

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

PRINTED: 02/11/2011
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052658 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 09/17/2010 |
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| NAME OF PROVIDER OR SUPPLIER KIDNEY INSTITUTE OF THE DESERT | STREET ADDRESS, CITY, STATE, ZIP CODE 81-715 DOCTOR CARREON BLVD, SUITE B- 2 INDIO, CA 92201 |
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| V 000 | <p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during a Re-Certification survey.</p> <p>The following Condition for Coverage were not met:</p> <ul style="list-style-type: none"> -Quality Assessment and Performance Improvement -Governance -Responsibilities of the Medical Director <p>Representing the California Department of Public Health:</p> <p>21211, HFEN 18821, HFEN</p> <p>The facility census was 132 patients.</p> <p>The sample size was 13 patients.</p> <p>Abbreviations list: CFU - Colony forming units CKD- Chronic Kidney Disease D/T- Diptheria/Tetanus ESRD- End Stage Renal Disease EU- Endotoxin Unit H- High HBV - Hepatitis B Virus HN - Head Nurse IDT - Interdisciplinary Team MD - Medical Director ML - milliliter MT - Machine Technician Oz - Ounce PPD- purified protein derivative (TB Skin Test)</p> | V 000 | | |
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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| V 000 | Continued From page 1 | V 000 | | | |
| V 117 | <p>QAPI - Quality Assessment Performance Improvement. QI - Quality Improvement.</p> <p>494.30(a)(1)(i) IC-CLEAN/DIRTY;MED PREP AREA;NO COMMON CARTS</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to store a nine foot ladder away from clean and sterile supplies in the central supply closet of the facility.</p> <p>Findings:</p> <p>During the initial tour on September 13, 2010, around 10 a.m., in the locked supply storage room, there was a nine foot ladder stored in this</p> | V 117 | | | |

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| V 117 | Continued From page 2 room. The ladder had a thick brown substance that was hanging off of several of the steps and was stored over a cart that held patient clean and sterile supplies. Supplies on this cart included the following items, towel bibs and sterile supplies used in the dialysis clinic. In an interview with the tech on the tour, he stated that the ladder was used to reach up high on the shelf for supplies but perhaps it could be stored some place else. | V 117 | | |
| V 184 | 494.40(a) ENVIRONMENT-SECURE & RESTRICTED 8 Environment: secure & restricted The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimizing the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system. This STANDARD is not met as evidenced by: Based on observation and interview the facility failed to secure the water purification and storage system by failing to lock the rear door of the water treatment area during the hours of operation. This failure had the potential for unauthorized people to enter a secure area. Findings: During the initial tour conducted on September 13, 2010, at 9:05 a.m., the rear door of the water treatment room was observed not to be fully closed and locked. | V 184 | | |

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| V 184 | Continued From page 3 In a concurrent interview with the water technician, he stated that the back door was not kept locked during normal operating hours due to deliveries. Observation on September 13, 2010, at 11:45 a.m., revealed that the back door was not fully closed shut and at 11:55 a.m., the surveyor observed the water treatment room was unattended. Further observation on September 14, 2010, at 10:40 a.m. revealed that the back door of the water treatment area was not completely shut and the water treatment area was unattended. An additional interview was conducted with the water technician on September 14, 2010, at 10:45 a.m. He confirmed that the water treatment room was unattended and that the rear door was not fully closed and locked. He further stated that the door should be closed and locked during operation hours. | V 184 | | | |
| V 196 | 494.40(a) CARBON ADSORP-MONITOR, TEST FREQUENCY 6.2.5 Carbon adsorption: monitoring, testing freq Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours. Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet. | V 196 | | | |

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| V 196 | <p>Continued From page 4</p> <p>Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N.N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].</p> <p>Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to provide color blind testing, an essential job function for the individual responsible for reading colorimetric tests used in testing for the presence of chloramine in the water to be used to produce dialysate.</p> <p>Findings:</p> <p>During the initial tour conducted on September 13, 2010, at 9:00 a.m., the water test kits were observed in the water treatment room.</p> <p>A concurrent interview with Staff 15 indicated that chloramine testing was completed by the dip and read test strip method. This method uses color shading to determine the amount of chloramine in the product water.</p> <p>Review of Staff 15's, employee file, conducted on September 17, 2010, at 11:15 a.m., indicated that he was hired on February 1, 2010. Further review</p> | V 196 | | |

