116).  5. Replace bloody transducers during treatment (refer to V120).  6. Dispose and/or dedicate items used in isolation room (refer to V130).  7. To assign staff person to HBV + patients and immune patients only (refer to V131).  The cumulative effect of these systemic practices had the potential to transmit infectious disease to all 92 hemodialysis patients and to facility staff.	V 110			
V 111	494.30 IC-SANITARY ENVIRONMENT  The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility's staff failed to adhere to standard precautions during patient care which had the potential to transmit diseases between patients, staff, and visitors.  Findings:  1. On entrance to the facility on January 31, 2011 at 8:47 AM, a Certified Hemodialysis Technician (CHT)7 opened the door to the lobby, glanced at the waiting area, and closed the door. CHT 7 had a protective gown, gloves, and mask on at the	V 111		5/18/11	

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V 111	<p>Continued From page 2 time.</p> <p>On January 31, 2011 at 9:26 AM, during an observation of the treatment area, observed CHT 3 touch a dialysis machine that was in use with her bare index finger. At 9:55 AM, CHT 7 touched a machine with his bare hands. At 9:53 AM, Registered Nurse (RN) 2 was seen touching a dialysis machine with her bare hands. At 10:10 AM, observed Senior Certified Hemodialysis Technician (SCHAT) 1 touch the dialysis machine, touch the patient, and clinical records with the same pair of gloves.</p> <p>On January 31, 2011 at 10 AM, CHT 7 changed gloves between patient care but did not perform hand hygiene after removing gloves.</p> <p>On January 31, 2011 at 1 PM, at Station 17, CHT 7 discharged a patient (Patient 4) from dialysis and accompanied the patient to obtain a post dialysis weight. CHT 7 returned with another patient to Station 17 and proceeded to dialysis treatment. CHT 7 did not clean the recliner.</p> <p>On January 31, 2011 at 4 PM, Charge Nurse (CN) and SCHAT 1 were observed in the treatment area providing care to multiple patients. They both had protective gowns on but left them unbuttoned. Unbuttoned protective gowns could not prevent clothing from being soiled during a blood splattering incident.</p> <p>On February 2, 2011 at 3:15 PM, during an interview, the above findings were related to the Clinical Coordinator (CC) and CN. No further information was provided.</p>	V 111			

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V 111	<p>Continued From page 3</p> <p>3. During an observation on January 31, 2011 at 9:10 AM, SCHAT 1 was observed wearing gloves while accessing a patient's vascular site at station 8. After the treatment had started, she removed her gloves, washed her hands and returned to the hemodialysis machine in use and pushed a button on the front of the machine with her ungloved hands.</p> <p>During an observation on January 31, 2011 at 9:15 AM, CHT 3 was observed pressing a button on the front of the hemodialysis machine in use at station 13 without gloves.</p> <p>During an observation on January 31, 2011 at 10 AM, CHT 3 was wearing gloves and touched a button on the front of the hemodialysis machine in use at station 10. Then CHT 3 opened the clipboard on top of the machine and wrote in the clipboard while wearing the contaminated gloves.</p> <p>During an observation of the hemodialysis treatment area on January 31, 2011 at 12:22 PM, the patient at station number 19 was observed wearing a glove on his right hand and holding pressure to the dialysis access on his left upper arm to prevent bleeding. SCHAT 1 was wiping the machine. The patient told SCHAT 1 he needed to go to the restroom. He walked to the patient restroom and with his gloved hand, opened the restroom door. At 12:29 PM, the patient exited the restroom without his glove.</p> <p>During a record review on February 1, 2011 at 4:30 PM, the policy titled "Infection Control" adopted July 2008 indicated "Gloves are removed and hands are washed with germicidal soap after each patient contact." The policy titled</p>	V 111			

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V 111	<p>Continued From page 4</p> <p>"Bloodborne Pathogens Exposure Control Plan" revised June 2010 indicated "Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, or other potentially infectious materials, mucous membranes, and non-intact skin, as when performing vascular access procedures, and when handling or touching contaminated items or surfaces."</p> <p>The facility policy titled "Infection Control" adopted July 2008 indicated "Personal Protective Equipment (PPE) gown (which fully covers the arms and torso from the neck area to the thigh/knee area), gloves, shield and shoe covers are worn at all times in the patient care areas and anytime a procedure is being performed that could expose the employee to the patients blood. MD, NP (Nurse Practitioner), Social Services and Dietary must wear a gown or laboratory coat, if they are providing service to a patient during high risk for spurting or spattering of blood."</p> <p>During an interview on February 2, 2011 at 2:50 PM, the CN acknowledged the staff are expected to wash their hands between patients and change gloves between patients. The CC stated he was not able to monitor staff frequently because of his additional duties. The CC stated staff knew to wear gloves when touching the hemodialysis machines in use. During this same time, the CC stated the physicians were expected to wash their hands after touching the patients or the hemodialysis machine. CC acknowledged Doctor 1 was in the unit without a gown, did not use gloves or use proper hand hygiene on January 31.</p> <p>The Center for Disease Control (CDC) "Infection</p>	V 111			

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V 111	<p>Continued From page 5</p> <p>Control Practices for Hemodialysis Units" (MMWR (MORBIDITY AND MORTALITY WEEKLY REPORT), Vol. 50/N0. RR-5), pages 19 to 22, recommended: "During the process of hemodialysis, exposure to blood and potentially contaminated items can be routinely anticipated; thus, gloves are required whenever caring for a patient or touching the patient's equipment ...Hands always should be washed after gloves are removed and between patient contacts, as well as after touching blood, body fluids..." In the same report, the CDC also recommended to "Clean and disinfect the dialysis station (e.g., chairs, beds, tables, machines) between patients." In addition, the report indicated one of the infection control precautions included: "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."</p> <p>2. During an observation of the treatment area on January 31, 2011 at 9:15 AM, Doctor 1 was talking with the patient at station three while the patient was undergoing dialysis. Doctor 1 was observed, without gloves, touching his ear and hair, the patient, removing the clip board from the top of the dialysis machine, and then replacing it back on top of the dialysis machine. Then without washing his hands, he went over to the patient at station 19 who was receiving dialysis and began touching the patient's arms and hands.</p> <p>During an observation of the treatment area on January 31, 2011 at at 9:25 AM, CHT 4 was observed removing her gloves after providing</p>	V 111			

