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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 153515 | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | X3) DATE SURVEY COMPLETED 09/25/2013 |
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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 |
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| V000000 | <p>This visit was a federal ESRD Complaint Survey. This was an expanded survey.</p> <p>Complaint #s IN00136608 and IN00136200 - Substantiated: Federal deficiencies related to the allegation are cited. Unrelated deficiencies are also cited.</p> <p>Survey dates: September 18, 19, 23, 24, and 25 2013</p> <p>Facility: 003229</p> <p>Medicaid Vendor: 200383830</p> <p>Surveyor: Susan E. Sparks, RN, PHNS Bridget Boston, RN, PHNS</p> <p>Indiana University Health Adult Dialysis Center was found to be out of compliance with the Conditions for Coverage 42 CFR 494.30: Infection Control, 494.60 Physical Environment, 494.110 Quality Assessment and Performance Improvement, and 494.150: Responsibilities of the Medical Director.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN October 1, 2013</p> | V000000 | | |

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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| V000110 | <p>494.30 CFC-INFECTION CONTROL</p> <p>Based on observation, interview, and review of facility documents, it was determined the facility failed to ensure a sanitary environment for its patients and staff in 1 of 1 facilities reviewed with the potential to affect all 63 patients and 20 staff (See V 111), failed to ensure the potentially infectious waste from the dialysate machines was appropriately disposed of for 16 of 16 dialysis machines observed with the potential to affect all 63 patients (See V 121), and failed to implement and monitor an infection control activity when a hazard was recognized in 16 of 16 dialysis machine water boxes observed with the potential to affect all 63 patients and 20 staff (See V 142).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements the Condition for Coverage 494.30: Infection Control.</p> | V000110 | <p>All staff was educated specifically in regards to Blood Borne Pathogens: transmission, exposure risks, control plan, reducing risks, and what to do. Quiz completed by 11/2/2013 Additional education completed including hand hygiene, PPE, CVC dressing change and Initiation/Discontinuation Dialysis for a Fistula. Education involved classroom, videos, interactive hands on, quiz and observations by the Infection Prevention staff. Monthly observations of Hand Hygiene and PPE along with detailed Environment of Care observations will be completed monthly by the Infection Preventionist and validated staff. Staff will be asked by auditor about "How do you respond to an unidentified fluid on floor" during monthly EOC rounds. The Infection Preventionist will receive monthly data by the fifth of each month and present to the Renal QAPI monthly and to the AHC Infection Control Committee quarterly for review and follow up. Infection Control Policies would be reviewed and updated every 3 years . All staff must complete as part of their mandatory annual eLMS education module "Infection Control Annual Education". Infection Control Policy IC 1.10 BLOODBORNE PATHOGENS</p> | 11/02/2013 | | | |

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| | | | EXPOSURE CONTROL PLAN is available on the Pulse Page and with any change in Infection Prevention process, practice and/or with product change. | |

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| V000111 | <p>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.</p> <p>Based on observation, interview, and review of facility documents, the facility failed to ensure a sanitary environment for its patients and staff in 1 of 1 facilities reviewed with the potential to affect all 63 patients and 20 staff.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff. | V000111 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| | <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the water.</p> | | | | | | |

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| | <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building. One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for</p> | | | | |

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| | <p>drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services,</p> | | | | |

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| | <p>that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the</p> | | | | | | |

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| | <p>drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through</p> | | | |

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| | the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls. 03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed." | | | |

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| V000121 | <p>494.30(a)(4)(i) IC-HANDLING INFECTIOUS WASTE [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- (i) Handling, storage and disposal of potentially infectious waste;</p> <p>Based on observation, interview, and review of facility documents, the facility failed to ensure the potentially infectious waste from the dialysate machines was appropriately disposed of for 16 of 16 dialysis machines observed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> | V000121 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| | <p>2. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood</p> | | | |

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| | <p>structure was saturated, and an odor was present. An electric wire was in the water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the</p> | | | | | | |

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| | <p>building . One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> | | | | | | |

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| | <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> | | | |
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| | D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer | | | | | | |

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| | <p>have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> | | | | |

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| V000142 | <p>494.30(b)(1) IC-O-SIGHT-MONITOR ACTIVITY/IMPLEMENT P&P The facility must-</p> <p>(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;</p> <p>Based on observation, interview, and review of facility documents, the facility failed to implement and monitor an infection control activity when a hazard was recognized in 16 of 16 dialysis machine water boxes observed with the potential to affect all 63 patients and 20 staff.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>2. On 9/19/2013 at 7:40 AM, patients</p> | V000142 | <p>All staff was educated specifically in regards to Blood Borne Pathogens: transmission, exposure risks, control plan, reducing risks, and what to do. Quiz completed by 11/2/2013.</p> <p>Additional education completed including hand hygiene, PPE, CVC dressing change and Initiation/Discontinuation Dialysis for a Fistula. Education involved classroom, videos, interactive hands on, quiz and observations by the Infection Prevention staff. Monthly observations of Hand Hygiene and PPE along with detailed Environment of Care observations will be completed monthly by the Infection Preventionist and validated staff . Staff will be asked by auditor about "How do you respond to an unidentified fluid on floor" during monthly EOC rounds. The Infection Preventionist will receive monthly data by the fifth of each month and present to the Renal QAPI monthly and to the AHC Infection Control Committee quarterly for review and follow up. Infection Control Policies would be reviewed and updated every 3 years. All staff must complete as part of their</p> | 11/02/2013 | | | |

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| | <p>were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was</p> | | <p>mandatory annual eLMS education module "Infection Control Annual Education". Infection Control Policy IC 1.10 BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN is available on the Pulse Page and with any change in Infection Prevention process, practice and/or with product change.</p> | | | | |

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| | <p>present. An electric wire was in the water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building . One day the leaked fluid was</p> | | | | | | |

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| | <p>yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> | | | | |

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| V000199 | <p>494.40(a) RO-MEETS AAMI/MONITORED, RECORDED ON LOG 5.2.7 Reverse osmosis: meets AAMI/monitored/recorded on log Refer to RD62:2001, 4.3.7 Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2.</p> <p>5.2.7 Reverse osmosis Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.</p> <p>6.2.7 Reverse osmosis All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review. Based on observation, interview and review of administrative documents, the facility failed to ensure both of two reverse osmosis water treatment systems were monitored daily for 1 of 1 facility with the potential to affect all 63 dialysis patients.</p> <p>The findings include:</p> <p>1. On 9/19/13 at 12:30 PM, two reverse osmosis water systems were observed in</p> | V000199 | <p>Both RO's will be checked daily. Water policy reviewed, updated. Education provided about change in practice. Check-offs completed by the water technician for all staff that will be assigned to task. New checksheet developed and began testing of both RO systems on 10-9. Monthly audits utilizing the BioMedical audit (#44) tool developed by the National Renal Administrators Association will be conducted. Audit data will be reviewed in monthly QAPI.</p> | 10/09/2013 |

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| | <p>the water room and in operation.</p> <p>2. A review of the facility documents titled "RO Data Collection Form" dated January through August 2013 indicated only one of two reverse osmosis water treatment systems was monitored daily.</p> <p>3. At 12:30 PM, employee N indicated there was no further documentation. He indicated the logs indicated only one of the two reverse osmosis water treatment systems were monitored though both were present and operating every day the clinic was open.</p> | | <p>Checklist and water policy attached. Unit Manager is responsible to ensure the deficiency has been correctly and compliance is maintained..</p> | | |