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| V 196 | Continued From page 5 of the file indicated that there was no documentation to indicate whether or not Staff 15 had taken a test to discern colors used for the chloramine testing strips. | V 196 | | |
| V 274 | Further interview with Staff 15 stated that he had not taken a color blind test. 494.40(c) H2O TEST-DEVIATIONS REQUIRE RESPONSE Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety. This STANDARD is not met as evidenced by: Based on observation, interview, and record review the facility failed to address and document action taken when multiple colony count dialysate and endotoxin dialysate (the material that passes through the membrane in dialysis) laboratory results came back at an actionable level. Findings: On September 13, 2010, at 1 p.m., a review of the facility's water treatment logs were conducted. -At 1:05 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the 48 hour colony count (A numerical computation of a group of bacteria) in the dialysate, showed the following result: abnormal > 1000 H (high), reference ranges 0-199 CFU/ml. (bacterial count) per milliliter, (unit of volume in the metric system.) -At 1:20 p.m., on September 13, 2010, the | V 274 | | |

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| V 274 | <p>Continued From page 6</p> <p>laboratory draw report dated March 24, 2009, indicated that the endotoxin, (gram negative bacteria), in the product water showed the following result: Endotoxin, product water, 2.29 H, reference ranges 0.00-1.99 EU/ml. (endotoxin unit per milliliter).</p> <p>-At 1:30 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the endotoxin in the dialysate showed the following result: Endotoxin, dialysate 2.39 H, reference ranges, 0.00-1.99 EU/ml.</p> <p>-At 1:40 p.m., on September 13, 2010, the laboratory draw report dated July 21, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 330 H, reference ranges, 0-199 CFU/ml.</p> <p>-At 1:50 p.m., on September 13, 2010, the laboratory draw report dated September 25, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 220 H, reference ranges, 0-199 CFU/ml.</p> <p>In an interview with the machine technician at 1:10 p.m., he was asked when the MD knew about these abnormalities; when they were recorded, and how the MD responded to them. The MT stated that he did not know and that he did not work at the facility at the time the laboratory values were taken.</p> <p>A review of the facility Policy and Procedure on September 13, 2010, around 2 p.m., indicated the following: ..."The Chief Technician or his/her designee will</p> | V 274 | | | |

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| V 274 | Continued From page 7 be responsible for obtaining the monthly cultures. Culture reports will be reviewed and logged by the Chief Technician. Any abnormal reports will be brought to the attention of the Head Nurse and/or Medical Director and or corrective action will be instituted." | V 274 | | |
| V 401 | 494.60 PE-SAFE/FUNCTIONAL/COMFORTABLE ENVIRONMENT The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment. This STANDARD is not met as evidenced by: Based on observation and interview, the facility failed to store dialysis supplies in safe place. Findings: During the initial tour on September 13, 2010, at 10 a.m., there were six boxes that held Danel, low calcium 2.5 mEq/L peritoneal dialysis solution with 25% dextrose 2500 cc, stored on the floor. In an interview with the HN on tour she stated that the supplies were for use with the training room patients. The surveyor stated to the HN that supplies for patients use should be stored the same throughout the facility. | V 401 | | |
| V 407 | 494.60(c)(4) PE-HD PTS IN VIEW DURING TREATMENTS Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement). This STANDARD is not met as evidenced by: | V 407 | | |

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| V 407 | <p>Continued From page 8</p> <p>Based on observation, interview, and record review, the facility failed to ensure patient safety for 1 of 13 sampled patients, (Patient 2), by failing to keep the patient's vascular access site and blood line connections in view of staff during hemodialysis treatment.</p> <p>Findings:</p> <p>Record review, conducted on September 16, 2010, at 11:20 a.m., indicated that Patient 2 was admitted to the facility on October 28, 2004, with diagnoses that included, acute renal failure, (kidney failure).</p> <p>During the observation of the facility's treatment area, conducted on September 13, 2010, at 10:05 a.m., Patient 2 was observed lying in a chair used by patients receiving hemodialysis treatment.</p> <p>Further observation revealed that the patient's right arm vascular site and blood line connections were covered with a blanket.</p> <p>In an interview with the HN on September 13, 2010, at 10:10 a.m., she stated that the site should be uncovered during treatment.</p> <p>Review of facility's policy and procedure was completed on September 16, 2010. The policy titled "Dialysis Technician" and dated September 2010, stated under "Principal Duties:</p> <p>1. Patient care, Paragraph 6 (six), Monitors patient's condition prior to, during and after the dialysis treatment."</p> <p>In an interview with the HN on September 16, 2010, at 10:05 a.m., she stated that the policy</p> | V 407 | | | |

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| V 407 | Continued From page 9 and procedure included keeping the patient access site and connectors uncovered during the dialysis treatment. | V 407 | | | |
| V 411 | The policy and procedure failed to indicate observation and care of the access site. 494.60(d)(1) PE-NURS STAFF TRAINED IN ER EQUIP & MEDS Staff training must be provided and evaluated at least annually and include the following: (iii) Ensuring that nursing staff are properly trained in the use of emergency equipment and emergency drugs. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to properly ensure that staff was trained in emergency equipment, and failed to store emergency supplies properly for a universe of 132 patients. Findings: 1. During a review of personnel files on September 17, 2010, at 10 a.m., two employee files were outdated for Emergency Procedures Preparedness. Facility staff that had not annual emergency procedures preparedness, included Staff 16 and 17. In an interview with the HN, she confirmed that both staff had not had their annual emergency preparedness training. 2. During the initial tour of the facility, on September 13, 2010,two Emergency Food | V 411 | | | |