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V 111	Continued From page 6 care to the patient at station three and putting on gloves just before giving care to the patient at station 17, without washing her hands or using hand sanitizer.  During an observation of the treatment area on January 31, 2011 at at 12:52 PM, SCHAT 1 was observed taking a culture sample (a procedure using cotton swabs to remove drainage from a potentially infected area that is then sent to a laboratory to identify bacteria growth) from Patient 12's catheter access site. SCHAT 1 changed her gloves without washing her hands or using hand sanitizer. SCHAT 1 removed Patient 12's clip board from the top of the dialysis machine, removed a pen from her uniform shirt pocket, wrote on a paper inside the clip board, and placed the clip board back on top of the dialysis machine.  During an observation of the treatment area on January 31, 2011 at 3:10 PM, two visitors were observed at station fourteen not wearing Personal Protective Equipment (PPE) during the patient's dialysis treatment. At 4:01 PM the CN, who had been giving patient care to Patient 6 in the isolation room, sat within one foot of both visitors while she asked questions.	V 111			
V 113	494.30(a)(1) IC-WEAR GLOVES/HAND HYGIENE  Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.	V 113		5/18/11	

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V 113	<p>Continued From page 7</p> <p>This STANDARD is not met as evidenced by:</p> <p>3. On January 31, 2011 at 9:55 AM, during an observation of patient treatment area, noticed the staff were using a hand sanitizer product "Clario" to perform hand hygiene between changes of gloves. The label of the "Clario" bottle read, "Alcohol free hand sanitizer."</p> <p>On February 1, 2011, during an interview, the Biomed Technician (BMT) stated he was the person who ordered supplies for the dialysis center and was instructed to order "Clario" as hand sanitizer.</p> <p>Based on CDC's recommendation, the chemical agent used in the "Clario" is not effective to kill fungi (yeasts or molds) and some bacteria. Therefore, "Clario" is not as effective as alcohol based hand sanitizers. CDC recommends hand hygiene products for health care workers: "If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all other clinical situations..." According to the CDC, hand hygiene is necessary after removing gloves because the possibility of the defects in gloves may contaminate hands during glove removal.</p> <p>On February 2, 2011 at 3:15 PM, during an interview, both the CC and infection control nurse (CN) stated they were not aware of the limited use of such product and could not recall the length of time the center had been using this product.</p> <p>Based on observation, interview, and record review, the facility staff failed to:</p>	V 113			

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V 113	<p>Continued From page 8</p> <ol style="list-style-type: none"> <li>Assure patients followed proper use of gloves and appropriate hand hygiene in the hemodialysis treatment area.</li> <li>Perform proper hand hygiene during patient care which had the potential to spread infectious disease to a universe of 92 hemodialysis patients.</li> <li>Use an approved hand sanitizer (a chemical used to apply on hands to destroy bacteria) to perform hand hygiene as recommended by the Center for Disease Control (CDC) which had the potential to spread infectious diseases to other patients, visitors, and staff.</li> </ol> <p>Findings:</p> <ol style="list-style-type: none"> <li>During an observation of the hemodialysis treatment area on January 31, 2011 at 12:22 PM, the patient at station number 19 was observed wearing a glove on his right hand and holding pressure to the dialysis access on his left upper arm to prevent bleeding. Senior Certified Hemodialysis Technician (SCHT) 1 was wiping the machine. The patient told SCHT 1 he needed to go to the restroom. He walked to the patient restroom and with his gloved hand, opened the restroom door. At 12:29 PM, the patient exited the restroom without his glove.</li> <li>During an observation on January 31, 2011 at 9:10 AM, SCHT 1 was observed wearing gloves while accessing a patient's vascular site at station 8. After the treatment had started, she removed her gloves, washed her hands and returned to the hemodialysis machine in use and pushed a button on the front of the machine with her ungloved hands.</li> </ol>	V 113			

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V 113	Continued From page 9  During an observation on January 31, 2011 at 9:15 AM, Certified Hemodialysis Technician (CHT) 3 was observed pressing a button on the front of the hemodialysis machine in use at station 13 without gloves.  During an observation on January 31, 2011 at 10 AM, CHT 3 was wearing gloves and touched a button on the front of the hemodialysis machine in use at station 10. Then CHT 3 opened the clipboard on top of the machine and wrote in the clipboard while wearing the contaminated gloves.  During a record review on February 1, 2011 at 4:30 PM, the policy titled "Infection Control" adopted July 2008 indicated "Gloves are removed and hands are washed with germicidal soap after each patient contact." The policy titled "Bloodborne Pathogens Exposure Control Plan" revised June 2010 indicated "Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, or other potentially infectious materials, mucous membranes, and non-intact skin, as when performing vascular access procedures, and when handling or touching contaminated items or surfaces."  During an interview on February 2, 2011 at 2:50 PM, the Charge Nurse (CN) acknowledged the staff are expected to wash their hands between patients and change gloves between patients. The Clinical Coordinator (CC) stated he was not able to monitor staff frequently because of his additional duties. CC stated staff knew to wear gloves when touching the hemodialysis machines in use.	V 113			

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V 113	Continued From page 10  During an observation of the treatment area on January 31, 2011 at 9:15 AM, Doctor 1 was talking with the patient at station 3 while the patient was undergoing dialysis. Doctor 1 was observed, without gloves, touching his ear and hair, the patient, removing the clip board from the top of the dialysis machine, and then replacing it back on top of the dialysis machine. Then without washing his hands, he went over to the patient at station 19 who was receiving dialysis and began touching the patient's arms and hands.  During an observation of the treatment area on January 31, 2011 at at 9:25 AM, CHT 4 was observed removing her gloves after providing care to the patient at station 3 and putting on gloves just before giving care to the patient at station 17, without washing her hands or using hand sanitizer.  During an observation of the treatment area on January 31, 2011 at at 12:52 PM, SCHAT 1 was observed taking a culture sample (a procedure using cotton swabs to remove drainage from a potentially infected area that is then sent to a laboratory to identify bacteria growth) from Patient 12's catheter access site. SCHAT 1 changed her gloves without washing her hands or using hand sanitizer. SCHAT 1 removed Patient 12's clip board from the top of the dialysis machine, removed a pen from her uniform shirt pocket, wrote on a paper inside the clip board, and placed the clip board back on top of the dialysis machine.	V 113			
V 115	494.30(a)(1)(i) IC-GOWNS, SHIELDS/MASKS-NO STAFF EAT/DRINK	V 115		5/18/11	

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V 115	<p>Continued From page 11</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: 2. During a record review on February 1, 2011 at 4:30 PM, the facility policy titled "Infection Control" adopted July 2008 indicated "Personal Protective Equipment (PPE) gown (which fully covers the arms and torso from the neck area to the thigh/knee area), gloves, shield and shoe covers are worn at all times in the patient care areas and anytime a procedure is being performed that could expose the employee to the patients blood. MD, NP (Nurse Practitioner), Social Services and Dietary must wear a gown or laboratory coat, if they are providing service to a patient during high risk for spurting or spattering of blood."</p> <p>During an interview on February 2, 2011 at 2:50 PM, the Clinical Coordinator (CC) stated the physicians were expected to wash hands after touching the patients or the hemodialysis machine. The CC acknowledged Doctor 1 was in the unit with a gown or using proper hand hygiene on January 31.</p> <p>Based on observation, interview, and record review, the facility failed to ensure a physician and visitors wore a cover garment while in the</p>	V 115			