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| V000213 | <p>494.40(a) DIST SYS-CULTURE/LAL/SITES/FREQ(NEW)/LOG 6.3.3 Water distribution systems: culture/LAL sample sites/frequency (new)/log Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL]</p> <p>Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits.</p> <p>Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken. Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).</p> <p>All bacteria and endotoxin results should be recorded on a log sheet to identify trends</p> | | | | | | |

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| | <p>that may indicate the need for corrective action.</p> <p>Based on administrative document review and interview, the facility failed to ensure the portion of the water distribution system that supplied the bicarbonate mixing tank was monitored for bacteria and endotoxin levels at least monthly for 1 of 1 facility with the potential to affect all 63 in-center hemodialysis patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. The water culture reports dated January through August 2013 failed to evidence monthly monitoring of the product water which is fed to the mixer and is used to make the bicarbonate solution used for the dialysis treatment. 2. On 9/19/13 at 11 AM, employee N indicated the facility policy was to collect a sample of the product water that fed the bicarbonate mixer once a year and indicated a sample has not been collected since January 2013. | V000213 | <p>Product water from bicarbonate tank will be cultured monthly.</p> <p>Water from the first and last outlets of the distribution loop will be cultured monthly. Process began with October water samples. Monthly audits will be completed utilizing the form Water/Dialysate Quality Monitoring and the Monthly Biomed audit tools (12,13,15-17) created by National Renal Administrators Associate, documented, and reported in monthly dialysis QAPI. See attached. Ongoing audit with a benchmark of 100% compliance; once benchmark reached, audits to drop to spot audits. Unit Manager is responsible to ensure compliance. Water policy reviewed and revised to reflect current changes.</p> | 11/02/2013 | |

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| V000400 | <p>494.60 CFC-PHYSICAL ENVIRONMENT</p> <p>Based on observation, interview, and review of agency documents, it was determined the facility failed to maintain the building in a safe manner in 1 of 1 facilities reviewed with the potential to affect all 63 patients (See V 401), failed to maintain a safe environment free from defects for patients and staff in 1 of 1 facilities reviewed with the potential to affect all 63 patients and 20 staff members (See V 402), and facility failed to implement a program to ensure the dialysis machine water drain boxes were maintained for 16 of 16 boxes with the potential to affect all 63 patients (See V 403).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to be in compliance 42 CFR 494.60 Physical Environment.</p> | V000400 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| V000401 | <p>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.</p> <p>Based on observation, interview, and review of agency documents, the facility failed to maintain the building in a safe manner in 1 of 1 facilities reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff. | V000401 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| | <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the water.</p> | | | | | | |

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| | <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building. One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for</p> | | | | | | |

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| | <p>drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services,</p> | | | | |

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| | <p>that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the</p> | | | |

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| | <p>drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through</p> | | | |

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| | the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls. 03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed." | | | |

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| V000402 | <p>494.60(a) PE-BUILDING-CONSTRUCT/MAINTAIN FOR SAFETY The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.</p> <p>Based on observation, interview, and review of agency documents, the facility failed to maintain a safe environment free from defects for patients and staff in 1 of 1 facilities reviewed with the potential to affect all 63 patients and 20 staff members.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>2. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern</p> | V000402 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| | <p>were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the water.</p> | | | | |

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| | <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building . One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an</p> | | | | | | |

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| | <p>estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O,</p> | | | | |

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| | <p>Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air</p> | | | | | | |

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| | <p>gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1</p> | | | |

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| | <p>section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> | | | |

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| V000403 | <p>494.60(b) PE-EQUIPMENT MAINTENANCE-MANUFACTURER'S DFU The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.</p> <p>Based on observation, interview, and review of agency documents, the facility failed to implement a program to ensure the dialysis machine water drain boxes were maintained for 16 of 16 boxes with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>2. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients</p> | V000403 | <p>Construction Plan Summary: Pre and Post pictures attached. Airducts were cleaned by outside contractor in preparation for complete repair under negative airflow conditions without patient presence. Grills/Diffusers were replaced by outside contractor. Water boxes replaced by outside contractor. Drywall replaced, access panels were installed for each water box by outside contractor. Damaged floor tiles to be replaced by November 2, 2013. Prior to allowing patients to return to area, an intense cleaning was completed. After installation of water boxes, a water sanitization of the system was completed. The Medical Director and Unit Manager are responsible to ensure the deficiency will be/has been corrected and compliance maintained. Access doors were installed to allow for continued monthly monitoring utilizing a standardized checklist which will evaluate all potential issues. Checklist attached.</p> | 10/06/2013 | | | |

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| | <p>who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the</p> | | | | | | |

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| | <p>water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building. One day the leaked fluid was yellow and smelled. The facility response</p> | | | | |

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| | <p>was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee</p> | | | | |

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| | <p>B sent an email to Employee O, Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02.</p> | | | | | | |

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| | <p>Clinical Impact It is imperative that an air gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl</p> | | | |

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| | <p>flooring in what we refer to as bay 1 section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> | | | |

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| V000452 | <p>494.70(a)(1) PR-RESPECT & DIGNITY The patient has the right to-</p> <p>(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD</p> <p>Based on observation, interview, and review of documents, the facility failed to ensure the patients assigned to sit in the east end of the dialysis unit where the used dialysate pooled from the leaking in the cracked water boxes were treated with respect and dignity in 1 of 1 dialysis units with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>2. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients</p> | V000452 | Leadership rounding will occur weekly on both patient shifts, for both weekly schedules to assess patient satisfaction of patient care, environment, and services being provided. Leadership rounds will be documented on a standard tool. Items that can be resolved immediately will be resolved aggregate information will be reported at the monthly QAPI meetings. | 11/02/2013 | | | |

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| | <p>who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the</p> | | | | | | |

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| | <p>water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building . One day the leaked fluid was yellow and smelled. The facility response</p> | | | | |

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| | <p>was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee</p> | | | | |

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| | <p>B sent an email to Employee O, Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02.</p> | | | | | | |

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| | <p>Clinical Impact It is imperative that an air gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl</p> | | | |

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| | flooring in what we refer to as bay 1 section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls. 03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed." | | | |

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| V000503 | <p>494.80(a)(2) PA-APPROPRIATENESS OF DIALYSIS RX The patient's comprehensive assessment must include, but is not limited to, the following:</p> <p>(2) Evaluation of the appropriateness of the dialysis prescription, Based on clinical record and facility policy review, the facility failed to ensure comprehensive assessments included an evaluation of the patients' dialysis prescription in 2 (#s 6 and 7) of 6 records reviewed that had comprehensive assessments with the potential to affect all 63 patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> 1. Clinical record number 6 included a follow up comprehensive assessment dated 1/29/13 that failed to include an evaluation of the dialysis prescription that addressed the number of treatments per week, the length of treatment time, and the dialyzer. 2. Clinical record number 7 included a comprehensive assessment dated 3/7/13 that failed to include an evaluation of the dialysis prescription that addressed the number of treatments per week, the length of treatment time, and the dialyzer. 3. The facility policy titled Patient | V000503 | <p>Adoption of the Interdisciplinary Comprehensive Assessment and Plan of Care form created by the National Renal Administrators Association. New form specifically includes adequacy of dialysis prescription assessment as well as the associated plan of care. Evaluated, updated Patient Assessment and Plan of Care Policy. Updated policy will be reviewed with staff in quarterly QAPI on Oct 23. Policy attached.</p> <p>The Medical Director and the Unit Manager will be responsible for monitoring these corrective actions to ensure that this deficiency is corrected without reoccurrence. Monthly audits utilizing the Monthly Medical Record Audit (#28) created by the National Renal Administrators Association on 3-5 random records. Goal of 100% with interventions necessary based upon findings to aid in reaching 100%. Audit results to be reported in monthly QAPI.</p> | 11/02/2013 |