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| V 411 | Continued From page 10 Supplies Containers contained the following expired items: Vanilla Wafers, four 1 lb. 14 oz boxes that had expired on August 30, 2010. Crackers-Honey Maid, four 1 lb. 12.8 oz boxes that had expired on August 29, 2010. Ritz Crackers four 1 lb. 14 oz boxes, that had expired on August 2010. In an interview with the technician on the tour, he confirmed that the items were expired and would need to be removed from the emergency food container. | V 411 | | |
| V 506 | 494.80(a)(3) PA-IMMUNIZATION/MEDICATION HISTORY The patient's comprehensive assessment must include, but is not limited to, the following: Immunization history, and medication history. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to screen and document for tuberculosis, HBV, Pneumovax and Influenza for 1 of 13 sampled patients, (Patient 5). Findings: During a review of Patient 5 record on September 14, 2010, at 8: 30 a.m., revealed that she was admitted to the facility on March 25, 2009. Patient 5's diagnoses included diabetes. Patient 5's initial assessment did not provide documentation of immunization for HBV, | V 506 | | |

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| V 506 | Continued From page 11 pneumovax, or influenza at the start of care. A review of the immunization record had the following documentation as follows: "Immunization Record and History PPD (given) April 27, 2009, declined test at local hospital". The Influenza, Pneumovax, Hepotvax (HBV vaccine) boxes were empty and nothing was recorded. In addition to the initial assessment Patient 5 was out of the country from August 28, 2010, to September 11, 2010, and there was no additional ppd testing upon entry to the dialysis center, after the patient visited an area that potentially has high cases of tuberculosis diseases. In an interview with the HN on September 14, 2010, around 10:30 a.m., she stated that the facility did not have a policy for patients regarding ppd testing when they leave the country and she confirmed that the immunization record was incomplete and was not updated. | V 506 | | | |
| V 519 | 494.80(d)(1) PA-FREQUENCY REASSESSMENT-STABLE 1X/YR 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- (1) At least annually for stable patients; This STANDARD is not met as evidenced by: | V 519 | | | |

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| V 519 | Continued From page 12 Based on interview, and record review, the facility failed to complete a comprehensive annual assessment for 1 of 13 patients (Patient 5). Findings: A review of the record for Patient 5 on September 14, 2010, at 8: 30 a.m., revealed she was admitted to the facility on March 25, 2009. Patient 5's diagnoses included diabetes, and chronic kidney disease, Stage V, (end stage renal disease). In an interview with the HN on September 14, 2010, at 10:30 a.m., she confirmed that Patient 5 had a prior start of care assessment completed April 22, 2009 but did not have a re-assessment on the record for 2010. In this same interview she was asked if the facility required a reassessment when Patient 5 traveled to Mexico. The HN was unaware of the procedure, when patients traveled to Mexico, for months or more at a time. She further stated that there was no travel policy for traveling out of the country. | V 519 | | | |
| V 625 | 494.110 CFC-QAPI This CONDITION is not met as evidenced by: Based on interview and record review, the facility failed to have an effective QAPI program by failing to have QAPI committee meetings from January 2010 through June 2010, to track health outcomes, for identification, prevention and reduction of medical errors, mortality, and morbidities in a universe of 132 patients (V626). The cumulative effect of this failure had the | V 625 | | | |

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| V 625 | Continued From page 13 potential to impact health and safety for 132 of 132 patients receiving hemodialysis treatment in the facility. | 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 have an effective QAPI program by failing to have QAPI committee meetings to track health outcomes, for identification, prevention and reduction of medical errors, mortality, and morbidities in a universe of 132 patients. Findings: On September 15, 2010, at 12:40 p.m., a review of the facility's QAPI program was conducted. There were no Quality Improvement and Governing Board minutes for the months of January 2010 through June 2010. The review indicated that there were an absence of an | V 626 | | |

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| V 626 | <p>Continued From page 14 effective QAPI program.</p> <p>In an interview with the HN conducted on September 15, 2010, at 12:50 p.m., she stated, "There was no nurse manager. She left in February or March. She resigned."</p> <p>The current HN stated that she had assumed the position in June 2010, and her first QAPI meeting had been held in July 2010. She further stated that she was not involved with the QAPI committee until the month of July.</p> <p>At 2:10 p.m. on September 15, 2010, an interview was conducted with the Social Worker. She stated, "I didn't attend any QAPI meetings. I don't schedule it." The Social Worker provided no further information about the QAPI committee meetings.</p> <p>In an interview with the MD on September 15, 2010, at 2:45 p.m., he stated, "I was under the impression it (QAPI meetings) was happening. Something happened from January to March. I don't know, some staff turmoil. She (previous HN) worked for 16 years and she left in March or April. I don't know what for."</p> <p>The surveyor asked the MD who participated on the QAPI committee. He stated, "Head Nurse, other nurses, Social Worker, Dietician, and myself."</p> <p>At 2:53 p.m., he stated, "We know, as I can't change the facts. We got caught off guard. We are starting and will change. We can't take the time back. The person we hired had no experience. We will and are training her to conduct the meetings."</p> | V 626 | | | |