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V 115	Continued From page 12 hemodialysis treatment area which had the potential to expose the physician and visitors to blood spatter.  Findings:  1. During an observation of the treatment area on January 31, 2011 at 9:15 AM, Doctor 1 was talking with the patient at station three while the patient was undergoing dialysis. Doctor 1 was observed, without gloves, touching his ear and hair, the patient, removing the clip board from the top of the dialysis machine, and then replacing it back on top of the dialysis machine. Then without washing his hands, he went over to the patient at station 19 who was receiving dialysis and began touching the patient's arms and hands.  During an observation of the treatment area on January 31, 2011 at 9 AM, visitors were observed at station thirteen and nineteen not wearing personal protective equipment during the patient's dialysis treatment. Each visitor was sitting within one foot of the patient.  During an observation of the treatment area on January 31, 2011 at 3:10 PM, two visitors were observed at station fourteen not wearing Personal Protective Equipment (PPE) during the patient's dialysis treatment. At 4:01 PM the Charge Nurse (CN), who had been giving patient care to Patient 6 in the isolation room, sat within 1 foot of both visitors while she asked questions.	V 115			
V 116	494.30(a)(1)(i) IC-IF TO STATION=DISP/DEDICATE OR DISINFECT  Items taken into the dialysis station should either	V 116		5/18/11	

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V 116	<p>Continued From page 13</p> <p>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.</p> <p>-- 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.</p> <p>-- 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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to disinfect contaminated items used during hemodialysis which had the potential to spread infectious diseases to a universe of 92 patients.</p> <p>Findings:</p> <p>During an observation on January 31, 2011 at 12:22 PM, Senior Certified Hemodialysis Technician (SCHT) 1 placed the clipboard from the contaminated hemodialysis machine at station 19 onto the recliner while she cleaned the hemodialysis machine. She then removed the clipboard without disinfecting it and returned it to the counter of the nurses' station.</p> <p>During an observation on January 31, 2011 at 4:12 PM, SCHT 1 removed the bloody tubing from hemodialysis machine 19 and returned a blue plastic hemostat (clamp) to the IV pole on</p>	V 116			

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V 116	Continued From page 14 the machine. The hemostat remained there after the machine was wiped down with a bleach rag.  During an observation on February 1, 2011 at 8:55 AM, Certified (CHT) 5 removed the bloody tubing from the hemodialysis machine at station 9 while wearing gloves. She picked up the clipboard with gloved hands and wrote on the paper inside of it. She then carried the clipboard in her gloved hands out of the clinic door and then returned with it several seconds later and placed it on the left side of the nurse's station on the counter. She then removed her gloves.  During a record review on February 1, 2011 at 4:30 PM, the facility policy titled "Disinfecting Fistula Clamps and Hemostats" adopted July 2008 indicated "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." The rationale written for this procedure indicated "These items may have blood on them and must be disinfected before used again or they could potentially spread infection." The facility policy titled "Bloodborne Pathogens Exposure Control Plan" revised June 2010 indicated "All equipment, environmental, and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials."	V 116			
V 120	494.30(a)(1)(i) IC-TRANSDUCER PROTECTORS-NOT WETTED/CHANGED  Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.	V 120		5/18/11	

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V 120	<p>Continued From page 15</p> <p>If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300-600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.</p> <p>Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the dialysis center's staff failed to inspect the external transducer protector (a device provides a protective barrier between dialysis bloodlines and the dialysis machine) when it was wet (wet with blood). Such failure could cause blood contamination to other patients.</p> <p>Findings:</p> <p>On February 2, 2010 at 10:42 AM, while Patient 4 was being dialyzed on station 12, observed the external transducer protector had blood inside the protector. At 10:55 AM, Patient 4 was taken off the machine by Certified Hemodialysis</p>	V 120			

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V 120	Continued From page 16 Technician (CHT) 7. At 11:05 AM, he was discharged. At 11:15 AM, CHT 7 started another patient on dialysis on the station 12. CHT 7 did not inspect station 12 between patients.  On February 3, 2011 at 1:55 PM, during an interview, the Charge Nurse (Registered Nurse 4) stated when the external transducer is wet, it should be changed. At 2:30 PM, the Clinical Coordinator (CC) stated when the transducer is wet, the transducer needed to be replaced and the machine should be checked for possible contamination.  The facility's policy and procedure on "Troubleshooting Blood Circuit Alarms (1)," adopted on July, 2008, was reviewed. It read, "If the transducer protector is soiled replace it..."  According to the Center for Disease Control, external transducer protectors, when wet with blood or fluids, must be changed immediately and the machine be inspected for visible blood or fluids. The purpose of such measure was to prevent blood contamination of the dialysis machines' pressure monitors.	V 120			
V 122	494.30(a)(4)(ii) IC-DISINFECT SURFACES/EQUIP/WRITTEN PROTOCOL  [The facility must demonstrate that it follows standard infection control precautions by implementing- (4) And maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the-] (ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.	V 122		5/18/11	

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V 122	<p>Continued From page 17</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to follow manufacturer's recommendations to clean its glucometer (a device used to check blood sugar levels) which had the potential to spread infectious diseases to its patients.</p> <p>Findings:</p> <p>On February 1, 2011 at 11:50 AM, during a concurrent observation and interview, Certified Hemodialysis Technician (CHT) 6 brought a glucometer the center used to check patients' blood sugar. CHT 6 stated the center had two glucometers, one in the general treatment area and one in the isolation room. When asked how these devices were cleaned between patient uses, she pointed at the tub filled with disposable wipes and stated, "I use the bleach wipe." A label, taped outside the tub, read, "Bleach 1:100."</p> <p>On February 1, 2011 at 2:10 PM, the handbook of the glucometer (Precision Xtra) was reviewed. The manufacturer's recommended: "Healthcare professionals: Acceptable cleaning solutions include 10% Bleach, 70% Alcohol, or 10% Ammonia.</p> <p>On February 2, 2011 at 9:25 AM, during an interview, the Infection Control Nurse stated she used the bleach wipes in the tub to clean the glucometer between patient uses.</p> <p>On February 3, 2011 at 2:15 PM, the above findings were related to the Clinical Coordinator of the dialysis center. No further information was</p>	V 122			