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| | Assessments" and dated April 2013 stated, "The Plan Of Care must address: 1) The dose of dialysis - Including services to manage the volume status." | | | |

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| V000520 | <p>494.80(d)(2) PA-FREQUENCY REASSESSMENT-UNSTABLE Q MO 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>At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis. Based on interview and review of policy and clinical records, the facility failed to ensure a comprehensive assessment was conducted and a revision of the plan of care was completed at least monthly for unstable patients and care was provided in a safe manner in 5 of 5 records reviewed of unstable patients with the potential to affect all 63 patients. (#3, 6, 12, 16, and 19)</p> <p>Findings:</p> <p>1. Patient # 3, with a first treatment at unit (FTU) 3/30/09, was declared unstable in June 2013 by the physician. On 7/23/13, a month after being declared unstable, the IDT met and the patient had returned to a stable status without the IDT</p> | V000520 | <p>Patient Assessment and Plan of Care Policy evaluated, and updated. Policy and new format for interdisciplinary comprehensive assessment and plan of care attached. Policy now defines assessment timeframes and minimum criteria to deem a patient unstable, which was previously not included . Adopted the Interdisciplinary Comprehensive Assessment and Plan of Care form created by the National Renal Administrators Association. Monthly audits will be completed utilizing the Monthly Medical Record Review (#9) created by the National Renal Administrators Association on 3-5 random records. Goal of 100% with the interventions necessary based upon findings to aid in reaching goal if not 100% Audits will be reported in monthly QAPI.</p> | 11/02/2013 | | | |

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| | <p>providing a assessment and plan of care.</p> <p>On 9/24/13 at 12:30 PM, Employee Q, the Social Worker, indicated the physician declares a patient unstable at one interdisciplinary meeting (IDT) and the staff will have a month to do the assessment and will determine a plan of care at the next month's staff meeting. She indicated she knew this patient was declared unstable by the physician but could not provide documentation of an assessment or revised plan of care.</p> <p>2. Patient # 6, with a FTU 3/30/09, on 9/19/13 at 8:00 AM, was observed on dialysis in a trendelenburg position, with a chair holding up the foot of the dialysis chair. The patient was moaning in pain and asking for pain medication. The patient's right arm was swollen and propped on a pillow. The clinical record evidenced the patient's last care plan was 1/29/13 and was stable. The record failed to evidence a comprehensive assessment and a revision to the plan of care had been completed with the patient's deterioration in health status.</p> <p>A. The record evidenced the patient was hospitalized on 6/19/13 due to a fall; on 6/21/13 due to hip pain, 8/14/13 through 8/16/13 for a revision of the right hip arthroplasty, on 9/7/13 due to</p> | | <p>Draft directed plan of care form usage began 10/10/ 2013.</p> <p>Education and quick reference cards were provided to staff and physicians on 10-4 with the minimum criteria to deem a patient unstable. Reinforced that any member of the interdisciplinary team can ask that a patient be made unstable. Educated staff on new policy on Oct 23, and will be reinforced in the quarterly QAPI on Oct 30 .</p> <p>The Medical Director and the Unit Manager will be responsible for monitoring audit results through QAPI.</p> | |

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| | <p>prolonged bleeding from the patient's access following dialysis, and on 9/10/13 through 9/14/13 due to a dislocation of the right hip. (These frequent hospitalizations caused the patient to meet the criteria for unstable.)</p> <p>B. The record evidenced progress notes written by employee M, a nurse practitioner, dated 6/25/13 which indicated the patient was residing in a rehabilitation facility due to a dislocated hip. The record also evidenced, on 8/1/13, the patient was treated for cellulitis of the left ankle and was complaining of pain.</p> <p>C. On 9/19/13 at 8:05 AM, Employee G indicated the patient had recent hip surgery and his hips dislocated easily and the patient was in a lot of pain. She indicated he had went from living at home to a nursing home recently. The facility does not have a Hoyer or a gait belt, and the patient arrives in a wheelchair and must stand and pivot with at least 2-3 staff members to do safely.</p> <p>D. On 9/19/13 at 10 AM, employee B indicated it was the policy of the facility for the medical director to make the determination of stable and unstable status and there was no reassessment of the patient's needs by the</p> | | | | |

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| | <p>IDT.</p> <p>E. On 9/24/13 at 12:30 PM Employee Q, the Social Worker, indicated the physician declares a patient unstable at the interdisciplinary meeting (IDT) and the staff will have a month to do the assessment and will determine a plan of care at the next month's staff meeting.</p> <p>F. On 9/25/13 at 2:30 PM Employee B, Clinical Manager, indicated this patient is unstable and they should be doing with this.</p> <p>G. Related to providing safe care: On 9/19/13 at 8:10 AM, Employee D was observed administering a liquid pain medicine to the patient who was in trendelenburg position and who promptly aspirated the medication. The patient had to be sat up and worked with to recover from the aspiration. Employee D indicated to Employee A the patient had a swallow test and needed thickener. When asked why the patient wasn't receiving pain medication by IV, Employee I responded, "Well, the patient is 99,"</p> <p>3. Patient # 12, with a FTU 11/23/09, was declared unstable in May 2013 by the physician. On 6/12/13 a month after being declared unstable, the IDT met and the patient had returned to a stable status</p> | | | | |

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| | <p>without the IDT providing an assessment and plan of care.</p> <p>On 9/24/13 at 12:30 PM, Employee Q, the Social Worker, indicated she knew this patient was declared unstable by the physician but could not provided the documentation of a comprehensive assessment or revision of the plan of care.</p> <p>4. Patient # 16, with a FTU 10/3/11, was declared unstable in May 2013 by the physician. The patient did not have a comprehensive assessment and plan of care until the following IDT in July.</p> <p>On 9/24/13 at 12:30 PM, Employee Q, the Social Worker, indicated she knew this patient was declared unstable by the physician but could not provided the documentation of a comprehensive assessment or revision of the plan of care.</p> <p>5. Patient # 19, with a FTU 8/25/11, was declared unstable in July 2013 by the physician. On 8/19/13 a month after being declared unstable, the IDT met and the patient had returned to a stable status without the IDT providing a assessment and plan of care.</p> <p>On 9/24/13 at 12:30 PM, Employee Q, the Social Worker, indicated she knew this patient was declared unstable by the</p> | | | | | | |

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| | <p>physician but could not provided the documentation of a comprehensive assessment or revision of the plan of care.</p> <p>6. A policy titled "Patient Assessment", Review/Revision Date: April 2013, states, "E. Further follow-up comprehensive reassessments must be completed at lest monthly for unstable patients and at least annually for stable patients. Updates to the plan of care must be performed within 15 days of the completion of all additional comprehensive assessments. ... The patients whose medical condition is considered not stable is identified by their primary care nephrologist. The nephrologist will document the Patient Status on the Plan of Care. If the Primary Care Physician identified the patient is unstable they will document this as "significant change" on the Care Plan."</p> <p>7. The facility policy titled "Patient Assessments" and dated April 2013 stated, "When a patient is unable to achieve the desired outcomes, the team must: 1) Adjust the plan of care to reflect the patient's current condition, 2) Document in the record the reasons why the patient is unable to achieve the goals, 3) Implement plan of care changes to address the issues identified. Responsibility The medical directors and Administrative Director are responsible to</p> | | | |