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| V 626 | Continued From page 15 The MD gave no further explanation as to why the facility had not had QAPI meetings from January 2010 through June 2010. On September 15, 2010, at 3:10 p.m., a review of the facility's policy and procedure, Quality Assurance Performance Improvement, (QAPI) and dated April 2009, was reviewed. It indicated: "#3 Objectives a. Hold monthly QAPI meetings with the committee... c. Maintain minutes of QAPI meetings." An additional telephone interview was conducted with the Dietician on September 16, 2010, at 9:00 a.m. She stated, "The leader of the nursing staff was suppose to conduct the meeting. I just assumed they were going to schedule the meeting. I should have been more proactive." | V 626 | | | |
| V 681 | 494.140 PQ-STAFF LIC AS REQ/QUAL/DEMO COMPETENCY 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 16 This STANDARD is not met as evidenced by: Based on interview and record review the facility failed to ensure that all staff completed competencies and skills testing annually. Findings: A review of personnel files was conducted on September 17, 2010, at 9:30 a.m. The files for staff members 16 and 17 show the following for inservices on February 5, 2009: "Universal Precautions Hazardous Material in workplace, MSDS Fire Safety and Evacuation Emergency Procedures Patient Rights and Responsibilities" In a concurrent interview with the HN during the file reviews, she stated the competencies are done annually. No additional competencies were located for staff 16 and 17 after February 5, 2009. | V 681 | | | |
| V 710 | 494.150 CFC-RESPONSIBILITIES OF THE MEDICAL DIRECTOR This CONDITION is not met as evidenced by: Based on staff interviews and record reviews, the MD failed to provide oversight and responsibility to ensure the delivery of quality patient care and patient clinical outcomes by: 1. Failing to ensure that the QAPI committee meetings were held monthly from January 2010 through June 2010, per facility policy and procedure. (V626, V712) | V 710 | | | |

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| V 710 | Continued From page 17 2. Failing to address and document action taken when multiple colony count dialysate and endotoxin dialysate laboratory results came back at an actionable level per the facility policy and procedure. (V 274, V715) The cumulative effect of these systemic problems resulted in the facility's inability to ensure the provision of quality health care in a safe environment for 132 of 132 patients receiving hemodialysis treatment in the facility. | V 710 | | | |
| V 712 | 494.150(a) MD RESP-QAPI PROGRAM Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program. This STANDARD is not met as evidenced by: Based on record review, and staff interview, the MD failed to ensure, via oversight through the corporate quality improvement program and his own scrutiny, that the facility's policy and procedure was followed as written for Quality Assessment Performance Improvement by failing to ensure that monthly QAPI meetings were conducted. Findings: On September 15, 2010, at 12:40 p.m., a review of the facility's QAPI program was conducted. There were no Quality Improvement and Governing Board minutes for the months of January 2010 through June 2010. The review indicated that there were an absence of an effective QAPI program. In an interview with the Nurse Manager | V 712 | | | |

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| V 712 | <p>Continued From page 18</p> <p>conducted on September 15, 2010, at 12:50 p.m., she stated, "There was no nurse manager. She left in February or March. She resigned." .</p> <p>The current Nurse Manager stated that she had assumed the position in June 2010, and her first QAPI meeting had been held in July 2010. She further stated that she had not involved with the QAPI committee until the month of July.</p> <p>At 2:10 p.m. on September 15, 2010, an interview was conducted with the social worker. She stated, "I didn't attend any QAPI meetings. I don't schedule it," and provided no further information about the QAPI committee meetings.</p> <p>In an interview with the medical director on September 15, 2010, at 2:45 p.m., he stated, "I was under the impression it (QAPI meetings) was happening. Something happened from January to March. I don't know, some staff turmoil. She (previous Nurse Manager) worked for 16 years and she left in March or April. I don't know what for."</p> <p>The surveyor asked the Medical Director who participated on the QAPI committee. He stated, "Head Nurse, other nurses, Social Worker, Dietician, and myself."</p> <p>At 2:53 p.m., he stated, "We know, as I can't change the facts. We got caught off guard. We are starting and will change. We can't take the time back. The person we hired had no experience. We will and are training her to conduct the meetings."</p> <p>On September 15, 2010, at 3:10 p.m., a review of the facility's policy and procedure, dated April</p> | V 712 | | | |