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V 122	Continued From page 18 provided.	V 122			
V 130	<p>494.30(a)(1)(i) IC-HBV-ISOLATION-MACHINES/EQUIP/SUPPLIES</p> <p>Isolation of HBV+ Patients</p> <p>To isolate HBsAg positive patients, ... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to observe isolation precautions when multiple staff entered the isolation room and did not remove contaminated personal protective equipment, i.e., shoe covers.</p> <p>Findings:</p> <p>During an observation on January 31, 2011 at 1:25 PM, the Charge Nurse (CN) was in the isolation room wearing a yellow gown, gloves, mask and shield. Patient 6, who is hepatitis B positive, entered the isolation room, sat in the chair, and CN accessed the patient's dialysis catheter on her chest. After Patient 6's hemodialysis treatment began, CN removed her gloves, washed her hands, and without donning gloves, used a paper towel to move the TV closer to Patient 6, and used the top of her foot to pull the footrest of the chair out. Then CN exited the room, walked to the nurses' station to get gloves, donned the gloves without performing hand hygiene and went to station 19 and readjusted that patient's blood pressure cuff. At 1:35 PM, Senior Certified Hemodialysis Technician (SCHT)</p>	V 130		5/18/11	

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V 130	Continued From page 19 1 was observed in the isolation room with a gown and gloves and shoe covers on. She removed her gloves and gown, washed her hands and exited the room while leaving her shoe covers on and went to station 20 in the unit. At 4:24 PM, Registered Nurse (RN) 2 entered the isolation room, donned gloves, gown and mask and terminated Patient 6's treatment.  During an interview on February 2, 2011 at 2:50 PM, CN acknowledged staff take care of hepatitis B positive patients and other patients on the same shift, but stated staff should only care for patients with immune status. CN stated several patients had not obtained hepatitis B immunity after their vaccinations.	V 130			
V 131	494.30(a)(1)(i) IC-HBV-ISOLATION-STAFFING  Isolation of HBV+ Patients  Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.  This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure Senior Certified Hemodialysis Technician (SCHT) 1 did not provide patient care to patients who were not immune to hepatitis B while she was also taking care of a hepatitis B positive patient (Patient 6), which placed Patient 11 in danger of becoming infected with hepatitis B.  Findings:	V 131		5/18/11	

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V 131	Continued From page 20 During an observation of the dialysis treatment area on January 31, 2011 at 3:20 PM, SCHAT 1 exited the isolation room (station 21) while wearing blue surgical shoe covers after giving patient care to Patient 6. Patient 6 was positive for infectious hepatitis B. At 3:30 PM, SCHAT 1 went to station 6 where Patient 11 was receiving dialysis and with un-gloved hands placed two packages of gauze and two adhesive bandages on the small table connected to his treatment chair. After putting on gloves, she placed her left foot on the dialysis machine's lower ledge, removed an ink pen from her uniform shirt pocket, removed the clip board from the top of the dialysis machine, touched the front of the dialysis machine, wrote on a sheet of paper in the clip board, and placed the clip board back on top of the dialysis machine.  The clinical record for Patient 11 was reviewed on February 1, 2011 at 9 AM. The documents titled "Adult Vaccine Administration Record" and "Consent to Administration of Hepatitis B Vaccine" indicated Patient 11 had refused the hepatitis B vaccine. Patient 11's laboratory report dated January 5, 2011 indicated he was not immune to the hepatitis B virus.	V 131			
V 142	494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P  The facility must- (1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;  This STANDARD is not met as evidenced by: Based on observation and interview, the facility	V 142		5/18/11	

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V 142	<p>Continued From page 21</p> <p>failed to monitor infection control compliance on the hemodialysis unit which exposed patients and staff to infectious disease.</p> <p>Findings:</p> <p>During an observation of the hemodialysis treatment area on January 31, 2011 at 12:22 PM, the patient at station 19 was observed wearing a glove on his right hand and holding pressure to the dialysis access on his left upper arm to prevent bleeding. Senior Certified Hemodialysis Technician (SCHT) 1 was cleaning the hemodialysis machine. The patient told SCHT 1 he needed to go to the restroom. He walked to the patient restroom and with his gloved hand, opened the restroom door. At 12:29 PM, the patient exited the restroom without his glove.</p> <p>During an observation on January 31, 2011 at 9:10 AM, SCHT 1 was observed wearing gloves while accessing a patient's vascular site at station 8. After the treatment started, she removed her gloves, washed her hands and returned to the machine and pushed a button on the front of the machine with her ungloved hands.</p> <p>During an observation on January 31, 2011 at 9:15 AM, Certified Hemodialysis Technician (CHT) 3 was observed pressing a button on the front of the hemodialysis machine in use at station 13 without gloves.</p> <p>During an observation on January 31, 2011 at 10 AM, CHT 3 was wearing gloves and touched a button on the front of the hemodialysis machine in use at station 10. Then CHT 3 opened the clipboard on top of the machine and wrote in the</p>	V 142			

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V 142	Continued From page 22 clipboard while wearing the contaminated gloves.  During an observation on January 31, 2011 at 9:05 AM, Doctor 1 was observed on the unit going from one hemodialysis machine to another. He was observed for several minutes and was seen touching the patients and touching the machines. No personal protective equipment (gloves or gown) was worn by Doctor 1.  During an observation on January 31, 2011 at 1:25 PM, the Charge Nurse (CN) was in the isolation room wearing a yellow gown, gloves, mask and shield. Patient 6 entered the isolation room, sat in the chair, and CN accessed the patient's dialysis catheter on her chest. After Patient 6's hemodialysis treatment began, CN washed her hands, used a paper towel to move the TV closer to Patient 6, and used the top of her foot to pull the footrest of the chair out. Then CN exited the room, walked to the nurses' station to get gloves, donned the gloves without performing hand hygiene and went to station 19 and readjusted that patient's blood pressure cuff. At 1:35 PM, SCHAT 1 was observed in the isolation room with a gown and gloves and shoe covers on. She removed her gloves and gown, washed her hands and exited the room while leaving the shoe covers on and went to station 20 in the unit.  During an interview on February 2, 2011 at 2:50 PM, the Clinical Coordinator (CC) stated he had not performed audits on infection control and monitors compliance "whenever I get a chance, which is not often." The CC stated he was responsible for the peritoneal dialysis program in addition to oversight of the hemodialysis unit.	V 142			
V 143	494.30(b)(2) IC-ASEPTIC TECHNIQUES FOR IV	V 143		5/18/11	