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| | <p>oversee the initiation and promotion of the comprehensive assessments and initiation of the care plan, all to be completed by the interdisciplinary team. The primary care Nephrologist and the Unit Managers have a leading role in this process as well. As stated in the definition section of this policy, the interdisciplinary team is defined as the patient or the patient's designee (if the patient chooses), a registered nurse, the Nephrologist treating the patient for ESRD, a social worker, a dietician, and a nurse practitioner."</p> | | | |

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| V000541 | <p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 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 and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record and facility policy review, the facility failed to ensure all members of the IDT participated in the plan of care and plans of care were current and included measurable goals and estimated timetables to achieve the desired goals in 2 (#s 6 and 7) of 6 records reviewed creating the potential to affect the facility's 63 current patients.</p> <p>The findings include:</p> <p>1. Clinical record # 6, date of first dialysis 3/23/2009, evidenced the patient's last care plan was 1/29/13 and the patient was stable. The record failed to evidence a reassessment of the patient's current health status and an updated plan of care with interventions and measurable goals.</p> | V000541 | <p>Patient Assessment and Plan of Care Policy evaluated, and updated. New form addresses the creation of goals, actions, and achievement for each patient based on the section's assessment. Adoption of the Interdisciplinary Comprehensive Assessment and Plan of Care created by the National Renal Administrators Association . Monthly audits utilizing the Monthly Medical Record Review audit tool created by the National Renal Administrators Association (#29) will be completed on 3-5 random records. Goal of 100% with interventions necessary based upon finding to aid in reaching goal if not 100%. Audit results to be reported in monthly QAPI. Updated policy was reviewed with staff during staff meeting on Oct 23. A Nursing Competency on</p> | 11/02/2013 | | | |

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| | <p>A. The record evidenced progress notes written by employee M, a nurse practitioner, dated 6/25/13 which indicated the patient was residing in a rehabilitation facility due to a dislocated hip. The record also evidenced, on 8/1/13, the patient was treated for cellulitis of the left ankle and was complaining of pain.</p> <p>B. The record evidenced the patient was hospitalized on 6/19/13 due to a fall; on 6/21/13 due to hip pain, 8/14/13 through 8/16/13 for a revision of the right hip arthroplasty, on 9/7/13 due to prolonged bleeding from the patient's access following dialysis, and on 9/10/13 through 9/14/13 due to a dislocation of the right hip.</p> <p>C. Laboratory data evidenced the patient's phosphorus level was above desired levels per CMS Clinical Performance Measures (CPM) "Measures Assessment Tool" (MAT) of 3.5 - 5.5 mg / dL [milligrams per deciliter]. On 7/4/13, the patient's phosphorus level was 6.1. .</p> <p>D. Laboratory data evidenced the patient albumin level was 3.3 grams per deciliter on 8/8/13. The patient's target albumin level on most recent plan of care dated 1/29/13 was to be greater of equal</p> | | assessment/reassessment will be completed by 11-2-2013 . | | | | |

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| | <p>to 3.5. The record failed to evidence the plan of care addressed the lower than desired level of albumin.</p> <p>E. On 9/19/13 at 8:30 AM, employee D, a registered nurse, was observed to administer liquid medication to the patient, who was in a trendelenburg position, to treat the patient's complaints of pain. After the liquid medication was administered, the patient began to cough and and continued coughing for over 30 minutes. The registered nurse indicated the patient had complained of difficulty swallowing days earlier and had a swallow evaluation. As a result, the patient's medication was changed from a tablet to the liquid form. The record failed to evidence the plan of care was updated and addressed the problems with swallowing.</p> <p>2. Clinical record 7, admission date 3/4/13, included an undated updated plan of care (PoC) established by the interdisciplinary team (IDT).</p> <p>A. The PoC indicated the targeted goal of blood pressure management was not met. The document failed to identify the current status, a targeted goals, and a timetable to achieve.</p> <p>B. The PoC indicated protein goal</p> | | | |

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| | <p>was not met and the albumin level was 3.3 and goal was not met. The PoC failed to evidence a timetable to achieve and maintain the desired albumin level.</p> <p>D. The PoC indicated bone metabolism goals were not met and the patient's intact parathyroid hormone was 97.3 without sensipar. The PoC failed to evidence a measurable goal, interventions, and a timetable to reach the level not attained.</p> <p>E. Clinical record included a plan of care established by the IDT dated 8/14/13. The plan of care indicated the targeted goals regarding vascular access, potential for infection, blood pressure, and patient education were not met. The plan of care failed to evidence interventions and a timetable to achieve measurable goals.</p> <p>F. Clinical record included a plan of care established by the IDT dated 9/12/13. The plan of care indicated the targeted goals regarding vascular access, potential for infection, blood pressure, and patient education were not met. The plan of care failed to evidence interventions and a timetable to achieve measurable goals.</p> <p>3. The facility policy titled Patient Assessments" and dated April 2013 stated, "When a patient is unable to</p> | | | |

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| | <p>achieve the desired outcomes, the team must: 1) Adjust the plan of care to reflect the patient's current condition, 2) Document in the record the reasons why the patient is unable to achieve the goals, 3) Implement plan of care changes to address the issues identified.</p> <p>Responsibility The medical directors and Administrative Director are responsible to oversee the initiation and promotion of the comprehensive assessments and initiation of the care plan, all to be completed by the interdisciplinary team. The primary care Nephrologist and the Unit Managers have a leading role in this process as well. As stated in the definition section of this policy, the interdisciplinary team is defined as the patient or the patient's designee (if the patient chooses), a registered nurse, the Nephrologist treating the patient for ESRD, a social worker, a dietician, and a nurse practitioner."</p> | | | |

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| V000625 | <p>494.110 CFC-QAPI</p> <p>Based on interview, observation, document review, and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, it was determined the facility failed to ensure its QAPI program was effective, reflected the complexity of the organization, and focused on medical errors and improved health outcomes and policies were congruent with requirements in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 626); failed to ensure its QAPI program achieved measurable improvement in health outcomes and reduction of medical errors in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 627); failed to ensure its QAPI program measured analyzed and tracked quality indicators or other aspects of performance in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 628); failed to ensure its QAPI program included adequacy of dialysis in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 629); failed to ensure its QAPI program included nutritional status in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 630); failed</p> | V000625 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators, to include crown web data, machine maintenance, vaccinations, personnel issues. buildings and grounds issues. New policy, audit tools, meeting minute template, and spread sheets attached.</p> <p>Review of new process to occur with staff at the quarterly QAPI meeting on Oct 30, and the October staff meeting on Oct 23. First QAPI meeting utilizing new format will occur on Nov 22.</p> <p>The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | 10/30/2013 | | | |

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| | to ensure its QAPI program included anemia management in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 632); failed to ensure its QAPI program included vascular access in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 633); failed to ensure its QAPI program included medical injuries and medical error identification in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 634); failed to ensure its QAPI program included patient satisfaction and grievances in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 636); failed to ensure its QAPI program included infection control in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 637); failed to continuously monitor its performance, take actions that result in improvements, and track performance to ensure improvements are sustained in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 638); failed to set priorities for performance improvement and giving priority to actives that affected clinical outcomes or patient safety in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients (See V 639); and failed to immediately correct an identified problem that threatened the health and | | | |

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| | <p>safety of the patients in 1 of 1 facilities reviewed with the potential to affect all 63 patients (See V 640).</p> <p>The cumulative effect of these systemic problems resulted in the facility's inability to meet the requirements of this Condition for Coverage 494.110 Quality assessment and performance improvement.</p> | | | |