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| V 712 | Continued From page 19 2009, was reviewed. It states, "Subject: Quality Assurance Performance Improvement, (QAPI), #3 Objectives a. Hold monthly QAPI meetings with the committee c. Maintain minutes of QAPI meetings." The Medical Director gave no further explanation as to why the facility had not had QAPI meetings from January 2010 through June 2010 during the interview that had been conducted at 2:45 p.m. on September 15, 2010. | V 712 | | | |
| V 715 | 494.150(c)(2)(i) MD RESP-ENSURE ALL ADHERE TO P&P The medical director must- (2) Ensure that- (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; This STANDARD is not met as evidenced by: Based on interview and record review, the facility's MD failed to ensure that the Chief Technician followed the facility's policy and procedure related to reviewing, logging and/or notifying the HN or MD of actionable level CFU and EU dialysate cultures reports when abnormal results had come back from the laboratory. Findings: On September 13, 2010, at 1 p.m., a review of | V 715 | | | |

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| V 715 | <p>Continued From page 20 the facility's water treatment logs were conducted.</p> <p>-At 1:05 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the 48 hour colony count (A numerical computation of a group of bacteria) in the dialysate, showed the following result: abnormal > 1000 H (high), reference ranges 0-199 CFU/ml. (bacterial count) per milliliter, (unit of volume in the metric system.)</p> <p>-At 1:20 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the endotoxin, (gram negative bacteria), in the product water showed the following result: Endotoxin, product water, 2.29 H, reference ranges 0.00-1.99 EU/ml. (endotoxin unit per milliliter).</p> <p>-At 1:30 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the endotoxin in the dialysate showed the following result: Endotoxin, dialysate 2.39 H, reference ranges, 0.00-1.99 EU/ml.</p> <p>-At 1:40 p.m., on September 13, 2010, the laboratory draw report dated July 21, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 330 H, reference ranges, 0-199 CFU/ml.</p> <p>-At 1:50 p.m., on September 13, 2010, the laboratory draw report dated September 25, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 220 H, reference ranges, 0-199 CFU/ml.</p> | V 715 | | | |

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| V 715 | Continued From page 21 In an interview with the machine technician at 1:10 p.m., he was asked when the MD knew about these abnormalities; when they were recorded, and how the MD responded to them. The MT stated that he did not know and that he did not work at the facility at the time the laboratory values were taken. A review of the facility Policy and Procedure on September 13, 2010, around 2 p.m., indicated the following: ..."The Chief Technician or his/her designee will be responsible for obtaining the monthly cultures. Culture reports will be reviewed and logged by the Chief Technician. Any abnormal reports will be brought to the attention of the Head Nurse and/or Medical Director and or corrective action will be instituted." | V 715 | | | |
| V 726 | 494.170 MR-COMPLETE, ACCURATE, ACCESSIBLE The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility. This STANDARD is not met as evidenced by: Based on observation, interview, and record review the facility failed to ensure that they maintained complete, and accurate records for all patients, by the following: | V 726 | | | |

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| V 726 | <p>Continued From page 22</p> <p>-The facility failed to maintain Patient 1's record, by having the patient's name inconsistent throughout the records.</p> <p>-The facility failed to maintain Patient 8's record properly, by placing unsampled Patient 14's paperwork in Patient 8's record.</p> <p>-The facility failed to maintain complete immunization record for Patient 11.</p> <p>Findings:</p> <p>1. A review of the record for Patient 1 was conducted on September 13, 2010, at 11 a.m. Patient 1 was admitted to the facility on September 7, 2009, with the following diagnoses; diabetes, diabetic retinopathy, a disorder of retinal blood vessels of the eye, kidney failure, blind left eye and history of non-healing necrotic the left foot ulcer.</p> <p>A review of Patient 1's MD orders had the patient listed as patient **. On this same patient her name was listed as == on her Medi-Cal card. On the patient's medical record, her name is listed as **.</p> <p>In an interview with the HN on September 13, 2010, at 2:45 p.m., she stated the patient's name was listed as ** on her Medi-Cal card, so they had to change it to what was listed on the Medi-Cal Card. The Surveyor told the HN it was confusing at times reading the patient record with different documents (labs, MD orders, identification, medi-Cal cards) with the two last names recorded on various forms in the record.</p> <p>The facility failed to follow-up and clarify with the patient regarding the last name and which one or both she was going to use for consistency with</p> | V 726 | | | |