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V 143	<p>Continued From page 23</p> <p>MEDS</p> <p>[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</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, facility staff failed to use aseptic technique when drawing up a syringe with saline to inject into a hemodialysis patient's vascular catheter which had the potential to expose patients to contaminated medications.</p> <p>Findings:</p> <p>During an observation of the hemodialysis treatment area on January 31, 2011 at 9:15 AM, Certified Hemodialysis Technician (CHT) 3 was at station 13. CHT 3 removed the wrapper from an empty sterile syringe and inserted the needle into the port of a liter bag of normal saline hanging from the dialysis machine and withdrew saline from the bag. CHT 3 did not use an alcohol wipe to cleanse the port prior to the insertion of the needle into the port. CHT 3 removed another syringe from its wrapper and repeated this process again without cleansing the port of the saline bag with an alcohol wipe.</p> <p>During an observation of the hemodialysis treatment area on January 31, 2011 at 10:05 AM, CHT 3 was at station 11 and withdrew saline from the liter bag without cleansing the port with an</p>	V 143			

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V 143	Continued From page 24 alcohol wipe first. CHT 3 repeated this process with a second syringe. Several seconds later, Registered Nurse 2 was observed injecting the saline into the patient's catheter seated at station 11.  During a record review on February 1, 2011 at 4:30 PM, the facility policy titled "Discontinuing Dialysis for Patients with Central Venous Catheter" revised January 2009 indicated "Strict aseptic technique will be used at all times."  The Centers for Disease Control and Prevention indicated in the Medication Preparation Questions dated December 10, 2010 "Parenteral (injectable) medications should be accessed in an aseptic manner. If a medication vial has already been opened, the rubber septum should be disinfected with alcohol prior to piercing it."  During an interview on February 2, 2011 at 2:50 PM, the Clinical Coordinator and Charge Nurse were notified of the above findings but did not offer additional information.	V 143			
V 253	494.40(a) MICROB MONITOR-MO DIALYS SAMPLE/COLLECT/FREQ  7.2 Microbial monitoring methods: 7.2.1 General: Dialysate: monthly dialysate sample/collection/freq Culture ...dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.  Dialysate samples should be collected from at least two machines monthly and from enough	V 253		5/18/11	

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V 253	<p>Continued From page 25</p> <p>machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1.</p> <p>7.2.2 Sample collection Dialysate samples should be collected from a dialysate port of the dialyzer ... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to perform endotoxin (poisonous substances produced by living bacteria) testing on its dialysis machines which had the potential to cause microbial (related to germ)contamination.</p> <p>Findings:</p> <p>On February 1, 2011 at 4 PM, the culture schedule of dialysis machines for 2010 was reviewed. The facility did tests on bacterial colony count but did not test any of its machines for the endotoxin level.</p> <p>On February 2, 2011 at 10:15 AM, during an interview, the Biomed Technician (BMT) stated</p>	V 253			

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V 253	Continued From page 26	V 253			
V 519	<p>he was not aware that both colony count and endotoxin tests were required.</p> <p>494.80(d)(1) PA-FREQUENCY REASSESSMENT-STABLE 1X/YR</p> <p>In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted-</p> <p>(1) At least annually for stable patients;</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to complete an annual care plan for Patient 2, which had the potential for adverse outcomes.</p> <p>Findings:</p> <p>During an interview with the Clinical Coordinator (CC), the clinical records for Patient 2 was reviewed on February 3, 2011 at 12:57 PM. At this time, Patient 2's plan of care was reviewed with the CC. He verified Patient 2's plan of care, which was due for the yearly update in November 2010, had not been completed except by the Dietitian.</p> <p>The facility policy and procedure titled, "Comprehensive Interdisciplinary Patient Assessment Tool" revised October 2008, read "Members of the dialysis unit health care team shall consist of the Medical Director or attending physician, the dialysis social worker, the renal dietitian, and a qualified dialysis nurse and</p>	V 519		5/18/11	

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V 519	Continued From page 27 patient. The team care planning conference will be held on all new patients within the first 45 days of admission to the facility. Otherwise, if their physician deems the patient unstable monthly and no less than yearly on patients defined as stable."	V 519			
V 559	494.90(b)(3) POC-OUTCOME NOT ACHIEVED-ADJUST POC  If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must- (i) Adjust the plan of care to reflect the patient's current condition; (ii) Document in the record the reasons why the patient was unable to achieve the goals; and (iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to care plan Patient 2's non-compliance with completing home peritoneal self-monitoring data sheets and returning the sheets to the facility for review, which had the potential for adverse treatment outcomes.  Findings:  During a concurrent interview and clinical record review with the Clinical Coordinator (CC) on February 3, 2011 at 12:57 PM, the clinical record for Patient 2 was reviewed. The documents titled "Clinic Visit" were reviewed from July 2, 2010	V 559		5/18/11	

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V 559	Continued From page 28 through January 19, 2011. During this time frame, the clinical record contained one home peritoneal self-monitoring data sheet partially filled out by Patient 2. The CC stated Patient 2 was non-compliant with bringing a filled-out self-monitoring data sheet with her when she came in for her office visits. Of the 26 clinic visit sheets reviewed, two sheets indicated Patient 2 was re-educated on the importance of bringing into the facility, completed home peritoneal self-monitoring data sheets. At this time, Patient 2's plan of care was reviewed with the CC. He verified Patient 2's plan of care, which was due for the yearly update on November 2010, had not been completed except by the Dietitian. He also verified this plan of care and the previous plan of care for 2009 did not include Patient 2's non-compliance with the home peritoneal self-monitoring data sheet completions.  The facility policy and procedure titled, "Comprehensive Interdisciplinary Patient Assessment Tool" revised October 2008, read, "The interdisciplinary team must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes. If the expected outcome is not achieved, then the team must adjust the patient's plan of care to reach the specified goals."	V 559			
V 587	494.100(b)(2),(3) H-FAC RECEIVE/REVIEW PT RECORDS Q 2 MONTHS  The dialysis facility must -	V 587		5/18/11	

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V 587	Continued From page 29 (2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and (3) Maintain this information in the patient ' s medical record.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to acquire and review Patient 2's home peritoneal self-monitoring data sheets, which had the potential for adverse treatment outcomes.  Findings:  During a concurrent interview and clinical record review with the Clinical Coordinator (CC) February 3, 2011 at 12:57 PM , the clinical record for Patient 2 was reviewed. The documents titled "Clinic Visit" were reviewed from July 2, 2010 through January 19, 2011. During this time frame, the clinical record contained one home peritoneal self-monitoring data sheet partially filled out by Patient 2. The CC stated Patient 2 was non-compliant with bringing a filled-out self-monitoring data sheet with her when she came in for her office visits. Of the 26 clinic visit sheets reviewed, two sheets indicated Patient 2 was re-educated on the importance of bring into the facility, completed home peritoneal self-monitoring data sheets.	V 587			
V 625	494.110 CFC-QAPI  This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to meet the Condition for	V 625		5/30/11	