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| V000626 | <p>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.</p> <p>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program was effective, reflected the complexity of the organization, and focused on medical errors and improved health outcomes and policies were congruent with requirements in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors</p> | V000626 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators, to include crown web data, machine maintenance, vaccinations, personnel issues. buildings and grounds issues. New policy, audit tools, meeting minute template, and spread sheets attached.</p> <p>Review of new process to occur with staff at the quarterly QAPI meeting on Oct 30 and the staff meeting on Oct 23. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every</p> | 10/30/2013 | | | |

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| | <p>and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance." The policy failed to include the role of the physician, social worker, dietitian, nurse and biomedical technician.</p> <p>A. The quarterly QAPI attendance sheet dated 11/16/12, 4/19/13, and 8/23/13 failed to evidence a Technical Representative was present.</p> <p>B. The quarterly QAPI attendance sheet dated 1/18/13 failed to evidence a Technical Representative, Social worker or a Dietitian was present.</p> <p>2. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and</p> | | <p>meeting. The Chief Medical Officer and Administrative Director have now defined the expectation of all members of the IDT to be present at all QAPI meetings or to send representation. Attendance will be monitored and tracked by the using the monthly sign in sheets that will be reviewed in the next month's QAPI meeting.</p> | | | | |

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| | <p>cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>3. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as</p> | | | | | | |

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| | <p>they come in, but there's not a bio medical technician for the facility.</p> <p>4. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> | | | |

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| V000627 | <p>494.110(a)(1) QAPI-ONGOING;USES INDICATORS=IMPROVEMENT</p> <p>The program must include, but not be limited to, 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>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program achieved measurable improvement in health outcomes and reduction of medical errors in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide</p> | V000627 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators, to include crown web data, machine maintenance, vaccinations, personnel issues. buildings and grounds issues. New policy, audit tools, meeting minute template, and spread sheets attached. New policy defines the interdisciplinary team as the Nurse, Physician, Unit Manager, Social Worker, Dietician, Nurse Practitioner, Biomedical Technician, and the patient or patient's designee. Review of new process to occurred with staff at staff meeting by unit manager on Oct 30. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting. The Chief Medical Officer and Administrative Director have now</p> | 10/30/2013 |

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| | <p>performance." The policy failed to include the role of the physician, social worker, dietitian, nurse and biomedical technician.</p> <p>A. The quarterly QAPI attendance sheet dated 11/16/12, 4/19/13, and 8/23/13 failed to evidence a Technical Representative was present.</p> <p>B. The quarterly QAPI attendance sheet dated 1/18/13 failed to evidence a Technical Representative, Social worker or a Dietitian was present.</p> <p>2. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion</p> | | <p>defined the expectation of all members of the IDT to be present at all QAPI meetings or to send representation. Attendance will be monitored and tracked by the using the monthly sign in sheets that will be reviewed in the next month's QAPI meeting.</p> <p>Adopted the Monthly Clinical Audit tool developed by the National Renal Administrators Association. Goal is to be 100% with interventions as necessary based on findings to aid in reaching 100% goal. Audit information to be reported at monthly QAPI meeting.</p> | | | | |

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| | <p>reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>3. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>4. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDAQOL.</p> | | | |

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| V000628 | <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>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program measured analyzed and tracked quality indicators or other aspects of performance in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure</p> | V000628 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. New policy, audit tools, meeting minute template, and spread sheets attached.</p> <p>Adopted the KDQOL tracking sheet developed by the National Renal Administrators Association . Reinforced need for unit Social Workers to gather and share information during the monthly QAPI meeting. Adopted Meeting Outline/Agenda on which KDQOL is one of the measures included to be discussed during monthly QAPI meetings. Review</p> | 10/30/2013 | |

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| | <p>Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical</p> | | <p>of new process to occur with staff at the quarterly QAPI meeting on Oct 30, and during the October staff meeting on Oct 23. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | |

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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 | | | |
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| | <p>technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> <p>6. On 9/24/13 at 3:45 PM, Employee B indicated the QAPI reviews the subjects on the IU Health Adult Renal HD Report Card for their QAPI.</p> | | | | | | |

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| V000629 | <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>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included adequacy of dialysis in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion</p> | V000629 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. Adopted the Adequacy Management tool developed by the National Renal Administrators Association. Adopted Meeting Outline/Agenda on which dialysis adequacy is one of the measures included to be discussed during monthly QAPI meetings.</p> <p>Review of new process to occur with staff at the quarterly QAPI meeting on Oct 30, and during the staff meeting on Oct 23.</p> <p>First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained.</p> | 10/30/2013 |

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| | <p>reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDAQOL.</p> | | The Chief Medical Officer and/ or the Administrative director will be present at every meeting. | | | | |

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| | <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | |

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| V000630 | <p>494.110(a)(2)(ii) QAPI-INDICATOR-NUTRITIONAL STATUS The program must include, but not be limited to, the following: (ii) Nutritional status.</p> <p>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included nutritional status in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer</p> | V000630 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management , Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control I, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data . Review of new process occur red with staff by unit manager at staff meeting on Oct 23. Adoption of National Rena I Administrators Association Monthly Medical Record Audit tool (#8) Nutritional Assessment . Goal 100% with interventions necessary based upon findings to aid in achieving 100% . Audits to be reported in monthly QAPI.</p> <p>First QAPI meeting utilizing new format will occur on Oct 30 .</p> <p>The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be</p> | 10/30/2013 |

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| | <p>set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> | | present at every meeting. | |

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| | <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | |

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| V000632 | <p>494.110(a)(2)(iv) QAPI-INDICATOR-ANEMIA MANAGEMENT The program must include, but not be limited to, the following: (iv) Anemia management. Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included anemia management in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in</p> | V000632 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators : Adequacy of dialysis, Nutritional status , Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification , Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. New policy, audit tools, meeting minute template, and spread sheets attached. Adopted the anemia management tracking sheet developed by the National Renal Administrators Association. Information will be presented at the monthly QA PI meeting . Adopted Meeting Outline/Agenda on which anemia management is one of the measures included to be discussed during monthly QAPI meetings . Review of new process occurred at staff meeting by the unit manager on Oct 23. First QAPI meeting utilizing new format will occur on Oct 30. The</p> | 10/30/2013 |

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| | <p>dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the</p> | | <p>Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting .</p> | | | | |

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| | <p>KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | | |

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| V000633 | <p>494.110(a)(2)(v) QAPI-INDICATOR-VASCULAR ACCESS The program must include, but not be limited to, the following: (v) Vascular access.</p> <p>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included vascular access in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion</p> | V000633 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/ Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. Adoption of National Renal Administrators Association Monthly Medical Record Audit tool (#23-27). Goal 100% with interventions necessary based upon findings to aid in achieving 100%. Audits to be reported in monthly QAPI. Review of new process occurred in staff meeting by the unit manager on Oct 23. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | 10/30/2013 |

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| | <p>reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDAQOL.</p> | | | |

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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 |
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| | <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 153515 | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | X3) DATE SURVEY COMPLETED 09/25/2013 |
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| V000634 | <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>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included medical injuries and medical error identification in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical</p> | V000634 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators : Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. New policy, audit tools, meeting minute template, and spread sheets attached.</p> <p>Adopted the medication error tracking sheet developed by the National Renal Administrators Association. Information will be presented at the monthly QAPI meeting . Adopted Meeting Outline/Agenda on which medication errors is one of the measures included to be discussed during monthly QAPI meetings. Review of new process to occurred during staff meeting by the unit manager on Oct 23 . First QAPI meeting utilizing new format will occur on</p> | 10/30/2013 |

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| | <p>errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not</p> | | <p>Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/o r the Administrative director will be present at every meeting</p> | | |