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| V 726 | <p>Continued From page 23</p> <p>her medical records.</p> <p>2. A review of the record for Patient 8 was conducted on September 15, 2010, at 9:30 a.m. Patient 8's start of care date was listed as April 2010. Patient 8's diagnoses included renal failure-inability of the kidneys to excrete wastes concentrate urine, and conserve electrolytes, hyperuricemia (a disease associated with an inborn error of uric acid metabolism that increases production or interferes with excretion of uric acid. Excess uric acid is converted to sodium urate crystals that precipitate from the blood and become deposited in joints an other tissues, hypertension), high blood pressure, anemia (a decrease in hemoglobin in the blood to levels below the normal range of 12-16 g/dl for women and 13.5-18 g/dl for men), and acute blurred vision left eye 2nd to retinal detachment-a separation of the retina from the retinal pigment epithelium in the back of the eye.</p> <p>While reviewing the record for Patient 8, a follow-up visit note for Unsampled Patient 14, was found in the record. In an interview with the HN, she was shown the follow-up visit note for Patient 14, and stated it had been placed in the wrong record.</p> <p>3. A review of Patient 11's record was conducted on September 14, 2010, at 10 a.m. Patient 11 was admitted to facility on March 25, 2008, with diagnoses of chronic glomerulonephritis (a noninfectious disease of the glomeruli of the kidney) of unknown cause. The disease progresses to kidney failure, CKD Stage 5 (a person with Stage 5 CKD has end stage renal disease. At this advanced stage of kidney disease the kidneys have lost nearly all their</p> | V 726 | | | |

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| V 726 | Continued From page 24 ability to do their job effectively and eventually dialysis or a kidney transplant is needed to live). Patient 11's immunization was documented as follows; "Immunization Record and History PPD (given) 4/28/09" The other boxes on the document were empty and there were no dates or documentation for influenza, pneumovax, DT, or Hepavax. In a concurrent interview with the HN on September 14, 2010, at 11 a.m., she stated the document had not been updated. | V 726 | | |
| V 750 | 494.180 CFC-GOVERNANCE This CONDITION is not met as evidenced by: Based on observation, staff interviews, and record reviews the governing body: 1. Failed to maintain responsibility for the operation of the facility through monthly QAPI committee meetings per facility policy and procedure from January 2010 through June 2010 to ensure the health and safety of 132 hemodialysis patients (V626 V756). 2. Failed to ensure that: the Chief Technician followed the facility's policy and procedure as it related to reviewing, logging and/or notifying the HN or MD of actionable level CFU and EU dialysate cultures reports when the results had come back from the laboratory (V274, V712). 3. Failed to ensure employees responsible for colorimetric testing of facility water had received testing to detect color blindness (V196, V751). | V 750 | | |

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FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 052658 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED 09/17/2010 |
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| NAME OF PROVIDER OR SUPPLIER KIDNEY INSTITUTE OF THE DESERT | | | STREET ADDRESS, CITY, STATE, ZIP CODE 81-715 DOCTOR CARREON BLVD, SUITE B- 2 INDIO, CA 92201 | | |
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| V 750 | Continued From page 25 | V 750 | | | |
| V 751 | <p>4. Failed to ensure the water purification and storage system area was secured at all times by leaving the rear door to the outside not fully closed and locked (V184, V751).</p> <p>5. Failed to ensure that staff had maintained annual training in emergency equipment and supplies (V411 V751).</p> <p>6. Failed to ensure that all employees had completed competencies and skill testing annually as required (V681, V751).</p> <p>The cumulative effect of these failures had the potential to impact health and safety for 132 of 132 patients receiving hemodialysis treatment in the facility.</p> <p>494.180 GOV-ID GOV BODY W/FULL AUTHORITY/RESPONS</p> <p>The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients ' personal and property rights, and to the general operation of the facility.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview and record review, the governing body failed to ensure that the facility's policies, procedures and rules were enforced to ensure the safety and well being of its patients and for the general operation of the facility by:</p> | V 751 | | | |

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| V 751 | <p>Continued From page 26</p> <ol style="list-style-type: none"> Failing to ensuring monthly QAPI meetings were conducted. Failing to ensure that: the Chief Technician followed the facility's policy and procedure as it related to reviewing, logging and/or notifying the HN or MD of actionable level CFU and EU dialysate cultures reports when the results had come back from the laboratory. Failing to ensure employees responsible for colorimetric testing of facility water had received testing to detect color blindness. Failing to ensure the water purification and storage system area was secured at all times by leaving the rear door to the outside not fully closed and locked. Failing to ensure that staff had maintained annual training in emergency equipment and supplies. Failing to ensure that all employees had completed competencies and skill testing annually as required. <p>Findings:</p> <ol style="list-style-type: none"> On September 15, 2010, at 12:40 p.m., a review of the facility's QAPI program was conducted. There were no Quality Improvement and Governing Board minutes for the months of January 2010 through June 2010. The review indicated that there were an absence of an effective QAPI program. <p>In an interview with the HN conducted on</p> | V 751 | | | |