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V 625	<p>Continued From page 30</p> <p>Coverage for Quality Assessment and Performance Improvement (QAPI) by failing to:</p> <ol style="list-style-type: none"> <li>1. Ensure that an effective data driven program was implemented, maintained and evaluated which resulted in an ineffective prevention, identification and monitoring of health outcomes such as the prevention and reduction of medical errors (refer to V626).</li> <li>2. Develop an ongoing program which achieved measurable improvement in health outcomes by failing to identify or monitor trend outcomes and develop an improvement plan when needed (refer to V627).</li> <li>3. Measure, analyze and track aspects of performance that reflects processes of care and facility operations (refer to V628).</li> <li>4. Identify a measurable goal for dialysis adequacy and track the performance in order to develop an improvement plan as needed (refer to V629).</li> <li>5. Identify a goal for anemia management and identify a method for achieving the measurable goal (refer to V632).</li> <li>6. Ensure that an effective, data driven program identified the prevalence of occurrences, commonalities and causes of medical error identification and patient safety events (refer to V634).</li> <li>7. Ensure that QAPI program analyzed and developed action plans to minimize infection transmission, promote immunization and perform</li> </ol>	V 625			

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V 625	Continued From page 31 trend analysis to reduce future incidents (refer to V637).  8. Continuously monitor its outcome performance data, develop improvement action plans for identified issues, implement the action plan, evaluate and revise the action plan as indicated (refer to V638).  The cumulative effect of these systemic practices had the potential to result in creating multiple risks to patients' health and safety. The facility failed to ensure compliance with the Condition for Coverage: Quality Assessment and Performance Improvement.	V 625			
V 626	494.110 QAPI-COVERS SCOPE SERV/EFFECTIVE/IDT INVOL  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.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to develop and implement a data driven	V 626		5/30/11	

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V 626	Continued From page 32 Quality Assessment Performance Improvement (QAPI) program which resulted in ineffective identification and monitoring of health outcomes such as the reduction of medical injuries and medical errors in a universe of 92 hemodialysis patients.  Findings:  During a record review on February 2, 2011 at 3:20 PM, the policy titled "Quality Assessment and Performance Improvement (QAPI) Statement (undated) read: "Purpose: To continually evaluate process for improvement" The QAPI meeting outlines for October 11, 2010; July 10, 2010; and April 1, 2010 indicated patient outcome screening forms for patients were reviewed. The Clinical Outcomes Screening Forms provided percentages of patients for adequacy, anemia, albumin, hepatitis immunization, dialysis access related infection, hospitalizations, and mortality. No facility goals were identified for these outcomes.  During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he was responsible for collecting QAPI data and did not have any written goals or action plans for the QAPI program.  During an interview on February 3, 2011 at 3 PM, the Medical Director was unable to identify percentage goals for the facility but stated the facility was meeting the goals with "no problems".	V 626			
V 627	494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT  The program must include, but not be limited to,	V 627		5/30/11	

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V 627	<p>Continued From page 33</p> <p>an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to maintain an ongoing Quality Assessment and Performance Improvement (QAPI) program which achieved measurable improvement in health outcomes by failing to identify or monitor outcomes and develop an improvement plan to meet their goals, which had potential for the facility not being able to recognize problems which affects patient safety.</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the policy titled "Quality Assessment and Performance Improvement Statement (undated) read: "Purpose To continually evaluate process for improvement" The QAPI meeting outlines for October 11, 2010; July 10, 2010; and April 1, 2010 indicated patient outcome screen forms for patients were reviewed. The Clinical Outcomes Screening Forms provided percentages of patients for adequacy, anemia, albumin, hepatitis immunization, dialysis access related infection, hospitalizations, and mortality. No facility goals were identified for these outcomes.</p> <p>During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he was responsible for collecting QAPI data and did not</p>	V 627			

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V 627	Continued From page 34 have any written goals or action plans for the QAPI program.	V 627			
V 628	<p>During an interview on February 3, 2011 at 3:00 PM, the Medical Director was unable to identify goals for the facility but stated the facility was meeting the goals with no problems.</p> <p>494.110(a)(2) QAPI-MEASURE/ANALYZE/TRACK QUAL INDICATORS</p> <p>The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to measure, analyze and track aspects of performance that reflected process of care and facility operations, which had the potential to cause unclear desired outcomes.</p> <p>Findings:</p> <p>During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he was responsible for collecting Quality Assessment and Performance Improvement (QAPI) data and did not have any written goals or action plans for the QAPI program.</p> <p>During an interview on February 3, 2011 at 3:00 PM, the Medical Director was unable to identify goals for the facility but stated the facility was</p>	V 628		5/30/11	

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V 628	Continued From page 35 meeting the goals with "no problems".	V 628			
V 629	<p>During a record review on February 2, 2011 at 4:30 PM, the facility policy titled "Quality Assessment and Performance Improvement Policy Statement" (undated) indicated, "This program is an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors. The facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time."</p> <p>494.110(a)(2)(i) QAPI-INDICATOR-ADEQUACY OF DIALYSIS</p> <p>The program must include, but not be limited to, the following: (i) Adequacy of dialysis.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify it's goal for adequacy and identify a method for achieving the measurable goal, which had potential to cause patients not receiving adequate fluids or toxin management.</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the 2010 Clinical Outcome Screening Form for Kt/V Adequacy indicated the percentage of hemodialysis patients with mean spKt/V greater than or equal to 1.2 and 1.4 and also identified the percentage of patients with mean URR (urea reduction rate) greater than or equal to 65%. URR and Kt/V, are laboratory values</p>	V 629		5/30/11	

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V 629	Continued From page 36 which identify how well the dialysis clears the blood of urea and indicates the effectiveness of the hemodialysis. No facility goal for how many patients to achieve these laboratories was identified. The percentages ranged from a high of 78.9% for Kt/V greater than 1.4 to a low of 67.1%. No analysis of the percentages was provided. The percentages for Kt/V greater than 1.2 ranged from a high of 96.4 to a low of 75.0. No analysis of the percentages was provided. The URR percentages ranged from a high of 79.8% to a low of 67.1%. No analysis of the percentages was provided.  During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he had no identified measurable goals for adequacy and had no written plan to improve the numbers.  During an interview on February 3, 2011 at 3:00 PM, the Medical Director was unable to identify goals for the facility but stated the facility was meeting the goals with no problems.	V 629			
V 632	494.110(a)(2)(iv) QAPI-INDICATOR-ANEMIA MANAGEMENT  The program must include, but not be limited to, the following: (iv) Anemia management.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to identify it's goal for anemia management and identify a method for achieving the measurable goal, which had the potential to cause patients' anemia status not being evaluated.	V 632		5/30/11	