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| | <p>asked for information such as the KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | | |

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| V000636 | <p>494.110(a)(2)(viii) QAPI-INDICATOR-PT SATIS & GRIEVANCES The program must include, but not be limited to, the following: (viii) Patient satisfaction and grievances.</p> <p>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included patient satisfaction and grievances in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical</p> | V000636 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators, to include crown web data, machine maintenance, vaccinations, personnel issues. buildings and grounds issues . New policy, audit tools, meeting minute template, and spread sheets attached . Leadership rounding will occur weekly on both patient shifts, for both weekly schedules to assess patient satisfaction of patient care, environment, and services being provided .</p> <p>Adopted Patient complaint/grievance log . All patient complaints and grievances are tracked on the log, effective Oct 30. Patient Satisfaction is collected by NRC Picker and reported to us through the NRC Picker Catalyst Tool.</p> <p>The Catalyst Tool allows us to trend the data as well as see the comments. This information will be shared at monthly QAPI. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/ or</p> | 10/30/2013 |

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| | <p>errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not</p> | | the Administrative director will be present at every meeting. | | |

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| | <p>asked for information such as the KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | | |

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| V000637 | <p>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-</p> <p>(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.</p> <p>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to ensure its QAPI program included infection control in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> | V000637 | <p>All of the key infection control metrics (included in part B of the National Renal Administrators Association QAPI Tool Kit) will be included as a part of QAPI. The infection preventionist has been added to monthly QAPI effective Oct 30. PDSA's will be created based upon information gained through the infection control metrics. All infection control data will also go through the Academic Health Center Infection Control Committee quarterly.</p> | 10/30/2013 |

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| | 1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff | | | |

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| | <p>education and visual practice audits.</p> <p>2. A facility QAPI document titled "IU health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to monitor vaccinations-hepatitis b vaccinations, influenza, pneumococcal and patient education.</p> <p>3. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>4. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> <p>5. On 9/24/13 at 3:45 PM, Employee B indicated the QAPI reviews the subjects on the IU Health Adult Renal HD Report Card for their QAPI.</p> | | | | |

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| | <p>6. The clinic manager indicated, on 9/19/13 at 11 AM, the infection control audits conducted were looking for the WHO [World Health Organization] Five (5) moments of hand hygiene. She indicated the in-center staff who observed for breaks in infection control was employee N, an individual that was trained to work as a patient care technician, had never worked as a patient care technician, and had no specialized training in infection control monitoring.</p> <p>On 9/19/13 at 11 AM, employee N indicated he had no specialized training in infection control beyond his training to be a patient care technician 4 years ago.</p> | | | |

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| V000638 | <p>494.110(b) QAPI-MONITOR/ACT/TRACK/SUSTAIN IMPROVE 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>Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to continuously monitor its performance, take actions that result in improvements, and track performance to ensure improvements are sustained in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function</p> | V000638 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. New policy, audit tools, meeting minute template, and spread sheets attached. Upon review of the quality measures, performance improvement (PDSA's) will be prioritized based upon a standardized rating scale utilizing 0-5 (none to high). The four indicators are as follows: 1) threat of immediate patient harm, 2) . Regulatory, 3). Impact to patient satisfaction, 4) Impact to patient throughput. The efforts of the quality monitoring process will be reported at the monthly QAPI meeting and reported at least annually to the IU Health Board</p> | 10/30/2013 | |

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| | <p>monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits. The policy failed to provide for continuous monitoring of performance, taking action to improve performance, and tracking to ensure improvements are sustained.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not</p> | | <p>Committee on Quality and Safety. The rating scale and categories will be reviewed with leadership on Oct 28. First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | |

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| | <p>know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | | |

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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | | | | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 | | | |
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| V000639 | <p>494.110(c) QAPI-PRIORITIZING IMPROVEMENT ACTIVITIES The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. Based on interview and QAPI (Quality Assessment and Performance Improvement Program) document and policy review, the facility failed to set priorities for performance improvement and giving priority to actives that affected clinical outcomes or patient safety in 1 of 1 QAPI program reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia</p> | V000639 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators: Adequacy of dialysis, Nutritional status, Mineral Metabolism and renal bone disease, Anemia Management, Vascular Access, Medical Injuries and medical error identification, Patient Satisfaction/Grievances and Complaints, Infection Control, Buildings and Grounds, Water and Dialysate Quality, Personnel Issues, Health Outcomes/Mortality Review, Machine Maintenance, Vaccinations, and Crown Web Data. New policy, audit tools, meeting minute template, and spread sheets attached. Upon review of the quality measures, performance improvement (PDSA 's) will be prioritized based upon a standardized rating scale utilizing 0-5 (none to high). The four indicators are as follows: 1) threat of immediate patient harm, 2). Regulatory, 3) . Impact to patient satisfaction, 4) Impact to patient throughput. The efforts of the quality monitoring process w ill be reported at the monthly QAPI meeting and reported at</p> | 10/30/2013 | | | |

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| | <p>management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits. The policy failed to set priorities for performance improvement and give priority to activities that affected clinical outcomes or patient safety.</p> <p>2. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as</p> | | <p>least annually to the IU Health Board Committee on Quality and Safety. The rating scale and categories will be reviewed with leadership on Oct 28 . First QAPI meeting utilizing new format will occur on Oct 30. The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | | | | |

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| | <p>they come in, but there's not a bio medical technician for the facility.</p> <p>3. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>5. A facility QAPI document titled "IU Health Adult Renal HD Report Card" dated 2013 that covered the months January through July failed to address any of the subjects in finding # 1.</p> | | | | |

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| V000640 | <p>494.110(c) QAPI-QAPI-IMMEDIATELY CORRECT ANY IJ ISSUES The facility must immediately correct any identified problems that threaten the health and safety of patients.</p> <p>Based on observation, interview, and policy and facility document review, the facility failed to immediately correct an identified problem that threatened the health and safety of the patients in 1 of 1 facilities reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>2. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff.</p> | V000640 | <p>On Oct 2, 2013, an emergency meeting was called by Chief Medical Director the IU Health Adult Renal Program and the medical director of N. Capitol Dialysis Center and the Unit Manager of the dialysis center. Other attendees included the VP of Ambulatory Services, Executive Director of Access Services, Director of Accreditation, Ambulatory Infection Preventionist, Ambulatory Quality Improvement Consultant, and the Ambulatory Risk Analyst. Plans formalized to remediate drywall and replace water boxes scheduled for Oct 5, 6 were reviewed. At that time the medical directors affirmed that any future developments/hazards that resulted in the potential/actual patient harm should be escalated immediately to the executive director and medical directors when discovered.</p> | 10/02/2013 | | | |

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| | <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the water.</p> | | | | | | |

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| | <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building. One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for</p> | | | | |

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| | <p>drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services,</p> | | | | | | |

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| | <p>that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the</p> | | | | | | |

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| | <p>drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through</p> | | | |

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| | <p>the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance. ... VII Action To Improve Care If the evaluation identified a problem or opportunity to improve care, the QAPI Committee and/or appropriate department staff decides what corrective action is necessary. ... In the event of identification of trends and events that pose an immediate threat to patient safety, action will be immediate and appropriate to the situation in order to reduce and</p> | | | |