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| V 751 | <p>Continued From page 27</p> <p>September 15, 2010, at 12:50 p.m., she stated, "There was no nurse manager. She left in February or March. She resigned."</p> <p>The current HN stated that she had assumed the position in June 2010, and her first QAPI meeting had been held in July 2010. She further stated that she was not involved with the QAPI committee until the month of July.</p> <p>At 2:10 p.m. on September 15, 2010, an interview was conducted with the Social Worker. She stated, "I didn't attend any QAPI meetings. I don't schedule it." The Social Worker provided no further information about the QAPI committee meetings.</p> <p>In an interview with the MD on September 15, 2010, at 2:45 p.m., he stated, "I was under the impression it (QAPI meetings) was happening. Something happened from January to March. I don't know, some staff turmoil. She (previous HN) worked for 16 years and she left in March or April. I don't know what for."</p> <p>The surveyor asked the MD who participated on the QAPI committee. He stated, "Head Nurse, other nurses, Social Worker, Dietician, and myself."</p> <p>At 2:53 p.m., he stated, "We know, as I can't change the facts. We got caught off guard. We are starting and will change. We can't take the time back. The person we hired had no experience. We will and are training her to conduct the meetings."</p> <p>The MD gave no further explanation as to why the facility had not had QAPI meetings from January</p> | V 751 | | | |

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| V 751 | <p>Continued From page 28 2010 through June 2010.</p> <p>On September 15, 2010, at 3:10 p.m., a review of the facility's policy and procedure, Quality Assurance Performance Improvement, (QAPI) and dated April 2009, was reviewed. It indicated:</p> <p>"#3 Objectives</p> <p>a. Hold monthly QAPI meetings with the committee...</p> <p>c. Maintain minutes of QAPI meetings."</p> <p>An additional telephone interview was conducted with the Dietician on September 16, 2010, at 9:00 a.m. She stated, "The leader of the nursing staff was suppose to conduct the meeting. I just assumed they were going to schedule the meeting. I should have been more proactive."</p> <p>2. On September 13, 2010, at 1 p.m., a review of the facility's water treatment logs were conducted.</p> <p>-At 1:05 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the 48 hour colony count (A numerical computation of a group of bacteria) in the dialysate, showed the following result: abnormal > 1000 H (high), reference ranges 0-199 CFU/ml. (bacterial count) per milliliter, (unit of volume in the metric system.)</p> <p>-At 1:20 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the endotoxin, (gram negative bacteria), in the product water showed the following result: Endotoxin, product water, 2.29 H, reference ranges 0.00-1.99 EU/ml. (endotoxin</p> | V 751 | | | |

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| V 751 | <p>Continued From page 29 unit per milliliter).</p> <p>-At 1:30 p.m., on September 13, 2010, the laboratory draw report dated March 24, 2009, indicated that the endotoxin in the dialysate showed the following result: Endotoxin, dialysate 2.39 H, reference ranges, 0.00-1.99 EU/ml.</p> <p>-At 1:40 p.m., on September 13, 2010, the laboratory draw report dated July 21, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 330 H, reference ranges, 0-199 CFU/ml.</p> <p>-At 1:50 p.m., on September 13, 2010, the laboratory draw report dated September 25, 2009, indicated that the 48 hour colony count in the dialysate showed the following result: colony count, dialysate 220 H, reference ranges, 0-199 CFU/ml.</p> <p>In an interview with the machine technician at 1:10 p.m., he was asked when the MD knew about these abnormalities; when they were recorded, and how the MD responded to them. The MT stated that he did not know and that he did not work at the facility at the time the laboratory values were taken.</p> <p>A review of the facility Policy and Procedure on September 13, 2010, around 2 p.m., indicated the following: ..."The Chief Technician or his/her designee will be responsible for obtaining the monthly cultures. Culture reports will be reviewed and logged by the Chief Technician. Any abnormal reports will be brought to the attention of the Head Nurse and/or Medical Director and or corrective action will be</p> | V 751 | | | |

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| V 751 | <p>Continued From page 30 instituted."</p> <p>The Chief Technician was unable to present documentation that the MD or HN had been made aware of the actionable level dialysate cultures listed above.</p> <p>3. During the initial tour conducted on September 13, 2010, at 9:00 a.m., the water test kits were observed in the water treatment room.</p> <p>A concurrent interview with Staff 15 indicated that chloramine testing was completed by the dip and read test strip method. This method uses color shading to determine the amount of chloramine in the product water.</p> <p>Review of Staff 15's, employee file, conducted on September 17, 2010, at 11:15 a.m., indicated that he was hired on February 1, 2010. Further review of the file indicated that there was no documentation to indicate whether or not Staff 15 had taken a test to discern colors used for the chloramine testing strips.</p> <p>Further interview with Staff 15 stated that he had not taken a color blind test.</p> <p>4. During the initial tour conducted on September 13, 2010, at 9:05 a.m., the rear door of the water treatment room was observed not to be fully closed and locked.</p> <p>In a concurrent interview with the water technician on September 13, 2010, at 9:05 a.m., he stated that the back door was not kept locked during normal operating hours due to deliveries.</p> <p>Observation on September 13, 2010, at 11:45</p> | V 751 | | | |