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NAME OF PROVIDER OR SUPPLIER  <b>PEGASUS DIALYSIS, LLC</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>3101 PEGASUS DRIVE SUITE 100 BAKERSFIELD, CA 93308</b>		
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V 632	<p>Continued From page 37</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the 2010 Clinical Outcome Screening Form for anemia indicated the percentage of hemodialysis patients with hemoglobin (a protein in the blood that carries oxygen and indicates anemia) less than 10 g/dL ranged from a low of 6.5% in May to a high of 19.1 in February. No analysis of the data was provided and no facility goal was identified. The percentages of patients with hemoglobin between 10 and 12 g/dl ranged from a low of 37.8 % in May to a high of 54.6% in November. No analysis of the percentages was provided and no facility goal was identified. The percentages for hemoglobin greater than 12 g/dL ranged from a low of 29.5% in August to a high of 55.5% in May. No facility goal was identified and no analysis of the percentages was provided. The percentages for patients with ferritin (iron stores) greater than 200 ng/ml ranged from a low of 75 % in March to a high of 97.5% in November. No facility goals or analysis of the percentages was provided. The percentages for patients with transferrin saturation (iron stores) greater than 20% ranged from a low of 74.5% in February to a high of 94.9% in July. No facility goals or analysis of the percentages was provided.</p> <p>During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he had no identified measurable goals for anemia and had no written plan to improve the numbers.</p> <p>During an interview on February 3, 2011 at 3:00 PM, the Medical Director was unable to identify goals for the facility but stated the facility was</p>	V 632			

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V 632	Continued From page 38	V 632			
V 634	<p>meeting the goals with no problems.</p> <p>494.110(a)(2)(vi) QAPI-INDICATOR-MEDICAL INJURIES/ERRORS</p> <p>The program must include, but not be limited to, the following: (vi) Medical injuries and medical errors identification.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to report, measure and develop a plan for decreasing adverse events such as medical errors which had the potential to cause injuries to a universe of 92 patients.</p> <p>Findings:</p> <p>During a record review on February 1, 2011 at 11:30 AM, Patient 6's medical record contained an entry dated November 10, 2010 at 12:25 PM in the progress record. This entry read "went into isolation room to put (patient) on machine. (Patient) has CVC (central venous catheter) and noticed heparin (a blood thinner given intravenously) had already been removed and flushed with NS (normal saline). (Patient) had done this herself. Told (patient) she can't put herself on the machine, it is against policy and the risk of infection is very dangerous in a CVC. (Patient) stated "but I know how to do it and the RN's (Registered Nurse) are busy". Told (patient) RN has told her before she is not to touch syringes or try to put herself on."</p> <p>During an interview on February 2, 2011 at 3 PM, the Charge Nurse (CN) acknowledged Patient 6</p>	V 634		5/30/11	

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V 634	Continued From page 39 had behaviors but did not know why the incident was not written in the adverse event log. The CN stated staff talk to her about "messaging with her stuff." The Clinical Coordinator (CC) was not aware of the incident and acknowledged it had not been reported on the adverse event log as a medical error.  During a record review and concurrent interview on February 2, 2011 at 3:20 PM, the Quality Assessment and Performance Improvement meeting outlines dated October 11, 2010, July 10, 2010, and April 1, 2010 had no entry for medical error issues. The CC stated he brought the logs to the meetings and the information would not be in the meeting minutes. He was unable to provide measurable goals or a plan to identify, track, analyze, or act on medical errors.	V 634			
V 637	494.110(a)(2)(ix) QAPI-INDICATOR-INF CONT-TREND/PLAN/ACT  The program must include, but not be limited to, the following: (ix) Infection control; with respect to this component the facility must- (A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence; (B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and (C) Take actions to reduce future incidents.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to:	V 637		5/30/11	

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V 637	<p>Continued From page 40</p> <ol style="list-style-type: none"> <li>1. Analyze trends in infection incidences.</li> <li>2. Gather, and analyze immunization rates and establish an action plan.</li> <li>3. Incorporate measures to reduce infection rates.</li> </ol> <p>As a result of such failures, the facility could not minimize the exposure of infectious diseases to its patients and staff.</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the Quality Assessment and Performance Improvement (QAPI) meeting outlines dated October 11, 2010, July 10, 2010, and April 1, 2010 had "none" written next to infection control issues. The immunization program had the words "in progress" written beside it. No measurable data was provided, and no goals or action plan was identified. No current data for immunization was presented; the last data was February 28, 2010 with a census of five patients. The current census was 83 hemodialysis patients.</p> <p>During a record review on February 2, 2011 at 3:30 PM, the infection log indicated in July 2010 the facility had six patients receiving antibiotics. The diagnoses included pseudomonas (bacteria), methicillin resistant staphylococcus aureus (a bacteria resistant to many antibiotics) and one patient with bacteremia (bacterial infection of the blood). The infection log for October 2010 indicated four patients had bacteremia and one patient had fever.</p> <p>During an interview on February 2, 2011 at 4:20</p>	V 637			

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V 637	Continued From page 41 PM, the Clinical Coordinator stated he had no identified goals for infection control rates or immunization and had no written plan to improve the numbers.	V 637			
V 638	<p>During an interview on February 3, 2011 at 3 PM, the Medical Director was unable to identify goals for the facility but stated the facility was meeting the goals with no problems.</p> <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE</p> <p>The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility's Quality Assessment and Performance Improvement (QAPI) program failed to continuously monitor and track performance indicators for identified issues, and evaluate and revise the action plan as needed. This failure had the potential to prevent patients from achieving optimal outcomes with hemodialysis.</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the policy titled "Quality Assessment and Performance Improvement Statement" (undated) read: "Purpose To continually evaluate process for improvement" The QAPI meeting outlines for October 11, 2010; July 10, 2010; and April 1, 2010 indicated patient outcome screen</p>	V 638		5/30/11	

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V 638	Continued From page 42 forms for patients were reviewed. The Clinical Outcomes Screening Forms provided percentages for adequacy, anemia, albumin, hepatitis immunization, dialysis access related infection, hospitalizations, and mortality. No facility goals were identified for these outcomes. No reporting mechanism was implemented for the reporting of medical errors.  During an interview on February 2, 2011 at 4:20 PM, the Clinical Coordinator stated he was responsible for collecting QAPI data and did not have any written goals or action plans for the QAPI program.  During an interview on February 3, 2011 at 3 PM, the Medical Director was unable to identify goals for the facility but stated the facility was meeting the goals with no problems.	V 638			
V 710	494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR  This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure that the Condition for Coverage for Responsibilities of the Medical Director was met by failing to ensure that the oversight regarding the delivery of quality patient care was met as follows:  1. The facility's Medical Director failed to ensure that the operational responsibility for the Quality Assessment and Performance Improvement (QAPI) was met by failing to ensure that the QAPI program was data driven and trends related to improved health outcomes monitored (refer to V712).	V 710		5/30/11	