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| | <p>eliminate the identified risk."</p> <p>5. QAPI notes dated May 31, 2013, state, "Cracked drainage boxes on the wall behind the dialysis machine. The drainage boxes are when the dialysate hose is placed. The leak is behind the wall. For a temporary fix, funnels have been put in the drainage boxes. The construction company gave a quote of \$38,000 for repairs. The construction will come in on a Saturday night, and work thru the night until Sunday. Then on Sunday, an extra sanitation will be done. The Infection Control adviser, will need to meet with the construction company prior to the repairs being done for a risk assessment."</p> <p>6. QAPI notes dated June 28, 2013, state, "Strata Cap request for repairs are waiting to be signed off in finance dept. The Nurse Manager will met with the inspector today to discuss possible mold issues. If mold is present in the walls he explained the plan of action. There will be a barrier wall put up at the time of repair. The repair of studs and clean up of any mold. All work will take a weekend to complete. The inspector will send a summary of the work that will be done to the nurse manager and infection control."</p> | | | |

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| V000710 | <p>Based on interview, observation, document review, and QAPI document (Quality Assessment and Performance Improvement Program) and policy review, it was determined the medical director failed to ensure the facility had an effective QAPI program that met all the requirements and addressed facility problems with the potential to affect all 63 patients (See V 712) and failed to ensure policies were to adhered to immediately correct an identified problem that threatened the health and safety of the patients in 1 of 1 facilities reviewed with the potential to affect all 63 patients (See V 715).</p> <p>The cumulative effect of these systemic problem resulted in the facility's inability to meet the requirements of this Condition for Coverage 494.150: Responsibilities of the Medical Director.</p> | V000710 | <p>Reevaluation of QAPI program which resulted in QAPI program redesign to encompass all ESRD quality indicators, to include crown web data, machine maintenance, vaccinations, personnel issues. buildings and grounds issues. New policy, audit tools, meeting minute template, and spread sheets attached.</p> <p>Review of new process to occur with staff at the quarterly QAPI meeting on Oct 30, and the October staff meeting on Oct 23. First QAPI meeting utilizing new format will occur on Nov 22.</p> <p>The Medical Director and Administrative director, and Clinical Managers are responsible to ensure that the QAPI program's integrity is maintained. The Chief Medical Officer and/or the Administrative director will be present at every meeting.</p> | 10/30/2013 | |

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| V000712 | <p>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.</p> <p>Based on interview, observation, document review, and QAPI document (Quality Assessment and Performance Improvement Program) and policy review, the medical director failed to ensure the facility had an effective QAPI program that met all the requirements and addressed facility problems with the potential to affect all 63 patients.</p> <p>Findings:</p> <p>1. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance." The policy failed to include the role of the physician, social worker, dietitian, nurse and biomedical technician.</p> | V000712 | <p>Education for the medical director will be completed by the review of the medical director role as CFC 494.110 on Oct 10, 2013.</p> <p>The medical director is a required attendee at monthly QAPI. The Chief Medical Officer and Administrative Director have now defined the expectation of all members of the IDT to be present at all QAPI meetings or to send representation. Attendance will be monitored and tracked by the using the monthly sign in sheets that will be reviewed in the next month's QAPI meeting.</p> | 10/10/2013 | | | |

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| | <p>A. The quarterly QAPI attendance sheet dated 11/16/12, 4/19/13, and 8/23/13 failed to evidence a Technical Representative was present.</p> <p>B. The quarterly QAPI attendance sheet dated 1/18/13 failed to evidence a Technical Representative, Social worker or a Dietitian was present.</p> <p>2. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, failed to evidence the facility would monitor Water & dialysate quality, Dialysis equipment repair and equipment, Physical plan safety "rounds", Staff issues, Patient modality choice & transplant referral, Health outcomes-physical and mental functioning, Mortality-expiration and cause, Fluid and Blood Pressure Management, Residual kidney function monitoring, Nutritional status-variance from usual body weight, Anemia management-symptoms of anemia, Vascular access-adverse events, Medical errors-deaths during dialysis, errors in dialysis prescription delivery, transfusion reactions, incorrect reprocessed dialyzer set up or used, blood loss > 100 cc, chlorine / chloramines / fluoride breakthrough, machine malfunction with treatment interruption, vascular access</p> | | | |

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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 |
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| | <p>infiltration, excessive bleeding, Intradialytic symptoms-chest pain, pyrogenic reactions, Staff incidents and injuries-needle sticks, blood / body fluid exposures, non-adherence to procedures, patient abuse / disrespect, Patient Satisfaction, Infection prevention and control-infection occurrence surveillance & recording / antibiotic starts, Hepatitis B virus, Tuberculosis surveillance, staff education and visual practice audits.</p> <p>3. On 9/24/13 at 10 AM, employee N indicated there is really not a Bio medical technician. The RO machine is contracted out to Mar-Cor and they are in charge of the water room. He does the testing that Mar-Cor asks him to do and sends the reports to them. He does not know if there are other tests that need to be done. He is trying to learn things as they come in, but there's not a bio medical technician for the facility.</p> <p>4. On 9/24/13 at 12:30 PM, employee Q, social worker, indicated she attends the QAPI meetings most the time but is not asked for information such as the KDQOL.</p> <p>5. On 9/23/13 at 1:30 PM, Employee L, Medical Director, indicated he had been the Medical Director for two years. He indicated he didn't know about the nature</p> | | | |

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| | <p>of the water problems until May 2013.</p> <p>6. On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present.</p> <p>7. On 9/19/2013 at 7:40 AM, patients were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At</p> | | | |

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| | <p>times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was present. An electric wire was in the water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the</p> | | | | | | |

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| | <p>problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building . One day the leaked fluid was yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine</p> | | | | |

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| | <p>what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>8. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they</p> | | | | | | |

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| | <p>were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13 for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards</p> | | | | | | |

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| | <p>the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination. The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> <p>9. A policy titled "Adult Renal Services Quality Assessment and Performance</p> | | | | |

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| | <p>Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance."</p> <p>10. QAPI notes dated May 31, 2013, state, "Cracked drainage boxes on the wall behind the dialysis machine. The drainage boxes are when the dialysate hose is placed. The leak is behind the wall. For a temporary fix, funnels have been put in the drainage boxes. The construction company gave a quote of \$38,000 for repairs. The construction will come in on a Saturday night, and work thru the night until Sunday. Then on Sunday, an extra sanitation will be done. The Infection Control adviser, will need to meet with the construction company prior to the repairs being done for a risk assessment."</p> <p>11. QAPI notes dated June 28, 2013, state, "Strata Cap request for repairs are waiting to be signed off in finance dept. The Nurse Manager will met with the inspector today to discuss possible mold</p> | | | |

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| | issues. If mold is present in the walls he explained the plan of action. There will be a barrier wall put up at the time of repair. The repair of studs and clean up of any mold. All work will take a weekend to complete. The inspector will send a summary of the work that will be done to the nurse manager and infection control." | | | |

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| V000715 | <p>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; Based on observation, interview, and policy and facility document review, the medical director failed to ensure policies were to adhered to immediately correct an identified problem that threatened the health and safety of the patients in 1 of 1 facilities reviewed with the potential to affect all 63 patients.</p> <p>Findings:</p> <ol style="list-style-type: none"> On 9/18/2013 at 8:30 PM, the surveyors entered the facility and observed drywall was bowed from the absorption of water on the northern half wall on the eastern end of the dialysis facility where used dialysate had been pooling. There was blue tape holding the wall molding to the drywall. The floor tile was loose around the chair in the north pod eastern end. The top of the half walls were sealed and it was not possible to view inside the wall. An odor was not present. On 9/19/2013 at 7:40 AM, patients | V000715 | <p>The Medical Director reviewed and identified action plans, auditing tools, and techniques which will montior and measure adherence to policies and procedures and confirm that corrective actions are instituted to ensure resolution of areas of deficiency. The Medical Director is responsible to review the results of the plan of correction and ensure activities are complete as well as provide oversight at all QAPI meetings. The Medical Director acknowledges his role to ensure that any issues not resolved will be reviewed and a plan of action is developed and instituted. Unresolvable issues will be reported to the Chief Medical Officer which will be presented to the board. Education for the medical director will be completed by the review of the medical director role as well as CFC 494.110 on the renal network.</p> | 11/02/2013 | | | |