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| V 751 | <p>Continued From page 31</p> <p>a.m., revealed that the back door was not fully closed shut and at 11:55 a.m., the surveyor observed the water treatment room was unattended.</p> <p>Further observation on September 14, 2010, at 10:40 a.m. revealed that the back door of the water treatment area was not completely shut and the water treatment area was unattended.</p> <p>An additional interview was conducted with the water technician on September 14, 2010, at 10:45 a.m. He confirmed that the water treatment room was unattended and that the rear door was not fully closed and locked. He further stated that the door should be closed and locked during operation hours.</p> <p>5a During a review of personnel files on September 17, 2010, at 10 a.m., two employee files were outdated for Emergency Procedures Preparedness.</p> <p>Facility staff that had not annual emergency procedures preparedness, included Staff 16 and 17.</p> <p>In an interview with the HN, she confirmed that both staff had not had their annual emergency preparedness training.</p> <p>5b During the initial tour of the facility, on September 13, 2010,two Emergency Food Supplies Containers contained the following expired items:</p> <p>Vanilla Wafers, four 1 lb. 14 oz boxes that had expired on August 30, 2010. Crackers-Honey Maid, four 1 lb. 12.8 oz boxes that had expired on August 29, 2010.</p> | V 751 | | | |

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| V 751 | Continued From page 32 Ritz Crackers four 1 lb. 14 oz boxes, that had expired on August 2010. In an interview with the technician on the tour, he confirmed that the items were expired and would need to be removed from the emergency food container. 6. A review of personnel files was conducted on September 17, 2010, at 9:30 a.m. The files for staff members 16 and 17 show the following for inservices on February 5, 2009: "Universal Precautions Hazardous Material in workplace, MSDS Fire Safety and Evacuation Emergency Procedures Patient Rights and Responsibilities" In a concurrent interview with the HN during the file reviews, she stated the competencies were done annually. No additional competencies were located for staff 16 and 17 after February 5, 2009. | V 751 | | | |
| V 756 | 494.180(a)(4) GOV-ADM RESP FOR RESOURCES FOR QAPI 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- (4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in §494.110. | V 756 | | | |

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| V 756 | Continued From page 33 This STANDARD is not met as evidenced by: Based on record review and interview the Governing Body failed to provide support and guidance to the members of the IDT team to continue the QAPI committee meeting audits for the months of January 2010 through June 2010, used to track patients health outcomes and identify, prevent and reduce medical errors, mortality and morbidities. This failure had the potential to impact patient health and safety for 132 of 132 patients receiving hemodialysis in the facility. Findings: 1- On September 15, 2010, at 12:40 p.m., a review of the facility's QAPI program was conducted. There were no Quality Improvement and Governing Board minutes for the months of January 2010 through June 2010. The review indicated that there were an absence of an effective QAPI program. In an interview with the Nurse Manager conducted on September 15, 2010, at 12:50 p.m., she. stated, "There was no nurse manager. She left in February or March. She resigned." . The current Nurse Manager stated that she had assumed the position in June 2010, and her first QAPI meeting had been held in July 2010. She further stated that she had not involved with the QAPI committee until the month of July. At 2:10 p.m. on September 15, 2010, an interview was conducted with the social worker. She | V 756 | | | |

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| V 756 | <p>Continued From page 34</p> <p>stated, "I didn't attend any QAPI meetings. I don't schedule it," and provided no further information about the QAPI committee meetings.</p> <p>In an interview with the MD on September 15, 2010, at 2:45 p.m., he stated, "I was under the impression it (QAPI meetings) was happening. Something happened from January to March. I don't know, some staff turmoil. She (previous Nurse Manager) worked for 16 years and she left in March or April. I don't know what for."</p> <p>The surveyor asked the MD who participated on the QAPI committee. He stated, "Head Nurse, other nurses, Social Worker, Dietician, and myself."</p> <p>At 2:53 p.m., he stated, "We know, as I can't change the facts. We got caught off guard. We are starting and will change. We can't take the time back. The person we hired had no experience. We will and are training her to conduct the meetings."</p> <p>The MD gave no further explanation as to why the facility had not had QAPI meetings from January 2010 through June 2010.</p> <p>On September 15, 2010, at 3:10 p.m., a review of the facility's policy and procedure, Quality Assurance Performance Improvement, (QAPI) and dated April 2009, was reviewed. It indicated:</p> <p>#3 Objectives</p> <p>a. Hold monthly QAPI meetings with the committee</p> <p>c. Maintain minutes of QAPI meetings."</p> | V 756 | | | |

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