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V 710	Continued From page 43	V 710			
V 712	<p>2. The Medical Director failed to ensure that facility staff received appropriate education and training in infection control and QAPI (refer to V713).</p> <p>3. The Medical Director failed to ensure that facility staff who provided care in the facility adhered to the facility's policy and procedure regarding implementation of infection control program and the QAPI program (refer to V715).</p> <p>494.150(a) MD RESP-QAPI PROGRAM</p> <p>Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility's medical director failed to ensure the operational responsibility of the Quality Assessment and Performance Improvement (QAPI) program was met by failing to ensure that an effective data driven program was implemented and maintained which resulted in an ineffective identification and monitoring of health outcomes such as the infection control and reduction of medical errors.</p> <p>Findings:</p> <p>During a review of the facility policy titled Quality Assessment and Performance Improvement Policy Statement (undated) indicated the policy of the facility's QAPI committee which "meets quarterly and assumes responsibility for assessment of processes, protocols, policies and</p>	V 712		5/30/11	

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V 712	Continued From page 44 procedures, and general functions of the dialysis facility. The Medical Director chairs the committee made up of the Clinical Manager, PD (Peritoneal Dialysis) Registered Nurse, Technical Manager, Dietitian, Social Workers and nursing staff are ad hoc members."  During an interview on February 3, 2011 at 3:11 PM, the Clinical Coordinator (CC) stated the QAPI committee consisted of the medical director, the clinical coordinator, dietician, social services director. The CC stated he had no written goals for performance indicators, "I don't have anything written, I just take the logs to the doctors" and was unable to provide planning to reduce medical errors from one quarter to another.  During an interview on February 3, 2011 at 4 PM, the Medical Director stated he was responsible for the oversight of the QAPI program and was unaware of any ongoing problems. He stated the facility was meeting the goals but was unable to provide any specific data.	V 712			
V 713	494.150(b) MD RESP-STAFF ED, TRAINING & PERFORM  Medical director responsibilities include, but are not limited to, the following: (b) Staff education, training, and performance.  This STANDARD is not met as evidenced by: Based on interview and record review, the facility's medical director failed to provide staff adequate training, which had caused the facility's staff the inability to perform required duties in infection control and Quality Assessment and Performance Improvement (QAPI) program.	V 713		5/30/11	

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V 713	<p>Continued From page 45</p> <p>Findings:</p> <p>During a record review on February 2, 2011 at 3:20 PM, the policy titled "Quality Assessment and Performance Improvement Statement" (undated) read: "Purpose To continually evaluate process for improvement" The QAPI meeting outlines for October 11, 2010; July 10, 2010; and April 1, 2010 indicated patient outcome screen forms for patients were reviewed. The Clinical Outcomes Screening Forms provided percentages for adequacy, anemia, albumin, hepatitis immunization, dialysis access related infection, hospitalizations, and mortality. No facility goals were identified for these outcomes.</p> <p>During an interview on February 2, 2011 at 2:50 PM, the Clinical Coordinator (CC) stated the Charge Nurse (CN) was responsible to log infections. The CC stated he was responsible for monitoring infection control in the facility but he had not performed audits on infection control and monitors compliance "whenever I get a chance, which is not often." The CC stated he was responsible for the peritoneal dialysis program for nine patients in addition to oversight of the hemodialysis unit.</p> <p>During an interview on February 2, 2011 at 4:20 PM, the CC stated he was responsible for collecting QAPI data and did not have any written goals or action plans for the QAPI program. The CC stated he had not received training on QAPI and had not attended training specific to nephrology in the past year. The CN indicated she had not received training regarding tracking infection control and attends QAPI meetings two</p>	V 713			

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V 713	Continued From page 46 to three times yearly and had not attended training specific to nephrology in the past year.	V 713			
V 715	<p>During an interview with the Medical Director on February 3, 2011 at 3 PM, he stated his involvement in staff training was to "hire fully trained staff to assure competency". The Medical Director was unable to provide plans for continuing education for the staff in order to maintain competency and stay current with nephrology practices.</p> <p>494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&amp;P</p> <p>The medical director must-</p> <p>(2) Ensure that-</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the medical director failed to ensure staff complied with the policies on infection control and treatment discontinuation which had the potential to expose a universe of 92 patients to infectious disease and vascular complications.</p> <p>Findings:</p> <p>1. Multiple observations of improper hand hygiene and improper infection control practices were observed from January 31, 2011 to February 3, 2011 (refer to V110).</p>	V 715		5/18/11	

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V 715	<p>Continued From page 47</p> <p>2. During an observation on February 1, 2011 at 8:45 AM, Certified Hemodialysis Technician (CHT) 5 was observed discontinuing hemodialysis treatment for the patient at station 9. The patient had an arteriovenous fistula (a surgically connected artery and vein for dialysis access with needles) in his left arm. CHT 5 was rinsing back the patient's blood with saline, then stopped the machine's blood pump and squeezed the bag of normal saline with force until the tubing was cleared of blood.</p> <p>During an observation on February 1, 2011 at 9 AM, CHT 6 was observed discontinuing the hemodialysis treatment for the patient at station 13. CHT 6 stopped the blood pump, removed the bag of normal saline from the IV pole and with the bag connected to the tubing, squeezed the bag with a large amount of force until the tubing was clear and the normal saline bag was completely empty.</p> <p>During an observation of the dialysis treatment area on January 31, 2011 at 10:15 AM, Senior Certified Hemodialysis Technician (SCHT) 1 placed a intravenous normal saline bag on the dialysis tubing system, which was connect to Patient 5's access site (the area needles are place for the removal and return of blood), and then placed the bag on a hook above the dialysis machine. SCHT 1 began squeezing and twisting the bag. Then she removed the bag from the hook, placed it at her chest level, and continued to squeeze it with force.</p> <p>During an observation of the dialysis treatment area on January 31, 2011 at 4:08 PM, CHT 4 was observed squeezing the intravenous normal</p>	V 715			

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V 715	<p>Continued From page 48</p> <p>saline bag with force which was connected to Patient 13's dialysis tubing that was connected to his access.</p> <p>During an interview on February 2, 2011 at 2:55 PM, the Charge Nurse acknowledged staff were allowed to return blood by allowing saline to flow by gravity but should not use force to squeeze the bag of saline.</p> <p>During a record review on February 2, 2011, the facility's policy titled "Discontinuing Dialysis Closed System Blood Return dated July 2008 indicated, "The height of the IV pole should provide enough pressure to rinse back blood. Excessive pressure can dislodge clots or other debris and rinse them back (sic) to the patient. Excessive pressure can also cause harm to the access."</p>	V 715			