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| | <p>were observed receiving dialysis. Patients who were sitting in the area of concern were interviewed as well as staff.</p> <p>A. On 9/19/2013 at 7:40 AM, Patient #9 indicated it gets wet around the chair, South pod chair 8, and the staff had to keep mopping it up. The patient did not indicate a smell was present. The patient indicated the patient had not fallen while the floor was wet.</p> <p>B. On 9/19/2013 at 7:40 AM, Patient # 4 indicated it gets very wet around the chair, North pod chair 4, and the staff had to keep mopping it up. The patient indicated there was a smell present. At times the liquid was yellow and the patient had complained to the facility. The patient indicated the patient had not fallen while the floor was wet.</p> <p>C. On 9/19/2013 at 11:20 AM, a flashlight was used to examine a hole in the wall behind the dialysis chair in South pod chair 8. The dialysis machine was being used to block the hole. The square covering over the hole was being held up by scotch tape and was removed. A shallow amount of standing liquid was observed behind the wall, the wood structure was saturated, and an odor was</p> | | | |

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| | <p>present. An electric wire was in the water.</p> <p>On 9/19/2013 at 11:40 AM, the Director of Accreditation and Surveys, Employee I, chose not to look behind the covering.</p> <p>D. On 9/19/2013 at 12:00 PM, Employee N, who is responsible for reporting maintenance, indicated the water issue has been going on for a year. At first they thought it was from outside and coming in. The owners of the building sealed the outside but the problem persisted. It has been determined the dialysate boxes are cracked in the wall. The hoses have to be shoved down into the boxes to make the post dialysis water drain. So the post dialysis water is leaking onto the floor inside the wall.</p> <p>E. On 9/19/2013 at 12:05 PM, the Manager, Employee B, indicated she started on 5/13/13. She inherited the leak. It leaks periodically. She indicated the owners had sealed the outside. The facility had a meeting in May about the building . One day the leaked fluid was</p> | | | | |

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| | <p>yellow and smelled. The facility response was to have another meeting. There is an estimate for new boxes and repair for drywall.</p> <p>On 9/19/2013 at 12:10 PM, Employee B indicated there were no meeting notes to document these meetings. She did have a Stratacap, which is the process and pricing method for approval.</p> <p>F. On 9/19/2013 at 12:23 PM, Employee N indicated there had not been a collection of the liquid to determine what is leaking. He indicated the wall boxes are cracked. Hoses that drain the by product are put in cracked boxes and the leaking is coming from the cracked boxes. The Infection Control Department from the hospital owners made them put on connectors so the water doesn't go directly into boxes at times.</p> <p>3. On 9/19/13 at 12:30 PM, Employee I presented documents indicating an awareness of the problem for several months.</p> | | | | |

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| | <p>A. On 5/3/13 at 10:09 AM, Employee B sent an email to Employee O, Executive Director of Access Services, that stated, "The second repair - This is bigger and more complicated. It has to do with the drain boxes that are associated with each dialysis machine. They are to be set up to prevent sewer water from backing up to the machine and patient, which obviously could be dangerous. We don't have any reason to believe that it is happening now but the risk is increasing. The boxes are old and Employee P discussed repair of them 6 months ago. But the plan was to expand 2140 so they were going to move all the current patients into the expanded area and then refurbish the old site. So he asked them to do a fix that would hold for about six months."</p> <p>B. Quote from Leach and Russell Mechanical dated 5/30/13 for \$38,371 to fix all RO boxes.</p> <p>C. Quote from Mar Cor Purification dated 6/4/13 for \$4,656.96 for the purchase of 16 wall station boxes.</p> <p>D. StrataCap Proposal dated 6/17/13</p> | | | | | | |

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 153515 | X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____ | X3) DATE SURVEY COMPLETED 09/25/2013 |
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| NAME OF PROVIDER OR SUPPLIER INDIANA UNIVERSITY HEALTH ADULT DIALYSIS CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 2140 N CAPITOL ST INDIANAPOLIS, IN 46202 |
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| (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 |
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| | <p>for \$36,181. The proposal states, "02. Clinical Impact It is imperative that an air gap be present between the end of the drainage hose and the opening of the drainage hole to prevent contamination of water that could be subsequently exposed to the patient. In order to prevent the drainage hose from slipping into the drainage hole, the adaptation was made to the boxes to keep the hose in place. As noted before this was a temporary fix and has not held up over the span of the 2 years since they have been in place. The boxes themselves have eroded and cracked, causing dialysis drainage (equivalent to a person's urine) to spray behind the wall. The floor slopes towards the front or east side of the building so anytime a dialysis machine drains and the drainage leaks behind the wall, it ends up pooling to the east side of the building. There are 2 dialysis chairs assigned to patients that sit in the corner where most of the water pools. Since we run 2 shifts a day we usually have 4 patients a day who occupy a chair with a puddle of someone's (not always their own) dialysis drainage under it. When this happens it requires staff to mop about every 15 to 20 minutes. To prevent flooding the staff will push the drainage tube down into the drainage hole which means we no longer have an adequate air gap and are exposing our patients to potential contamination.</p> | | | |

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| | <p>The most recent flood affected the vinyl flooring in what we refer to as bay 1 section 2. Water was seeping up through the vinyl. The potential for mold in the walls is high due to the large number of times water has leaked behind the walls.</p> <p>03. Financial Impact Since the cost to fix the leaks at 2140 was included in the original expansion, the funds for the project already exist. If the state board of health were to visit 2140 North Capitol and found a problem with water leaks and or mold they would likely have the facility closed."</p> <p>4. A policy titled "Adult Renal Services Quality Assessment and Performance Improvement Program", approved 5/10/10, states, "The Medical Directors and Administrative Director are responsible for overseeing the design and promotion of the quality improvement and assurance program. The Unit Medical Directors and the Unit Managers have a leading role in determining and prioritizing those unit activities that have a major impact on department-wide performance. ... VII Action To Improve Care If the evaluation identified a problem or opportunity to improve care, the QAPI Committee and/or appropriate department staff decides what corrective action is necessary. ... In the event of identification of trends and events that</p> | | | |

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| | <p>pose an immediate threat to patient safety, action will be immediate and appropriate to the situation in order to reduce and eliminate the identified risk."</p> <p>5. QAPI notes dated May 31, 2013, state, "Cracked drainage boxes on the wall behind the dialysis machine. The drainage boxes are when the dialysate hose is placed. The leak is behind the wall. for a temporary fix, funnels have been put in the drainage boxes. The construction company gave a quote of \$38,000 for repairs. The construction will come in on a Saturday night, and work thru the night until Sunday. Then on Sunday, an extra sanitation will be done. The Infection Control adviser, will need to meet with the construction company prior to the repairs being done for a risk assessment."</p> <p>6. QAPI notes dated June 28, 2013, state, "Strata Cap request for repairs are waiting to be signed off in finance dept. The Nurse Manager will met with the inspector today to discuss possible mold issues. If mold is present in the walls he explained the plan of action. There will be a barrier wall put up at the time of repair. The repair of studs and clean up of any mold. All work will take a weekend to complete. The inspector will send a summary of the work that will be</p> | | | | | | |

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| | done to the nurse manager and infection control." | | | |